United States Senate

HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

Patty Murray, Ranking Member

Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients



Minority Staff Report

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Executive Summary

In September 2013, staff at Virginia Mason Hospital and Medical Center in Seattle, Washington, traced a cluster of antibiotic-resistant infections in patients to a medical device called a closed-channel duodenoscope, which is used to identify and treat conditions of the pancreas and bile duct. Around the same time, staff at Advocate Lutheran General Hospital outside of Chicago, with the help of the Centers for Disease Control and Prevention, similarly linked an outbreak of superbug infections to closed-channel duodenoscopes.

- Both hospitals concluded that closed-channel duodenoscopes remained contaminated even after proper cleaning, spreading bacteria between patients, but it took 17 more months for duodenoscope manufacturers and the Food and Drug Administration (FDA) to alert hospitals, doctors, and the public to the risk posed by the devices.
- In January 2015, after several outbreaks of serious infections, including in Seattle, became public, Senator Patty Murray, the Ranking Member of the Senate Health, Education, Labor, and Pensions Committee, initiated an investigation to determine the extent of duodenoscope-linked infections, understand the slow response, and determine if legislative changes were needed to prevent similar problems in the future.
- Senator Murray's staff investigation has demonstrated that the clusters of infections at Virginia Mason and Advocate Lutheran were not isolated incidents. Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide.
- The investigation found that by early 2013, Olympus, the manufacturer of 85 percent of the duodenoscopes used in the United States, knew of two independent lab reports finding that the closed-channel model duodenoscope could harbor and spread bacteria even after cleaning according to the manufacturer's instructions. Olympus never brought this information to FDA, and did not alert hospitals, physicians or patients in the U.S. to the risk of infection until February 2015.
- The investigation also found that Olympus, as well as the other two manufacturers of duodenoscopes used in the United States, Pentax and Fujifilm, and Custom Ultrasonics, the manufacturer of the automated cleaning machine in use at many of the hospitals that experienced infections, failed to meet the obligations placed upon them by the current regulatory system. Two of the manufacturers failed to seek FDA clearance before selling the "closed-channel" duodenoscopes, all failed to adequately test whether the scopes could be cleaned reliably in real-world settings, and fully comply with adverse events reporting requirements.
- Additionally, although at least 16 separate U.S. hospitals traced antibiotic-resistant infections directly to duodenoscopes, the hospitals generally did not raise alarms about these infections with federal regulators. It appears that not a single hospital that experienced infection outbreaks tied to the duodenoscopes sent the required adverse event form to the device manufacturers.
- When hospitals did take required action to report adverse events to device manufacturers
 it was often late, notification was made informally by phone or email, and reports were not

- inclusive of all the information necessary for the manufacturers to themselves submit accurate and complete information to FDA.
- While FDA started investigating how closed-channel duodenoscopes cleaned according to manufacturers' instructions spread infection in September of 2013, the agency took no action to alert hospitals, doctors and the public to the risk posed by closed-channel duodenoscopes for 17 months. At least 68 patients in seven different hospitals in the United States were infected with antibiotic-resistant bacteria linked to duodenoscopes during this period.
- Problems with FDA's outmoded adverse event device database, as well as slow and incomplete reporting by manufacturers and hospitals, appear to have left FDA staff unable to develop an accurate sense of the frequency and severity of the infection outbreaks. FDA was also unaware that by early 2013, two independent labs in Europe had documented the Olympus closed channel duodenoscope remaining contaminated after repeated cleaning, or that a Dutch Health Ministry report in 2013 had already concluded that Olympus did not have the data to show their cleaning instructions worked consistently and effectively.
- As a result, the FDA wasted valuable time seeking cleaning data from manufacturers and trying to conclusively determine that cleaning mistakes by hospital staff in cleaning were not the responsible for the infections. Unlike FDA's surveillance of drugs, where the agency is increasingly able to use the "Sentinel" system to develop fast and accurate information about adverse events, FDA had no way to seek independent information about adverse events linked to medical devices.
- The failure of FDA's current device safety reporting system to rapidly identify duodenoscope-related, antibiotic-resistant infections, including superbug infections, should serve as warning that without a comprehensive postmarket device surveillance system that supplements self-reporting from hospitals and manufacturers, future device issues are likely to go undetected for far too long and with life-threatening consequences.
- To minimize future delays in identifying and addressing device safety issues, the report recommends:
 - Congress require unique device identifiers (UDIs) to be included in insurance claims and fully fund a National Medical Device Evaluation System to ensure that FDA is able to effectively monitor the safety of medical devices on the market rather than relying on adverse event reporting.
 - o FDA quickly evaluate the design of closed-channel duodenoscopes and implement a phased recall to fix or modify the devices if necessary.
 - o FDA update its guidance to clarify when manufacturers are required to seek 510(k) clearance when medical devices are modified, and that Congress clarify FDA's authority to consider a 510(k) application incomplete in the absence of sufficient data to demonstrate a medical device can be safely cleaned and reused.
 - FDA implement new draft guidance to more quickly disseminate information to health care providers when the agency becomes aware of information that patient safety might be compromised by a medical device; and
 - Compliance by hospitals with adverse event reporting related to medical devices be made a Condition of Participation in Medicare.

Introduction

In the summer of 2013, staff at Virginia Mason Hospital in Seattle, Washington realized that multiple patients were contracting the same type of antibiotic-resistant infection after undergoing a specific procedure at the hospital. By September 2013, after conducting an extensive epidemiological investigation in conjunction with the King County and Washington State Health Departments, the hospital linked the infections to closed-channel duodenoscopes. Duodenoscopes are medical devices used in a procedure called endoscopic retrograde cholangiopancreatography (ERCP) to diagnose and treat problems in the bile or pancreatic ducts. By the time the hospital successfully contained the outbreak of infections in early 2014, at least 32 patients at Virginia Mason were infected with antibiotic-resistant infections after undergoing ERCP. At least eleven of those patients later died, although it is unclear whether those deaths were a direct result of the infections.²

During the same period in 2013 when patients at Virginia Mason were falling ill, 32 patients contracted carbapenem-resistant Enterobacteriacea (CRE), a bacteria that is resistant to even the most potent antibiotics, after undergoing ERCP at Advocate Lutheran General Hospital in Park Ridge, Illinois. CRE is a deadly bacteria, often called a "superbug," that kills almost half of those infected. The Centers for Disease Control and Prevention (CDC) investigated the outbreak after Advocate Lutheran requested assistance with identifying the source of the bacteria and containing the infection. By September 2013, CDC and Advocate Lutheran had determined that the CRE outbreak in Illinois – like the outbreak in Washington – was linked to ERCP procedures using closed-channel duodenoscopes.

After *The Seattle Times* broke the news in late January 2015 that Virginia Mason had experienced an outbreak of antibiotic-resistant infections in ERCP patients, Senator Patty Murray, Ranking Member of the Senate Committee on Health, Education, Labor, and Pensions (HELP), initiated an investigation into these dangerous duodenoscope-linked infections. In February and March 2015, Senator Murray sent two letters to the Food and Drug Administration (FDA), and in June she sent requests for documents to the three manufacturers of closed-channel duodenoscopes sold in the United States: Olympus Medical Systems (Olympus), Hoya Corporation PENTAX Life Care Division (Pentax), and Fujifilm Medical Systems (Fujifilm). All three manufacturers provided significant information in response to the request, including previously unavailable independent reports provided by Olympus. Senator Murray's staff also conducted interviews with hospitals, subject matter experts, independent investigators, state and local health departments, CDC, and FDA.

Senator Murray's staff investigation has demonstrated that the clusters of infections at Virginia Mason and Advocate Lutheran linked to closed-channel duodenoscopes were not isolated incidents. Between 2012 and spring of 2015, the Olympus closed-channel duodenoscope used at Virginia Mason, together with closed-channel models made by Pentax and Fujifilm, were linked to at least 25 different instances of antibiotic-resistant infections that sickened at least 250

Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different instances of antibiotic-resistant infections that sickened at least 250 patients worldwide.

patients worldwide. Because some of the identified infections had unique markers that made the

bacteria possible to track, and because the hospitals that have reported infections are primarily large research hospitals and medical centers adept at spotting and addressing antibiotic-resistant infections, it is likely that there are more incidents of infections linked to these devices that have never been identified.

The investigation found that Olympus, the manufacturer of 85 percent of the duodenoscopes used in the United States, knew by May 2012 that the closed-channel duodenoscope model used at Virginia Mason could harbor and spread bacteria even after proper cleaning. By the fall of 2012, Olympus was aware that its duodenoscopes had been linked to antibiotic-resistant infections, including superbug infections, caused by life-threatening multidrug-resistant organisms at hospitals in both the United States and Europe. By early 2013, independent laboratory tests of at least two different closed-channel duodenoscopes showed the devices remained contaminated after careful repeated cleaning and reprocessing.

Despite this, Olympus issued no safety alerts or guidance to hospitals and physicians in the United States until February 2015 – almost three years after first realizing the problem in April 2012. In contrast, Olympus sent some hospitals in Europe two separate alerts in 2013 and 2014, which, at the very least, advised extra caution when cleaning these duodenoscopes.

Olympus, Fujifilm, and Pentax also failed to meet their obligations to provide FDA with the

At the time duodenoscope manufacturers sold their devices to hospitals in the United States, they lacked sufficient data to show their cleaning instructions worked.

information the agency needs to keep patients safe. Olympus and Fujifilm never applied for FDA clearance for the new design of the closed-channel duodenoscope before selling the devices in the United States. The manufacturers also attested to FDA that they had tested their duodenoscope cleaning instructions and demonstrated that they worked reliably. However, none of the manufacturers actually had sufficient data to show that duodenoscopes could be reliably cleaned between

uses. Finally, the manufacturers did not consistently report the information they had regarding infections linked to the devices.

Additionally, the investigation found that many, although not all, of the domestic hospitals with duodenoscope-linked outbreaks used an automated endoscope reprocessor (AER) manufactured by Custom Ultrasonics. Custom Ultrasonics, like the duodenoscope manufacturers, failed to meet its regulatory obligations, including filing appropriate applications with FDA, testing its machines sufficiently to make sure they worked, and filing complete and accurate adverse event reports. In November 2015, FDA issued a mandatory recall of all Custom Ultrasonics AERs.

Further, the investigation established that although at least 16 separate domestic hospitals traced antibiotic-resistant infections directly to ERCP procedures, as a group, the facilities generally failed to quickly raise alarms with FDA and CDC. In some cases, hospitals completely failed to make the required reports of infections to the devices' manufacturers. This limited and slow reporting by hospitals likely impaired FDA's ability to accurately assess the frequency and severity of outbreaks of duodenoscope-linked infections.

Failures by device manufacturers and hospitals to quickly and completely disclose important information to FDA, and FDA's outmoded adverse event system, hampered the agency's ability to accurately assess and respond to the infections. Because FDA did not have prompt and complete

information, it took the agency overly long to accept that duodenoscope-linked infections were not the result of hospital cleaning errors. As a result, contaminated duodenoscopes spread serious infections for at least three years before manufacturers and FDA alerted hospitals in the United States. FDA's first safety communication regarding duodenoscope cleaning did not occur for almost 17 months after the agency first became aware of the spread of infections. In the interim, at least 68 patients were affected in seven different hospitals in the United States.

Between the time FDA learned duodenoscopes could remain contaminated even after proper cleaning and the first safety alerts, at least 68 patients in seven different hospitals in the United States were infected with antibiotic-resistant infections.

The investigation provides a vivid example of the failure of FDA's current system for tracking and monitoring the safety of medical devices on the market (the postmarket surveillance system). FDA's postmarket surveillance system relies too heavily on self-reporting from manufacturers and hospitals with competing priorities that weigh against full and fast disclosure of patient safety concerns. This passive postmarket surveillance system inhibits FDA's ability to quickly identify information related patient health and device safety. Until a system is implemented that allows FDA to independently monitor, track, and assess the performance of devices, the agency will not be able to adequately identify risks to patient safety from particular devices like duodenoscopes and move quickly to address those risks.

Many Hospitals Experienced Infections Linked to Closed-Channel Duodenoscopes

Senator Murray's staff investigation has revealed that outbreaks of antibiotic-resistant infections caused by deadly multidrug-resistant organisms spread by duodenoscopes were vastly more widespread than previously reported. In June 2015, when Senator Murray first sought information from Olympus, Pentax, and Fujifilm, the three manufacturers of duodenoscopes sold in the United States, the Food and Drug Administration (FDA) had recently announced that there had been at least nine outbreaks of infections related to duodenoscopes.³ According to documents provided to the Health, Education, Labor, and Pensions (HELP) Committee, however, from 2012 through spring of 2015, there have actually been at least 25 separate outbreaks of patient infections following endoscopic retrograde cholangiopancreatography (ERCP) procedures with closed-channel scopes in four different countries and 10 states. These outbreaks infected at least 250 people with life-threatening illnesses including carbapenem-resistant Enterobacteriaceae (CRE), a dangerous superbug that is resistant to our most potent antibiotics and that kills about half of those it infects.⁴

Institutions where antibiotic-resistant infections linked to duodenoscopes occurred include:¹

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¹ The number of patients infected and date of infections indicate committee staffs' understanding based on the totality of the information obtained during this investigation. They are <u>estimates only.</u>

Hospital	Estimated # of Patients Infected	Approximate time infections	Duodenoscope Manufacturer	
Erasmus Medical Center, Rotterdam, Netherlands	30	January 2012	Olympus	
Clinique De Bercy, Charenton-le-Pont, France	3	October 2012	Olympus	
University of Pittsburgh Medical Center Presbyterian Hospital, Pittsburgh, PA	135	November 2012	Olympus	
New York-Presbyterian/Weill Cornell Medical Center, New York City, NY	15	December 2012	Olympus	
UMass Memorial Medical Center, Worchester, MA	20	December 2012	Olympus	
Carolinas Medical Center, Charlotte, NC	1	2013	Olympus	
Thomas Jefferson University Hospital, Philadelphia, PA	8	January 2013	Olympus	
Charite-Universitatsmedizin, Berlin, Germany	5	February 2013	Olympus	
Advocate Lutheran General Hospital, Park Ridge, IL	32	March 2013	Pentax	
Froedtert Hospital, Milwaukee, WI	5	May 2013	Olympus	
Virginia Mason Hospital and Medical Center, Seattle, WA	32	Spring/Summer 2013	Olympus	
Clinique De Bercy, Charenton-Le-Pont, France	2	November 2013	Olympus	
Hartford Hospital, Hartford, CT	12	January 2014	Olympus	
Massachusetts General Hospital, Boston, MA	7	Before Spring 2014	Pentax	
Advocate Good Samaritan Hospital, Downers Grove, IL	3	May 2014	Fujifilm	
Evangelisches Waldkrankenhaus, Spandau, Berlin, Germany	4	May 2014	Olympus	
Boca Raton Regional Hospital, Boca Raton, FL	96	August 2014	Olympus	
Cedars-Sinai Medical Center, Torrance, CA	4	August 2014	Olympus	
UCLA Medical Center, Los Angeles, CA	7	October 2014	Olympus	

Carolinas Medical Center, Charlotte, NC	18	2015	Olympus	
MGH Gastroenterology Associates, Boston, MA	5	January 2015	Pentax	
Massachusetts General Hospital, Boston, MA	3	January 2015	Pentax	
Universitair Medisch Centrum, Utrecht, Netherlands	8	January 2015	Olympus	
Allegheny General Hospital, Pittsburgh, PA	1	February 2015	Olympus	
Fox Chase Cancer Center, Philadelphia, PA	3	April 2015	Fujifilm	

Because some of the infections identified had unique markers that made the bacteria possible to track, and because the hospitals that have reported infections are primarily large, well-resourced research hospitals adept at spotting and addressing antibiotic-resistant infections, it is likely that there have been more incidents of infections linked to these devices that were never identified.

Background

Duodenoscopes, Reprocessing, and Automated Endoscope Reprocessors

Duodenoscopes are flexible, hollow tubes that are typically used during ERCP to treat patients suffering from blockage in their bile or pancreatic ducts due to tumors and other serious medical conditions. Doctors in the United States performed more than 660,000 potentially lifesaving ERCP procedures in 2014. Duodenoscopes are currently sold in the United States by three companies based in Japan: Olympus, Fujifilm, and Pentax. Olympus manufactures about 85 percent of the duodenoscopes used in the United States, Pentax about 12 percent, and Fujifilm only about three percent.

All types of endoscopes can spread infection by passing bodily fluids or debris from one patient to subsequent patients if they are not properly cleaned between uses. Careful cleaning is especially critical for duodenoscopes because they are used in parts of the body with high levels of bacteria and patients undergoing procedures with duodenoscopes are often already very ill, raising the risk of infection. Also, a duodenoscope's elevator channel, which allows physicians to insert a guidewire and catheter into the duodenum, is particularly difficult to clean between uses. In early duodenoscopes, the elevator wire channel was open and exposed to bodily fluids, while the newer "closed-channel" duodenoscope model seals off the elevator wire channel from contaminants.¹⁰



Picture taken from www.olympus.co.uk

To ensure that a duodenoscope does not spread infection, it must undergo reprocessing, a multistep cleaning procedure to ensure the device is safe for re-use.¹¹ There are generally three steps to duodenoscope reprocessing:

- 1) <u>Point-of-use Processing:</u> Hospitals perform point-of-use processing immediately after a device has been used by rinsing or wiping the device to make sure that contaminants do not dry and make cleaning more difficult.¹²
- 2) <u>Thorough Cleaning:</u> After point-of-use processing, a technician uses a brush to ensure all parts of the device are cleansed of any soil and debris. Thorough cleaning is essential because debris and other material remaining on a duodenoscope can interfere with the final disinfection or sterilization phase of reprocessing. ¹³
- 3) <u>High Level Disinfection</u>: Devices like duodenoscopes that contact mucous membranes or non-intact skin, but that cannot withstand heat sterilization, are required to undergo high level disinfection (HLD), which kills most microbes remaining after thorough cleaning.¹⁴ Most hospitals achieve HLD by using an AER. AERs flush liquid chemicals through the scope to destroy lingering contamination after cleaning and then rinse the scope to remove the chemical before reuse.¹⁵

FDA's Regulation of Devices

FDA oversees the safety and effectiveness medical devices, more than 1,700 of which are classified by the agency into three different categories based on the amount of risk they pose to patient health and safety. Duodenoscopes are classified as Class II devices, which pose a medium level of risk. When a manufacturer modifies the design of a Class II device in a way that might implicate the safety or effectiveness of that device, it must make what is known as a "510(k) submission" to show FDA that the device remains "substantially equivalent" to a device the agency has already cleared and that the design change does not put patients at any additional risk. It is the manufacturer's responsibility to determine when a 510(k) submission to FDA is required. PDA is required.

It is also the manufacturer's responsibility to validate the design of their new or modified devices to make sure they work properly, which includes the ability for that device to be safely reprocessed between uses. ²⁰ Manufacturers must test their devices and collect evidence to show that reprocessing will consistently result in a device that meets certain decontamination specifications. ²¹ Proper validation should test all stages of reprocessing, and "the characteristics of the user population and operating environment [should be] considered."²²

Once a medical device is sold and in use in the United States, FDA monitors the device primarily by relying on manufacturers and hospitals to observe when a device is working and to report when it is not. Manufacturers are required to submit medical device reports (MDRs) within 30 days of learning information that reasonably suggests a device may have caused or contributed to a death or serious injury. Within in 10 work days, hospitals must report serious injuries potentially caused by devices to the manufacturers, and report deaths connected to a device to both the manufacturers and FDA. Additionally, the Medical Product Safety Network (MedSun) provides a secure online mechanism for 250 participating hospitals to report adverse events related to medical devices before a patient is injured or dies. Finally, anyone, including hospitals and patients, may submit a voluntary "MedWatch" report to alert FDA to any suspected device issues.

FDA receives over one million MDRs each year, and relies on a small number of human reviewers to spot safety issues.²⁶ MDRs are often incomplete and lack key details, in part because FDA encourages quick filing with additional follow-up as more information is learned, and thus expects

initial submissions to be incomplete. MDR reports are primarily useful once FDA has already identified a problem; the agency can then search the MDR databases to identify similar or related reports. MDRs are extremely difficult to search and query, however. A simple spelling error or inconsistency in naming products can prevent the agency from tracking or identifying MDRs related to specific devices or patient outcomes.²⁷ Moreover, MDRs are not designed to identify trends, alert FDA to emerging problems, or track particular devices over time.

Finally, FDA can also require device manufacturers to conduct a postmarket surveillance study of the safety or effectiveness of a device (a section 522 postmarket surveillance study). FDA sets out specific questions, and the manufacturer designs and conducts a study to answer those questions over a three year period. The manufacturer then produces a Postmarket Surveillance Study Report setting forth the results of its study.²⁸ These section 522 postmarket surveillance studies have been criticized by some observers because there is very little infrastructure developed to assist device manufacturers as they design and carry out the studies, including a lack of device registries or identification codes that allow manufacturers to track and link devices to outcomes. ²⁹ Additionally, there are few incentives for clinicians and patients to participate in the studies, which may make it difficult for manufacturers to obtain the information they need.³⁰ As an example, while FDA has sought studies on 104 metal-on-metal hip products. However, just 24 products have FDA-approved study plans while the remaining 80 are listed as having either a "Plan Pending" or a "Plan Overdue.³¹

Currently, device manufacturers are essentially responsible for determining when a new clearance is required, how much information to report about adverse events, and how to conduct safety studies. This forces FDA to rely too heavily on manufacturers and user facilities to alert the agency to problems, help it accurately assess the severity of a potential safety issue, and move quickly to address it.

The Current Surveillance System to Ensure Medical Devices are Safe and Effective is Inadequate

The investigation found that FDA's current regulatory system for monitoring the safety of devices failed to quickly identify and resolve the spread of duodenoscope-linked, antibiotic-resistant infections. It took FDA almost a year and a half from the time the agency first became aware that closed-channel duodenoscopes could remain contaminated after proper cleaning to alert hospitals and the public. While responsibility for the slow response is shared among Olympus and the other device manufacturers, hospitals, and FDA, the investigation overall demonstrates that FDA's device surveillance system is overly-reliant on device manufacturers and user facilities to make quick and complete reporting of safety issues over their own competing priorities.

FDA relies on device manufacturers and hospitals to provide information so that FDA has the data it needs to assess the safety and effectiveness of medical devices. The regime relies on compliance with the law and self-reporting from device manufacturers and hospitals, ignoring the reality that manufacturers and health care providers have strong competing priorities that weigh against rapid and robust disclosure, such as moving new products to market quickly and avoiding costly litigation.

The current postmarket surveillance system relies on device manufacturers to self-monitor and self-report by: 1) determining when it is necessary to submit design modifications to FDA for review; 2) adequately testing that the devices work consistently in real-world settings; and 3) reporting when adverse events occur. The device manufacturers in this investigation failed to fully comply with any of these three regulatory requirements, providing a vivid example of the flaws with the current system.

FDA's reliance on manufacturers and hospitals to quickly and accurately report safety concerns related to devices stands in contrast to FDA's ability to independently monitor the safety of drugs. FDA increasingly has access to information about the postmarket safety and effectiveness of drugs through its "Sentinel" surveillance system.³² Because all drugs carry a National Device Code (NDC), which is also included on all pharmacy insurance claims and electronic health records, FDA has been able to leverage the wealth of information available through these sources to identify potential problems with a particular drug and proactively monitor drugs that are new to the market or are of particular interest. Sentinel allows FDA to query databases that contain real-time information, reducing the agency's reliance on the information reported by drug manufacturers and hospitals. Sentinel has the added advantage of allowing the agency to assess the frequency of adverse events relative to the overall use of a drug and relative to the rate of adverse events for similar drugs.

At this time, no similar system exists for devices. While the Food and Drug Administration Amendments Act of 2007 required devices to have a Unique Device Identifier (UDI) placed on medical device labels and packages comparable to the NDC number for drugs, and the Food and Drug Administration Safety and Innovation Act of 2012 required that Sentinel be expanded to devices, the UDI requirement does not go into effect for all devices until 2020.³³ Of more significant concern, UDIs are not currently included in insurance claims, which contain the critical information necessary to draw conclusions about device safety and patient outcomes. Without widespread adoption of UDI in electronic health records and claims, FDA will remain overly reliant on information reported by manufacturers and hospitals and unable to utilize a Sentinel-like system to ensure critical information about problematic devices is rapidly identified.

As detailed below, Olympus, Pentax, Fujifilm, and Custom Ultrasonics failed to report to FDA the information necessary to make the current postmarket surveillance system work properly. Hospitals also generally failed to provide manufacturers with required information about antibiotic-resistant infections linked to their devices or to proactively alert federal authorities to their concerns. As a result, FDA was unable to accurately assess and quickly react to the risks posed by closed-channel duodenoscopes.

Device Manufacturers Failed to Meet Regulatory Requirements and Endangered Patients

By the end of 2012, at least one duodenoscope manufacturer, Olympus, was aware that the new closed-channel duodenoscope the company had marketed since 2010 had the potential to remain contaminated even after cleaning and reprocessing according to manufacturers' instructions. Properly cleaning reusable devices like duodenoscopes is challenging, and failures to clean the devices correctly have resulted in patient infections in the past. An elevator wire channel located at the end of the duodenoscope allows doctors to move tools inserted through the duodenoscope

to perform procedures. ³⁴ In early duodenoscope models, the elevator wire channel remained open and exposed to the same type of contamination as the rest of the scope.

In an effort to protect this part of the scope from contamination, in 2010 Olympus introduced a new closed-channel model that sealed off the elevator wire channel with an "O-ring" designed to prevent exposure to any contaminants from a patient. ³⁵ The other two duodenoscope manufacturers, Pentax and Fujifilm, similarly moved to closed-channel duodenoscopes although Pentax did so considerably earlier.

After a lengthy investigation by FDA throughout 2014 and 2015, it is now evident that, unlike open-channel duodenoscopes, closed-channel duodenoscopes can trap and transmit bacteria even when the devices are cleaned according to manufacturers' instructions. Moreover, at least one manufacturer, Olympus, the manufacturer of 85 percent of the duodenoscopes used in the United States and in 19 of the 25 reported incidents, was aware of the problems well before FDA's findings, but failed to adequately alert either FDA or the hospitals and patients using these scopes.

Olympus knew in 2012 that the design of its closed-channel duodenoscope could prevent effective cleaning.

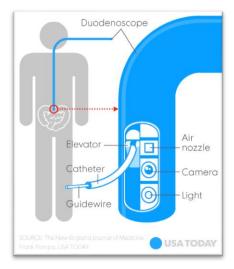
Erasmus Medical Center, Rotterdam, Spring 2012

In January 2012, there was an outbreak of antibiotic-resistant infections affecting 30 patients at Erasmus Medical Center in Rotterdam, the Netherlands. Hospital staff traced the infections to patients undergoing ERCP, and then directly to an Olympus TJF-Q180V closed-channel scope first marketed in the United States in mid-2010.³⁶

After Erasmus contacted Olympus, the hospital and manufacturer jointly asked Dr. Arjo Loeve of the Delft University of Technology to conduct an independent investigation into the Olympus

duodenoscope.³⁷ Dr. Loeve's investigation took place on April 23, 2012, at Olympus Netherlands headquarters with assistance from an Olympus employee flown in for the purpose of correctly disassembling the scope.³⁸ The investigation was observed by two Olympus Europa employees, three Olympus Netherlands employees, and six staff from Erasmus Medical Center.³⁹

The study identified two critical design flaws in the TJF-Q180V duodenoscope that made it difficult to clean reliably. First, Dr. Loeve found a series of tiny crevices that are too small to clean with a brush but large enough to allow in and trap bodily fluids and bacteria. In his report, Dr. Loeve points in particular to the space created by the axial clearance of the elevator, the area behind the curve of the elevator, and the hinges of the elevator as "locations where lingering and/or increasing moisture and/or biological materials are quite likely." 40



Picture from USA TODAY

Dr. Loeve also found that poor-quality sealing at the end of the scope is a potential mechanism for transmitting bacteria between patients. Dr. Loeve describes cracks in the material around the

camera, scale that was found behind the glass that covers the camera face, and open air bubbles, which can trap contaminants. ⁴¹ The O-ring, which seals off the elevator channel from contamination, was torn, worn, and contained "brownish scale," which indicates the O-ring may not have created a tight seal. ⁴² This is particularly dangerous because the closed elevator wire channel, unlike the open channel of the previous duodenoscope model, does not undergo HLD. Dr. Loeve concluded that it was "very likely [the] O-ring has not done its job" and "reliable sealing by means of the O-ring cannot be guaranteed."

Ultimately, in his May 2012 report, Dr. Loeve concluded that there needed to be a series of design changes to the TJF-Q180V scope to ensure it could be effectively decontaminated between uses. Dr. Loeve suggested changing the design of the scope to either have multiple sealing barriers or return to an open channel, to regularly ensure proper sealing between the O-ring and the scope, to frequently replace the O-ring to ensure the sealing mechanism remains functional, to alter the design to make various cracks and spaces larger so that a cleaning brush can reach them, and to rework the cleaning instructions to better address the hard-to-clean spaces in the scope.⁴⁴

On May 25, 2012, one month after five Olympus officials participated in the examination of the

"Reliable sealing by means of the O-ring cannot be guaranteed."

—Dr. Ario Loeve

relevant scope at Delft University and ten days after the Delft report finding that the design of the scope hinders reprocessing was published, Olympus filed an MDR with FDA regarding the infections at Erasmus. The MDR stated that "the device was being investigated by independent organization [sic]" and that "the photograph of the distal end of the device which was sent

from OLYMPUS NEDERLAND showed the debris around the objective lens."⁴⁵ While the MDR provided FDA with notice that the infections were linked to the scope, it was fundamentally misleading. The MDR did not discuss the findings of the Loeve report, misstated the number of patients impacted, and specifically stated it could not "conclusively determine the cause [sic] this event," claiming that "it can be considered as a possible cause of this phenomenon that the patient infected from other than the endoscope and procedure such as environmental factor in the facility [sic]."⁴⁶

Following Dr. Loeve's report, the Dutch National Institute for Public Health and the Environment

(RIVM) requested additional documents and information from Olympus and Erasmus and produced a follow-up report in July 2013 that confirmed many of Dr. Loeve's findings. The RIVM report agreed with Dr. Loeve that "the construction of the endoscope hinders optimum manual cleaning." The RIVM report similarly confirmed that Olympus had no substantive response to Loeve's concern about the O-ring, although RIVM could not rule out that the scale seen by Loeve was a result of previous repairs made to the scope rather than O-ring failure. ⁴⁹

"The construction of the endoscope hinders optimum manual cleaning."

— RIVM

Olympus did not update FDA regarding the events at Erasmus Medical Center until March 2015, and the company still did not fully describe the findings of the Delft or RIVM reports.⁵⁰

University of Pittsburgh Medical Center Presbyterian Hospital, Pittsburgh, fall 2012

A few months after Dr. Loeve's report first raised alarms about whether the Olympus closed-channel duodenoscope could be consistently disinfected by following the manufacturer's cleaning

instructions, Olympus was contacted by officials at the University of Pittsburgh Medical Center Presbyterian hospital in Pittsburgh, Pennsylvania ("UPMC"). ⁵¹ In the fall of 2012, UPMC experienced an outbreak of CRE, infecting about 13 patients who had undergone ERCP procedures with Olympus duodenoscopes. ⁵² Repeated cultures of one particular duodenoscope by UPMC staff found bacteria in the biopsy and water channels even after the scope had been reprocessed three times. ⁵³

After UPMC traced the infections back to the device, Olympus and an outside consulting group, ECRI Institute, evaluated UPMC's reprocessing procedures. ECRI found that UPMC's reprocessing was "consistent with standard practice and manufacturer recommendations." ECRI told UPMC officials that it could not make a "definitive" assessment about whether "there is a defect within the endoscope that would provide a reservoir for bacteria" because the small crevices in the scope made it impossible for ECRI to fully examine the device. ⁵⁵

When Olympus officials raised the possibility that the hospital's Custom Ultrasonics AERs could be at fault, UPMC officials went so far as to purchase an Olympus AER and demonstrated that the use of Olympus' own reprocessing machine did not prevent scopes from remaining contaminated after cleaning.⁵⁶ On December 18, 2012, Olympus filed an MDR with FDA, which documented some of the events at UPMC and the findings of ECRI. This MDR appears to have never been entered into FDA's system.⁵⁷

Additional independent testing, Jan 2013-2014

Documents obtained from Olympus show that from December 2012 through at least the summer of 2014 the company engaged independent laboratories to test company's closed-channel duodenoscopes for contamination, to assess whether the devices could be consistently disinfected, and to validate revised cleaning procedures. On January 8, 2013, before the infections at Virginia Mason had occurred, the French medical device evaluation company Biotech-Germande completed a report evaluating the Olympus duodenoscope with the same serial number as the scope involved in the December 2012 infections at Clinique de Bercy in France. The evaluation showed that "three cleaning/disinfection procedures were needed to eliminate the contamination that was initially present in the internal channels of the endoscope" and noted the "difficulty of eliminating all contamination present at the air/water and suction/biopsy valves and the operator channel cap through the application of a standard manual cleaning/disinfection procedure." ⁵⁸ A follow-up study in July 2014 further confirmed "that after a complete reprocessing procedure consistent with the guidelines of the Ministry of Health and the recommendations of [Olympus] a contamination may persist at the distal end of the endoscope "59 Studies at Bonn University conducted from March to November 2013, did confirm that a separate closed-channel duodenoscope was successfully cleaned using an Olympus AER.⁶⁰

European Alerts

By the end of 2012, Olympus had two clear examples of contaminated scopes spreading antibiotic-resistant infections even after correct reprocessing but neglected to alert hospitals or regulators in the United States. While Olympus left American doctors and hospitals in the dark about the duodenoscope design issues, in January 2013, Olympus sent a letter informing some European hospitals that they needed to carefully follow all reprocessing instructions and to "pay particular attention to the detailed pre-cleaning instructions, especially for the distal end and forceps elevator." ⁶¹ By the time Olympus sent the letter, the company was aware of at least three

duodenoscope-linked outbreaks impacting about 46 patients in three different countries; however, the letter only references "a recently reported case" of a contaminated TJF-Q180V scope. 62

Again, in August 2014, Olympus disseminated in Europe an urgent field safety corrective action. The August 2014 safety communication references "a few complaints of residual debris in the distal end of the TJF-Q180V duodenoscope after reprocessing." By that time, Olympus knew of at least ten different instances of hospitals reporting contaminated TJF-Q180V scopes spreading antibiotic-resistant infections between patients. 64

FDA Investigation

In September 2013, after CDC alerted FDA to an outbreak of infections at Advocate Lutheran General Hospital linked to a Pentax duodenoscope, and CDC confirmed that Advocate Lutheran reprocessed scopes correctly according to the manufacturer's instructions, FDA began an investigation into closed-channel duodenoscopes. Throughout 2014, FDA worked to better understand the extent of the problem and to develop recommendations. It appears that at the time the investigation was initiated, FDA was unable to locate either the Erasmus or UPMC MDRs filed by Olympus and was without the benefit of reports from Dr. Loeve's Delft University or RIVM. By April 2014, FDA had independently sought validation data from the duodenoscope manufacturers in order to determine if the cleaning instructions worked reliably. FDA became aware of and obtained a copy of the Delft report only sometime after September 2014; had Olympus shared the existence of the report earlier, it likely would have sped FDA's investigation and led to more rapid alerts from both Olympus and the agency.

Instead, Olympus did not acknowledge the problem in the United States until February 19, 2015, six months after the urgent safety communication in Europe and almost three years after the Delft report. In May 2015, Olympus provided additional updates to their reprocessing instructions and distributed a new brush to help ensure that duodenoscopes are clean before undergoing HLD – a brush that was available in Europe for nearly five years before it was provided in the United States. Had hospitals been alerted to the risk and the need to use increased efforts to ensure that duodenoscopes were appropriately disinfected, some if not all of the infections, including in Seattle, may have been prevented.

Olympus's failure to take action and alert regulators likely contributed to the at least 141 patient infections linked to Olympus duodenoscopes that occurred in domestic hospitals between the spring of 2012, when Olympus was well aware of potential flaws with the device, and February of 2015, when the company finally alerted doctors and hospitals in the United States.

Olympus failed to meet its regulatory obligations.

Olympus's failure to act upon the information it knew about the problems decontaminating closed-channel duodenoscopes and the spread of deadly infections is consistent with the company's failure to meet its obligations at each step of the device regulatory process. During its investigation in 2014 and 2015, FDA determined that Olympus failed to seek required clearance for the modification from an open to closed-channel device, failed to validate the closed-channel duodenoscope cleaning instructions to make sure they worked consistently, and failed to fully report information it knew about the adverse events linked to its device.

Olympus did not clear its duodenoscope design modification with FDA.

Manufacturers of Class II devices like duodenoscopes are required to make a 510(k) submission in order to market a new device, an existing device for a new purpose, or a device that is changed or modified in a way that might implicate its safety or effectiveness. This allows FDA to ensure that the modified device remains "substantially equivalent," or at least as safe and effective, as a device that is already legally on the market. It is the manufacturer's responsibility to determine if and when a 510(k) application should be submitted to FDA.

Olympus did not file a 510(k) application for the TJF-Q180V duodenoscope because it determined the new model was similar to a previous device, the TJF-Q160, approved in 2008. However, unlike the TJF-Q180V, the TJF-Q160 has an open elevator wire channel. FDA subsequently determined Olympus was wrong to assert that the TJF-Q160 and TJF-Q180V are substantially equivalent devices, and found that the change from an open to a closed elevator channel "impacts the safe use of the device" because the newly sealed elevator channel "prevent[s] sterilization and high level disinfection." FDA notified Olympus that it should have made a 510(k) submission to account for the substantial changes between the TJF-Q160 and the TJF-Q180V and, in March 2014, required the company to belatedly make that submission. FDA is currently in the process of evaluating those documents to assess the substantial equivalency of the elevator channel sealing mechanism.

Olympus failed to ensure duodenoscope cleaning instructions worked before selling closed-channel duodenoscopes to hospitals.

The investigation also found that Olympus has been selling its closed-channel duodenoscope since 2010 without sufficiently testing its cleaning instructions to ensure that they actually work in real-world settings, and that Olympus knew that its testing data was insufficient since at least 2013.

FDA requires device manufacturers to validate the design of their devices, which includes the ability for that device to be safely reprocessed between uses.⁶⁹ In other words, manufacturers must test their devices and collect evidence to show that reprocessing will consistently result in a device that meets certain decontamination specifications.⁷⁰ Proper validation should test all stages of reprocessing and should consider "the characteristics of the user population and operating environment."⁷¹

However, in July 2013, following the infections at Erasmus Medical Center in Rotterdam, RIVM examined Olympus' validation of the TJF-Q180V reprocessing instructions and found the data analysis "unacceptable as a demonstration of effective cleaning." RIVM concluded that the data Olympus provided to show that manual cleaning could decontaminate the elevator mechanism

"left so much to be desired that it is not possible to support the conclusion drawn by the manufacturer, namely that the cleaning and disinfection procedure for the elevator is effective." ⁷³ Olympus also did not provide RIVM with information to substantiate that the O-ring effectively seals the elevator wire channel from contamination or attempt to show

[Olympus's reprocessing data] is "unacceptable" and left so much to be desired that it is not possible to support the conclusion . . . that the disinfection procedure. . .is effective." – *RIVM*

that the leak testing that hospitals are supposed to conduct during reprocessing is an accurate way of assessing when an O-ring is wearing out and in need of maintenance from the manufacturer. After requesting Olympus's validation data in April 2014, FDA reached the same conclusion –

Olympus did not have sufficient data to show closed-channel duodenoscopes could be reliably cleaned with an adequate margin of safety.

In the 19 months between RIVM's conclusion that Olympus did not have sufficient validation data and Olympus' first safety notice, at least 49 patients in the United States were infected with antibiotic-resistant bacteria connected to an Olympus closed-channel duodenoscope.

At the time Olympus' closed-channel duodenoscopes were first sold in the United States, FDA relied on manufacturers to attest that their devices had been validated effectively before being marketed. Unsurprisingly in view of the RIVM findings, in April 2014 when FDA similarly asked Olympus to produce suitable data to show their cleaning instructions actually worked, the company could not do so.⁷⁵ The faith that patients, doctors, hospitals, and public health officials placed in Olympus to thoroughly test their cleaning instructions before putting devices in the marketplace was clearly misplaced.

In February 2015, Senator Murray requested FDA update its draft reprocessing guidance for reusable devices, and on March 17, the agency issued final guidance, "*Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*" ⁷⁶ This final guidance requires manufacturers of high-risk reusable devices such as duodenoscopes to provide FDA with their actual reprocessing data when applying for clearance to market devices so that FDA can assess the validity of cleaning instructions for itself. While the guidance is a useful step, under current law, manufacturers of reusable devices are still not required, as a condition of market clearance, to produce data that actually demonstrates the devices can be reliably and repeatedly cleaned in real world conditions.

Olympus submitted incomplete and misleading medical device reports to FDA.

Finally, while Olympus generally submitted MDRs to account for duodenoscope-linked infections the company was aware of, Olympus did so in such a cursory manner as to make it nearly impossible for the agency to accurately assess the scope and severity of the infections liked to duodenoscopes. Because device manufacturers and importers are the only entities required to submit adverse event reports to FDA when a device is linked to a serious injury, the agency relies heavily on the accuracy of manufacturers' reports to track problems with medical devices.⁷⁷

Some Olympus MDRs, particularly those submitted for outbreaks in Europe, understate the number of patients affected, ⁷⁸ point to environmental contamination as a source of the infections rather than problems with the device itself, ⁷⁹ and fail to provide the full information available to Olympus. Following the reports of contaminated scopes at Erasmus Medical Center and Clinique de Bercy in France, Olympus received results from independent labs that found the duodenoscopes linked to infections in those hospitals could contain bacteria even after being cleaned correctly, but never updated their adverse event reports or communicated that information to FDA.

As a result of inspections conducted in 2015, FDA found that Olympus "fail[ed] to adequately develop, maintain, and implement written MDR procedures" as mandated by adverse event reporting regulations and did not have a consistent process for "submit[ting] all information reasonably known to it for each event." While FDA's findings regarding the MDRs submitted by Olympus are certainly correct, the violations also understate the real impact of Olympus' larger failure to alert regulators in the United States and Europe about significant problems in cleaning the TJF-Q180V closed-channel scope.

Pentax and Fujifilm also failed to comply with regulatory requirements.

While the majority of the infections that occurred between 2012 and spring of 2015 were connected to an Olympus duodenoscope, closed-channel devices manufactured by Pentax and Fujifilm were also linked to six outbreaks and at least 53 antibiotic-resistant infections during this time. Pentax sells about 12 percent of the duodenoscopes used in the United States and Fujifilm about three percent. These duodenoscope manufacturers contributed to the dangerous superbug and other antibiotic-resistant infections linked to ERCP procedures at hospitals in the United States and around the world by failing both to comply with the same basic regulatory expectations as Olympus and communicate thoroughly with FDA about the outbreaks.

Fujifilm failed to clear their duodenoscope design modifications with FDA.

Similar to Olympus, FDA determined that Fujifilm never made a 510(k) submission for the modifications in the design of its closed-channel scope ED-530XT. ⁸² Fujifilm had concluded that there were only minor changes between ED-530XT and the already-approved open-channel model ED-450XT5. However, FDA's inspection identified least four potentially substantial differences between the ED-450XT5 and the ED-530XT. In August of 2015, FDA sent a 510(k) status letter to Fujifilm summarizing these findings and requested a 510(k) application for the ED-530XT. ⁸³ FDA has not yet determined whether Pentax should have submitted a 510(k) application to account for the changes between the Pentax ED-3490TK and ED-3670TK. ⁸⁴

Pentax and Fujifilm failed to properly validate their duodenoscope reprocessing instructions.

Once FDA launched its investigation into closed-channel duodenoscopes, it requested the data from Pentax and Fujifilm demonstrating that each company's closed-channel duodenoscope could be consistently cleaned. Also like Olympus, both Pentax and Fujifilm were unable to produce the required underlying data to show that the cleaning instructions were consistently effective. In fact, after FDA inspections of Fujifilm plants in April and May 2015, the agency observed multiple flaws in Fujifilm's validation process including that the company did not evaluate the O-ring, ⁸⁵ performed validation on a mock-up of a duodenoscope channel rather than the actual device, ⁸⁶ did not produce the appropriate reduction in bacterial spores during ethylene oxide sterilization validation, ⁸⁷ and did not evaluate the design of the closed-channel model under actual or simulated conditions of use. ⁸⁸

FDA inspections also found that Pentax had validated its HLD and sterilization protocols for the ED-3670TK duodenoscope using an entirely different model of scope and could not show that the two duodenoscopes responded comparably to reprocessing. ⁸⁹ Moreover, Pentax tested sterilization of the scope with a different mixture of gas than it instructed hospitals to use. ⁹⁰

On December 23, 2015, FDA announced that new Fujifilm reprocessing instructions that included additional brushing, washing, and flushing were sufficiently validated, and "demonstrate consistent and reliable cleaning and high level disinfection." Meanwhile, Pentax has not yet demonstrated to FDA that its new cleaning instructions were validated, leaving doctors and hospitals in the disconcerting position of using a device without cleaning instructions they can feel confident about.

Pentax and Fujifilm submitted late and incomplete medical device reports.

Similarly, Fujifilm and Pentax failed to meet their obligations to self-report serious illnesses and deaths that may have been caused by their duodenoscopes. After inspecting manufacturers' files in 2015, FDA found that both companies had substandard MDR reporting practices. Pentax failed to "adequately develop, maintain, and implement written MDR procedures" or "internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements." Meanwhile, Fujifilm lacked procedures for "receiving, reviewing, and evaluating complaints."

These failures may well explain why neither Fujifilm nor Pentax appears to have filed a single adverse event report related to antibiotic-resistant infections and closed-channel duodenoscopes with FDA for any incidents in any foreign country until the fall of 2015 despite the regulatory requirement to report adverse events that occur anywhere in the world for any device sold in the United States. The Americas are only about 36 percent of Pentax's business worldwide with 15 percent in the Asia Pacific region, 49 percent in Europe, the Middle East, and Africa, and less than one percent in Japan. Fifty percent of Fujifilm duodenoscopes are sold in Europe, 22 percent in Asia, and 18 percent in Latin and South America. Since Pentax and Fujifilm scopes were collectively linked to six outbreaks domestically by Spring 2015, it is hard to imagine that no infections during this time were connected to the more than 90 percent of Fujifilm scopes in use outside of North America and more than 64 percent of Pentax duodenoscopes used outside of North and South America.

Overall, FDA inspections documented that all three duodenoscope manufacturers put patients' lives in jeopardy by failing to meet their obligations at each step of the regulatory process. The manufacturers failed to seek FDA clearance for their modified devices when they changed to the closed-channel design. When confronted with evidence that the design of closed-channel duodenoscopes was contributing to the spread of infections across the United States and worldwide, the duodenoscope manufacturers did not take adequate action to alert device users or regulators, allowing its device to spread superbug and other serious infections among ERCP patients for years.

Custom Ultrasonics' automated endoscope reprocessors likely contributed to patient infections.

On November 13, 2015, FDA took the unusual step of issuing a mandatory recall of all of the approximately 2,800 Custom Ultrasonics AERs in hospitals and clinics across the United States. FDA is so concerned about Custom Ultrasonics AERs' ability to perform as marketed that the agency deemed a mandatory recall necessary to protect the public's health, and has recommended that hospitals using Custom Ultrasonics AERs switch to alternative methods of HLD. 97

HELP Committee staff has been able to confirm that Custom Ultrasonics machines were used by at least nine out of 16 domestic hospitals that experienced infections after ERCP procedures accounting for about 141 patient infections at:

- UPMC Presbyterian Hospital, Pittsburgh, PA
- NYP/Weill Cornell Medical Center, New York City, NY
- UMass Memorial Hospital, Worchester, MA
- Advocate Lutheran General Hospital, Park Ridge, IL
- Hartford Hospital, Hartford, CT
- Massachusetts General Hospital, Boston, MA
- UCLA Medical Center, Los Angeles, CA
- Carolinas Medical Center, Charlotte, NC
- Thomas Jefferson University Hospital, Philadelphia, PA



Picture from www.customultrasonics.com

Considering that only about ten to 20 percent of the AERs used in American hospitals are Custom Ultrasonics AERs, it appears the defective machines played a significant role in allowing the duodenoscopes to remain contaminated between uses.

However, it is also clear that duodenoscope-linked infections cannot be solely attributed to Custom Ultrasonics machines. Erasmus Medical Center, Virginia Mason Hospital, Froedtert Hospital, and Advocate Good Samaritan Hospital all experienced contaminated duodenoscopes while using other brands of AER machines. Additionally, UPMC, which used Custom Ultrasonics machines, took the unusual step of purchasing an Olympus-made AER and demonstrated that their Olympus closed-channel duodenoscope remained contaminated even after cleaning it in Olympus' own AER.

Similar to washing machines, AERs flush liquid chemicals through scopes to destroy lingering contaminants after the device is hand cleaned with small brushes in order to achieve HLD. If an AER is not working correctly, it may not completely disinfect the scopes. Custom Ultrasonics' AERs do not appear to have consistently provided HLD when used to clean duodenoscopes after procedures, and the company, like the duodenoscope manufacturers, appears to have repeatedly abused the expectations of the current regulatory system.

FDA first cleared the Custom Ultrasonics AER for use in 1984 but the company has faced regulatory challenges dating back to at least 2005. After FDA inspections in 2005-2007 revealed that Custom Ultrasonics failed to comply with regulations designed to ensure that devices are manufactured according to certain standards of quality, Custom Ultrasonics and FDA entered into a consent decree in 2007 preventing Custom Ultrasonics from manufacturing and distributing any devices – including AERs. Although the company was able to resolve some of the issues and resume manufacturing five months later, FDA subsequently found Custom Ultrasonics in violation of the terms of the consent decree at least three separate times since 2008, including failure to seek 510(k) clearances for significant changes to its devices.

In the spring of 2015, FDA asked for data from all AER manufacturers. In April 2015, an inspection of the Custom Ultrasonics plant in Ivyland, Pennsylvania found Custom Ultrasonics:

➤ <u>Never validated the compatibility of its AERs with closed-channel models of duodenoscopes;</u>

- ➤ Did not validate their AERs with specific types of HLD cleaning solutions;
- ➤ Did not validate the effectiveness of pre-filters that prevent large particulates and debris from contaminating devices; and
- ➤ Did not sufficiently validate the water filtration system. ¹⁰¹

Ultimately, FDA concluded that Custom Ultrasonics machines could not consistently provide the adequate margin of safety required by liquid chemical sterilant and HLD-specific guidance. ¹⁰²

Overall, the investigation found that the current regulatory regime places obligations on device manufacturers that each of the four manufacturers above repeatedly failed to meet. At each step of the regulatory process – the determination of whether new device clearances need to be sought, quality testing that truly proves a device will consistently perform in real world settings, and prompt and complete reporting of all required adverse events – each of the four device manufacturers discussed above failed to meet these obligations. These failures are directly responsible for the spread of antibiotic-resistant infections in already critically ill patients.

Hospitals Were Slow to Report Infections

While this investigation has demonstrated that duodenoscope manufacturers and Custom Ultrasonics failed to quickly and comprehensively report problems with their devices to FDA, the investigation has also revealed a similar problem among hospitals. At least 16 domestic hospitals, primarily large, sophisticated health systems, identified outbreaks of antibiotic-resistant infections linked to ERCP, but none actually followed all of the required steps to promptly notify manufacturers or, in cases of death, FDA.

FDA regulations require hospitals to submit an adverse event report to a device manufacturer within ten working days of becoming aware of information that reasonably suggests that a device "may have caused or contributed" to a serious injury or death. The hospital is supposed to report the information to the manufacturer on FDA form 3500A or an approved electronic substitute, which includes a variety of information about the facility, the patient, and what happened, in order to help the manufacturer meet their own reporting obligations to FDA. 104

Because they are on the front lines of treating patients, doctors and hospitals are often the first to recognize device related problems. Health care providers thus play a critical role in alerting manufacturers and federal regulators to suspected issues. However, conversations between Senator Murray's HELP Committee staff and hospital staff, state and local health departments, and manufacturers have revealed a disconcerting lack of awareness that these reporting obligations even exist.

Hospitals did not comply with mandatory requirements to report information to manufacturers.

As part of this investigation, HELP Committee staff spoke with staff at eight hospitals that had

infections linked to closed-channel duodenoscopes before or around September 2013 – when FDA first understood that some duodenoscopes remained contaminated after cleaning according to manufacturers' instructions. ¹⁰⁵ These conversations demonstrated that numerous hospitals were able to identify, track, and contain superbug and other antibiotic-resistant infections within their hospitals, but not a single hospital that experienced infection outbreaks tied to the duodenoscopes appears to

It appears that not a single hospital that experienced infection outbreaks linked to the duodenoscopes sent the required adverse event form to the device manufacturers.

have sent the required adverse event form to the device manufacturers. Several hospitals appear to have failed entirely to alert the device manufacturer in any way.

Multiple hospitals across the country engaged in exemplary public health work to identify clusters of antibiotic-resistant infections, isolate the source, and contain the problem. At least 16 hospitals across the United States were able to identify that they had patients with unusual infections and trace those infections back to ERCP procedures performed with duodenoscopes. These investigations were often complicated and sophisticated. For example, Virginia Mason, with the assistance of the Washington State Department of Health, undertook enhanced surveillance efforts that identified a cluster of patients infected after ERCP. From that cluster, hospital officials were able to identify a unique isolate that was then used to trace the infections.

Similarly, UMass Hospital in Worchester, Massachusetts used isolate testing and DNA fingerprinting to confirm that liver transplant patients were infected with the same strain of antibiotic-resistant bacteria. Massachusetts General Hospital in Boston and NYP/Weill Cornell Medical Center in New York City conducted in-depth retrospective analyses that retroactively linked patient infections with ERCP procedures. It is likely that many hospitals with fewer resources similarly experienced infections but did not identify or track the infections.

Most hospitals also alerted either their state or local health departments about the infections. States have varying reporting requirements and not all hospitals are required to report infections to health department officials, or may be required only to report certain types of infections or infections impacting a large number of patients. Even in cases when reporting was not required, however, hospitals generally appear to have communicated with their local or state officials about outbreaks. However, with the exception of Advocate Lutheran General Hospital, and Virginia Mason hospital which worked with a CDC staffer embedded in the King County Health Department who kept the agency informed, no hospital directly notified CDC, and there is no federal reporting requirement for hospitals to do so.

Startlingly, after identifying the source of the outbreaks, none of the eight hospitals entirely fulfilled their legal obligation to quickly alert manufacturers or FDA to adverse events at their hospitals traced to devices. Certain hospitals, including UMass, Carolinas Medical Center and Thomas Jefferson, failed entirely to alert manufacturers to problems, leaving Olympus, Fujifilm, Pentax, and FDA unaware of the outbreaks of infections potentially caused by contaminated duodenoscopes. Some hospital staff have explained they did not inform manufacturers, even after tracing infections back to ERCP procedures, because they could not demonstrate that a particular

scope harbored contamination, or be entirely certain that a problem with a specific duodenoscope caused a particular illness or cluster of infections among ERCP patients.

When hospitals did report adverse events, it was generally late, notification was made informally by phone or email, and reports did not include all of the information necessary for the manufacturers to submit accurate and complete information to FDA. Olympus relayed that none of the 12 domestic hospitals with outbreaks linked to Olympus scopes sent the required FDA form 3500A to the manufacturer.

Moreover, UPMC, NYP Weill/Cornell Medical Center, Advocate Lutheran, and Virginia Mason notified manufacturers of a potential problem months after they were aware of the connection. For example, by December 2013, Virginia Mason knew that duodenoscopes were contaminated and spreading antibiotic-resistant infections between patients but did not alert the manufacturer to the issue until July 2014. When a team from Olympus evaluated Virginia Mason's reprocessing procedures in the fall of 2013, the hospital never mentioned the infections. Hartford Hospital reported a patient tested positive for "bacterial micro-organisms" after an "unspecified procedure," vague information at best. Olympus followed up but received no response from the hospital. Pentax MDRs also documented difficulty obtaining information from Massachusetts General Hospital, receiving no response after multiple requests for information.

Overall, not one of the hospitals that had identified infection outbreaks by the time FDA became aware of the problem in September 2013 notified the manufacturer within the period dictated by FDA regulation.

Hospital	Notified the Manufacturer *	Notified FDA *	Notified CDC	Notified Patients	Notified State/Local Health Departments **
UPMC Presbyterian					
Hospital,	Late	Late	No	Unk	Yes
Pittsburgh, PA					
NYP Weill/ Cornell	T 4	Ŧ ,	3 .7	** 1	T 7
Medical Center	Late	Late	No	Unk	Yes
NYC, NY UMass Memorial					
Hospital,	No	No	No	Yes	Ves
Worchester MA	110	110	110	1 65	165
Advocate Lutheran General Hospital, Park Ridge IL	Late	Yes	Yes	Yes	Yes
Froedtert Hospital, Milwaukee WI	Late	Unk	No	Unk	Unk
Virginia Mason Hospital and Medical Center, Seattle WA	Late	Late	Indirectly	Late	Late
Thomas Jefferson University Hospital, Philadelphia, PA	No	No	No	No	Yes

Carolinas Medical Center, Charlotte, NC	Unk	Unk	No	Unk	Unk
* Required ** May be required depending on the state					

Hospitals did not proactively communicate information to federal agencies.

Hospitals also generally failed to communicate directly with FDA and CDC. Hospitals are required to report information related deaths (but not serious injury) to FDA no more than ten days after becoming aware of the incident, and may always submit adverse event reports relaying other suspected problems to the agency.¹¹¹ While several hospitals did eventually submit MedWatch reports to FDA, less than one percent of all the adverse event reports were submitted by hospitals, suggesting that hospitals are not meeting their obligations to report deaths that devices may have caused or contributed to.¹¹² Moreover, hospital staff interviewed by Committee staff almost universally were unfamiliar with any obligation to report to FDA.

Even the hospitals that did file reports typically failed to provide FDA with a full picture of what they knew. For example, in its one-paragraph MedWatch report filed March 4, 2013, about five months after linking infections to duodenoscopes, UPMC reported that the "source of the [infection] remains undetermined at this time." The report included neither that UPMC's reprocessing procedures had been validated by Olympus nor that the hospital was unable to decontaminate the duodenoscope after multiple attempts at reprocessing. NYP Weill/Cornell filed a MedWatch report on October 9, 2013 clearly explaining that the duodenoscopes could not be reliably cleaned, but filed the report seven months after identifying the duodenoscope elevator as a source of the infections. Virginia Mason also filed a MedWatch report but did so in May 2014, at least five months after connecting patient infections to duodenoscopes. No hospital that identified clusters of antibiotic-resistant infections linked to closed-channel duodenoscopes reported those infections to CDC until May 2013.

Overall, hospitals' slow approach left FDA with an inaccurate picture of the frequency and severity of these events. Reporting by the hospitals as a whole suggests that rather than collaborate to quickly alert regulators to a potential device problem, hospitals were reluctant to share unconfirmed information. Hospitals as a whole appear to have believed they had an obligation to report only what they could demonstrate beyond any doubt. Such narrow reasoning reveals a misunderstanding about hospital reporting requirements, which are triggered by information that reasonably suggests a device may have caused or contributed to a death or serious injury. Hospitals' slow reporting may have had the effect of impairing FDA's initial understanding of the number and severity of infections tied to duodenoscopes, and is further evidence of the need to move beyond self-reporting to identify and address issues posed by medical devices.

FDA Failed to Recognize the Prevalence of Duodenoscope-Linked Infections and Respond Quickly

FDA first became aware that closed-channel duodenoscopes could not be reprocessed consistently to prevent transmission of deadly superbug and other antibiotic-resistant bacteria between patients in September 2013, after CDC alerted them to infections at Advocate Lutheran General Hospital. By this point, at least 11 hospitals, including Virginia Mason, had experienced outbreaks linked to reprocessed duodenoscopes. Because of FDA's reliance on a passive postmarket surveillance system, the agency had no way to identify this trend until the issue was directly brought to their attention.

FDA reviews reports filed by manufacturers and others largely by having staff with clinical backgrounds read the more than one million adverse event reports submitted every year. As discussed above, FDA does not flag incomplete reports because the agency expects MDRs to be filed before all the relevant information is known, and expects manufacturers to supplement the reports as they learn more. Therefore, it is challenging for reviewers to identify trends that might involve a relatively low number of incidents. Additionally, because there is no way to measure how a series of adverse event reports relate to the total number of devices and procedures, the system provides no way to assess the prevalence of adverse events.

In the spring of 2013 Advocate Lutheran General Hospital contacted CDC about an ongoing CRE outbreak, the only hospital to proactively contact the agency. CDC officials sent to the hospital in August 2013 were able to trace the infection back to the closed-channel Pentax duodenoscopes used in ERCPs *and* confirm that the scopes had been carefully reprocessed by the hospital. CDC in turn alerted FDA that duodenoscopes were potentially transmitting bacteria even after being cleaned in accordance with the manufacturer's instructions.

At that point, FDA began an investigation into infections transmitted by closed-channel duodenoscopes. One of FDA's initial steps was to query their adverse event reporting system to determine if similar events had been reported elsewhere. When FDA initially queried its adverse event database after learning from CDC of the infections at Advocate Lutheran, FDA had received the following information about six outbreaks involving closed-channel duodenoscopes:

- 1) *Erasmus Medical Center, Rotterdam, Netherlands*. Notified in May 2012 that 16 patients had tested positive for Pseudomonas aeruginosa after undergoing an ERCP with an Olympus duodenoscope, and that an independent investigation was being conducted. ¹²¹
- 2) *UPMC Presbyterian Hospital, Pittsburgh, PA*. Notified in November 2012 that ten to 13 patients may have been infected with CRE after undergoing a procedure with an Olympus duodenoscope. ¹²² Also notified that CRE had been found on one of the scopes, and that the scopes tested positive for Klebsiella pneumonia on two separate occasions after multiple cultures. In October 2013, an additional report relayed that another scope tested positive for contamination. ¹²³
- 3) *Clinique de Bercy, Charenton-le-Pont, France*. Notified in December 2012 that three patients were infected with Escherichia coli after undergoing an ERCP performed with an Olympus duodenoscope. Mentions that the scope is being sent to an independent lab for testing.¹²⁴

- 4) *Charite-Universitatsmedizin*, *Berlin*, *Germany*. Notified in April and July 2013, that five patients at Charite-Universitatsmedizin in Berlin were infected with Klebsiella after undergoing treatment with an Olympus duodenoscope that had been used earlier on a patient with the same infection. Two of the five infected patients died. ¹²⁵
- 5) NYP/Weill Cornell Medical Center, NYC, NY. Notified in June 2013 that 15 patients at NYP/Weill Cornell Medical Center were infected with CRE after undergoing a procedure with an Olympus duodenoscope and that four different duodenoscopes tested positive for CRE even after the scopes had undergone HLD. Olympus also reported the hospital was not using the correct reprocessing procedures. 126
- 6) Advocate Lutheran General Hospital, Park Ridge, IL. Notified in July 2013 that a patient had undergone ERCP with a Pentax closed-channel duodenoscope and then developed a CRE infection. The hospital confirmed that its staff used proper reprocessing procedures, and that an organism had been found under the elevator on the duodenoscope. 127

Taken together these reports should have provided FDA with considerable information to suggest cleaned scopes were continuing to spread infection; however, the agency appears to have lost the report filed describing the 2012 outbreak at UPMC (it is not available in the agency database). This left FDA without the key information that reported the earliest domestic antibiotic-resistant infections linked to a correctly reprocessed duodenoscope. It also appears that FDA's initial search of their adverse event report database did not identify the foreign adverse event reports that accounted for half of the incidents reported before September 2013. Accordingly, FDA's initial query may have left the agency with information about just one additional instance of closed-channel duodenoscope linked infections.

By the time FDA started its investigation, outbreaks of antibiotic-resistant infections had likely already occurred at Thomas Jefferson University, Virginia Mason, Carolinas Medical Center, and Froedtert hospitals. However, those outbreaks had not yet been reported to the agency, or, in some cases, to the device manufacturers. FDA appears to have been left with such incomplete information that it was unable to develop an accurate sense of the frequency and severity of these outbreaks. This lack of complete information made it difficult for the agency and outside experts to conclusively determine that mistakes in the cleaning and reprocessing of the duodenoscopes were not the source of the infections.

Throughout late 2013 and 2014, as the agency became aware of the clusters of infections in Pennsylvania, Massachusetts, Connecticut, Washington, Illinois, and Wisconsin, and the number of patients infected with potentially deadly bacteria continued to rise, FDA continued to investigate and collaborate with CDC and outside experts. FDA had not yet determined whether the infections occurred because hospitals did not correctly follow manufacturers' cleaning instructions or whether the closed-channel duodenoscopes could remain contaminated even after reprocessing was correctly carried out. FDA had also not yet developed supplemental reprocessing recommendations to ensure hospitals initiated enhanced cleaning procedures. As a result, FDA still had not issued any safety communication to alert hospitals to the risk posed by these devices.

In April 2014, FDA sought the validation data from duodenoscope manufacturers to show that they had properly tested their cleaning instructions to make sure that the data showed the instructions worked consistently. It was not until September 2014, when an FDA official met someone involved with the investigation of the outbreak in the Netherlands at a conference, that

FDA learned of the RIVM report detailing Olympus' lack of cleaning validation data almost a full year earlier. As a result, it took an additional year for FDA to receive the data, determine it was insufficient, and for the manufacturer to develop enhanced cleaning procedures cleared by FDA in the spring of 2015.

By late 2014, FDA had sufficient information to begin preparing a safety communication for hospitals. In January 2015, news reports revealed the infections in Seattle as well as more recent infections at UCLA and Cedar Sinai hospitals in California. On February 4, 2015, Senator Murray wrote to FDA seeking additional information about the infections, urging the agency to provide hospitals with safety information and to finalize the guidance for the cleaning of reusable devices that had been issued as a draft in 2010. 128

Following those events, U.S. federal agencies took the following steps in 2015:

- **February 19: FDA issues a Safety Communication.** FDA warns for the first time that duodenoscopes may transmit antibiotic-resistant infections between patients "even when manufacturer reprocessing instructions are followed correctly." ¹²⁹
- March: The Department of Justice (DOJ) launches a criminal investigation into duodenoscope manufacturers. DOJ has since issued subpoenas to Olympus, Fujifilm, and Pentax as well as several hospitals for information related to duodenoscopes and antibiotic-resistant infections.
- March 12: CDC issues an interim duodenoscope surveillance protocol. CDC issued an interim protocol that instructs hospitals about how to culture and quarantine devices to assess whether their reprocessing procedures and manufacturers cleaning instructions are working correctly, and to identify contaminated scopes before they are used during procedures. ¹³⁰
- March 17: FDA finalizes reprocessing guidance for reusable devices. The finalized guidance makes clear that FDA expects to see in 510(k) applications underlying data demonstrating that cleaning instructions actually work for certain reusable devices, including duodenoscopes.¹³¹
- March–May: FDA inspects Olympus, Fujifilm, and Pentax manufacturing plants. The inspections noted failures to make requisite 510(k) submissions by Olympus and Fujifilm, failures to maintain adequate MDR reporting systems, and failures to properly validate cleaning instructions.
- April: FDA inspects Custom Ultrasonics' facility. Inspectors documented a series of violations including that the company had insufficient data to show their AERs worked effectively.
- May 15 and 16: FDA convenes a meeting of the Gastroenterology-Urology Device Advisory Committee. FDA issues an Executive Summary of the meeting indicating the agency is aware of at least nine outbreaks of infections linked to closed-channel duodenoscopes. The Advisory Committee discusses potential options for hospitals to ensure that devices are consistently cleaned after every procedure, including the culture and quarantine protocol developed and implemented by Virginia Mason staff. None of the three device manufacturers attended the advisory committee meetings.

- August 4: FDA issues a safety communication for supplemental reprocessing. The safety communication included four potential supplemental reprocessing measures including the microbiological culturing method put in place by Virginia Mason, Ethylene Oxide Sterilization, a liquid chemical sterilant processing system, or repeat HLD. None of these options are ideal. For example, ethylene oxide sterilization may pose health risks to hospital staff and microbiological culturing requires a hospital to purchase additional duodenoscopes. 133
- August 12: FDA issues warning letters to Fujifilm, Pentax, and Olympus. The letters included requests for the manufacturers to submit 510(k) applications so that FDA can evaluate the safety of the modification from an open to closed elevator wire channel. 134
- October 5: FDA orders postmarket surveillance studies. The manufacturers must answer whether their instructions are sufficient to ensure user adherence, the percent of scopes that remain contaminated after proper reprocessing, and the factors that contribute to contamination and what is needed to fully decontaminate the device. 135
- November 13: FDA issues a mandatory recall of Custom Ultrasonics AERs. FDA warned that Custom Ultrasonics AERs may not reliably clean devices and recommended that the hospitals and health facilities using about 2,800 Custom Ultrasonics machines move as quickly as possible to a different manufacturer's AERs. 136
- **December 31: FDA issues draft "emerging signals" guidance.** FDA's new guidance explains the agency will now notify the public when it learns about potentially serious device issues rather than wait until the agency has reached a conclusion about a problem or formed recommendations.¹³⁷

While FDA has taken a number of actions to address the outbreaks in 2015, the inability to access information about adverse events independently from hospitals and manufacturers, and the inability to query data in electronic health records and claims data, stymied FDA's investigation and response to the spreading superbug infections and other dangerous illnesses.

Overall, FDA had major gaps in information, or delays in receiving information, which led to an unacceptably slow response to the spread of deadly infections in ERCP patients. While some of the responsibility for this failure lies with the agency for losing a key adverse event report and missing relevant international adverse event reports, without a more robust surveillance system independent from the reporting of manufacturers and hospitals, it is likely that the same gaps and delays will occur in other device related investigations.

FDA Needs a More Robust Device Safety Surveillance System

A passive device surveillance system is ineffective even when manufacturers and hospitals self-report information about device safety to FDA.

Even if device manufacturers and hospitals had worked to fulfill their regulatory obligations and provide FDA with the information they knew about device issues as rapidly and completely as

possible, FDA's passive device surveillance system probably would have still taken an unacceptably long time to identify the extent of the device issues. Assuming an MDR is filed and contains relevant information, staff reviewers can assess the seriousness of a particular incident, but are unlikely to make connections or see patterns because MDRs are not linked to the reports of similar devices from the same or other manufacturers with the same type of adverse event. Even in the unlikely event that a staff member sees a sufficient number of reports related to particular device to notice a pattern, FDA reviewers lack a denominator of the total number of times a device is used, and accordingly, have no way of assessing how frequent or serious issues are relative to how often a device is used. If a reviewer sees ten MDRs reporting a device failure, it is almost impossible to know if that is ten out of 100 procedures, ten out of 10,000 procedures, or ten out of one million.

The current system provides no ability to run data analytics to help identify patterns or to alert FDA to unusual types of reports. The system as it is currently designed allows FDA only to query the passive database to pull up all the information it has about a specific device. This is only useful, however, once FDA suspects there is a problem and specifically runs a search related to that issue. Even so, FDA queries do not always pull up all the relevant information. Spelling mistakes and differences in the way that devices are named make searches difficult, and prior to February 2014, FDA relied on paper rather than electronic submissions. Occasionally, as in the case of the initial Olympus UPMC MDR, paper adverse event reports received by the agency have been lost.

In contrast to the outdated and ineffective post-market monitoring system for devices, FDA has moved towards a more modern and effective system for overseeing the postmarket safety and effectiveness of drugs. The Food and Drug Amendments Act of 2007 (FDAAA) required FDA to establish a surveillance system that uses electronic health care data to monitor drugs using the unique product identifier known as an NDC, which is also included on all pharmacy insurance claims and on Medicaid claims for outpatient drugs prescriptions. In 2009, FDA began to leverage the data provided by NDCs through the "Sentinel" initiative, which queries multiple health care data sources, including electronic health records and insurance claims information, to make links between patient outcomes and specific drugs. The NDCs provide the key to making that link.

A system like Sentinel for devices is critical for two primary reasons. First, it does not rely exclusively on hospitals or manufacturers to report adverse events against weighty competing interests, but rather pulls information directly from databases that contain real-time information from insurance claims and other data that tracks patient care. This reduces the reliance on hospitals and manufacturers to self-report which, as this investigation has revealed, can happen months or even years after the fact and often lack important information. Second, Sentinel provides FDA with a "denominator" so that FDA can understand the number of adverse incidents reported in the context of the total number of patients treated.

Although it is not yet fully developed, a pilot "mini-Sentinel" has already substantially improved FDA's postmarket surveillance of drugs. For example, after being alerted to cases of serious intestinal issues linked to the blood pressure drug Olmesartan, FDA analyzed the data in Sentinel to assess whether such issues were limited to the particular drug or whether all similar drugs caused intestinal problems. FDA was able to determine that only Olmesartan was linked to higher rates of celiac disease, and therefore notify patients of particular issues with a specific drug rather than

an entire class of drugs.¹⁴³ Similarly, after receiving a large number of reports of fatal bleeding associated with the drug Dabigatran to treat abnormal heart rhythms, FDA used the information in Sentinel to assess whether the rates of bleeding in Dabigatran patients were in fact higher than the rates in the clinical trial.¹⁴⁴ FDA found that the rates were not significantly different from the results of the trial or from other similar drugs on the market, which ensured that doctors knew they could safely continue prescribing Dabigatran.¹⁴⁵

A Sentinel-like system can also assist FDA and manufacturers to complete postmarket surveillance studies of the safety or effectiveness of a device required under section 522 of the Food, Drug, and Cosmetic Act (section 522 postmarket surveillance studies). Currently, there are few incentives for clinicians and patients to participate in the studies, and without UDI codes in claims data, it is difficult for device manufacturers to find ways to link use of their devices to patient outcomes. A Sentinel system would help manufacturers to run more accurate studies quickly to answer lingering questions around the safety of duodenoscope and AER design. Moreover, a Sentinel system would allow FDA to run its own queries and investigations without relying on manufacturers, who have few incentives to complete the studies quickly.

Currently FDA cannot use Sentinel or similar system to perform surveillance on devices because there is no similar way to track specific devices across different health claims databases. The Food and Drug Administration Amendments Act of 2007 required FDA to issue regulations to create a UDI system for medical devices. Like the NDCs for drugs, UDIs will be placed on medical device labels and packages. FDA issued the final rule in September of 2013 which phases in the UDI requirements over time starting in September 2014 and ending in September of 2020. 148

UDIs will be required to be included on MDR reports, which should make it easier for FDA to query its system to identify reports linked to particular devices. ¹⁴⁹ The UDIs, however, unlike NDCs, are not currently included on insurance claims. ¹⁵⁰

A system like Sentinel for surveillance of devices could have prevented life-threatening infections worldwide.

In September 2013, when FDA first started investigating the design of duodenoscopes, outbreaks of CRE potentially linked to closed-channel devices had occurred at Thomas Jefferson Hospital, Virginia Mason, Carolinas Medical Center, and Froedtert Hospital but had not yet been reported to federal regulators by device manufacturers or hospitals. If FDA had access to UDIs in insurance claims, it is possible that the agency could have identified those outbreaks for itself at the beginning of its investigation and potentially moved faster to understand that the design of duodenoscopes makes them difficult or impossible to reliably clean, developed consensus internally about the source of the problems, and more promptly taken action to warn patients and hospitals.

Instead, after learning about the reprocessing problems at Advocate Lutheran from CDC, FDA

took more than 17 months to issue its first safety alert to hospitals and almost two years to provide hospitals with additional measures to supplement their reprocessing of duodenoscopes. In the intervening months, at least 68 patients in the United States and 82 patients worldwide were

68 patient infections in the United States may have been prevented if hospitals had been alerted by FDA earlier to reprocessing difficulties.

infected with superbug and other antibiotic-resistant bacteria. Those infections, along with other infections that likely occurred but were never identified, could possibly have been prevented if

hospitals been aware of the reprocessing difficulties known to FDA a year and a half before its first safety warning about the devices.

In the case of duodenoscopes, FDA was overly cautious and waited to alert the public and hospitals to the risks posed by duodenoscopes until the agency had finished its investigation and developed recommendations for supplemental reprocessing procedures. FDA's release of draft guidance on December 31, 2015, which explains that the agency will now notify the public about emerging serious device issues more quickly, is a positive step that will allow the agency, the public, and hospitals to take action sooner when new device issues arise.

The inability to access adequate information about adverse events independently from hospitals and manufacturers, and the inability to gather information about devices from insurance claims data, stymied FDA's investigation and expedient attention and response to the spreading antibiotic-resistant infections and other dangerous illness.

Overall, major gaps or delays in receiving information led to an unacceptably slow response from the FDA to the spread of deadly infections in ERCP patients. Without a more robust surveillance system independent from the self-interested reporting of manufacturers and hospitals, it is likely the same gaps and delays will continue to occur with other device related investigations.

Conclusion

Senator Murray's staff investigation demonstrates that duodenoscopes spread life-threatening superbug and other antibiotic-resistant infections among patients in a number of hospitals throughout the United States and Europe in 2013 and 2014. These outbreaks occurred despite the fact that the manufacturer of 85 percent of the duodenoscopes used in the United States, Olympus, was aware by early 2012 that its closed-channel duodenoscope could harbor dangerous bacteria even after repeated and careful cleaning according to instructions.

Multiple hospitals were also aware that duodenoscopes were linked to superbug and other antibiotic-resistant infections in ERCP patients. Yet none of the three manufacturers of duodenoscopes sold in the United States – Olympus, Fujifilm, and Pentax – and only one hospital, ever alerted CDC to the infections. The device manufacturers and most hospitals also largely failed to meet their legal obligations to provide complete and timely information about serious patient infections and deaths to manufacturers and/or FDA.

The duodenoscope manufacturers and Custom Ultrasonics, the manufacturer of an AER used to clean duodenoscopes between uses, failed at every level to meet basic expectations of transparency and openness and to actively engage with FDA to address contamination issues. This disregard for the spirit, and sometimes the letter, of the law resulted in potentially preventable serious and potentially fatal illnesses in hospitals around the world.

As a result, when FDA first became aware of the outbreak at Advocate Lutheran, the agency lacked critical pieces of information that would have better allowed its staff to understand the frequency with which infections were occurring and that duodenoscopes could remain contaminated even after reprocessing instructions were followed correctly. Throughout 2014, FDA investigated the infections but did not issue any safety communications to inform hospitals of the risk posed by even duodenoscopes that are reprocessed according to manufacturers' instructions and reprocessed with cleared AERs. While FDA took significant steps in 2015 to alert hospitals to the risks of

contaminated duodenoscopes, study supplemental cleaning procedures to help ensure the devices are safe for reuse, require new data from manufacturers to prove that their cleaning instructions work, recall about 2,800 AERs, and require manufacturers to conduct postmarket surveillance studies, these steps ought to have been taken months or even a year sooner.

This investigation clearly demonstrates the inability of FDA's current device surveillance system to accurately identify the extent of device problems when they occur, which poses an unacceptable risk to patients. In contrast to the surveillance system for drugs, which increasingly uses unique identifiers to track drug performance through electronic health records and insurance claims, the

In contrast to the surveillance system for drugs, the device surveillance system relies almost exclusively on the selfreporting of manufacturers and hospitals. device surveillance system continues to rely almost exclusively on the self-reporting and self-regulation of manufacturers and hospitals. Had FDA been able to utilize a similar surveillance system to pull information about ERCP patient outcomes from insurance claims and health records data, it is possible that as early as September 2013 the agency would have understood the extent of the threat posed by contaminated closed-channel duodenoscopes. FDA would have been able to

identify outbreaks in far more facilities than were identified at the time and link those infections to particular models of duodenoscopes and AERs. As a result, the agency could have completed its investigation sooner and more quickly issued safety alerts to hospitals.

The failure of FDA's device surveillance system to rapidly identify and respond to duodenoscoperelated superbug and antibiotic-resistant infections serves as just one example of the fallacy of a system that is primarily reliant on hospitals and device manufacturers to self-report information to FDA. This investigation has shown that the expectation for device manufacturers and hospitals, despite strong competing priorities, to file 501(k) applications for device modifications, adequately validate devices before they are marketed, and quickly and accurately report potential devicerelated injuries and deaths as required by the current system, is ineffective.

The systematic failures identified in this report are, unfortunately, likely not confined solely to duodenoscopes. Without improved communication for each stakeholder from hospitals to manufacturers to state and local health departments, to FDA and CDC, and without a comprehensive postmarket device surveillance system that supplements self-reporting from hospitals and manufacturers, future device-related safety issues are likely to go undetected for far too long and with life-threatening consequences.

Recommendations

In order to address the issues raised by this investigation, the HELP Committee minority staff recommends the following legislative and regulatory changes:

Recommendation #1: Congress should require and promote that unique device identifiers (UDIs) be included in insurance claims, electronic health records, and device registries.

The investigation demonstrates that FDA's reliance on self-reporting of adverse events by manufacturers and hospitals is unworkable and outdated, particularly when contrasted with the active postmarket surveillance system for drugs. The widespread inclusion of UDIs in medical

data including claims data, electronic health records, and registries, is an absolutely essential piece of any fully functional, high-quality device surveillance system. Without widespread adoption of UDIs in claims and electronic health data, FDA is severely hampered in its ability to move forward to implement an improved device surveillance system. Congress should require that claims data include the UDI number associated with medical devices used in procedures in order to ensure FDA is not caught in the dark when the next medical device is linked to serious illness, injury, or death.

Recommendation #2: FDA should evaluate whether modifications to the design of closed-channel duodenoscope are necessary to prevent the spread of infection, and if so, require manufacturers to rapidly implement any repairs through a phased recall to ensure that devices used by hospitals are safe for reuse.

This investigation has suggested that closed-channel duodenoscopes may spread infection between uses even when manufacturers' instructions are followed correctly and an effective AER is used. At least three independent evaluators have found that potential design flaws with the Olympus closed-channel duodenoscope prevent hospitals from reliably cleaning the devices between procedures. FDA should thoroughly evaluate the design of closed-channel duodenoscopes and consider immediate implementation of a phased recall to make any repairs or modifications necessary to ensure effective reprocessing.

Recommendation #3: FDA should update its guidance to clarify when manufacturers are required to submit a notification to FDA for 510(k) clearance before marketing modified devices.

In 2011, after becoming concerned about the number of manufacturers that failed to submit a notification to FDA for 510(k) clearance to account for substantial device modifications, FDA promulgated new draft guidance to clarify the existing 1997 document, to update the instructions, and to accommodate new technological advances. That guidance was subsequently withdrawn at the instruction of Congress in the Food Drug Administration Safety and Innovation Act (FDASIA) of 2012. The investigation provides renewed evidence of the need for updated guidance for device modifications.

Consistent with FDASIA, FDA should issue updated guidance that clarifies important terms that may confuse manufacturers regarding whether a 510(k) clearance is required, and that makes clear that manufacturers should verify and validate any determinations that safety and effectiveness are not impacted by a device modification.

Recommendation #4: FDA should move faster to provide information to health care providers when the agency becomes aware of information suggesting that patient safety might be compromised by a medical device.

A key finding of the investigation is that it took FDA almost 18 months from the time they learned of duodenoscope-linked infections to issue a safety communication alerting hospitals and the public to the risk posed by closed-channel duodenoscopes. Had FDA promptly notified hospitals earlier that there were potential safety issues with the reprocessing of closed-channel duodenoscopes, additional cleaning measure could have been adopted more quickly and issues with AER machines may have been identified more rapidly. Overall, earlier communication might

have prevented dozens of life-threatening infections including some that have never been identified.

The HELP Committee minority staff are pleased to note that on December 31 2015, FDA issued draft guidance to update the agency's procedures for notifying the public about potential device safety issues.¹⁵¹ Rather than wait until the agency has finishes an investigation and reaches a conclusion, FDA will now alert the public about to emerging safety concerns when the agency receives new information about serious or widespread public health issues.

Recommendation #5: FDA should have clear authority to deny a 510(k) submission based upon insufficient reprocessing validation data.

The investigation conclusively demonstrates that relying on reusable device manufacturers to attest that their reprocessing instructions have been sufficiently tested and will work reliably in real-world conditions is insufficient. FDA guidance issued in March 2105, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling guidance for Industry and Food and Drug Administration Staff," provides additional clarity that reprocessing data should be included with 510(k) submissions for some reusable devices. In order to ensure that manufacturers submit all the requisite validation data when marketing a new or modified device, Congress should clarify in statute FDA's authority to consider a 510(k) submission incomplete and deny marketing clearance if a reusable device manufacturer fails to provide validation data with the 510(k) submission.

Recommendation #6: Compliance with MDR reporting requirements should be a Condition of Participation in Medicare.

The investigation demonstrates that hospitals that performed exemplary public health work to identify and halt duodenoscope-linked antibiotic-resistant infections often failed to share that information with device manufacturers and to collaborate effectively with federal regulators. Hospitals that wish to participate in Medicare must meet certain conditions of participation specified and laid out in statute and regulation, including certain requirements for infection control and medical records services. In addition to enforcement efforts by FDA, Centers for Medicare and Medicaid Services should require that compliance with relevant medical device reporting requirements be included as a condition of participation in Medicare to ensure that state survey agencies and accrediting bodies such as the Joint Commission on Hospital Accreditation specifically examine whether hospitals are filing timely required medical device reports with hospitals or FDA.

Recommendation #7: Congress should fully fund a National Medical Device Evaluation System (NMEDS).

Widespread adoption of UDIs is an important step but is just one of many parts of a complete and robust device evaluation system. FDA must also facilitate a coordinating center to ensure interoperability between data sources and a governance structure to operate the system. Congress should provide sufficient funds for the agency to move towards these goals as rapidly as possible.

www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM445592.pdf [hereinafter FDA Executive Summary].

www.fda.gov/downloads/Medical Devices/Device Regulation and Guidance/Guidance Documents/UCM 253010.pdf.

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=876.1500.

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

¹ Kristen Wnedorf, et.al, "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak," Infection Control & Hospital Epidemiology, (March 30, 2015).

² *Id*.

³ FDA, Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures, Executive Summary 14 (2015),

⁴ Press Release, CDC, Action Needed Now to Halt Spread of Deadly Bacteria (2013), www.cdc.gov/media/releases/2013/p0305_deadly_bacteria.html.

⁵ Documents show discrepancies in the number of patients reported and the date of the infections. An additional five patients may have been infected with a multidrug-resistant infection after ERCP procedures at UMPC in summer and fall 2013 that were not reported to FDA.

⁶ Only six of these infections were linked to an Olympus duodenoscope. The remaining infections were linked to an unknown manufacturer's device.

⁷ FDA Executive Summary at 14.

⁸ *Id.* at 9.

⁹ *Id.* at 24; Letter from Keiichi Nagata, Division President, FUJIFILM Medical Systems USA, to Senator Patty Murray (June 19, 2015) (on file with the HELP Committee).

¹⁰ FDA Executive Summary at 24-25.

¹¹ FDA Executive Summary at 17-18.

¹² FDA, Center for Devices and Radiological Health, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff 5-6 (March 7, 2015).

¹³ *Id*.

¹⁴ *Id*. at 10.

¹⁵ FDA Executive Summary at 32-40.

¹⁶ FDA, "Classify Your Medical Device,"

¹⁷ 21 C.F.R. § 876.1500.

¹⁸ A device is substantially equivalent to another device if it (1) has the same intended use and the same technological characteristics, or (2) has the same intended use but with different technological characteristics that (a) do not raise new questions of safety and effectiveness and (b) demonstrate that it is at least as safe and effective as the legally marketed device. *See* FDA, Premarket Notification 510(k), "What is Substantial Equivalence?", www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/#se.

¹⁹ See 21 C.F.R § 807.

²⁰ See FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

²¹ *Id.*; 21 C.F.R. 820.75.

²² See FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

²³ 21 C.F.R. Section 803.50(a).

²⁴ 21 C.F.R. Section 803.30(a).

²⁵ FDA, "MedSun: Medical Product Safety Network," www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm?source=govdelivery.

- ²⁸ FDA, Draft Guidance for Industry and Food and Drug Administration Staff Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act (Aug. 16, 2011), www.fda.gov/RegulatoryInformation/Guidances/ucm268064.htm.
- ²⁹ The Brookings Institution, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," 12 (Feb. 2015), www.brookings.edu/~/media/research/files/papers/2015/02/23-medical-device-policy-surveillance/med-device-report-web.pdf
- ³⁰ *Id*.
- ³¹ Josh Rising, Ian Reynolds, and Art Sedrakyan, Pew Charitable Trusts, "Delays and Difficulties in Assessing Metal-on-Metal Hip Implants" (July 6, 2012), www.pewtrusts.org/en/about/news-room/opinion/2012/07/16/delays-and-difficulties-in-assessing-metalonmetal-hip-implants.
- ³² FDA, "FDA's Sentinel Initiative- Background," www.fda.gov/Safety/FDAsSentinelInitiative/ucm149340.htm.
- ³³ 21 U.S.C. § 360(i); Unique Device Identification System 78 Fed. Reg. 58786 58828.
- ³⁴ See FDA Executive Summary at 9.
- ³⁵ *Id.* at 25-27. The closed-channel duodenoscope models include the Olympus TJF-Q180V, the Fujifilm ED-530XT, and the Pentax ED-3490TK and ED-3670TK.
- ³⁶ MDR 8010047-2012-00157.
- ³⁷ Dr. Ir. Arjo Loeve, Delft University of Technology, "Investigation Olympus TJF-Q180V scope: Following detected contamination after cleaning and disinfection" (May 15, 2012) [hereinafter Delft report].
- ³⁸ Telephone conversation with Dr. Arjo Loeve (October 2, 2015).
- ³⁹ Delft report at 11.
- ⁴⁰ *Id.* at 23-24.
- ⁴¹ *Id.* at 23.
- ⁴² Id.
- ⁴³ *Id.* at 23-24.
- ⁴⁴ Delft report at 23-24.
- ^{45}Id .
- ⁴⁶ *Id*.
- ⁴⁷ A. Bruijn, A. Drogelen,, National Institute for Public Health and the Environment Ministry of Health, Welfare, and Sport, "Disinfection of Olympus TFJ-Q180V ERCP endoscope" (July 30, 2013) [hereinafter RIVM report].
- ⁴⁸ *Id*. at 1.
- ⁴⁹ *Id.* at p. 6.
- ⁵⁰ See, e.g., MDR 8010047-2015-00216.
- ⁵¹ Telephone conversation with staff at UPMC (October 29, 2015).
- ⁵² MDR 8010047-2012-00481.
- ⁵³ Letter from Scott Lucas, Program Manager at ECRI Institute to William Schaffner, Senior Associate Counsel at UPMC (December 26, 2012) (on file with the HELP Committee).
- ⁵⁴ MDR 8010047-2012-00481; Memorandum from Mary Ann Drosnock to David Barlow, Simon Nguyen, Laura Storms-Tyler, and Mia Zhang (December 14, 2012) (on file with the HELP Committee); Letter from Scott Lucas, Program Manager at ECRI Institute to William Schaffner, Senior Associate Counsel at UPMC (December 26, 2012) (on file with the HELP Committee).
- ⁵⁵ Letter from Scott Lucas, Program Manager at ECRI Institute to William Schaffner, Senior Associate Counsel at UPMC (December 26, 2012) (on file with the HELP Committee).
- ⁵⁶ Telephone conversation with staff at UPMC (October 29, 2015).
- ⁵⁷ Olympus has provided documentation that confirms the MDR was sent to FDA.

²⁶ FDA Executive Summary at 11.

²⁷ As of Aug. 13, 2015, manufacturers and importers have been required to submit all MDRS electronically which should address some of these issues. (Medical Device Reporting: Electronic Submission Requirements, 79 Fed. Reg. 8832 – 8855).

www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

⁵⁸ Biotech Germande study 2128.Oly.2012 (: 08-Jan-2013) (on file with the HELP Committee).

⁵⁹ Biotech Germande study 2231.Oly.2013 (July 2, 2014) (on file with the HELP Committee).

⁶⁰ Bonn University studies on file with the HELP Committee. It is unclear whether the scope evaluated by Bonn University was linked to a particular outbreak

⁶¹ Letter from Olympus to customers, "Important Safety Advice" (Jan. 2013), www.swissmedic.ch/recalllists_dl/07207/Vk_20130123_15-e1.pdf (emphasis added).

⁶² These three outbreaks are: Erasmus Medical Center in the Netherlands, UPMC in the United States, and Clinique de Bercy in France.

⁶³ Letter from Olympus to customers, "URGENT: Field Safety Corrective Action" (2014, www.swissmedic.ch/recalllists_dl/10220/Vk_20140729_02-e1.pdf (emphasis added).

⁶⁴ These ten outbreaks are: Erasmus Medical Center, UPMC, Clinique de Bercy (two outbreaks), Evangelisches Waldkrankenhaus Spandu, Hartford Hospital, Froedtert Hospital, NYP/Weill Cornell Medical Center, UMass Memorial Hospital, and Charite-Universitatsmedizin,

⁶⁵ See 21 C.F.R 807.81(a)(3).

 $^{^{66}}$ FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device. Memorandum # K97-1" (1997), www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm.

⁶⁷ *Id*

⁶⁸ Letter from LaShonda M. Long, Chief of Surveillance and Enforcement Branch I, to Laura Storms-Tyler, Vice President of Olympus Medical Systems Corporation, "It Has Come to Our Attention" (March 18, 2014), www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM436587.pdf.

⁶⁹ See 21 C.F.R. § 820.30(g).

⁷⁰ See 21 C.F.R. 820.75; FDA Executive Summary at 30.

⁷¹ FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff, 22-23 (2015),

⁷² RIVM report at p. 9.

⁷³ *Id.* at p. 4.

⁷⁴ *Id.* at ps. 7-8.

⁷⁵ In March 2015 FDA found that Olympus had validated updated reprocessing instructions. FDA, Safety Communication "Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes" (March 26, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm.

⁷⁶ FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

⁷⁷ Hospitals and other user facilities are required to report serious injuries linked to devices to manufacturers but are not required to report serious injuries to FDA.

⁷⁸ MDR 8010047-2012-000157 (understating the number of patients infected at Erasmus Medical Center).

⁷⁹ See, e.g., MDR 8010047-2013-00595 (Clinique de Bercy) ("improper reprocessing could not be ruled out as a contributory factor"); MDR 8020047-2013-00092 (Charite-Universitatsmedizin); MDR 8010047-2012-000452 (Clinique de Bercy).

⁸⁰ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA, to Akihiro Okubo, President, Olympus Medical Systems Corporation, "Warning Letter" (Aug. 12, 2015), www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458510.htm.

⁸¹ Letter from Keiichi Nagata, Division President FUJIFILM Medical Systems USA to Senator Patty Murray (June 19, 2015) (on file with the HELP Committee).

⁸² Letter from Anastacia M. Bilek, Director, Division of Premarket and Labeling Compliance, FDA, to Mr. Teiichi Goto, Corporate Vice President, Fujifilm Corporation, "It has come to our attention" (Aug. 12, 2015), www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM458552.pdf.

⁸³ *Id*.

- ⁸⁵ FDA, Form 483, Observation 1, inspection of a Fujifilm Facility in Ashigarakami Gun, Japan (April 23-May 01, 2015).
- ⁸⁶ *Id*.
- ⁸⁷ *Id*.
- ⁸⁸ *Id.* (observation 3).
- ⁸⁹ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), Warning Letter (Aug 12, 2015), www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458487.htm.
- ⁹⁰ Pentax instructs user facilities to use either an EtO/Carbon Dioxide 80:20 or 90:10 mixture when sterilizing a duodenoscope but the validation was performed with an EtO/HCFC 10:90 gas mixture a different mixture from the gas included on the label. (*Id.*).
- ⁹¹ FDA, Safety Communication, "FUJIFILM Medical Systems, U.S.A., Inc. Validates Revised Reprocessing Instructions for Model ED-530XT Duodenoscopes" (Dec. 23, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm
- ⁹² Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), Warning Letter (Aug 12, 2015), www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458487.htm.
- ⁹³ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Teiichi Goto, Corporate Vice President, Fujifilm Corporation, Warning Letter (Aug. 12, 2015), www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm458453.htm.
- ⁹⁴ In November, 2014 Pentax reported patients at a hospital in Udine, Italy developed a Klebsiella pneumoniae infection after undergoing ERCP. MDR 9610877-2015-00046.
- ⁹⁵ Email from counsel to Pentax to HELP committee staff (October 28, 201) (on file with the HELP Committee).
- ⁹⁶ Letter from Counsel for Fujifilm to Senator Patty Murray (October 2, 2015) (on file with the HELP Committee).
- ⁹⁷ Press Release, FDA, "FDA orders recall under consent decree for all custom ultrasonics automated endoscope reprocessors" (Nov. 13, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472605.htm.
- ⁹⁸ Letter from Thomas D. Gardine, District Director, FDA, to Frank J. Weber, President & CEO, Custom Ultrasonics, Warning Letter (June 22, 2005),

/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075455.htm.

- ⁹⁹ FDA, Safety Communication, "Custom Ultrasonics, Inc. Endoscope Washer/Disinfectors" (Feb. 27, 2007), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm064361.htm.
- ¹⁰⁰ Telephone conversation with FDA (Dec.7, 2015).
- ¹⁰¹ Letter from Anne E. Johnson, Acting Director, Philadelphia District, Office of Regulatory Compliance and Capt. Sean Boyd, Acting Director of Compliance, FDA, to Alicia Nakonetschny, President and CEO, Custom Ultrasonics (Nov. 12, 2015),

www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProducts and Tobacco/CDRH/CDRHFOIAE lectronic Reading Room/UCM472567.pdf.

- ¹⁰² *Id*.
- 103 21 C.F.R. § 803.30.
- ¹⁰⁴ *Id*.
- ¹⁰⁵ Committee staff were unable to obtain information from Carolinas Medical Center in Charlotte North Carolina after repeated inquiries.
- ¹⁰⁶ For state reporting requirements *see* Association for Professionals in Infection Control and Epidemiology, "Summary of State CRE Reporting Requirements," www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/CRE ReportingRequirements Final.pdf.
- ¹⁰⁷ Telephone conversation with staff at Virginia Mason (October 29, 2015).
- ¹⁰⁸ *Id*.

⁸⁴ Letter from Anastacia M. Bilek, Director, Division of Premarket and Labeling Compliance, to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), "It has come to our attention" (Aug. 12, 2015), www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM458554.pdf.

- ¹⁰⁹ MDR 2951238-2014-00644.
- ¹¹⁰ MDR 2518897-2015-00329.
- ¹¹¹ 21 C.F.R. § 803.30(a)(1).
- ¹¹² Letter from Thomas Kraus, Associate Commissioner for Legislation, FDA, to Senator Patty Murray (May 14, 2015) (on file with the HELP Committee).
- ¹¹³ MedWatch 5029305.
- ¹¹⁴ MedWatch 5032234.
- ¹¹⁵ Telephone Call with staff at Virginia Mason (October 29, 2015).
- ¹¹⁶ There is no federal requirement that user facilities report all antibiotic-resistant infections, or even all CRE outbreaks, to the CDC. Instead, hospitals voluntarily report hospital-acquired infections to the National Healthcare Safety Network (NHSN) or the Gram-Negative Bacilli Surveillance Initiative (MuGSI). MuGSI was created specifically to track CRE infections but includes data from only eight surveillance sites in Colorado, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. The CDC has been unable to confirm that any of the identified outbreaks prior to fall 2013 were reported to any of their databases. *See* CDC, "What is NHSN?" (last accessed Nov. 30, 2015), www.cdc.gov/nhsn/about-nhsn/index.html; CDC, "Technical Information-Multi-Site Gram-Negative Bacilli Surveillance Initiative (MuGSI)" (last accessed Nov. 30, 2015), www.cdc.gov/hai/eip/mugsi_techinfo.html.
- ¹¹⁷ 21 C.F.R. § 803.30 (emphasis added).
- ¹¹⁸ FDA Executive Summary at 11.
- ¹¹⁹ Telephone conversation with staff at Advocate Lutheran (November 19, 2015).
- 120 Id
- ¹²¹ MDR 8010047-2012-00157. There were actually at least 30 patients infected.
- ¹²² MDR 8010047-2012-00481. Olympus has provided supporting documentation that the original report was sent to FDA, but it does not appear that it was ever entered into FDA's adverse event reporting database and FDA experts conducting the investigation do not appear to have seen this MDR until a later time.
- ¹²³ MDR 2951238-2013-00031.
- ¹²⁴ MDR 8010047-2012-00452.
- ¹²⁵ MDR 8010047-2013-00092.
- ¹²⁶ MDR 8010047-2013-00176.
- ¹²⁷ MW 5031083.
- 128 Letter from Senator Patty Murray to Margaret Hamburg, FDA Commissioner (February 3, 2014), www.murray.senate.gov/public/_cache/files/096ecf61-0004-4076-b2e0-8fd4f1a25e78/020315-virginia-mason-letter.pdf.
- ¹²⁹ FDA, Safety Communication, "Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning" (February 19, 2015 updated March 4, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm.
- ¹³⁰ CDC, "Interim Duodenoscope Surveillance Protocol," www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html.
- ¹³¹ FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),
- www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf
- ¹³² FDA Executive Summary. Virginia Mason has extensively studied the culture and quarantine protocol at its facility, and continues to find about two percent of its duodenoscopes remain contaminated after reprocessing even using Olympus's updated cleaning instructions.
- ¹³³ FDA, Safety Communication, "Supplemental Measures to Enhance Duodenoscope Reprocessing" (Aug. 4, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm.
- ¹³⁴ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Teiichi Goto, Corporate Vice President, Fujifilm Corporation, Warning Letter (Aug. 12, 2015), www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm458453.htm; Letter from Jan B. Welch, Acting

Director, Office of Compliance, FDA to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), Warning Letter (Aug 12, 2015),

www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458487.htm; Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA, to Akihiro Okubo, President, Olympus Medical Systems Corporation, "Warning Letter" (Aug. 12, 2015),

www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458510.htm.

- ¹³⁵ Press Release, FDA, "FDA orders duodenoscope manufacturers to conduct postmarket surveillance studies in health care facilities" (Oct. 5, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465639.htm.
- ¹³⁶ Press Release, FDA, "FDA orders recall under consent decree for all custom ultrasonics automated endoscope reprocessors, (Nov. 13, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472605.htm.
- ¹³⁷ Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals"); Draft Guidance, 80 Fed. Reg. 81829 81830.
- ¹³⁸ FDA published a final rule on February 13, 2014 requiring manufacturers and importers to submit electronic MDRs in a reviewable format, but allowed for hardcopy submissions until August 13, 2015. User facilities are allowed to continue submitting hardcopy MDRs but are given the option of e-filing reports as well. Medical Device Reporting: Electronic Submission Requirements, 79 Fed. Reg. 8832 8855.
- ¹³⁹ See Deficit Reduction Act of 2005 § 6002; 42 U.S.C. § 1396r-8(a); 21 U.S.C. § 360; Drug Listing Act of 1972, §§ 3, 4.
- ¹⁴⁰ FDA, "Sentinel Program Interim Assessment (FY 15)" (Sept. 24, 2015), www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM464043.pdf.
- ¹⁴¹ *Id*. at 12.
- ¹⁴² *Id.* at 23-24.
- ¹⁴³ *Id.* at 23-24.
- ¹⁴⁴ *Id.* at 21-22.
- ¹⁴⁵ *Id*.
- ¹⁴⁶ See Brookings Institution, Strengthening Patient Care: Building an Effective National Medical Device Surveillance System (Feb. 2015), www.brookings.edu/~/media/research/files/papers/2015/02/23-medical-device-policy-surveillance/med-device-report-web.pdf.
- ¹⁴⁷ Food and Drug Administration Amendments Act of 2007 § 226; 21 U.S.C. § 360i(f).
- ¹⁴⁸ Unique Device Identification System 78 Fed. Reg. 58786 58828.
- ¹⁴⁹ "Medical Device Reporting" 21 C.F.R. §§ 803.32-33, 803.42, 803.52.
- ¹⁵⁰ The Office of the National Coordinator for Health Information Technology's "2015 Edition Health Information Technology Certification Criteria" rule made progress towards enabling access to and sharing of unique device identifier information. This rule requires that federally-certified health information technology allow a user to access a list of UDIs for a patient's implantable devices and share it with other authorized users. 80 Fed. Reg. 62601.

Appendix I: Letters

The following are reproductions of the letters Senator Murray sent to Olympus, Pentax, Fujifilm, and FDA.

MICHAEL B. ENZI, WYOMING
RICHARD BURR, NORTH CAROLINA
JOHNNY ISAKSON, GEORGIA
RAND PAUL, KENTUCKY
SUSAN M. COLLINS, MAINE
LISA MURKOWSKI, ALASKA
MARK KIRK, ILLINOIS
TIM SCOTT, SOUTH CAROLINA
ORRIN HATCH, UTAH
PAT ROBERTS, KANSAS
BILL CASSIDY, M.D., LOUISIANA

PATTY MURRAY, WASHINGTON BARBARA A. MIKULSKI, MARYLAND BERNARD SANDERS (I), VERMONT ROBERT P. CASEY, JR., PENNSYLVANIA AL FRANKEN, MINNESOTA MICHAEL F. BENNET, COLORADO SHELDON WHITEHOUSE, RHODE ISLAND TAMMY BALDWIN, WISCONSIN CHRISTOPHER S. MURPHY, CONNECTICUT ELIZABETH WARREN, MASSACHUSETTS

DAVID P. CLEARY, STAFF DIRECTOR EVAN SCHATZ, DEMOCRATIC STAFF DIRECTOR

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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510–6300

June 8, 2015

Karl Watanabe President and Chief Financial Officer Olympus Corporation of the Americas 3500 Corporate Parkway, P.O. Box 610 Center Valley, PA 18034-0610

Dear Mr. Watanabe:

As questions continue to arise regarding your company's actions to adequately protect patients treated with your duodenoscopes, I write to seek more information and express my serious and growing concern. As you are aware, between late 2012 and January 2014, Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate *E coli* infection, and 18 of those who developed infections later died. ¹

In addition, multiple cases of CRE infections traced back to Olympus duodenoscopes have now been confirmed at two other hospitals in 2014, as well as a series of CRE infections involving an Olympus duodenoscope in Florida in 2009. In all, the Food and Drug Administration (FDA) confirmed at the recently convened Advisory Committee Meeting of the Gastroenterology-Urology Devices Panel that there have been at least nine hospital outbreaks of multidrug-resistant infections traced to duodenoscopes in the United States, and that six of those outbreaks are traceable to scopes manufactured by Olympus.² Olympus is reported to have told health care professionals in February that the company was aware of 95 complaints of infection in patients who had undergone procedures with TJF-Q180V, the "closed elevator" duodenoscope sold since 2010, without Olympus seeking FDA approval or clearance before marketing.³

Overall, FDA has informed me it received 139 separate reports of contamination or infection related medical device reports, or adverse event reports involving duodenoscopes between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone. Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus (85 percent market share of duodenoscopes), Fujifilm, and Pentax Medical.

⁵ Id.

¹ Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE infections.

² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee</u>, pp.14-15.

³ Chad Terhune and Melody Petersen, "Scope maker Olympus faces scrutiny over patient deaths, infections" Los Angeles Times, March 1, 2015.

⁴ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

I have become increasingly concerned by the failure of Olympus to proactively warn patients and providers in the United States of the potential for infections. It is my understanding that in November of 2013, at the invitation of officials at Virginia Mason concerned about the CRE infections at the hospital, an endoscopy support specialist from Olympus spent two days at the hospital and validated that the hospital was properly cleaning Olympus duodenoscopes between uses. That review by Olympus staff demonstrated that "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope cleaning in a manner consistent with manufacturer guidelines." Olympus officials subsequently removed a number of the scopes in use at Virginia Mason for repair.

Thus, as early as November 2013, it appears that Olympus knew or should have known that even in cases where hospital staff were carefully executing Olympus' instructions for cleaning, duodenoscopes continued to be contaminated with CRE and other bacteria. Further, it strongly suggests that Olympus knew its current cleaning and reprocessing standards were insufficient, and that use of the company's duodenoscopes, particularly the TJF-Q180V model sold since 2010 and featuring a "closed elevator," were placing patients undergoing procedures at risk of multi-bacteria resistant infections. Moreover, although medical device manufacturers are required to file reports of possible safety risks within 30 days, press reports suggest that Olympus did not even file the required Medical Device Report with the FDA in connection with the Virginia Mason infections until August 2014.⁷ And as recently as February of this year, more than a year after the Virginia Mason CRE outbreak, I understand that the Olympus manager of infection control told a meeting of health care professionals that "endoscopes reprocessed properly pose virtually no risk of patient-borne or environmental organisms." ⁸

This stands in marked contrast to the actions taken by Olympus in Europe. According to press reports, as early as January 2013, Olympus is reported to have issued "important safety advice" to European hospitals instructing staff to use a specific brush supplied by Olympus to clean duodenoscopes. This action is reported to have been taken following a series of infections at Erasmus University in Rotterdam in early 2012. Dr. Margreet Vos provided testimony at the recent FDA Advisory Committee meeting that in 2012 independent reviewers found bacteria present in reprocessed Olympus scopes.

Again in August 2014, Olympus is reported to have sent a second safety alert to European hospitals that asked hospital staff to sign and return an acknowledgement that the warning had been shared with staff. No such alert was sent in this country until February of this year, and the cleaning brushes apparently sent to European hospitals in early 2013 were not provided to U.S. hospitals until last month.

These facts build upon my existing concerns regarding Olympus' 2010 failure to seek clearance or approval from the FDA prior to marketing TJF-Q180V, the "closed elevator" duodenoscope at issue in a number of the infections. I find it very troubling that when Olympus

⁶ See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

⁷ Peter Eisler, "Reports to Feds on deadly bacteria outbreaks arrived late" USA Today, April 15, 2015.

⁸ Chad Terhune and Melody Petersen, "Scope maker Olympus faces scrutiny over patient deaths, infections" Los Angeles Times, March 1, 2015.

became aware of increased reports of infections linked to the TJF-Q180V, the company appears not to have taken additional steps to alert health professionals and regulators in the United States to the risks this particular device posed. Moreover, when asked by the FDA in the spring of 2014 to provide the data that validated that Olympus duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Olympus (as well as Fujifilm and Pentax Medical) was unable to do so through two rounds of testing. New cleaning guidance was finally approved by FDA in March 2015.

I find it similarly troubling that Olympus (as well as Fujifilm and Pentax Medical) declined to participate in the subsequently convened FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures," despite manufacturing 85 percent of the scopes used in these procedures. But at the same time, the company was apparently able to have representatives present at two large professional conferences in Washington, D.C. that same week. ¹⁰ Just days before the FDA Advisory Panel meeting, Olympus announced that the company was reducing its expected earnings forecast for this year as a result of an ongoing investigation by the Department of Justice into potential violations of the Anti-Kickback Statute, and last week Olympus announced that it is under investigation by the United States Attorney for the District of New Jersey relating to the duodenoscope infections. ¹¹

Even with enhanced cleaning procedures adopted earlier this year, these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing. While representatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria, this process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes. Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington State and across the country get answers and accountability. In order to better understand the timeline of events and your company's response to reports of infections related to duodenoscopes manufactured by Olympus, including the TJF-160, TJF-Q180V-1 and TJF-Q180V-2, please provide the following information by June 19, 2015.

⁹ "FDA Moves to Ensure Scope Safety", Los Angeles Times, March 15, 2015; Information provided by Dr. Vos to the Advisory Committee panel indicated that Olympus failed to provide requested information regarding the efficacy of cleaning procedures to the Dutch National Institute of Public Health and the Environment.

¹⁰ Chad Terhune, "Scope maker defends device design" Los Angeles Times, May 19, 2015.

Olympus News Release, Recognition of Extraordinary Loss Due to the Investigation by the U.S. Department of Justice Against Our Subsidiary and Notice of Difference Between Consolidated Earnings Forecast and Actual Results, May 8, 2015; Olympus Financial Results filing, Consolidated Financial Results for the Fiscal Year Ended March 31, 2015; Chad Terhune and Melody Petersen "Justice Department investigates scope maker Olympus over superbug outbreaks" Los Angeles Times, May 28, 2015.

¹² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee</u> p. 15.

¹³ Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

- 1. Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Olympus used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.
- 2. Unredacted copies of all medical device reports or adverse event reports sent by Olympus to FDA regarding the TJF-Q180V-1 and TJF-Q180V-2 or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.
- 3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Olympus.

Sincerely,

Senator Patty Murray

Ranking Member, HELP Committee

MICHAEL B. ENZI, WYOMING
RICHARD BURR, NORTH CAROLINA
JOHNNY ISAKSON, GEORGIA
RAND PAUL, KENTUCKY
SUSAN M. COLLINS, MAINE
LISA MURKOWSKI, ALASKA
MARK KIRK, ILLINOIS
TIM SCOTT, SOUTH CAROLINA
ORRIN HATCH, UTAH
PAT ROBERTS, KANSAS
BILL CASSIDY, M.D., LOUISIANA

PATTY MURRAY, WASHINGTON BARBARA A. MIKULSKI, MARYLAND BERNARD SANDERS (I), VERMONT ROBERT P. CASEY, JR., PENNSYLVANIA AL FRANKEN, MINNESOTA MICHAEL F. BENNET, COLORADO SHELDON WHITEHOUSE, RHODE ISLAND TAMMY BALDWIN, WISCONSIN CHRISTOPHER S. MURPHY, CONNECTICUT ELIZABETH WARREN, MASSACHUSETTS

United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510-6300

DAVID P. CLEARY, STAFF DIRECTOR EVAN SCHATZ, DEMOCRATIC STAFF DIRECTOR

http://help.senate.gov

June 8, 2015

Masataka Akiyama President and Chief Executive Officer Fujifilm Medical Systems USA, Inc. 419 West Avenue Stamford, CT 06902

Dear Mr. Akiyama:

As questions continue to arise regarding Fujifilm Medical Systems USA's (Fujifilm) actions to adequately protect patients treated with duodenoscopes, I write to seek more information and express my serious and growing concern. As you are likely aware, between late 2012 and January 2014 Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus Corporation. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate *E. coli* infection, and 18 of those who developed infections later died.¹

Multiple cases of CRE infections traced back to duodenoscopes have now been confirmed at other hospitals in 2014. In fact, the Food and Drug Administration (FDA) stated at the recently convened Advisory Committee Meeting of the <u>Gastroenterology-Urology Devices Panel</u> that there have been at least nine hospital outbreaks of multi-drug resistant infections traced to duodenoscopes in the United States, including one outbreak of CRE in 2014 traceable to scopes manufactured by Fujifilm.²

Overall, FDA has informed me that 139 separate reports of contamination or infection-related medical device reports, or adverse event reports involving duodenoscopes were received between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.³ Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus, Pentax Medical and your company.⁴

⁴ Id.

Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE infections.

² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> Committee, pp.14-15.

³ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

I have become increasingly concerned by the failure of the three manufacturers to proactively warn patients and providers of the potential for infections. By September 2013 the Center for Disease Control and Prevention (CDC) had notified the FDA of the possible connection between multi-resistant bacteria hospital infections and duodenoscopes even when reprocessed according to the manufacturer's instructions. At approximately the same time, in November of 2013, an Olympus endoscopy support specialist found that Virginia Mason, which was attempting to contain a CRE outbreak, was properly reprocessing duodenoscopes stating "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope cleaning in a manner consistent with manufacturer guidelines." Thus, it appears that duodenoscope manufacturers should have been aware by at least late 2013 of the very real risk of multi-drug resistant infection from procedures using duodenoscopes even when cleaned according to instructions provided by the manufacturers.

While it has been reported that Fujifilm submitted a timely adverse incident report to the FDA related to a May 2014 infection linked to a Fujifilm ED 530 XT duodenoscope, when asked by the FDA in the spring of 2014 to provide the data that validated that Fujifilm's duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Fujifilm (as well as Olympus and Pentax Medical) was apparently unable to do so through two rounds of submissions. It appears that no updated cleaning guidance has been issued by Pentax for these scopes. Fujifilm, in addition to Olympus and Pentax Medical, also declined to participate in the May 14-15, 2015 FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures" despite manufacturing the scopes used in these procedures.

Even with enhanced cleaning procedures and more rigorous validation, it is clear that these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing. Representatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria. This process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes. Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington state and across the country get answers and accountability. In order to better

⁵ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

⁶ See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

⁷ Fujifilm was apparently able to have representatives present at two large professional conferences in Washington, D.C. despite not attending the FDA Adivsory Panel meeting. *See* "Scope maker defends device design" Los Angeles Times, May 19, 2015.
⁸ FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u>

Committee p. 15

⁹ Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

understand the timeline of events Fujifilm's response to reports of infections related to duodenoscopes manufactured by Fujifilm, including the ED 530 XT, please provide the following information by June 19, 2015.

- 1. Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Fujifilm used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.
- 2. Unredacted copies of all medical device reports or adverse event reports sent by Fujifilm to FDA regarding the ED 530 XT or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.
- 3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Fujifilm Medical Systems.

Sincerely,

Senator Patty Murray

Ranking Member, HELP Committee

MICHAEL B. ENZI, WYOMING RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA RAND PAUL, KENTUCKY SUSAN M. COLLINS, MAINE LISA MURKOWSKI, ALASKA MARK KIRK, ILLINOIS TIM SCOTT, SOUTH CAROLINA ORRIN HATCH, UTAH PAT ROBERTS, KANSAS BILL CASSIDY, M.D., LOUISIANA

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COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510-6300

June 8, 2015

Christopher Burton President of the Americas Region Pentax Medical 3 Paragon Drive Montvale, New Jersey 07645

Dear Mr. Burton:

As questions continue to arise regarding Pentax Medical's actions to adequately protect patients treated with duodenoscopes, I write to seek more information and express my serious and growing concern. As you are likely aware, between late 2012 and January 2014 Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus Corporation. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate E. coli infection, and 18 of those who developed infections later died.1

Multiple cases of CRE infections traced back to duodenoscopes have now been confirmed at two other hospitals in 2014. In fact, the Food and Drug Administration (FDA) stated at the recently convened Advisory Committee Meeting of the Gastroenterology-Urology Devices Panel that there have been at least nine hospital outbreaks of multi-drug resistant infections traced to duodenoscopes in the United States, two of which are traceable to scopes manufactured by Pentax Medical.²

Overall, FDA has informed me that 139 separate reports of contamination or infectionrelated medical device reports, or adverse event reports involving duodenoscopes were received between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.³ Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus, Fujifilm and your company.4

⁴ Id.

Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE

² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u>

Committee, pp.14-15.

Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

I have become increasingly concerned by the failure of the three manufacturers to proactively warn patients and providers of the potential for infections. As early as January 2013, more than 38 patients were infected with CRE at a hospital near Chicago, Illinois that was linked to duodenoscopes manufactured by Pentax Medical. By September 2013 the Center for Disease Control and Prevention (CDC) had notified the FDA of the possible connection between multi-resistant bacteria hospital infections and duodenoscopes even when reprocessed according to the manufacturer's instructions. At approximately the same time, in November of 2013, an Olympus endoscopy support specialist found that Virginia Mason, which was attempting to contain a CRE outbreak, was properly reprocessing duodenoscopes stating "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope cleaning in a manner consistent with manufacturer guidelines." Thus, it appears that duodenoscope manufacturers should have been aware by at least late 2013 of the very real risk of multi-drug resistant infection from procedures using duodenoscopes even when cleaned according to instructions provided by the manufacturers.

I am not aware of that any additional steps were taken by Pentax Medical that may have alerted health professionals to the risk of infection even when properly cleaned. Moreover, when asked by the FDA in the spring of 2014 to provide the data that validated that Pentax Medical's duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Pentax (as well as Olympus and Fujifilm) was apparently unable to do so through two rounds of submissions. It appears that no updated cleaning guidance has been issued by Pentax for these scopes. Pentax Medical, in addition to Olympus and Fujifilm, also declined to participate in the May 14-15, 2015 FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures" despite manufacturing the scopes used in these procedures.⁸

Even with enhanced cleaning procedures and more rigorous validation, it is clear that these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing. Pepresentatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria. This process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes. Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate. Percentage of the process requires a distinct the process requires a scope given that they continue to

⁵ "Pentax scope data are sought," Los Angeles Times, March 31, 2015.

⁶ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

⁷ See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

⁸ Pentax Medical was apparently able to have representatives present at two large professional conferences in Washington, D.C. despite not attending the FDA Adivsory Panel meeting. *See* "Scope maker defends device design" Los Angeles Times, May 19, 2015.

⁹ FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> Committee, p. 15.

¹⁰ Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington state and across the country get answers and accountability. In order to better understand the timeline of events and Pentax's response to reports of infections related to duodenoscopes manufactured by Pentax Medical, including the ED-3490 TK, please provide the following information by June 19, 2015.

- 1. Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Pentax Medical used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.
- 2. Unredacted copies of all medical device reports or adverse event reports sent by Pentax Medical to FDA regarding the ED-3490 TK or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.
- 3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Pentax Medical.

Sincerely,

Senator Patty Murray

Ranking Member, HELP Committee

United States Senate WASHINGTON, DC 20510-4704

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VETERANS' AFFAIRS

VASITING TON, DC 20310-4704

February 3, 2014

The Honorable Margaret Hamburg Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Hamburg,

Last week, news reports highlighted a recent cluster of infections caused by carbapenem-resistant *Escherichia coli* (CRE), which were linked to the use of contaminated medical devices, known as duodenoscopes, at a well-known Seattle medical center, Virginia Mason. While outbreaks of CRE have occurred across the country, world class surveillance and timely engagement by the hospital and the Washington State and Seattle & King County Departments of Health identified the cause of this unusual outbreak and worked quickly to minimize its spread.

CRE infections are serious, with fatality rates as high as 40-50%. In Seattle, at least 32 patients were infected with CRE via duodenoscope contamination, and though 11 of these patients died, it remains unclear whether CRE was the cause. Without the rapid and conscientious responses of Virginia Mason and the state and local health departments, the public health impact could have been much worse. Other recent outbreaks associated with the use of duodenoscopes occurred in Pittsburgh and Chicago, with dire consequences.

Due to their complicated and intricate design, duodenoscopes are harder to clean and disinfect than many reusable medical devices. Yet in Seattle, parallel assessments of duodenoscope reprocessing procedures by both the Washington State Department of Health and the Centers for Disease Control (CDC) found that duodenoscopes used by Virginia Mason routinely failed to pass testing for pathogenic bacteria, despite strict adherence by the hospital staff to the manufacturer's labeling. In some cases, cleaning measures recommended by the manufacturer were insufficient to remove debris and soil, forcing medical staff to adopt more aggressive cleaning techniques. These findings indicate that – even when providers carefully follow manufacturers' labeling regarding cleaning and disinfection of duodenoscopes – contamination still poses grave risks to patients.

The Food and Drug Administration (FDA) issued a draft guidance in 2011 entitled "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," which updated prior guidance on the reprocessing of reusable medical devices. This

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update is an important step forward in addressing antibiotic resistant infections caused by reprocessed duodenoscopes, bolstering criteria used to evaluate product labeling and reprocessing procedure validation measures. I appreciate these efforts to improve the safety of reusable medical devices.

In light of the infections in Seattle and other communities across the country, I am writing to urge the FDA to finalize this guidance and provide health care professionals with updated best practices for reusable medical devices as soon as possible. In doing so, FDA should focus on the unique issues surrounding the reprocessing of complex devices, such as duodenoscopes. The FDA should also consider whether more robust post-market surveillance, beyond that discussed in the draft guidance, is appropriate given the nature of these devices and recent outbreaks.

FDA also should work closely with manufacturers of duodenoscopes and other complex reusable devices to ensure that product labeling reflects the most recent available knowledge regarding effective reprocessing techniques. Because that process will take some time, FDA also should consider whether additional safety information should be communicated to providers, patients and other stakeholders in the meantime.

Your ongoing collaboration with FDA's sister agency, the CDC, is also critical to ensure a comprehensive approach to preventing and detecting future outbreaks.

While recognizing that many stakeholders have a part to play in combatting device-borne infection, the FDA plays a critical role. I urge you to take the steps identified above as soon as possible.

Sincerely,

Patty Murray

United States Senator

I AMAR ALEXANDER, TENNESSEE, CHAIRMAN

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COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510-6300

March 20, 2015

The Honorable Margaret Hamburg Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Hamburg,

Thank you for your actions in response to my February 3, 2015, letter regarding "superbug" infections at Virginia Mason Hospital in Seattle, Washington, and in other facilities around the country. In that letter, I urged the Food and Drug Administration (FDA) to take several steps in the wake of these serious outbreaks. The agency's actions last week represented important progress. However, in light of the tragic impact these outbreaks have had on patients and families in my state and nationwide, I write today to seek additional information from the agency. We must do everything we can to understand how these outbreaks occurred and find out what more can be done to protect patients.

As you know, it appears that these infections were potentially caused by duodenoscopes cleaned according to current protocols, but nonetheless harboring carbapenem-resistant Enterobacteriaceae (CRE) bacteria. In Washington State, at least 32 patients were infected and, although the cause is not clear, 11 died.

I appreciate that, as requested in my earlier letter, the FDA has issued new guidance to better ensure the safety of all "reprocessed" medical devices. Specifically, the guidance outlined that manufacturers of certain types of scopes, including duodenoscopes, are expected to demonstrate that testing of cleaning protocols and procedures is sufficiently rigorous and then provide complete testing reports to FDA for review.

In my earlier letter, I also discussed the importance of FDA providing updated safety information to health care providers and stressed the need to work closely with manufacturers on product labeling. I appreciate that last Thursday's guidance also provided updated information for reprocessing of devices in health care settings. This information will help to ensure that health care professionals are informed about current best practices.

In addition, I appreciate your collaboration with the Centers for Disease Control and Prevention (CDC) on a protocol, released last week, that hospitals can use to culture these devices to detect bacterial contamination – a protocol modeled on the best practices used at Virginia Mason Hospital in Seattle.

All of these actions are productive steps. However, since I sent my previous letter, new information has surfaced that heightens my concern about this tragic situation. For example, I understand that the reprocessing procedures recommended by manufacturers of currently-marketed duodenoscopes may not have been undertaken and validated in a sufficiently rigorous manner. There are also reports that one manufacturer failed to seek FDA clearance before marketing a specific duodenoscope model, although I understand from FDA that there is no evidence at this time that the lack of clearance is associated with infections. Finally, some public sources have indicated that FDA received numerous adverse event reports dating back to 2013 related to microbial transmission via reprocessed duodenoscopes. At least 15 of the patients noted in these adverse event reports may have died from CRE infections.

This additional information raises questions about why updated guidance, including enhanced cleaning protocols, was not released sooner and the rigor of FDA's examination of post-market data to assess the risks of these devices for patients if not adequately cleaned during reprocessing.

I am glad that you committed to me at the March 10, 2015, Health, Education, Labor and Pensions (HELP) Committee hearing to undertake a full review of this situation. We must determine the facts, and only then can we formulate additional steps to minimize the risk to patients in the future. As part of FDA's efforts, I request that you provide the following information to the HELP Committee:

- 1. FDA's internal review of the adequacy of reprocessing procedures, including review of the validation procedures undertaken by manufacturers of all currently-marketed duodenoscopes, bronchoscopes, endoscopes, and other devices in Appendix E of the new final guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."
- 2. Updates regarding FDA's work with manufacturers of all marketed duodenoscopes on any necessary revisions to product design and labeling, particularly with regard to reprocessing procedures.
- 3. A summary of all adverse event reports from 2011 forward for duodenoscopes, bronchoscopes, endoscopes, and other devices in Appendix E of the guidance, including when and how FDA responded to these reports.
- 4. An assessment of the adequacy of the 510(k) process regarding revisions to product design and labeling, particularly with regard to reprocessing procedures for duodenoscopes, bronchoscopes, endoscopes, and other devices in Appendix E.

I understand, as you noted at the hearing, that duodenoscopes are important devices that serve a critical role in medical care. But as we have seen, insufficient cleaning procedures can create huge risks and cost lives. We cannot afford to be complacent regarding the danger that CRE infections, or other "superbugs," pose. I look forward to continuing to work together to improve reusable device cleaning and monitoring recommendations, and I request that you continue briefing my staff regularly. I appreciate your prompt response to my questions above and all of the steps being taken to protect the public from further infections.

Sincerely,

Patty Murray

Ranking Member

Cc: Lamar Alexander, Chairman

Appendix II: Reports

This appendix includes a report of the results of Dr. Arjo Loeve's investigation of the TJF-Q180V closed-channel duodenoscope involved in the outbreak of antibiotic-resistant infections at Erasmus Medical Center in the Netherlands. It also includes the report of the Dutch National Institute for Public Health and the Environment (RIVM) investigation into the design and safety of the TJF-Q180V duodenoscope and the response of Erasmus Medical Center. The translation of this report from the original Dutch to English is not endorsed or verified by RIVM.

Investigation Olympus TJF-Q180V Scope

following detected contamination after cleaning and disinfection

(Internal title: Report Investigation Scope G-206)

Reporting, Conclusions and Recommendation

May 15, 2012

Final Version - Revision June 27, 2012 - Adding external title August 29, 2014

Dr. Ir. Arjo Loeve

Delft University of Technology

Electronic Instrumentation Laboratory
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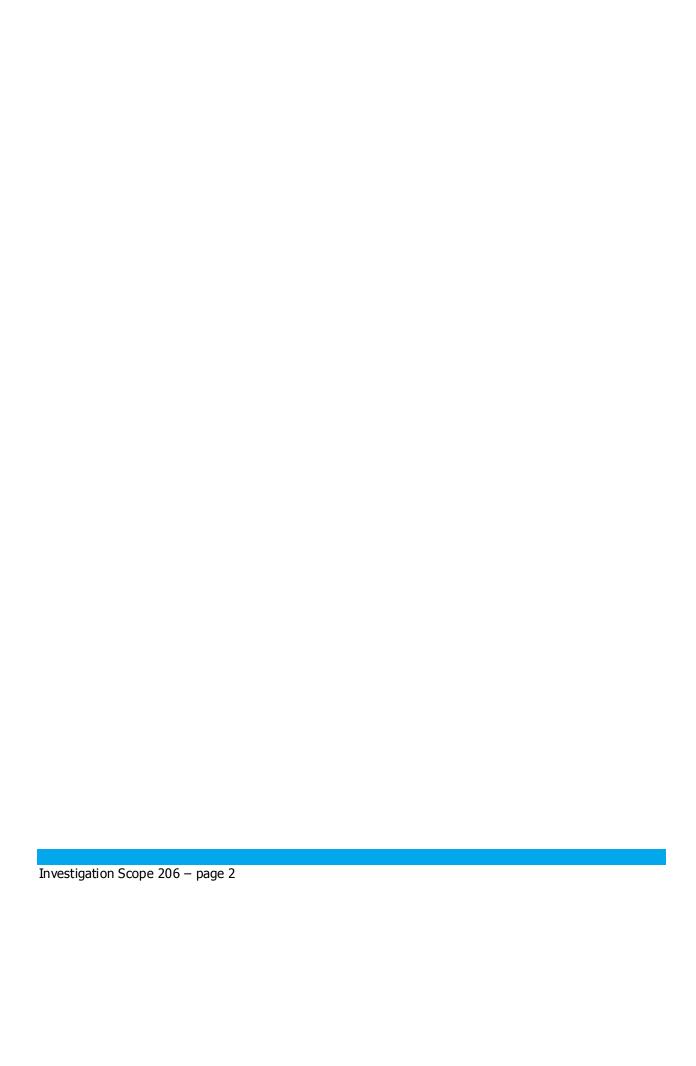


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1 Background - Contamination 'Scope G-206'

Recently the bacterium Pseudomonas Aeruginosa was found at the Erasmus Medical Center ('Erasmus MC') in the cavity of the tip of an Olympus video duodenoscope TJF-Q180V (hereinafter referred to as 'Scope G-206', where the number 206 refers to the internal registration number of the related scope within the Erasmus MC). This bacterium persisted after manual cleansing and mechanical cleaning and disinfection in the Olympus ETD3 scope disinfector.

In order to locate the cause of the persistence of the detected bacteria, it was decided to extensively inspect Scope G-206, to take samples at places that are normally within reach. It will then step by step disassembled and inspected. Sampling will be taken in areas that have become accessible through the disassembly. Also due to these sampling-and disassembling steps and the subsequent microbiological and viral investigations (hereinafter referred to as *'the investigation)*, it is attempted to discover if the persistence of the bacteria is caused by:

- Incorrect or insufficient following of the cleaning instructions
- Incorrect or insufficient formulated cleaning instructions
- Insufficient functioning of sealing in Scope G-206
- Other cause(s)

Olympus Nederland and the Erasmus MC have decided together to take care of and to carry out a further investigation of the contamination of Scope G-206. On April 23, 2012 an investigation team (hereinafter referred to as *'the investigation team')*, consisting of representatives of the Erasmus MC and Olympus, as well as an independent expert of the Delft University of Technology ('TU Delft'), has conducted the investigation at Olympus Nederland B.V., Industrieweg 44, Zoeterwoude, Netherlands.



2 Purpose and layout of this report

Purpose of this report is to come to an objective determination of the cause / causes of the persistence of the Pseudomonas Aeruginosa bacterium in Scope G-206.

For this purpose, first a factual record (supported by photos as well as registration and result lists) of the briefing and execution of *the investigation* is provided.

Following the findings during *the Investigation*, the independent expert of the TU Delft has formulated an opinion concerning the most likely cause / causes of the persistence of the Pseudomonas Aeruginosa bacterium in Scope G-206.

In this report, the sample reference numbers are given as {0000}



3 Disclaimer

Photo used in this report were taken by a professional photographer. The photos were corrected visually regarding color to compensate for deviations by changing light sources and using different cameras. (Overview and macro photos were made with a Nikon D300s and microscope photos with the connected camera). Colors may therefore still differ slightly from the actual colors as they would have been observed under daylight or under daylight lamps. Due to differences in color rendering by different monitors, printers or kinds of paper, possible deviations could be stronger.

Conclusions regarding observations should in no way be based on shades of color or specific characteristic, absolute color values based on the utilized photos.

The conclusions, estimations and recommendations as shown in Chapter 6 "Opinion of the independent expert" are conclusions, estimations en recommendations based on the observed facts during the investigation, the know-how and experience of the independent expert (Arjo Loeve, see Chapter 4) and confidential discussions between the independent expert, experienced fellow scientists and Head of the Department Prof. Dr. Jenny Dankelman in the Biomechanical Engineering Department of the Delft University of Technology, Faculty 3ME.

Therefore conclusions, estimations en recommendations in Chapter 6 can be seen as an informed expert opinion, but in no way a formal position of the Delft University of Technology.

The names used to refer to parts of the scope in this report are not necessarily the same as names commonly used or names used within Olympus. For example: A 'sealing' can also be known as 'bonding' or a 'cap' can be referred to as 'cover'/'sleeve'/housing'. In this report, consistent and unambiguous use of names was taken care of as much as possible.

In case of uncertainty or doubt about which part is identified by a particular name, you will need to contact the author before drawing conclusions and / or take consequences regarding this report.



4 Briefing Report

The investigation was conducted on April 23, 2012 at Olympus Nederland B.V., Industrieweg 44, Zoeterwoude.

At around 10:15 hrs., the *investigation team* gathered there consisting of:

Name	Job Function	Organization		
Name Henk Braat Knut Burmester Viktor Tran Kees Verdouw Marcel Vonk Leo Abel Jolanda Buijs-Hegeman Leo Groenendaal Johan de Kat	Job Function Managing Director Section Manager Service Engineering Production Support Specialist MSD Service Engineer Flexible Instruments Sales Support Manager CDS Unit Head Gastroenterology & Liver Diseases Dept. Staff Advisor Medical Devices Unit head of Medical Technology Hospital Hygienist	Olympus Olympus Olympus Olympus Olympus Erasmus Erasmus Erasmus	Nederland Europa Holding Europa Holding Nederland	
	, ,5	Erasmus		
Jolanda Buijs-Hegeman	Staff Advisor Medical Devices	Erasmus	Medical	Center
Annelies Poth Annette Sandijck	Expert Medical Devices Hospital Hygienist Researcher Biomechanical Engineering	Erasmus Erasmus	Medical Medical Center	Center
Arjo Loeve	Researcher biomechanical Engineering	Delit Univ	versity of Techno	logy

A number of issues relating to the people present are specifically addressed:

- Henk Braat leading the meeting indicates that he will not be present during the investigation.
- Arjo Loeve as an independent expert from the TU Delft will take care of reporting, photo / video shooting for recording, and will observe the process objectively and critically and will manage when necessary.
- Leo Abel will take care of the sampling and will wear latex gloves.
- Viktor Tran takes care of the scope disassembly and will wear latex gloves.
- Annette Sandijk takes care of the storage of the sample materials.
- Johan de Kat will take care of the labeling and packaging of the samples.
- Kees Verdouw will provide and operate any auxiliary equipment such as microscopes.

It is discussed what the approach during the investigation will be:

- Sampling working channels and tip of Scope G-206 with a 3mm diameter cytology brush in order to determine possible presence of residual patient material. Only those samples will be taken in the clean room and attendees present will be wearing gloves and masks.
- 2 Step-by-step disassembling of Scope G-206. For each disassembly step, the relevant part of the scope will be visually inspected, photographed and sampled with cytology brushes and / or swabs. Components of Scope G-206 would also partially or completely be packed for further investigation (cultures, NACT PCR and viral).
- 3 At a later stage components of Scope G-206 will be examined with an electron microscope in order to determine the presence of possible biofilms.

Investigation Scope 206 – page 12

- 11:23 hrs. Preparing the work tables (disinfecting and covering them with a sterile cloth). Those present in the clean room are wearing protective coats and surgical masks. Leo Abel samples the scope and wears in addition to the protective coat and the surgical mask, also sterile gloves and a surgical cap.
- 11:31 hrs. Sampling for PCR in a clean room. Present in the clean room are: Leo Abel, Arjo Loeve, Annelies Poth, Annette Sandijck, Marcel Vonk. The rest of *the investigation team* observes from a technical location.
 - Sampling the parts below with sterile 3 mm diameter cytology brushes (after sampling by brushing and/or pigging, each brush is collected in a new and sterile laboratory jar):
 - Air/water channel and instrument channel tip {5379} (Figure 1).



Figure 1: Tip of Scope G-206 and the cytology brush used.

The cavity under the forceps elevator ("behind the forceps elevator" according to the sample list) {5388} (Figure 2). It should be noted that it was impossible to reach behind/below the forceps elevator cytology brushes since these have a hard tip. Grooves, holes and cracks in that part of the tip could not be reached



Figure 2: Sampling of the cavity under the forceps elevator.



Figure 3: Sampling biopsy channel (above and left middle) and biopsy port (right middle and below).

11:40 hrs.

The investigation team is located in the technical area. The rest of the investigation will take place there. It was decided that the Scope G-206 or parts exposed between the disassembly steps do not need to be cleaned due to the low probability of relevant crosscontamination (since the search is focused on a very specific bacterium).

11:43 hrs.

Viktor makes the first cut in the sealant of cardan rubber, directly behind the steerable tip of the scope and observes air bubbles in the sealing. He suspects that the sealant was applied by a third party. Further investigation shows that Erasmus MC does not use a third party for repairs; this sealant was applied by Olympus Nederland B.V.. Arjo requests to pause in order to first take photos of the coating, Figure 4. The scope is moved to the microscope in order to take photos of the tip.

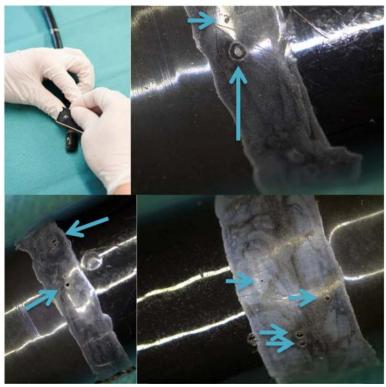


Figure 4: Cutting the sealant of cardan rubber open and microscope photos of the air bubbles (some of them are open) in the still untouched parts of the sealing. The air bubbles are indicated with arrows.

Photos of the camera and light source in the tip show:

- brownish scale **behind** the cover glass of the camera (Figure 5)
- cracks in the sealing of the housing of the tip around the camera (Figure 5)

Afdekglas camera met daarachter bruinige aanslag

Figure 5: Visual inspection camera housing. On the left and right, it is clearly visible that the scale is located behind the glass covering of the camera. On the right, a vertical arrow points to the tear in de sealing of the housing. Furthermore, on the right another tear can be seen in de sealing of the camera which is indicated with the diagonal arrow.

Photos of the cavity in which the forceps elevator moves, made with the microscope and a small diameter fiberscope, show (Figure 6 en 7):

- scratches and grooves reaching under the forceps elevator,
- whitish scale in the tip housing and also brownish scale on the metal part where the forceps elevator runs {5412, 5423, 5434}.

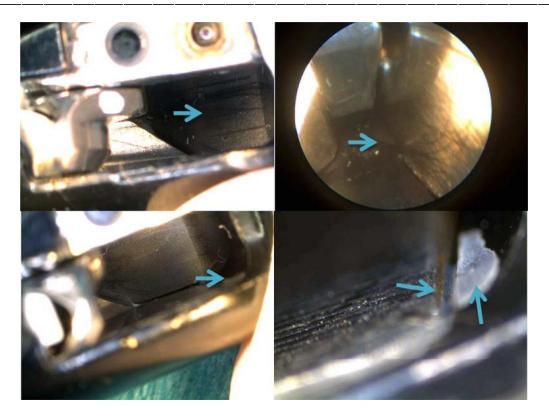


Figure 6: Visual inspection of the tip around the forceps elevator. Above: scratches and grooves well below the forceps elevator; the arrows point to the scratches. Below: whitish and brownish scale (arrow) on the surface where along the forceps elevator moves.



Figure 7: From left to right: sampling of the space around the forceps elevator with swab; scraping sample of white and brown scale; overview of work setting, cutting of scalpel point for packaging.

12:22 hrs.

Viktor Viktor removes the sealing with which the hard plastic cap of the cardan part of the scope is connected. This sealing is packaged as sample {5445}. Then under the adhesion on the flexible sleeve which covers the steerable part will take place using a swab {5456, 5467} (Figure 8).



Figure 8: Removing and packaging of the sealant between the hard plastic cap of the tip and the cardan rubber of the scope and (far right) sampling under the cardan rubber.

Viktor removes the hard plastic cap from the tip by cutting it open and prying it loose from the adhesive layer that glues it to the metal interior of the tip. Waste from cutting the cap is packaged for further testing {5478} (Figure 9). Then sampling with swabs took place inside the housing on which the hard plastic cover was glued {5489, 5490} (Figure 9).

Figure 9: (First two photos on the left) Cutting open and prying loose of the hard plastic cap on the tip. (Two photos on the right)
Sampling interior under the removed hard plastic cap.

It was attempted twice to reach behind the forceps elevator with a swab for sampling. However, the limited space does not lend itself for a deep sampling. Therefore superficial sampling at the rear end of the forceps elevator took place as well as in the forceps elevator channel {5507, 5516} (Figure 10). Another attempt was made to sample deep behind the forceps elevator using a cytology brush. This was a bit more successful, but the space was still too limited for the brush to reach behind the forceps elevator {5521} (Figure 10).



Figure 10: Sampling behind the forceps elevator with swabs and cytology brush.

Inspection of the forceps elevator hinge under the microscope (Figure 11) showed that the hinge has relatively speaking a lot of room to maneuver. When the forceps elevator was moved, a fiber catapulted from this hinge. This fiber was picked up with the point of a scalpel and packaged for further investigation {5535}.

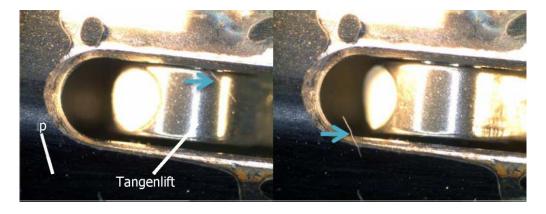


Figure 11: Microscope images of the forceps elevator hinge and the fiber that emerged from it. The axial shifting of the forceps elevator due to room for maneuvering is clearly visible in the two photos. Arrows point to the location of the fiber

12:56 hrs. **LUNCH BREAK**. All participants leave the technical area and continue with *the investigation* only after Arjo was present again.

13:27 hrs. **CONTINUATION.** Het investigation team is present again in the technical area. Viktor removes the cover plate that covers de actuator area of the forceps elevator (Figure 12, left). The cover plate is packaged for further testing {5609}. Then the propulsion cable of the forceps elevator is sampled twice with swabs {5542, 5558} (Figure 12, right). What is immediately noticeable is the fact that all metal surfaces inside the opened actuator area are covered in brown scale. Further testing is needed to determine if this is the result of oxidation or something else.

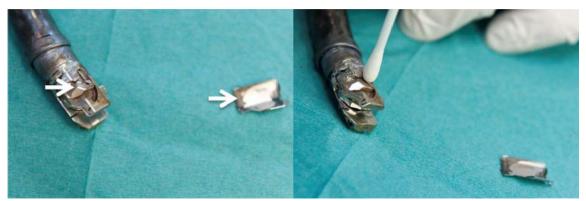


Figure 12: (Left) Verwijdering afdekplaat (rechter piji) van actuator area forceps elevator (linker piji). (Right) Sampling propulsion cable forceps elevator.

Two swab samples were taken from the deep area in which the lever of the forceps elevator moves back and forth {5560, 5573} (Figure 13, first three on the left). After disconnecting and pushing aside the propulsion cable of the forceps elevator (using a precision screwdriver), the area where the propulsion cable was originally running on was sampled twice with swabs {5584, 5599} (Figure 13, far right).

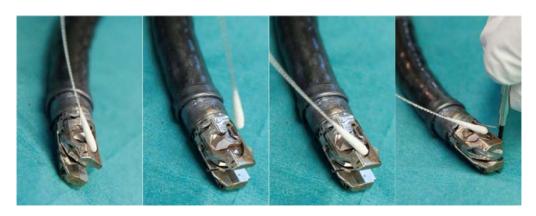


Figure 13: (First three photos on the left) Sampling of the deep area in which the lever of the forceps elevator moves back and forth. (Far right) Sampling under the propulsion cable of the forceps elevator.

13:54 hrs.

Viktor removes the glue from the screw which mounts the forceps elevator on the axis of the lever, lifting axle. The screw is removed and packaged for further testing {5677}. The lever with lifting axle forms one single part which is lifted from the actuator area and put under the microscope (Figure 14). There is an O-ring around the lifting axle that should create a watertight separation between the actuator area and the patient.



Figure 14: From left to right: lifting away of the lever with lifting axle; actuator area from where the lever was removed; lever with lifting axle and O-ring photographed from the side that was in the actuator area; lever with lifting axle and O-ring photographed from the side of the lifting axle.

The O-ring was mounted on the forceps elevator.

In the far right photo in Figure 14, it can be clearly seen that all surfaces of the lever and lifting axle that were located in the actuator area, the actuator area-side, was covered with brown scale. The lifting axle looks clean at the side where the forceps elevator (and therefore also the patient) was located, the patient-side.

Under the microscope, the lever is sampled twice with swabs at the actuator area-side {5613, 5620} and twice on the lifting axle that was located in the forceps elevator {5636, 5648} (Figure 15).

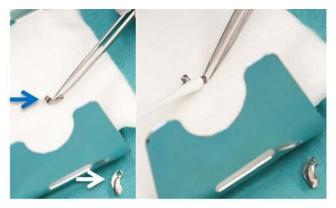
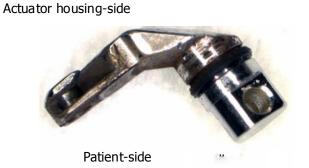


Figure 15: Lever with lifting axle and O-ring (dark blue arrow) and the forceps elevator (white arrow).

Under the microscope the difference between the brown-scaled actuator-side area and the clean-looking patient-side of the lever with lifting axle is clearly visible again (Figure 16). The O-ring shows signs of wear and is on the actuator-side area heavily covered with brown scale. On the surface of the O-ring (where it is wedged in the housing) the brown scale is also prominently present. On the patient-side of the O-ring is the brown scale still present, but to a lesser extent.



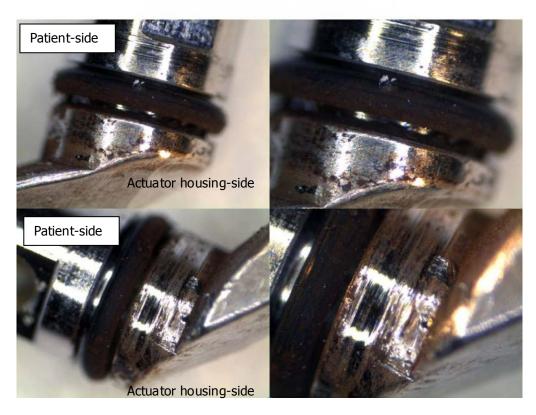


Figure 16: Microscope images of the lever with lifting axle and O-ring. In each of the bottom four photos, there is an enlargement of the central part of the photo on the left.

Viktor removes de O-ring from the lifting axle. The O-ring is cut into two halves, both of them are packaged for further testing {5651, 5664} (Figure 17). The forceps elevator and the lever with lifting axle are also packaged for further testing {5682, 5695}. Finally, a virological sample is taken from the water suction channel {5706} before the tip of Scope G-206 is packaged with a sterile bag and the scope in is stored in its case (Figure 17).

Figure 17: From left to right: removing the O-ring; cutting the O-ring in half; virological sample from water suction channel; packaging of Scope G-206.

14:23 Since Viktor and Knut must catch their plane back to Germany, *the investigation* is terminated. Therefore it is refrained from sampling of the inside of the scope shaft, the removal and cutting up of the working channel for further testing, and the sampling of the inside of the handle of Scope G-206.

6. Opinion independent expert

Accessibility for brushes

Observations: During the sampling it became repeatedly clear that the tip of Scope G-206 contains several cracks, corners and spaces that are hard to reach or cannot be reached at all with the 3 mm diameter cytology brush. In particular:

- the crack under the hinge point of the forceps elevator,
- the crack caused by the axial clearance of the forceps elevator,
- and the area under/behind the curve of the forceps elevator,

proved unreachable for this brush (Figures 2, 10 and 11).

Recommendation: Enlarge in the scope design the space around the mentioned points so that these can be reached by brushes and / or make sure that the cleaning instructions are such that those points are cleaned thoroughly in the current scope in one way or another. Validate that the customized designs and / or instructions actually result in sound cleaning.

Quality of sealing

Observations: The sealing in and around the tip were found to show abnormalities that could result in potential leakage. Specific observations:

- air bubbles, some of them open, in the adhesion between the hard plastic cap of the tip and the flexible sleeve over the steerable part of the scope (Figure 4),
- cracks in the sealing around the camera housing (Figure 5),
- Worn looking O-ring which should ensure the sealing around the lifting axle (Figure 12).

The air bubbles in the adhesion and the tear in the sealing can open the door for the appearance of moisture and micro-organisms. Visualization of the O-ring with a scanning electron microscope. Based on the images of the O-ring, in particular the rough / powdery texture of the surface and the crack that can be seen in the electron microscope photo (see Appendix B), it appears that reliable sealing by means of this O-ring cannot be not guaranteed. This is further supported by the findings as described below under 'Scale found on parts'.

Recommendation: Ensuring regular, strict control of sealing between moments of use. Take care of regular replacement of the O-ring (it might have performed well over time, but it remains a moving sealing which requires maintenance). Improve in future scope designs the sealing by creating multiple barriers or, and this would be preferred, avoid such sealing at all and design a forceps elevator with no moving parts that run from the patient into a "sterile" area of the instrument.

Scale on parts

Observations: At a number of locations in the tip of Scope G-206, scale was detected:

- brownish scale behind the glass covering of the camera (Figure 5),
- brownish and whitish scale on the edge of the space around the forceps elevator (Figure 6),
- brownish scale on the surfaces in de actuator area (Figure 12),
- brownish scale on the surfaces of the lever at the actuator area-side (Figure 16),
- brownish scale on the O-ring, mainly at the actuator area-side, but also at the patient-side (Figure 16).

Scale behind the covering glass of the camera implies that this area was not properly sealed, so that growth of micro-organisms, scale from residual liquids or deterioration of a possible coating occurred.

Scale on the edge of the area around the forceps elevator should be investigated further before arriving at any conclusions. This could be oxidation, but in case of a contamination it could also indicate insufficient / incorrect cleaning by the Erasmus MC, since this location is well and easily accessible.

The brownish scale on the surfaces in de actuator area, the actuator area-side of the lever and the O- ring is so consistent and evenly distributed that it is highly unlikely that this oxidation is caused by, for example, skin contact during assembling. It is more likely that somewhere from the shaft or the tip of the endoscope moisture and / or biological material has entered the actuator area and lingered and / or augmented.

The fact that the brownish scale of the O-ring can be seen on each side of the O-ring (area actuator-side and patient-side) suggests that this scale around and on the O-ring has migrated from one side to the other. It is therefore very likely that this O-ring has not done its job. Furthermore, it appears that also the the size of the cracks between the forceps elevator and the housing as well as between the lifting axle and the housing are too small to be able to be brushed (and perhaps also to be rinsed) and too large to be inaccessible for liquids and / or biological materials.

Experience with O-ring-sealing on this scale shows that less than 0.01mm deviation from the ideal clearance can already cause leakage. More scale could therefore increase the chance of leakage or scale can be caused by leakage. During the axial back and forth movement of the lifting axle, the O-ring could make axially rolling movements, which could cause moisture and / or organic material to enter between the O-ring and the lifting axle. With each further movement of the lifting axle, moisture and / or organic material could migrate further from the actuator housing- side to the patient-side or vice versa.

Recommendation: Find out what the scale behind the glass covering of the camera is, measure the quality of the sealing and correct when necessary. Review the cleaning process critically in order to trace how the scale in the forceps elevator channel on an easily accessible location could linger and stay unnoticed.

Improve the sealing of the actuator area or avoid in future designs the use of such sealing. Check the existing sealing in all existing scopes and ensure an objective, critical, quantitative measuring of the sealing quality.

Cultures

Observations: Culture results are shown in Appendix A, Table A.2. Only the cultures (specific as well as generic) of the hard plastic cap of the tip provided positive culture results. Since the exterior of the cap has been cleaned repeatedly, can be accessed easily, has been dry for a long time, (the detected bacterium normally does not thrive on dry surfaces), it is therefore highly likely that the bacterium was located on the inside of the cap. This finding also fits the observations made regarding the quality of the sealing.

The fact that there were no positive culture results at other points does not mean that none were there. The inaccessibility of many places on the tip, the limitations of the sampling with swabs and the fact that biofilms grow more easily on plastics and rubbers than on metals, result in the fact that little can be concluded based on the negative test results.

Recommendation: Also make a culture of the spare sample of the O-ring {5651}. If possible, conduct a detailed investigation to exclude the presence of unwanted biomaterials in the actuator area. Since apparently Pseudomonas Aeruginosa was found inside the tip, it seems prudent to investigate immediately all scopes worldwide of a similar type. See also recommendations in the 'Quality of Sealing' and in the 'Conclusion' sections.

Conclusion

Observations: All in all, it seems that this scope has suffered badly from usage, possible insufficient quality of sealing, inadequate maintenance and lack of critical mechanical control. The very small cracks and spaces in the forceps elevator channel form a number of locations where lingering and / or increasing moisture and / or biological materials are quite likely.

It goes without saying that the sealing, actuator area en O-ring require direct and serious attention in all existing and future scopes similar to Scope G-206.

Recommendation: Increase direct global control and maintenance of similar scopes, revise especially scopes with degraded sealing, and conduct extensive sampling. Update the cleaning instructions and conduct strict controls to ensure compliance and acceptable results. Improve the quality of the sealing in the scope design and minimize the amount of sealing points.

In case during further testing Pseudomonas Aeruginosa or other bacteria/viruses/substances are also found that should not be present in the actuator area, it is recommended to immediately recall all similar scopes and/or in parallel to investigate if there could (also) be a leakage trail that does not run via the Oring or other sealing.

Appendix A – Registration numbers and descriptions of cultures Scope G-206

Table A.1: Sample material and locations and relating reference numbers.

Material / Location	Reference number
Air/water channel tip	5379
Behind forceps elevator	5388
Biopsy channel	5396
Biopsy port	5401
Contamination tip, top	5412
Scalpel 1	5423
Scrapings after scalpel 1	5434
Adhesion cap	5445
Swab under adhesion 1	5456
Swab under adhesion 2	5467
Cap	5478
Culture without cap 1	5489
Culture without cap 2	5490
Under forceps elevator after removing cap 1	5507
Under forceps elevator after removing cap 2	5516
Brush under forceps elevator without cap	5521
Scalpel with fiber	5535
Cable forceps elevator tip 1	5542
Cable forceps elevator tip 2	5558
Housing forceps elevator channel for O-ring 1	5560
Housing forceps elevator channel for O-ring 2	5573
Sample under cable in tip 1	5584
Sample under cable in tip 2	5599
Cover plate forceps elevator operating housing	5609
Operating forceps elevator patient side 1	5613
Operating forceps elevator patient side 2	5620
Operating forceps elevator instrument side 1	5636
Operating forceps elevator instrument side 2	5648
Half of O-ring 1	5651
Half of O-ring 2	5664
Screw backside forceps elevator	5677
Forceps elevator	5682
Lever	5695
Water suction channel (virological sample)	5706

Reference number	Lab Number	Туре	Date	Result
5379	Handed to Annelies	Poth for DN	A Investigati	on
5388	Handed to Annelies	Poth for DN	A Investigati	on
5396	Handed to Annelies	Poth for DN	A Investigati	on
5401	Handed to Annelies	Poth for DN	A Investigati	on
5412	20120072678101	AERK	2012-04-	negative
5423	20120072674701	AERK	2012-04-	negative
5434	20120072680001	AERK	2012-04-	negative
5445	20120072666701	VIM	2012-04-	negative
5456	20120072681901	AERK	2012-04-	negative
5467	20120072683501	VIM	2012-04-	negative
5478	20120072675501	VIM	2012-04-	VIM pseu, B-DYK-9760
5478	20120072677101	AERK	2012-04-	E. Faecium, B-DYK-9757
5478	20120072677101	AERK	2012-04-	VIM pseu, B-DYK-9756
5489	20120072686101	AERK	2012-04-	negative
5490	20120072688601	VIM	2012-04-	negative
5507	20120072689401	AERK	2012-04-	negative
5516	20120072695801	VIM	2012-04-	negative
5521	Handed to Annelies	Poth for DN	A Investigati	on
5535	20120072673901	AERK	2012-04-	negative
5542	20120072700201	AERK	2012-04-	negative
5558	20120072705301	VIM	2012-04-	negative
5560	20120072711701	AERK	2012-04-	negative
5573	20120072717601	VIM	2012-04-	negative
5584	20120072729901	AERK	2012-04-	negative
5599	20120072734401	VIM	2012-04-	negative
5609	Spare for possible t	future culture	s and / or c	counter-expertise
5613	20120072737901	AERK	2012-04-	negative
5620	20120072740801	VIM	2012-04-	negative
5636	20120072745901	AERK	2012-04-	negative
5648	20120072750401	VIM	2012-04-	negative
5651	Spare for possible t	future culture	es and / or co	ounter-expertise
5664	Handed to Annelies Poth for DNA Investigation			
5677	Electron microscopy			
5682	Electron microscopy			
5695	Electron microscopy			
5706	6159-E	CELK	2012-04-	negative

Appendix B - Electron microscope photos

The electron microscope photos in this appendix are made with a scanning electron microscope by the Vossius-institute in Leiden.

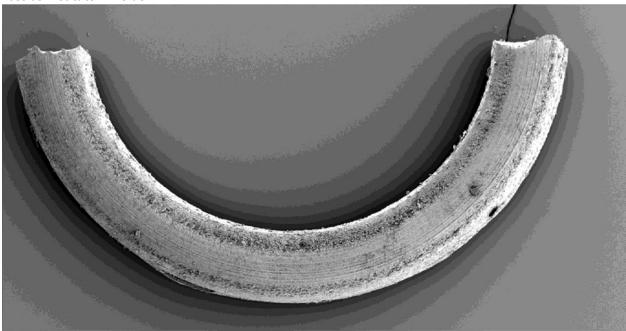


Figure B. 1: Photo of the O-ring which clearly shows that the surface of the O-ring is rough and fibrous, contains scale and was torn at the left bottom.

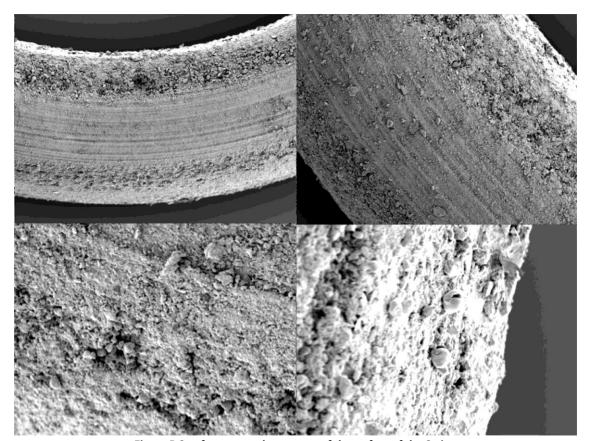


Figure B.2: a few more enlargements of the surface of the O-ring.

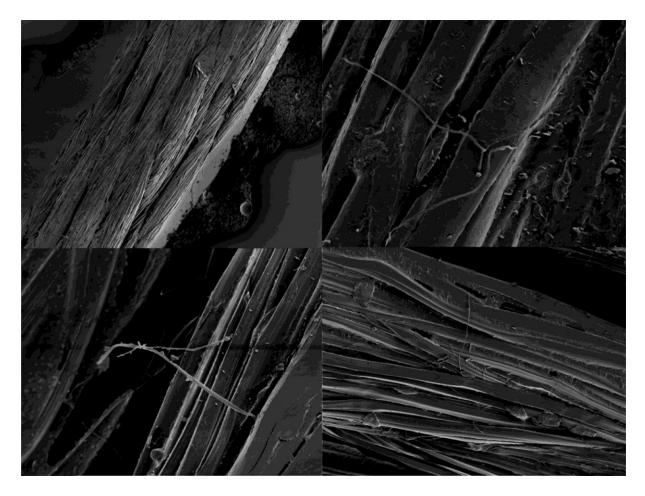


Figure B.3: Photos of the surface from the bottom of the sealing between the hard plastic cap of the tip and the cardan rubber of the scope.

Appendix C - Contact sheets all photos of the investigation	





D300s-ACL0002-eKLsq.jpg



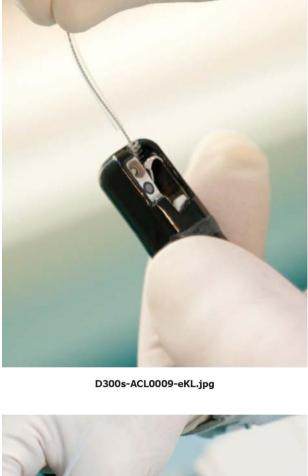
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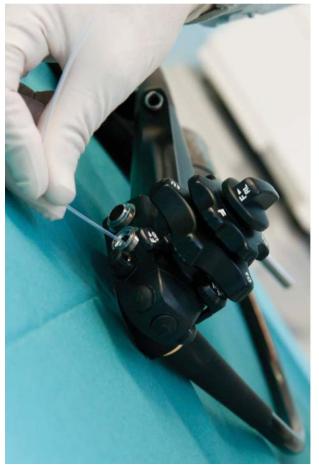


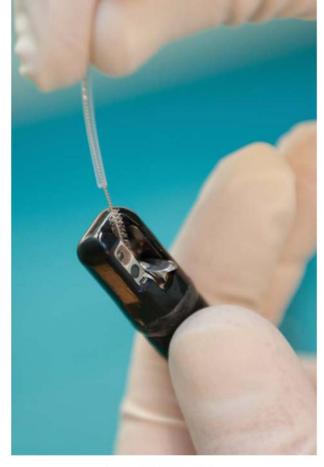
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D300s-ACL0008-eKLsq.jpg









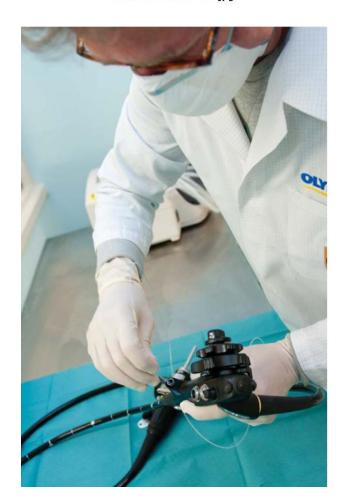
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D300s-ACL0012-eKL.jpg



D300s-ACL0015-eKL.jpg



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D300s-ACL0016-eKL.jpg



D300s-ACL18-eKL.jpg





D300s-ACL0019-eKLsq.jpg

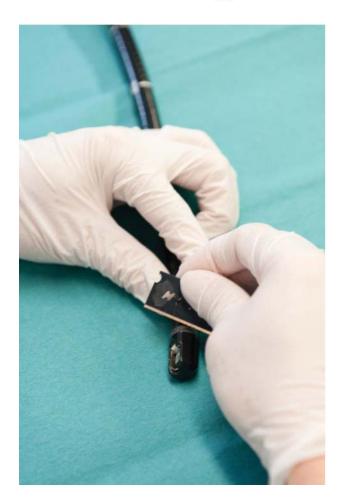


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D300s-ACL0024-eKL.jpg



D300s-ACL0027-eKL.jpg



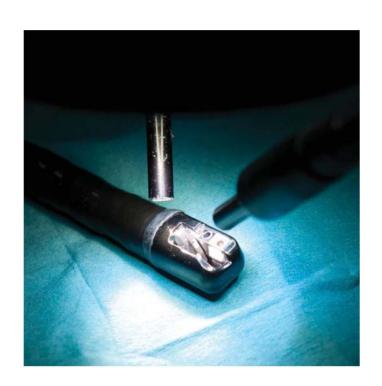
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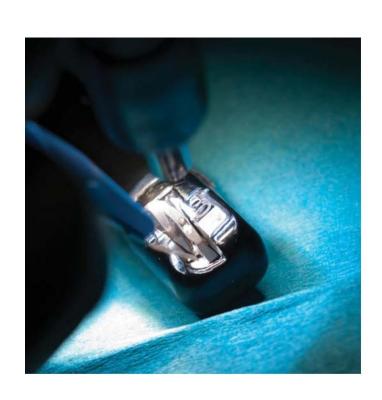
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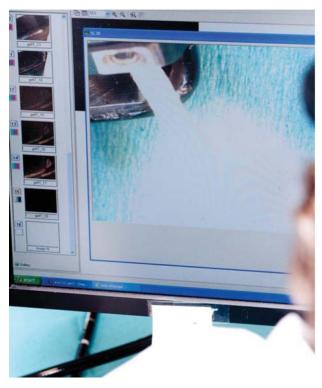


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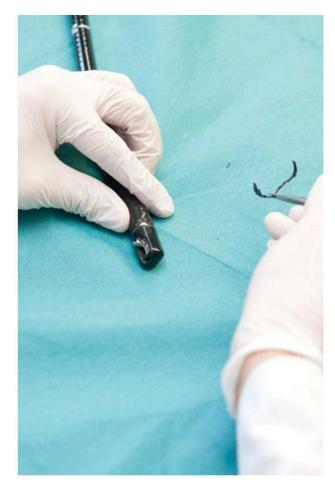
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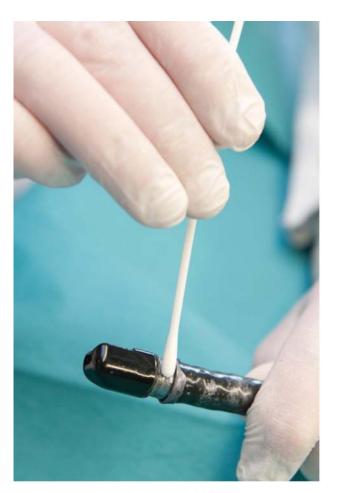
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D300s-ACL0053-eKL.jpg



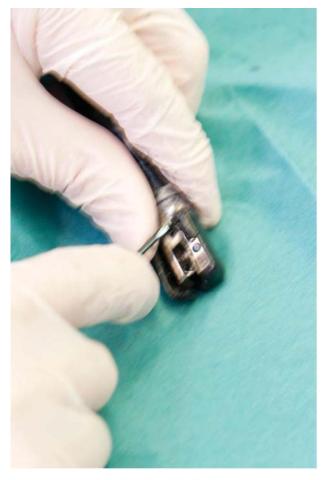
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D300s-ACL0054-eKL.jpg



D300s-ACL0057-eKL.jpg



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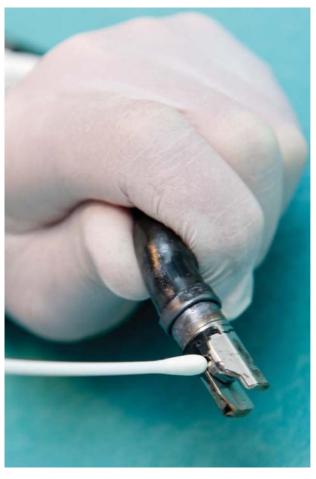


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D300s-ACL0070-eKL.jpg





D300s-ACL72-eKL.jpg



D300s-ACL0073-eKL.jpg



D300s-ACL0074-eKL.jpg





D300s-ACL0077-eKL.jpg

D300s-ACL79-eKL.jpg

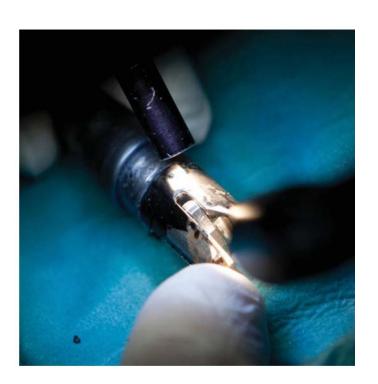




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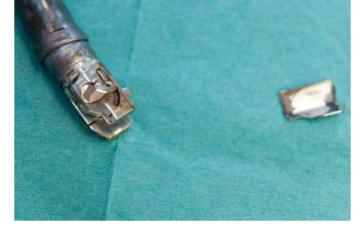
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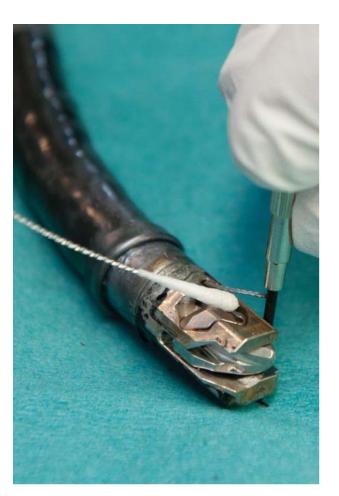
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D300s-ACL101-eKL.jpg









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Stap 7

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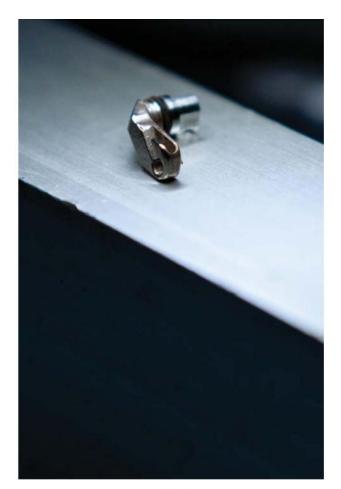


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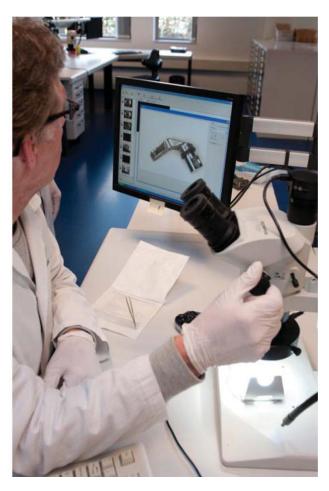


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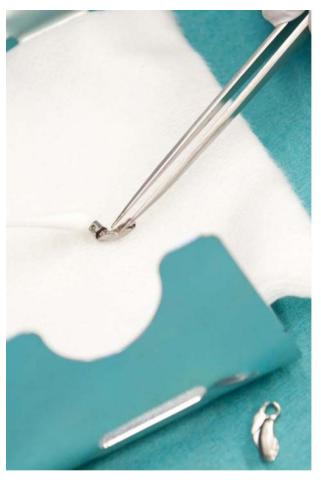




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D300s-ACL125-eKL.jpg



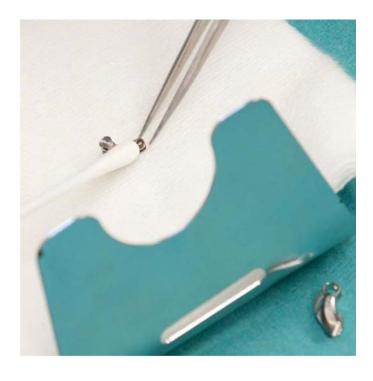
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D300s-ACL0129-eKL.jpg



D300s-ACL0130-eKL.jpg



D300s-ACL0131-eKLsq.jpg

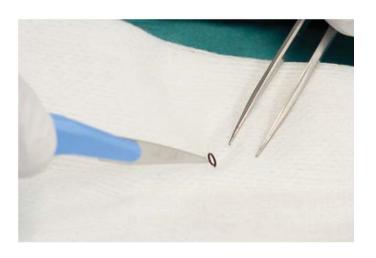




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D300s-ACL0134-eKL.jpg



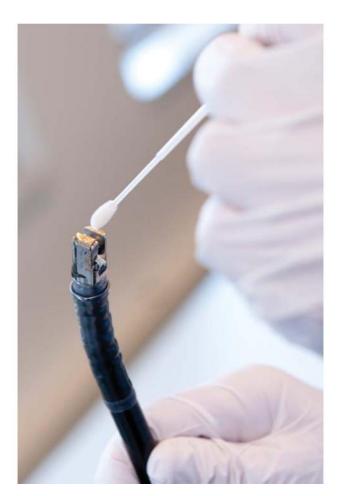
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D300s-ACL136-eKL.jpg





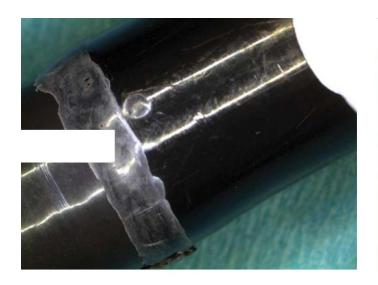
D300s-ACL0137-eKL.jpg D300s-ACL0139-eKL.jpg



D300s-ACL140-eKL.jpg



D300s-ACL0141-eKL.jpg



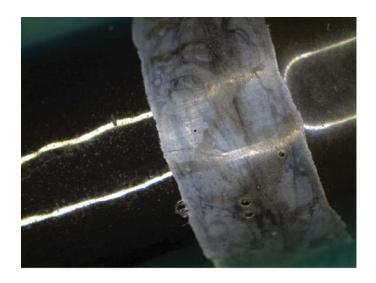


Microsc-001.jpg Microsc-002.jpg



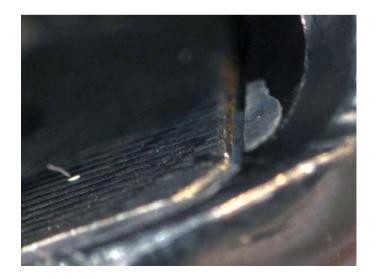


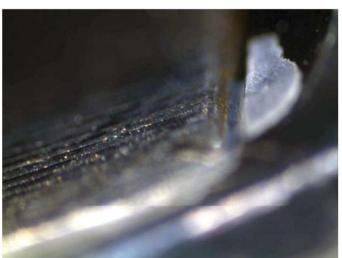
Microsc-003.jpg Microsc-4.jpg



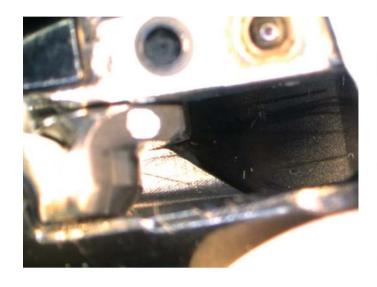


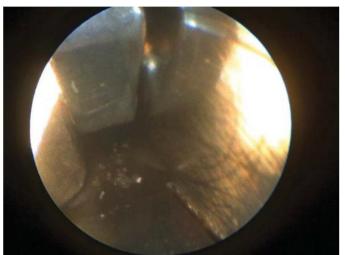
Microsc-005.jpg Microsc-006.jpg





Microsc-008.jpg Microsc-12.jpg





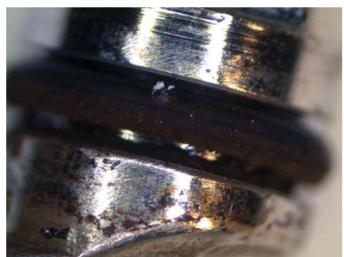
Microsc-013.jpg Microsc-015.jpg



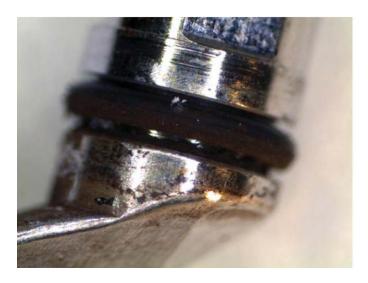


Microsc-19.jpg Microsc-020.jpg



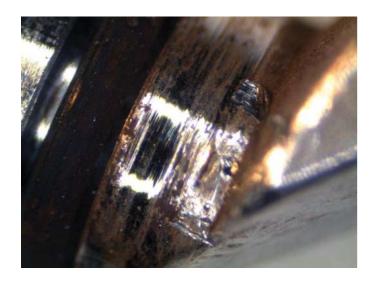


Microsc-022.jpg Microsc-023.jpg





Microsc-024.jpg Microsc-25.jpg



Microsc-026.jpg

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Disinfection of Olympus TFJ-Q180V ERCP endoscope

Advice requested by: Advice formulated by:

Verified by:

Date of request: 22 October 2012 Date completed: 30 July 2013 Ad-hoc number: 2012-12 Project number: V/080118/01/AH

Ad-hoc request

The Healthcare Inspectorate (IGZ) asked the National Institute for Public Health and the Environment (RIVM) to give its opinion in connection with a report from the Erasmus Medical Centre (EMC) regarding problems when disinfecting the Olympus TFJ-Q180V flexible endoscope for endoscopic retrograde cholangiopancreaticography (ERCP).

Background

Following an outbreak of Verona integron-encoded metallo- β -lactamase (VIM) positive *Pseudomonas*, the EMC conducted an investigation into the possible sources of contamination. At the beginning of 2012, a source of contamination was found in the endoscope at hand, under the elevator. The endoscope was then taken out of service. By order of the EMC, the endoscope was subjected to a destructive examination by the TU Delft (Delft University of Technology) in April 2012, in the presence of representatives of the manufacturer and the hospital. The cap of the tip of the endoscope was opened. Samples were taken from inside the endoscope and examined for the presence of microorganisms. The resistant *Pseudomonas* stem was found in one place (sampling point 5478, denoted as "Cap").

The report on this investigation was sent to the manufacturer for comments and the manufacturer responded. As the conclusions of the report and the response from the manufacturer are contradictory, the IGZ was keen to get an opinion from the RIVM. In March 2013, a meeting was held between IGZ, EMC and RIVM to discuss and shed light on the problem.

RECOMMENDATIONS

The construction of the endoscope hinders optimum manual cleaning. The cap on the tip has been glued on so that it cannot be removed to brush clean the back of the elevator. The manufacturer acknowledges this and gives directions on how to rinse the back of the elevator with cleaning fluid during the (pre-)cleaning process and fixing the elevator in an open position before it is placed in the washer-disinfector. However, it is not evident from the information provided by the hospital that these details in the user manual were acknowledged and followed. It is not possible to establish the extent to which these two factors contributed towards the outbreak of *Pseudomonas*.

Although the manufacturer was asked expressly to provide information to show that the recommended cleaning procedure is effective, that the O-ring seal of the elevator is actually capable of preventing bacteria from getting into the endoscope and that the leak test, as user test or automatic test in the washer-disinfector, is accurate enough to establish the integrity of the O-ring seal, such information was not supplied.

Disinfection of the Olympus TFJ-Q180V flexible ERCP endoscope

Introduction

Endoscopes for endoscopic retrograde cholangiopancreaticography (ERCP) have a so-called elevator that is used to guide a device in the right direction from the endoscope's work channel to, for example, the bile duct. The elevator is served by a wire in the so-called elevator channel. It is usual for the elevator channel of an ERCP endoscope to be constructed in such a way that it is open on the patient side of the endoscope. This channel, just like the other channels in the endoscope, becomes dirty when the endoscope is used and has to be cleaned and disinfected before it is used again. The operating body of the endoscope is fitted with an access port along which the elevator channel can be flushed to clean and disinfect it internally. However, this is complicated by the fact that the channel is very narrow and is also largely filled with the wire that operates the elevator. Due to this narrow passageway, relatively high pressure has to be used, which still results in a very restricted flow.

The Olympus TFJ-Q180V endoscope in question is special, because the elevator channel is completely closed, so the inside of the channel does not, in principle, become contaminated during use and need not therefore be cleaned and disinfected. However, important questions which must be posed here are:

- · Is the construction of the seal at the tip effective enough to keep out even microscopically small contamination?
- · Is it possible to clean and disinfect the external part (in this case the elevator) well? The EMC investigation also reveals that the construction of the tip makes effective cleaning difficult. For instance, the cap that covers the tip of the endoscope during use is glued on so that it cannot be removed to provide better access to the elevator below for brushing. EMC also makes use of other types of ERCP endoscope, the cap of which can be removed. No positive cultures were found with these endoscopes.

The report from the TU Delft and the manufacturer's response to this report led to further questions being posed to both the manufacturer and the hospital. The questions, the answers and our opinion can be found in annex 1 and annex 2 respectively. Also, on 18 March 2013, a visit was made to the EMC, where IGZ staff and the authors of this report discussed the matter with hospital representatives. A visit was also made to the cleaning and disinfection department.

Findings

- 1. In its response to the report from the TU Delft (see document 'Views on Report on Scope G-206' of 7 September 2012), the manufacturer emphatically draws attention to the cleaning instructions and repeatedly expresses doubts as to whether the hospital actually carried out the prescribed cleaning and disinfection procedures. From the information provided by the hospital, we can conclude that the manufacturer's cleaning instructions were partly followed by the hospital. The manufacturer's manual describes the manual cleaning of the endoscope. With respect to the elevator, Chapter 3 of the manual (pages 25-39) describes and illustrates with drawings how the elevator should be brushed. On page 45 of Chapter 3 it also states, independently of the other steps in cleaning the elevator, that the back of the elevator must be rinsed. This must be done by injecting cleaning fluid into the space behind the elevator by means of a syringe. A drawing of this has also been enclosed by way of illustration (see figure 1). The hospital stated that it followed the instructions described on pages 36-39 (see letter from the EMC to RIVM dated 29 March 2013).
- 2. The manufacturer also has available an abridged version of the cleaning instructions. This only mentions brushing the elevator, but not injecting the back. This document contains a clear warning that it is not complete and refers users to the user manual for full instructions. The status of the document is unclear.
- 3. With regard to mechanical cleaning, the manufacturer specifies that the endoscope must first be cleaned in accordance with the instructions in Chapter 3 of the manual. The manufacturer also states that one must check that the endoscope washer-disinfector is suitable for this endoscope. EMC uses Olympus ETD3 washer-disinfectors for the mechanical cleaning and disinfection. According to the manufacturer, these machines are

suitable for cleaning and disinfecting the TJF-Q180V endoscope. Finally, it is stated that the elevator must be fixed at an angle of 45° prior to mechanical cleaning and disinfection. This aspect is not mentioned in the hospital's work instructions for the mechanical cleaning of the endoscopes (document 'Disinfection of flexible endoscopes, Mechanical cleaning and disinfection in the disinfector').

Cleaning fluid Syringe Elevator Figure 1

- 4. The manufacturer provided a test report in which the validation of the manual cleaning and disinfection of the elevator is described (see Annex 1, point 8). However, the quality of the investigation left so much to be desired that it is not possible to support the conclusion drawn by the manufacturer, namely that the cleaning and disinfection procedure for the elevator is effective. Apparently, the manufacturer also failed to examine the efficacy of the procedure used by the hospital, consisting of a manual pre-clean followed by mechanical cleaning and disinfection. This procedure is the standard working method in the Netherlands, as prescribed by both the Werkgroep Infectie Preventie (WIP) and the Stuurgroep Flexibele Endoscopen Reiniging en Disinfectie (SFERD).
- 5. The manufacturer does not respond to the comments from the TU Delft examiner regarding the construction of the tip of the endoscope and the elevator which makes it impossible to brush the back and sides of the elevator effectively. The manufacturer refers to the previously mentioned validation report on the cleaning and disinfection.
- 6. Nor does the manufacturer discuss in a substantive way the comments made by TU Delft on the construction of the O-ring seal of the axis of the elevator. It is essential that this O-ring seal functions properly if contamination of the inside of the endoscope is to be prevented. During the meeting on 18 March 2013, the EMC technicians expressed their thoughts regarding the fact that no maintenance was prescribed for the O-ring.
- 7. The failure of the O-ring is mentioned in the manufacturer's risk analysis. As management measures, the manufacturer refers to durability tests which are carried out and the leak test that must be performed every time the endoscope is used. In the durability tests, the elevator is moved up and down a few thousand times, in stages, and a leak test is carried out after every stage in order to establish the integrity of the O-ring. However, three factors are not taken into account in the durability tests. Firstly, the overpressure to which the endoscope is exposed during normal use and which can aid the ingress of contamination along the O-ring. Secondly, the endoscope is not cleaned and disinfected during the test. It cannot be ruled out that the O-ring is adversely affected by the cleaning and disinfection process and deteriorates in quality as a result. This is analogous to the damage caused to rubber parts in the ETD3 washer-disinfector in the course of time. It is possible that this results, in practice, in a shorter life span than can be assumed on the basis of the durability tests. Thirdly, there is the time factor. O-rings age, so their elasticity decreases in the course of time.
- 8. All in all, the manufacturer states that the leak test is <u>the</u> method by means of which the user must determine the integrity of the O-ring seal, based on the assumption that the O-ring is in order if the leak test is satisfactory. The manufacturer does not give a substantive answer to our question regarding the degree of evidence that the leak test is suitable for demonstrating that the O-ring seal is tight enough to keep out bacteria too. The manufacturer adopts the stance that air molecules are smaller than bacteria and, consequently, that bacteria cannot pass through if there is no air leak. There are two arguments against this. Firstly, the manufacturer is ignoring the fact that the leakage of air only becomes visible to the user when the air bubbles have reached a certain size and that not every leak will therefore be visible in the leak test. Also, the leak test in the washer-disinfector is conducted as an instrumental method, whereby the absence/presence of leaks is checked on the basis of the fall in pressure in the endoscope in a certain period. The manufacturer of the endoscope must state what fall in pressure can be considered acceptable. The manufacturer fails to do this, however. Secondly, the end of the endoscope must be moved (so-called wagging) during the leak test, in

accordance with the manufacturer's instructions. This makes it easier to see any small cracks in the cardan rubber. Analogous to this, it is advisable with the endoscope in question to move the elevator up and down during the leak test. As a result, the interfaces between the axis of the elevator and the O-ring will move in relation to one another and possible leakages will be more easily visible as a result. The endoscope manual provides no instructions about this, however.

9. During the examination of the endoscope by the TU Delft, corrosion was observed on the internal parts of the endoscope. However, this does not necessarily mean that the Oring in the seal of the elevator functioned badly and contributed towards the infections with VIM positive *Pseudomonas*. This is because the maintenance history of the endoscope reveals that the endoscope had been repaired twice due to a leaking cardan rubber. It cannot be ruled out that fluid penetrated the endoscope during these leakages, resulting in the observed corrosion of the metal parts.

Conclusions - general

The construction of the endoscope hinders optimum manual cleaning. The cap on the tip has been glued on and cannot therefore be removed to brush clean the back of the elevator. The manufacturer acknowledges this and provides instructions for rinsing the back of the elevator with cleaning fluid during cleaning and for fixing the elevator in an open position before it is placed in the washer-disinfector. It was not evident from the information provided by the hospital that these instructions had been followed. It is not possible to establish to what extent the two factors (limitations in the design and the failure to follow fully the cleaning instructions) contributed towards the outbreak of VIM positive *Pseudomonas*.

Patients who undergo an ERCP always run the risk of becoming infected with *Pseudomonas*. From the information provided by the hospital, it is evident that, in a certain period, 36 patients were found to have a *Pseudomonas* infection. 22 of these patients had been treated with the TJF-Q180V endoscope.

Conclusions - with respect to the construction of the endoscope

The construction of the endoscope in question deviates in a number of ways from the 'conventional' ERCP endoscopes (see introduction). An O-ring seal, in principle, prevents contamination of the elevator channel, so it is no longer necessary to clean and disinfect this channel. With this construction, the integrity of the O-ring is of vital importance. If the O-ring leaks, the inside of the endoscope becomes contaminated and the (cross-)infection of patients cannot be ruled out. The manufacturer must therefore investigate if his design does actually provide an adequate seal. The manufacturer was asked for the validation data on the O-ring construction. These were not supplied, so we must conclude that the construction has not been validated in terms of keeping bacteria out. The durability test carried out does not provide an alternative to this. In addition, it must be possible for the user to check the integrity of the seal. The manufacturer assumes that the leak test as conducted by the user provides enough guarantees for this, but has not investigated this. It has not been established, namely, that the leak test would detect a leak along the Oring large enough to let bacteria through. In addition, the leak test is conducted statically, in accordance with instructions, whereas it is better, for technical reasons, to move the elevator when carrying out the leak test.

During the destructive examination of the endoscope, brown discolouration was observed on the inside. However, it cannot be concluded from this that the O-ring seal had failed, as was suggested by the examiners, because the maintenance history of the endoscope reveals that the endoscope had been repaired twice due to leakage. It is therefore also possible that the observed corrosion resulted from this.

A second detail of the construction is the glued-on cap on the tip of the endoscope. As this cap cannot be removed, it is not really possible to brush the back of the elevator clean. The manufacturer takes account of this in the user manual by stating that the back of the elevator must be rinsed during manual cleaning and that the elevator must be fixed at an angle of 45° before it is placed in the washer-disinfector.

Conclusions – with respect to the cleaning procedure followed The hospital partly followed the manufacturer's instructions when cleaning and disinfecting the endoscope. The endoscope was cleaned and disinfected mechanically in an Olympus ETD3 washer-disinfector, which the manufacturer considers suitable for the endoscope in question. Before the endoscope was placed in the washer-disinfector, it was cleaned manually. In doing so, the hospital did not follow all the instructions in the user manual. The elevator was brushed, but the second step, flushing the back of the elevator with cleaning solution, was not carried out. There were no specific instructions in the protocol received that the elevator had to be fixed at an angle of 45° before the endoscope was placed in the washer-disinfector.

As part of the manual pre-clean, a leak test was conducted. The elevator was not moved up and down during this test. Nor does the manufacturer prescribe this.

Annex 1: Manufacturer's response to RIVM questions

This Annex is in English to facilitate the communication with the manufacturer. The response of the manufacturer to the report of TU Delft was studied by RIVM. On a number of issues clarification was asked from the manufacturer. The RIVM comments, the responses from the manufacturer and the evaluation of those responses are given below.

1. Comment RIVM: The elevator channel is of a different design than that in other endoscopes for ERCP. Normally the elevator channel is open at the tip, which allows the ingress of contamination during use in the patient. To remove the contamination from the inside of the elevator channel it is fitted with an entry port that allows flushing with detergent and disinfectant. The elevator channel of the TJF-Q180V endoscope is sealed, probably with the intention to prevent contamination of the inside of the channel. The precleaning instructions that we retrieved from the internet clearly state: "The sealed forceps elevator wire of the TJFQ180V means that the elevator wire channel does not require flushing and rinsing." It is unclear at this moment whether flushing the channel is at all possible, although not required. If it is not possible to flush the channel, this means that the inside cannot be decontaminated, even when the seal of the channel fails and the inside of the channel becomes inadvertently contaminated.

The manufacturer responded by stating that sealed cavities do not need to be reprocessed as they cannot be contaminated as long as the endoscope is in perfect condition. The manufacturer states that the latter can be verified by performing the leakage test as part of each reprocessing procedure.

The manufacturer describes that the leakage test is performed by raising the internal pressure

in the endoscope to 'approx. 30 kPa'. The manufacturer suggests that this should be sufficient as the external pressure during clinical use is only 3 kPa.

Evaluation

The manufacturer does however not consider:

- That during use in the patient the elevator is raised and lowered, which causes the seal to be challenged under dynamic conditions, when rotational forces and axial forces are applied, which may aid the ingress of contaminants past the seal,
- The fact that during leakage testing the pressure to the seal is applied from the opposite side compared to the use situation. The test may not be suitable for all possible seal failure modes.
- 2. RIVM request: The risk analyses for the TJF-Q180V endoscope, especially the risk analyses of the possible failure modes of the seals in relation to the consequent contamination of the elevator channel and subsequent cross infection between patients. The manufacture has provided a part of the risk analysis in which he recognizes three hazards:
- A water seal gets damaged during a procedure, and contaminants invade into the device. A reprocessing operator does not notice the leak, the device is used in the next procedure, and it results in patient infection.
- A water seal gets damaged due to the broken O-ring during a procedure, and contaminants invade into the device. A reprocessing operator does not notice the leak, etc.
- A water seal gets damaged due to the broken O-ring during a procedure, and contaminants invade into the device. A bubble did not emerge during the leak test, etc. These hazards are mitigated by the instruction to the user to perform a leakage test as described in the user manual.

Evaluation

Two documents containing reprocessing instructions could be retrieved from the internet. The first document is a single sheet, titled 'Pre-cleaning your TJF-Q180V'. This instruction sheet, albeit in a different format, has also been sent to the users of the TJF-Q180V endoscope in the Netherlands, as part of the Field Safety Notice of January 2013. The sheet does not mention the performance of a leak test.

The second 14 page document is titled 'OnTrack Reprocessing In-Service/Competency for JF/TJF Endoscopes'. The instructions state that a, non-specified, leakage tester should be connected to the endoscope and the endoscope should be inflated. The inflated endoscope should be immersed in water completely. The user should 'observe' for 30 seconds while

angulation the bending section. No instruction is given to raise and lower the elevator, which means that the elevator axle seal is only challenged under static conditions, rather than the more realistic dynamic conditions. See also response to point 6 regarding the use of automated procedures in the Netherlands.

The IFU of the endoscope prescribes that the distal end of the endoscope shall be moved during leak testing. It is however not prescribed that the elevator shall be raised and lowered to ensure that the O-ring seal is challenged under dynamic conditions.

3. RIVM request: The validation of the design of the seals of the elevator wire channel; the establishment of the mean time between failures of the seals and how this impacts the maintenance schedule for this type of endoscope.

The manufacture states that the mean time between failures is not established. Failure of the seal should be detected during leakage testing.

Data are provided that show that the performed durability test in which the elevator is repeatedly raised (up to 18000 times) gives no detectable leakage.

Evaluation

The manufacturer again presumes that the leakage test can demonstrate the capability of the elevator axle seal to prevent the ingress of contamination. However, no information has been provided that demonstrates that this presumption is valid. Moreover, the durability tests have not been performed under actual use conditions. The presence of body fluids and contamination during the operation of the endoscope, the subsequent cleaning and disinfection and general ageing could influence the outcome of the durability testing.

4. RIVM request: The validation of the design of the seals of the elevator wire channel; the ability of the seal to prevent the ingress of bacteria into the sealed area under movement of the elevator lever, both in radial and axial direction, for the duration of the planned maintenance interval or the expected number of uses of the endoscope.

Evaluation

The manufacturer has not responded to this request.

5. RIVM request: Validity of the leakage test; The data that demonstrates that a leak in the seals on a microscopic level, that is a leak that is very small, but nevertheless allows the passage of bacteria into the sealed area of the scope and back, will be detected by leak testing as described in the user manual. The leak test has been identified as an important, and apparent only, mitigation to the risks of a leaking seal in the endoscope (see 2). The leak test is also used as the pass/fail criterion in the durability study (see 3). It should therefore be demonstrated that the leak test is actually suitable to detect failures of the seal that will allow the ingress of microorganisms into the endoscope during use. The manufacturer responded by pointing out that air molecules are smaller than bacteria. "Therefore, if the air cannot pass through the seal, the bacteria can also not penetrate the seal."

Evaluation

The leakage test procedure described by the manufacturer relies on visual observation by the person performing the test. No information has been provided to demonstrate that a leakage that will allow the passing of bacteria will be detectable by visual observation. Visibility also depends on the abilities of the observer.

The manufacturer should provide information that demonstrates this principle, because the formation of visible air bubbles does depend on several factors such as surface tension of the liquid and leak rate.

6. RIVM request: Validity of the leakage test; the allowable leak for this type of endoscope when tested in accordance with the instructions of the manufacturer.

Evaluation

The leakage test procedure prescribed by the manufacturer is a manual procedure that relies on the visual observation by the person performing the test. However, in the Netherlands it is common that the leakage test is performed in the washer-disinfector as part of the automatic reprocessing procedure. The washer-disinfector shall give an alarm when during the automatic leak test the pressure in the endoscope drops more than is

allowed. According to ISO 15883-4 (standard for washer-disinfectors for flexible endoscopes) the allowed pressure drop shall be specified by the manufacturer of the endoscope. It is this information that we requested, but did not receive.

7. RIVM request: Validity of the leakage test; construction drawings of the endoscope indicating the parts of the endoscope that are pressurized during leak testing.

Evaluation

This information was not received, but we understand that entire inner volume of the endoscope is pressurized so that all seals are challenged, including the elevator axle seal.

8. RIVM request: The data that demonstrate that the areas of the elevator and its surroundings as identified by EMC are effectively cleaned and disinfected applying the reprocessing instructions that are provided by Olympus. The EMC gave comments on the design of the elevator. The design of the elevator does not facilitate the cleaning of the back of the elevator and the sides of the elevator. The EMC also commented that the tip of the endoscope has several cracks, corners and cavities which could not or only with great difficulty be reached with a cytology brush for sampling. They specifically mention: "The following areas in particular proved difficult to reach for this brush: - the crack under the hinge point of the elevator, - the crack caused by the axial play of the elevator, - the space below/behind the curve of the elevator.".

The aforementioned instructions for pre-cleaning prescribe that the front and the back of the elevator shall be brushed, but given the difficulty EMC experienced in sampling these positions one may question the validity of the brushing instructions.

The manufacturer provided the test report "Cleaning and Disinfection efficacy in TJFQ180V", for the manual cleaning and disinfection procedure. The results from this study were included in the information that was received earlier, but is now complete including the method used. The test has been performed in June and July of 2008, the report is signed however on January 21, 2013.

Evaluation

The study is unacceptable as a demonstration of effective cleaning, because it has the following flaws:

- In the test only the manual cleaning and disinfection is evaluated, not the automated procedure in an ETD3 washer-disinfector.
- ISO 15883-5 gives in annex I a method to evaluate the combined efficacy of the cleaning and disinfection process of a flexible endoscope. The required total reduction factor of the test organism should be at least log 9. This is considerable higher than the 4 log reduction that the manufacturer regards to be sufficient.
- The pass criteria are copied from EN14563:2008, that is the European standard for the in-vitro testing of disinfectants against mycobacteria. The standard requires that the efficacy in the test shall be at least 4 lg. This reduction factor has only meaning for the in-vitro test method and has no bearing on the required reduction in the practice of endoscope reprocessing.
- In clause 2 the manufacturer mentions that the cleaning and disinfection will be performed on seven test devices (samples) and will not be performed on five other test devices (controls). The results are only shown for five samples and two controls.
- In 7-2 (1) the manufacturer describes the use of a suspension of microorganisms. The composition of the suspension is not prescribed. Since the complete process, cleaning plus disinfection is evaluated the suspension should also provide a challenge to the cleaning process. Annex G of ISO15883-4 indicates that the number of microorganisms that is left on the device after the cleaning should be established to ensure that sufficient microorganisms are present to present a challenge to the disinfection stage of the process. This has not been done.
- 7-2 (4) typo, 200 ml instead of 200 μ l.
- In 7-2 (6) the manufacturer describes that the inoculated elevator shall be left for 30 minutes at room temperature to fix the microorganisms to the test instrument. No data have been provided to demonstrate that the microorganisms are indeed fixed.
- 7-3 and 7-4 cleaning/disinfection of the elevator wire, despite the fact that this wire is sealed in this endoscope type. This raises the question whether the test has actually been performed on a TFJ-Q180V endoscope.
- From 7-5 (1) we learn that the residual contamination that is present after the process shall be transferred into 200 ml of extraction fluid. Starting with an initial

contamination of 600 μ l the dilution into 200 ml gives an additional reduction of approx. 2.5 log. It is unclear whether the test results have been corrected for this. - 7-5 (3) the method of incubation of the extraction fluid is not specified; spread plate or filtration.

Annex 2: EMC response to questions from RIVM

In its initial reaction to the report from TU Delft, the manufacturer places a strong emphasis on the importance of following the correct cleaning and disinfection procedure. In order to find out if the hospital possibly fell short in this respect, IGZ was asked to request additional information from the hospital. This never happened, however. During the meeting on 18 March, the authors of this report requested the information orally. On 29 March, further details of the information obtained orally were provided by e-mail. It concerns the following:

1. The details of the previous investigation conducted by the EMC, whereby the bacterium *Pseudomonas aeruginosa* was found in the tip of the endoscope. We would like to know the precise location on/in the endoscope where the bacterium was found and how the samples were taken.

Response from EMC: the contamination was found on the back of the elevator in the narrow passage between the back of the elevator and the bottom of the endoscope tip. The sampling was not simple and is described as follows by EMC: "A culture was made of the underside of the elevator in a sterile environment. First of all, the elevator in question was moistened with sterile water. Then a number of fibres were removed from a sterile cotton swab using sterile tweezers. These fibres were pushed under the space behind the elevator with the aid of the tweezers and moved backwards and forwards. The fibres were then deposited in a sterile container and cultured."

The hospital also stated that the bacterium persisted following manual pre-cleaning and mechanical processing. We would like to see the details of the manual pre-cleaning, in particular which parts of the tip of the endoscope were cleaned during this process and how this was done.

EMC stated that the manual pre-cleaning took place in accordance with the manufacturer's manual, pages 36-39. This section of the manual describes brushing the elevator.

NB: Apparently, the hospital does not flush the back of the elevator as described on page 45 of the manual. This is an important step, however, because it is difficult for the brush to reach the back of the elevator.

The instructions for cleaning and disinfecting the Olympus TJF-Q180V endoscope as supplied with the endoscope.

EMC enclosed a copy of the manual for the endoscope.

3. The work instructions for cleaning and disinfecting this endoscope as applied by the EMC.

Response from EMC: See 1, second point.

The use of the endoscope washer-disinfector is described in the protocol 'Disinfection of flexible endoscopes, Mechanical cleaning and disinfection in the disinfector'

This does not state that the elevator must be fixed at an angle of 45° before being placed in the washer-disinfector.

During the guided tour of the department, we came across brief work instructions. There were none for the endoscope in question. These had possibly existed but had been removed because the scope was no longer in use. Nor is it possible to trace the work instructions, as the brief work instructions are produced by the departmental staff themselves and are not controlled documents.

4. Possible work instructions applied by EMC when carrying out a manual leak test.

Response from EMC: the execution of the leak test is described in the protocol 'Disinfection of flexible endoscopes, Leak tests on the endoscope' and is carried out

in accordance with the manufacturer's instructions. The distal end of the endoscope is 'wagged' here, but the elevator is not moved up and down.

- 5. The following details of the endoscope washer-disinfectors in which this endoscope was cleaned and disinfected, in particular:
 - a. brand and type
 - b. the washing process, name of detergent, concentration and temperature
 - c. the disinfection process, name of disinfectant, concentration and temperature
 - d. details of the leak test performed by the washer-disinfector, in particular the size of the leakage permitted.

Response from EMC: The hospital uses the ETD3 washer-disinfectors to clean and disinfect all endoscopes. The specifications of the leak test performed by the washer-disinfector were not known. The manufacturer does not state that this leak test would have been unsuitable for the endoscope in question.

6. A copy from the list of endoscopes which the manufacturer of the washer-disinfector states can be cleaned and disinfected effectively, from which it appears that the TJFQ180V is on the list.

From RIVM archives: the document 'Adapters for ETD3 - Compatibilities' version 08/2011 names the adapters needed to connect the TJF-Q180V endoscope in the ETD3 washer-disinfector. This implies that the endoscope can be cleaned and disinfected effectively in the washer-disinfector.

National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport

Advice centre for medical devices and consumer products e-mail:

Disinfection of Olympus TFJ-Q180V ERCP endoscope

Response from Erasmus MC

Advice requested by:

Advice formulated by:

Verified by:

Date of request: 10 September 2012 Date completed: 14 October 2013

Ad-hoc number: 2013-06

Project number: V/080118/01/AH

Ad-hoc request

The Healthcare Inspectorate (IGZ) asks for comments on the letter dated 10 September 2013 from Doctor B.J. Smit regarding his response to the National Institute for Public Health and the Environment's (RIVM) recommendations on disinfecting the Olympus TFJ-Q180V flexible endoscope (ad-hoc request 2012-12), by 15 October at the latest.

Background

The IGZ asked the RIVM to pass judgement in connection with a report from the Erasmus Medical Centre regarding the problems when disinfecting the Olympus TFJ-Q180V flexible endoscope for endoscopic retrograde cholangiopancreaticography (ERCP). The IGZ sent the recommendations drawn up by the RIVM (ad-hoc request 2012-12) to the Erasmus MC on 2 August 2013. The Erasmus MC sent a letter to the IGZ on the matter on 10 September 2013.

RECOMMENDATIONS

In these recommendations, the comments from the Erasmus MC on our earlier advice concerning the problems when disinfecting the Olympus TFJ-Q180V flexible endoscope (ad-hoc number 2012-12), as expressed in the letter with reference DPZ-10686 of 10 September 2013, are addressed point by point.

Disinfection of the Olympus TFJ-Q180V flexible ERCP endoscope. Response from the RIVM to the letter from Erasmus MC dated 10-09-2013, reference DPZ-10686

From the letter from Erasmus MC dated 10 September 2013: Conclusion

On the basis of the report from the National Institute for Public Health and the Environment (RIVM), we conclude that this involves a medical instrument of dubious construction, which has not yet undergone all the necessary validation studies and which comes with cleaning and testing instructions for which the same applies. Insofar as we can judge, this means that the medical instrument in question does not comply with the basic/essential requirements as referred to in the Medical Device Directive (MEDDEV) and so should not be used in a clinical setting. In fact, the RIVM report contains all the necessary information to support this conclusion. We trust that the Healthcare Inspectorate (IGZ) extracts and acknowledges the same message from the report. It would make things a lot clearer if the RIVM and the IGZ were to actually put this conclusion into words. The Erasmus MC has a great need for a concrete conclusion or recommendation from IGZ and RIVM as to whether or not the TJF-Q180V can be used safely when treating patients at the Erasmus MC.

<u>Response from RIVM</u>: Here, Erasmus MC presents its interpretation of the contents of our report. We leave it up to IGZ to respond to this as necessary.

From the letter from Erasmus MC dated 10 September 2013: Factual inaccuracies/ other comments

• General comment: please replace EMC with Erasmus MC

<u>Response from RIVM</u>: It is our custom to write a frequently used term in full the first time followed immediately by the abbreviation we will subsequently use in brackets; see p.1 under 'Ad-hoc request'. In any future reports, we will write "Erasmus MC".

Recommendation on page 1: in our opinion, this block does not contain any advice, but
a summary of the findings. It is incorrectly stated that the Erasmus MC failed to
acknowledge and follow the instructions in the user manual.

Response from RIVM: We must take the information provided by the hospital as our basis; this is also how we expressed the finding. It was noted that a number of specific directions from the manufacturer of the TJFQ180V endoscope were missing from the work instructions provided by the hospital for cleaning and disinfecting flexible endoscopes. No specific work instructions were received for the endoscope in question.

- Page 3, finding 1: It is stated that the instructions were only partially followed. This is incorrect in our opinion. We always complied with the complete user manual (IFU).

 Response from RIVM: It was noted that a number of specific instructions from the manufacturer of the TJFQ180V endoscope were missing from the work instructions provided by the hospital for cleaning and disinfecting flexible endoscopes. No specific work instructions were received for the endoscope in question.
 - Page 3, finding 2: The field safety warning (brief guide) from Olympus dated January 2013 was not applied by the Erasmus MC, as the scope had already been out of service since March 2012. The full user instructions were available in the department.

Response from RIVM: As stated in the report, the complete user manual is decisive here.

 Page 4, finding 3: It is said of 'the work instructions from the hospital' (document Disinfection of flexible endoscopes, Mechanical cleaning and disinfecting in the disinfector) that these are a general protocol and not a specific protocol for the TJF-Q180V.

Response from RIVM: During the conversation with Erasmus MC, specific work instructions for the Olympus TJF-Q180V endoscope were discussed. These proved not to be available, however. It was said at the time that these work instructions had possibly existed, but had been removed after the endoscope was taken out of service. It was not certain if specific work instructions had ever existed. It was said that such specific work instructions were not a controlled document, but drawn up by the member of staff charged with cleaning and disinfecting the endoscopes him or herself. In our opinion, such work instructions should be a controlled document within a good quality system. The RIVM received no work instructions to

show that the specific directions from the manufacturer were acknowledged and followed; we base our finding on this.

3

Page 4, finding 3: You state that the work instructions 'Disinfection of flexible endoscopes, Mechanical cleaning and disinfection in the disinfector' do not describe fixing the elevator at an angle of 45° prior to mechanical cleaning and disinfection. An objective fact is that, considering the construction of the elevator, it cannot be fixed as can e.g. the large and small switch. The elevator is fixed in such a way (in a closed position) that the area behind it can be cleaned and disinfected mechanically as well as possible. We suggest removing this sentence.

Response from RIVM: No work instructions were provided which contained directions on how to position the elevator at an angle of 45° or in any other way prior to the endoscope being placed in the washer-disinfector. When Erasmus MC realised that the manufacturer's instructions could not be followed, they should have discussed this with the supplier. It is apparent from the information provided that no such feedback was provided. For the time being, we therefore assume that the instructions in the user manual are valid. The modification of the manufacturer's instructions, as described above by Erasmus MC (fixing the elevator in a closed position), was not mentioned earlier. Restraint must always be shown when modifying the user manual according to one's own judgement. In the case in question, fixing the elevator in a closed position could perhaps result in a diminished flow through the biopsy channel and hence in less effective cleaning and disinfection.

Page 4, finding 6: It says here: 'Nor does the manufacturer discuss in a substantive way
the comments made by TU Delft on the construction of the O-ring seal' whilst the
findings from the extensive technical investigation, including photographic evidence,
show that there is a significant problem here, with potentially major consequences for
patient safety.

Response from RIVM: correct.

Page 4, finding 7: The fact that Olympus referred to the failure of the O-ring in the risk analysis creates obligations. Olympus should take additional measures itself in accordance with the MEDDEV to prevent this "fault condition". It is now quite wrongly left solely to the user to take control measures (leak test) and, alongside the meagre underpinning of the control measure, Olympus also fails here to provide a substantive response to the issue of keeping out bacteria.

Response from RIVM: According to the Medical Device Directive (MEDDEV), Annex I, I.2, the manufacturer is obliged to eliminate or reduce risks as much as possible, with the solution first being sought in the design ("inherently safe design and construction"). If this is impossible or not sufficiently possible, the MEDDEV gives the manufacturer the option of taking other measures (e.g. providing the user with specific instructions to carry out checks).

Page 5, conclusions regarding the construction: We have a problem with how the RIVM formulates its views on finding the brownish deposit on the inside of the mechanism in the tip. The RIVM stresses emphatically that this was not necessarily caused by a leak, but fails to repeat that this is definitely one of the possibilities. This last possibility has potentially major consequences for patient safety and thus for the use of the equipment. Due to this safety issue, we believe that the explanation that a leak is the cause of the deposit takes precedence over an alternative, more innocent explanation, unless this possibility can be rejected with a probability bordering on certainty by means of a thorough investigation and analysis. All of this must be seen in the light of the proven causal role of the scope in question in the transmission of the *Pseudomonas aeruginosa* bacterium (of the clonal type). Also, the idea is created that the researchers made a one-sided suggestion on the matter, which is certainly not the case. We request that you qualify this.

<u>Response from RIVM</u>: The RIVM report looks at the considerations concerning the O-ring construction and the way in which the condition of the O-ring should be checked for use. In the report from the TU Delft, the brown deposit is discussed and the only possible cause given is that the O-ring leaked.

However, the RIVM noted that there was also another possible cause, i.e. a leaking cardan rubber. For reasons of meticulousness, this was included in the RIVM assessment. The reason for the corrosion cannot be established with any certainty.

 Page 11, point 1: This concerns the scope that came out of the disinfector and had therefore undergone the complete manual and mechanical cleaning and disinfection process.

Response from RIVM: correct.

 Page 11, point 3. It is true that work instructions for the endoscope in question were no longer available, as this type of scope had been held in quarantine for more than a year at the time of your visit to the MDL endoscopy department of the Erasmus MC. The work instructions had been removed to avoid confusion.

Response from RIVM: See Page 4, finding 3 above.

Appendix III: Communications from Olympus to Customers in Europe

The following are letters sent by Olympus to customers in Europe.

Important Safety Advice

Safe reprocessing of TJF-Q180V

Dear Olympus Customer

With view to a recently reported case of a contaminated Olympus Video-Duodenoscope TJF-Q180V, we would like to draw your enhanced attention to the following points:

- Closely observe all instructions from the reprocessing manual for TJF-Q180V
- Pay particular attention to the detailed pre-cleaning instructions, especially for the distal end and forceps elevator

For your review, please find enclosed a paper safe for quick reference. It should be regarded as additional information to the reprocessing instructions from the manual.

In addition to the above mentioned points, we would also like to remind you that TJF-Q180V, as all Olympus endoscopes, has to undergo detailed preparation and inspection before patient use. In case you observe any damages or irregularities, do not use the endoscope and contact Olympus for inspection and repair. Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.

For further information on the required steps, please refer to Chapter 3 "Preparation and Inspection" of the instruction manual of TJF-Q180V. Additional copies of the instruction manual or the above mentioned reprocessing manual are available at any time upon request.

We trust the enclosed information will prove helpful, but if you have any questions or would like to receive additional training on any aspect of the care and maintenance of your Olympus TJF-Q180V, please contact your local Olympus representative who will be delighted to make the necessary arrangements.

Yours sincerely,

REPLY FORM

Olympus Subsidiary	ı/Distributor	
[Dept/Attn]		
[Street No.]		
[ZIP City]		
,,	_	
		Date
		Ref No.
		EXT-xxx
Important Safety Ac	lvice: Safe reprocessing of TJF-Q180V	
'		
Dear Sirs and Mada	ams,	
We herewith confirm	n the receipt of your customer letter. We will :	share this information with
the relevant departr	nents.	
Name		_
Hospital		-
Department		
Берагиненс	-	-
Street		_
Postal Code/ City	_	_



TJF TYPE Q180V

Medical Endoscopy

Pre-cleaning your TJF-Q180

The TJF-Q180V has a number of features enabling easier reprocessing. This quick reference guide provides an overview of the main improvements to the pre-cleaning procedure.

At the light source:

The distal cap of the TJF-Q180V is fixed and is therefore not removed prior to pre-cleaning

The sealed froceps elevator wire of the TJF-Q180V means that the elevator wire channel does not require flushing and rinsing



During manual cleaning:

Use one of the recommended brushes to brush the front and rear side of the forceps elevator

The MAJ-1888 brush can be used for heavy soiling or delayed reprocessing situations and enables deeper access to the forceps elevator

The sealed forceps elevator wire of the TJF-Q180V means that the elevator wire channel does not require flushing and rinsing





Before automated reprocessing:

Set and lock the forceps elevator to 45° before placing the endoscope into an automated washer disinfector to enable cleaning and disinfection of both sides of the forceps elevator



This sheet is for quick reference only. For detailed reprocessing instructions, please refer to the TJF-Q180V reprocessing manual.

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.



OLYMPUS EUROPA HOLDING GMBH

Postbox 10 49 08, 20034 Hamburg, Germany Wendenstrasse 14-18, 20097 Hamburg, Germany Phone: +49 (0)40 237 730, Fax: +49 (0)40 230 761 www.olympus-europa.com

QIL 145-006, 07.01.13

May X, 2014

URGENT: Field Safety Corrective Action

Attention:

Re: EVIS EXERA II DUODENOVIDEOSCOPE TJF-Q180V

Dear Customer,

Recently Olympus has received a few complaints of residual debris in the distal end of the TJF Q180V duodenoscope after reprocessing. Olympus is always very concerned about patient safety issues including the prevention of cross infection among patients through endoscopy.

As a result of our complaint investigations, Olympus has determined to revise our reprocessing instructions and recommends the use of an additional cleaning brush. additional brush is the MAJ 1888. Olympus recommends brushing around the forceps elevator with the MAJ-1888 brush in addition to the existing MH-507 brush in order to adequately clean around the forceps elevator more thoroughly. The reprocessing manual was updated accordingly.

For a detailed procedure, please refer to the enclosed updated reprocessing manual.

OLYMPUS regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local vendor/OLYMPUS partner who will be delighted to support you or make the necessary arrangements.

Please fill out, sign and return the attached Reply Form to your local vendor/OLYMPUS partner.

Yours sincerely,

- <Name>
- <Position>
- <Address>
- <Contact information>

REPLY FORM

	rance S.A.S	
[Street No.]		
[ZIP City]		
D (
Date		
Ref No. EXT-xxx		
EX1-XXX		
Technical Advice: Additi	onal Cleaning Procedure of TJF-Q180V	
	Ğ	
Dear Sirs and Madams,		
)		
	e receipt of your customer letter. We will share	e this information
with the relevant departr	nents.	
Name		
Hospital		
Department		
2 oparament		
Street		
Postal Code/ City		

Appendix IV: Selected Adverse Event Reports

The following reports are copies of medical device reports and MedWatch reports sent by manufacturers and hospitals to FDA to account for incidents of antibiotic-resistant infections linked to ERCP procedures. This compilation is not inclusive of all device reports filed by manufacturers and hospitals but rather is meant to provide a sample of the reports for each outbreak of duodenoscope-linked infections between 2012 and spring 2015.

Advocate Good Samaritan Hospital Downers Grove, Illinois

U.S. Department of Health and Human Services Food and Drug Administration

MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Ifr Report #	2431293-2014-00006
JF/Importer F	Report #

Page 1 of 3

Use Only

FORM FDA 3500	0A (2/13)		1 490 1	~·			FDA Use Only
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	Date	Male	or	#2			
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	ted to Adverse Event			#2 4. Diagnosis for Use (India	cation)		Abated After Use
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				3815 Highland A	venue, Downe	ers Grove, IL	60515
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f. Check One User Facility

4. Contact Person

9. Approximate Age of Device

Yes

☐ No

Yes

No

Name

11. Report Sent to FDA?

Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufecturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

FORM FDA 3500A (2/13) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report initial Follow-up # 10. Event Problem Codes (Refer to coding manual)

Importer

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

Page 2 of 3

		FDA USE ONLY
f 3		
H. DEVICE MANUF	ACTURERS ONLY	
Type of Reportable Ev		2. If Follow-up, What Type?
	411-	Correction
Death		Additional Information
Serious Injury		Response to FDA Request
Maifunction		Device Evaluation
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Not Returned to M	fanufacturer	(тт/уууу)
✓ Yes ✓ Evalua	ation Summary Attached	06/01/2007
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		L les A vo
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Device	2895 -	1091 -
Code		
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Results	195 - 213	
	71 -	
Conclusions		
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Replace	Lattelit Moustoning	·
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Address FUJIFILM Medical System Endoscopy Division 10 High Point Drive, Wa FUJIFILM Optical Corpor	yne, NJ 07470	Report Source (Check all that apply) Foreign Study Literature
Email Address 4. Date Received by Manufacturer (mm/dd/yyyy) 10/14/2014 6. If IND, Give Protocol #	5. (A)NDA#	Consumer Health Professional User Facility Company Representative Distributor
7. Type of Report (Check all that apply) 5-day 30-day 7-day Periodic 10-day Initial 15-day Follow-up # 1	PMA/ 510(k)# K042076 Combination Product Yes Pre-1938 Yes OTC Product Yes	
9. Manufacturer Report Number 2431293-2014-00001	8. Adverse Event Term(s)	

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gethering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to

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MDR 2431293-2014-00006

12/03/2014

(Continued from section H 10)

A letter was e-mailed to the Initial Reporter, detailing inspection findings on the subject scopes, explaining the findings of general wear and tear. The letter further detailed FMSU-ESD's intent to replace the insertion sections assemblies and all internal channels on both subject endoscopes in an abundance of caution.

Repairs on both subject endoscopes were completed. The subject endoscopes passed QC inspection and were returned to the customer.

There has been no response to a Complaint Follow Up questionnaire sent to the customer requesting patient information about the incidents. In addition, the insertion section assemblies removed from the subject endoscopes were placed in quarantine, in case further examination is needed. No further similar complaints have been received from this customer or any other customer.

confirmed there have been no further similar incidents since this reported incident occurred. Further stated culturing of the endoscopes is performed monthly.

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

F/Importer Report#	Afr Report #	2431293-2014-00	0002.	-
	F/Importer I	Report#		_

MEDWATCH

FORM FDA 3500	OA (1/09)			Page 1	of 2			FDA Uşe Only
A. PATIENT INF	ORMATION				C. SUSPECT PRO	DDUCT(S)		
Patient Identifier			3. Sex	4. Weight	1. Name (Give labeled s	trength & mfr/labe	ler)	
	of Event:		Female	ibs	#1			
	Date			or	#2			
in confidence	of Birth:		Male	kgs	2. Dose, Frequency & I	Route Used		les (If unknown, give duration)
B. ADVERSE EV	ENT OR PRODU	CT PROBLE	М		4.1		from/to (or be #1	est estimate)
1. 📝 Adverse Event	and/or Pro	duct Problem (e	.g., defects/mall	unctions)	#1		-	
Outcomes Attribut (Check all that appli					#2		#2	
Death:	77	Disability o	r Permanent Da	mage	4. Diagnosis for Use (h	ndication)		ent Abated After Use opped or Dose Reduced?
Life-threatening	(mm/ad/yyyy)		Anomaly/Birth I	-	#1		#1 [Yes No Doesn't
	e initial or prolonged	-	ous (Important N		#2			- Doesn't
1	vention to Prevent Perm				6. Lot#	7. Exp. Date		Yes No Apply
3. Date of Event (mm.		4. Date of This			#1	#1		rent Reappeared After eintroduction?
1	014	ł .	05/20/2014		#2	#2	#1 [Yes No Doesn't
5. Describe Event or					9. NDC# or Unique ID			Doesn't
	, FUJIFILM Medi ntacted by Advo							Tes No Apply
	ised of Fujinon				10. Concomitant Medic	al Products and	Therapy Dates (Excl	ude treatment of event)
1	d name of "Fuji		_					
Enterobacteria	ing positive fo aceae).	or CRE (Car.	papenem-re	sistant				
				1				
				l	D. SUSPECT MEI	DICAL DEVIC	E	
					1. Brand Name Fujin	non		
					2. Common Device Na	me		
							ope	
					3. Manufacturer Name, FUJIFILM Optical Bitachicmiya City	Corporation,		4112 Tone,
					4. Model#	Lot#		5. Operator of Device
					ED-530XT			✓ Health Professional
					Catalog #	Expir	ation Date (mm/dd/y)	Lay User/Patient
					Serial #	Othe	r#	Other:
					ND102A125			
				İ	6. If Implanted, Give Da	ate (mm/dd/yyyy)	7. If Explanted	, Give Date (mm/dd/yyyy)
6. Relevant Tests/Lat	ocratory Data, includin	g Dates			8. Is this a Single-use I	Device that was F	l Reprocessed and Re	used on a Patient?
					Yes V No			
					9. If Yes to Item No. 8,	Enter Name and	Address of Reproce	ssor
				1				
				i				
					10. Device Available fo	r Evaluation? (Do	not send to FDA)	
				1	Yes 🗸 No	Returned	to Manufacturer on:_	
					11. Concomitant Medic	al Products and	Therapy Dates (Exc	(mm/dd/yyyy) lude treatment of eventi
7. Other Relevant His	tory, including Preexis	sting Medical Co	nditions (e.g. a	lleraies .			, , , , , , ,	,
race, pregnancy, sn	tory, including Preexistoking and alcohol use, i	hepatic/renal dysf	function, etc.)					
					E. INITIAL REPO	OTED		
					1. Name and Address	_	one#	
					Advocate Good S	Samaritan Bo	ospital	
					3815 Highland A		-	L 60515
					1			
Submission of a re	eport does not con	stitute an ad	mission that	medical	2. Health Professional	2 3. Occupation		4. Initial Reporter Also Sent
personnel, user fa caused or contribu	cility, importer, dis	stributor, mar	nufacturer or	product	Yes No	Administrator/	Supervisor	Report to FDA Yes No Link.

SE BLACK INK PLEASE TYPE U

FUJIFILM0000322

User Facility

4. Contact Person

9. Approximate

Yes _

No

Yes Yes

☐ No

Age of Device

11. Report Sent to FDA?

6. Date User Facility or

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

Contact Office - Name/Address (and Manufacturing Site for Devices)

U.S.A, Inc. Endoscopy Division

1. Check One

FORM FDA 3500A (1/09) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

[] Initial Follow-up #

Importer

2. UF/importer Report Numbe

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

3. Report Source (Check all that apply)

(mm/dd/yyyy)

Page 2

	FDA USE ONLY
of 2	
H. DEVICE MANUFACTURERS ONLY	
Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
Other CRE Positive Growth	Device Evaluation
3. Device Evaluated by Manufacturer?	4. Device Manufacture Date
✓ Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary Attached	04/25/2012
No (Attach page to explain why not) or	5. Labeled for Single Use?
provide code:	
	Yes 7 No
6. Evaluation Codes (Refer to coding manual)	
Method 3263 -	
Results 3233 -	
Conclusions 11 -	
	Jsage of Device
Recall Notification	Reuse
Repair Inspection Replace Patient Monitoring	Unknown
Delebelor Storiffenties/ 9 I	action reported to EDA under
Adjustment	11 USC 360i(f), list correction/ emoval reporting number:
Other:	
10. Additional Manufacturer Narrative and	/ or 11. Corrected Data
FUJIFILM Medical Systems 0.S.A., 1	nc. (FMSU) immediately
initiated an investigation, include to identify the root cause for the	ling a visit to AGSH,
personnel were informed that, in a	esponse to CRE
incidents at its sister hospital,	Advocate Lutheran
General, AGSH had conducted a revi	ew of prior medical
records for its patients who were the time of this report, FMSU has	positive for CRE. At
of three endoscopes (SN # 1D102A04	S and SN # ND102A125)
have allegedly been cultured posit	ive for CRE. Three
patients who had undergone ERCP pr	ocedures tested
positive for CRE and two of three expressed symptoms consistent with	Of these patients
customer is unsure whether the pat	ients transferred CRE
to the endoscope or vice versa. No	n-FUJIFILM equipment,
including a channel cleaning device	e instead of cleaning
brush, is used to manually clean t AER is used for automated high-lev	he endoscopes and an
review of FMSU service records for	AGSH indicated no
abnormalities other than general w	ear and tear repairs
attributable to normal usage and h	andling of the device.
FMSU has requested but has not rec	eived any information
on any treatment or hospitalizatio at the time of this initial report	ns for these pathents, . In addition, FMSO
has requested that the duodenoscop	es that tested
positive for CRE be returned for a	detailed examination.
To date, the customer has not retu to FMSU. The investigation is stil	rned any duodenoscopes
submit a supplemental MDR once the	investigation is .
completed.	,
•	

10 High Point Drive, Wayne, NJ 07470 Foreign Study FUJIFILM Optical Corporation, Mito Literature Factory, 4112 Tono, Hitachiomiya City, Consumer Ibaraki, Japan, 319-2224 Health Professional User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 05/20/2014 Distributor IND# 6. If IND, Give Protocol # Other: STN# PMA/ 510(k) # K042075 Type of Report (Check all that apply) Combination Product √ 30-day Yes 5-day Periodic 7-day Pre-1938 Yes 10-day | Initial OTC Product Yes 15-day Follow-up # 9 Manufacturer Report Number 8. Adverse Event Term(s) 2431293-2014-00002 The public reporting burden for this collection of information has been estimated to average 66

The public reporting burner for this collection or information has been estimated to average on hindles per response, including the time for reviewing instructions, searching existing data burdes, gathering and maintaining the data needed, and completing and reviewing the sollection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Advocate Lutheran General Hospital Park Ridge, Illinois

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Form Approved: OMB No. 10-029 1, Expires 12/31/	
See OMB statement on revers	e.

MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 3

	FDA Use Only
UF/Importer Report #	
Mfr report#	2518897-2013-00004

A PATIENT INTEGRIZATION In Protect Identities In Age of Time								
NA In scription of the Product PRODUCT PROBLEM					C. SUSPECT PRO	DUCT(S)		
B. ADVERGE EVENT OR PRODUCT PROBLEM B. ADVERGE EVENT OR PRODUCT PROBLEM C. Outcomes An Fished of Adverse berry C. Outcomes And Adverse of Company (Adverse) C. Outcomes Adverse of Company (Adverse of Company) C. Outcomes Adverse of Company (Adverse	1. Patient Identifier	2. Age at Time	3. Sex	4. Weight	1. Name (Give labeled stre	ength & mfr/ labeler)		
B. ADVERSE EVENT OR PRODUCT PROBLEM 2 2 2 2 2 2 2 2 2					#1			
S. Adverse Event order o	N/A				#2			
B. Adviewas Event CR PRODUCT PROBLEM					2. Dose, Frequency,& Rou	ite Used	3. Therapy Date	s (If unknown, give duration)
B. ADVERSE EVENT OR PRODUCT PROBLEM Color	In confidence						· '	est estimate)
Commonweal Period works Product Product Product Product Product Product Product Produc	B. ADVERSE EVE	ENT OR PRODU	CT PROBLEM				<u> </u>	
2. Outcomes Albibude to Advise Event Congenital Anomaly Sets Defect Congenital Anomaly Sets Def	1. Adverse Event	and/or 🛛 Pro	oduct Problem (e.g. defe	ects/malfunctions)				t Abeted After Llee
Common Personal Consisting Processing Secretary		Adverse Event			4. Diagnosis for Use (Indic.	eation)		
Use-Threatening	Death:		Disability or Perr	manent Damage	#1		#4 □	L∨os □ No. □ Doesn't
Common Device Production Device Production Device		mm/dd/yyyy)	Congenital Anon	naly/ Birth Defect	#2		#' 🗀	— — Арріу
3. Date of Event / monitority part / monitority /	Mospitalization – Ir	nitial or prolonged	Other Serious (In	mportant Medical Events)	C 1 -4 #	7 Fra Data	#2	
Substitution Subs	Required intervent	tion to Prevent Perman	ent Impairment/ Damag	e (devices)	0. LDI #	/. Exp Date	8. Event Reintrod	t Reappeared After duction?
5. Describe Servit or Problem On August 29, 2013, PENTAX Medical received MedWatch Report (MMV5031083) regarding an incident at Advocate Lutheran General Hospital forth following: "Professional and Production and therapy Dates (Excised treatment of event) Apply Types No Describ Production No De	3. Date of Event (mm/dd/		4. Date of This repor	rt (mm/dd/vvvv)	#1	#1		Decen#
So Describe Fear of Problem On August 29, 2013, PENTAX Medical received MedWatch Report (MMNS031083) regarding an incident at Adviceable Lutherson General Hospital for the following: "Briefinet underwent an ERCP procedure using a PENTAX ED-3490TK At 10084 side viewing duodenoscope. Patient developed a CRE infection. Proper cleaning of scope confirmed as per company recommendations. Organism found under elevator on scope." Additional information obtained from the customer confirmed there were a total of 4 patients that became infected with CRE after they underwent ERCP using ED-3490TK, A110084: D. SUSPECT MEDICAL DEVICE 1. Brand Name PENTAX 2. Common David Name VIDEO DUODENOSCOPE 3. Manufacturer Name, City and State PENTAX Medical, Montvale, NJ 4. Model # A110084 D. Health Professional Luty User Patient Luty User Patient Luty User Patient A110084 F. If Implanted, Give Date (montidity)yyy) 7. If Explanated, Give Date (montidity)yyy) 8. Is this \$180jet-wise Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes No 9. If Yes No 9. If Yes No 9. If Yes No 9. If Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 10. Device Available for Evaluation? (Do not send to FDA) Yes No 11. Concomitant Medical Products and Therapy Dates (Evolute treatment of event) Submission of a report does not constitute an admission that medical Patient Products and Therapy Dates (Evolute treatment of event) Submission of a report does not constitute an admission that medical Patient Products and therapy Dates (Evolute Invariant Allowance) 10. Concomitant Medical Products and therapy Dates (Evolute Invariant Allowance) 11. Concomitant Medical Products and therapy Da					#2	#2	— _{#1} □	
On August 29, 2013, PENTAX Medical received Med/Watch Report (MW5031083) regarding an incident at Advocate Lutheran General Hospital for the following: "Patient underwent an ERCP procedure using a PENTAX ED-3490TK A 110084 site viewing ductions of seasons for the following: "Patient underwent an ERCP procedure using a PENTAX ED-3490TK A 110084 site viewing duction elevator on socies." D. SUSPECT MEDICAL DEVICE 10. Concomitant Medical Products and therapy Dates (Exclude treatment of event) D. SUSPECT MEDICAL DEVICE 13. Brand Name PENTAX 2. Common Device Name 2. Montacture Name. City and State PENTAX Medical, Montrole, NI 4. Model # ED-3490TK, A 110084 5. Operator of Device 18. Braid Name PENTAX 2. Common Device Name 2. Montacture Name. City and State PENTAX Medical, Montrole, NI 4. Model # ED-3490TK Medical, Montrole, NI 4. Model # ED-3490TK Device Name of Address of Reprocessors 6. If Implanted, Give Date (immission) processors 6. If Implanted, Give Date (immission) processors 7. Other Relevant History, Including Pre-existing Medical Conditions (e.g., allowpies, race, preprintory, emoking and allowful use, Appatitol dyndinctions, etc.) 7. Other Relevant History, Including Pre-existing Medical Conditions (e.g., allowpies, race, preprintory, emoking and allowful use, Appatitol dyndinctions, etc.) 8. In this is Single-use Device that was Reprocessed and Reused on a Patient? 9. If the to blam No. 8. Eiter Name and Address of Reprocessor 10. Device Available for Evaluation? (Co not sent for IPA) 11. Concomitant Medical Products and therapy Dates (Exclude treatment of event) 12. Concomitant Medical Products and therapy Dates (Exclude treatment of event) 13. Device Available for Evaluation? (Co not sent for IPA) 14. Initial reporter Also Sent Report for Evaluation and Address of Reprocessors 15. Device Available for Evaluation? (Co not sent for IPA) 16. If Image Pentacture (Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 17. Device Available for Evaluation?	5. Describe Event or Prob	olem				#4	—— _{#2} 🗖	
(MMV503 1083) regarding an incident at Advocate Lutheran General Hospital for the following: "Patient underwent an ERCP procedure using a PENTAX ED-3490TK A110084 side viewing duodenoscope. Additional information obtained from the customer confirmed there were a total of 4 patients that became infected with CRE after they underwent ERCP using ED-3490TK, A110084: D. SUSPECT MEDICAL DEVICE 1. Brand Name PENTAX 2. Common Device Name PENTAX 2. Common Device Name PENTAX 2. Common Device Name PENTAX 2. Common Device Name PENTAX 2. Common Device Name PENTAX 3. Manufacture Name, City and State PENTAX Medical, Montrale, NJ 4. Model # ED-3490TK Castiog # Expiration Date (mmidstyyyy) 7. If Expiration Date (mmidstyyyy) 8. Is this a Single-sea Device that was Reprocessed and Reused on a Patient? vec. No.	On August 29, 20	013. PENTAX Me	dical received Me	dWatch Report	9. NDO# of Offique ID		#2 L	Tres 1100 11 7 Apply
a total of 4 patients that became infected with CRE after they underwent ERCP using ED-3490TK, A110084: Substitute	Hospital for the fousing a PENTAX Patient developed as per company r	ollowing: "Patient ED-3490TK A11 d a CRE infection	t underwent an EF 0084 side viewing n. Proper cleaning	RCP procedure duodenoscope. of scope confirmed	10. Concomitant Medical P	Products and therapy Da	ates (Exclude trea	atment of event)
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2. Common Device Name VIDEO DUODENOSCOPE 3. Manufacturer Name, City and State PENTAX Medical, Montivale, NJ 4. Model # ED-3490TK Catalog # Expration Date (mm/dd/yyyy) Serial # A110084 6. Relevant Tests/ Laboratory Data, Including Dates* 1/2 6. If Implanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 1/2 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 8. In this a Single-use Device that was Reprocessed and Reused on a Patient? 1. One of the Relevant History, Including Pre existing Medical Conditions (e.g., altergles, race, pregnancy, smoking and skicohol use, reputific dysfunctions, etc.) 8. If the procession and the products and Threapy Dates (Exobote treatment of event) see page 3 of 3, Concomitant Medical products 8. In this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Explanted, Give Date (mm/dd/yyyy) 1. If Explanted on the product (mm/dd/yyyy) 1. If Explanted on the product (mm/dd/yyyy) 1				arter triey underwent		JICAL DEVICE		
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3. Marufacturer Name, City and State PENTAX Medical, Montvale, NJ 4. Model # Lot # Soprator of Device ED-3490TK Catalog # Expiration Date (mm/dd/yyyy) Serial # A110084 Other:# A110084 Other:# A110084 Other:# Catalog # Expiration Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor O. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) To Committed Manufacturer on: (mm/dd/yyyy) To Comm					2. Common Device Name VIDEO	DUODENOSCO	PE	
4. Model # ED-3490TK Catalog # Expiration Date (mm/dd/yyyy) Serial # A110084 Other # A110084 Other # A110084 Other # A110084 6. Relevant Tests/ Laboratory Data, Including Dates' n/a 6. Relevant Tests/ Laboratory Data, Including Dates' 10. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No Returned to Manufacturer on: (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) See page 3 of 3, Concomitant Medical products Name and Address Phone # Patient Information		_			3. Manufacturer Name, City	y and State		
ED-3490TK Catalog # Expiration Date (mm/old/yyyy) Serial # A110084 Other # A110084 Other: 6. If Implanted, Give Date (mm/old/yyyy) 7. If Explanted, Give Date (mm/old/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8. Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/old/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) see page 3 of 3, Concomitant Medical products E. INITIAL REPORTER 1. Name and Address Phone # Patient Information Initial reports Also Sent Report for DA Park Ridge, IL 60068 Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product						·		5 Operator of Davice
Serial # A110084 Cother:						LOI #		o. Operator of Device
A 110084 Cure A 110084					Catalog #	Expiration Date	e (mm/dd/yyyy)	Health Professional
A 110084 Other: A 110084 Other: Cother: Cothe					Serial#	Other#		Lay User/ Patient
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8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No Seturned to Manufacturer on:		atory Data, Including Da	ates'		6 If Implanted Give Date	(mm/dd/www)	7 If Evalented (Cive Date (mm/dd/ywy)
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Yes No Returned to Manufacturer on:					9. If Yes to Item No. 8, Ent	er Name and Address o	of Reprocessor	
7. Other Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ dysfunctions, etc.) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 12. See page 3 of 3, Concomitant Medical products 13. Name and Address 14. Initial reporter Also Sent Report to FDA 15. Initial reporter Also Sent Report to FDA 16. Initial reporter Also Sent Report to FDA 17. Ves No					10. Device Available for E	valuation? (Do not send	d to FDA)	
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) see page 3 of 3, Concomitant Medical products 12. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) see page 3 of 3, Concomitant Medical products 13. Name and Address Phone # Patient Information Advocate Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068 Park Ridge, IL 60068 Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product					Yes No	Returned to Ma	anufacturer on: _	(mm/dd/ssss)
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Patient Information Advocate Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068 Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product Patient Information	I // CI					RIER		
Advocate Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068 Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product Advocate Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068 2. Health Professional? Average A					1. Name and Address		Phone # Patie	ent Information
personnel, user facility, Importer, distributor, manufacturer or product					Advocate Lutheran (1775 Dempster St.	•		
personnel, user facility, Importer, distributor, manufacturer or product					2. Health Professional? 3	. Occupation		
			butor, manufacture	r or product	X Yes ☐ No			

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

X Yes

☐ No

X Yes

☐ No

4 yrs

11. Report Send to FDA?

13. Report Sent to Manufacturer?

14. Manufacturers Name and Address

G. ALL MANUFACTURERS

Pentax Medical 3 Paragon Drive Montvale, NJ 07645

Date User facility or Importer Became
 Aware of Event (mm/dd/yyyy)

08/29/2013

Patient

Device Code

09/20/2013 (mm/dd/yyyy)

09/20/2013 (mm/dd/yyyy)

30-2 Okada Aza-Shimomiyano

Hoya Corporation PENTAX Miyagi Factory

Contact Office - Name/ Address (and Manufacturing Site for devices)

Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203

FORM FDA 3500A (6/10)

3. User facility or Importer Name/ Address

F. FOR USE BY USER FACILITY/ IMPORTER (DEVICES Only)

7. Type of Report

X Initial

1735

1091

★ Hospital

■ Nursing Home Outpatient Treatment Facility

☐ Home

Other:

Follow-up#

10. Event Problem Codes (Refer to coding manual)

12. Location Where Event Occurred

2. UF/ Importer Report Number 2518897-2013-00004

5. Phone Number

2303

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Center

(Specify)

09/20/2013

Page 2 o

					FD/	٩U	SE ONLY				
of 3											
<u>-</u>											
H. DEV	ICE MA	ANUFACT	URI	ERS ONL	Y.						
1. Type of	Reportat	ole Event				2.	If Follow⊣	Jp, W	hat T	ype?	
☐ Dea	ath						Con	rection	n		
⊠ Ser	ious Injur	у					Add	itiona	Info	mation	
Mal Mal	Ifunction						Res	ponse	e to F	DA Request	
☐ Oth	ner				_		Dev	ice Ev	valuat	tion	
3. Device	Evaluate	d by Manufact	urer's	?			Device M		cture	Date	
I ⊠ №	t Returne	ed to Manufact	urer			ľ	(mm/dd/y)	יצצי			
	_						04/02/2	2009			
∐ Ye	s LL E	valuation Sun	nmar	y Attached		L					
□ No pro	(Attach p vide code	nage to explain	why	not) or		5.	Labeled fo	or Sin	gle U	se?	
, ,	H.10 bel						□ Y	es		⊠ No	
6 Freehand	inn Codo	- /Defende ee	alla a	man:a()	_	L					
b. Evaluat	ion Code	s (Refer to co	aing .	manuai)							,
	Method	10	-			-			-		
	Results	204	i	224	Ħ				í		1
	Nesuits	204	-	234		-] -		
Con	clusions	46	-	54		-] -]
7 If Dome	dial Actic	on Initiated, Ch	l nack	Type	<u> </u>	enn	e of Devi	-			
		_ `	ficati		. ا		Initial Use		vico		
=	pair	=	ectio		1 5	=	Reuse	OI De	SVICE		
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=	labeling	□ Adjı	ustme		2	1 U	SC 360 I(oval report	f), list	corre	ction/	
⊠ Oti	her <u>se</u>	e H.10 bel	WC		"	SIIIC	vai repon	ung ni	unibe	١.	
10. 🛛 🗛	dditional I	Manufacturer	Narra	ative	and	/ or	. ,	11.	1 Co	rected Data	
								_	•		
		ference ca									on
Sept.	6, 201	3, PENTA	X W	as inform	ed t	ha	t four pa	atien	nts d	eveloped	
carba	penem	resistant ERCP prod	Ente	erobacter iros i isini	1ace	eae on	ED-3	ınıe 49∩7	CTIO	n aπer ∆110084	
These	e patier	nts were tr	eate	ed with ar	ntibio	otic	cs. Twe	entv-	two	additiona	
patier	nts scre	ened posi	tive	for CRE	but	dic	d not de	velo	p ar	n infection	, this
occur	red afte	er this sam	e so	cope was	use	ed	on the	patie	ents	for ERCP	
The s	cope w	as tested	at th	ne user fa	cilit	v a	and pos	itive	cult	ure was fo	ounc
behin	d the e	levator and	d th	rouah the	hol	e c	of the s	cope	 C 	ustomer	
confin	med th	at non-PE	NT/	XX brushe	es a	re	used to	mai	nual	ly reproce	SS
Pull-T	scopes. hru™	. The clea Pre-Clean	nınç ina	j brusnes Device	ln a	a dd	at the t	acılıı ura-F	y ar -nz(i	e Medival ଶି is the	ors
enzyn	natic de	etergent/cl	ean	er used t	o re	pro	cess th	ne so	cope	and Cide	×
OPÁ	is used	l for High L	eve.	l Disinfe	ction	i.			Ċ		
Accor	rdina fo	the PENT	·ΑΧ	Reproce	ssin	a/N	Mainten	ance	e Ins	struction F	or
		specificall									0.
		eas around									
		an approp	oriat	ely sized	cyli	nd	er clear	ning	brus	sh (e.g. C	S-
C9S)		detergent	sol	ution."							
						.				@ auc	
		on-PENTA off-label us							⊏nz	w are	
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ONLY	/ PENT	AX cleanii	ng b	rushes s	pec	ifie	d in ou	r inst	truct	tions for u	se
		ed to man									n,
		not listed o Reprocess						pro/	vea	list of	
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		ope has sir									ently
		y the Cent							ner	etore,	
LEINI	AV IIG	s not been	aIJ	e to evali	uale	: u1	e scope	♂.			

Contact Office = see F.3	Report Source (Check all that apply)	
Manufacturing Site = see	F.14 above	Foreign Study Literature Consumer Health Professional User facility
Date Received by Manufacturer	5.	
08/29/2013	(A)NDA #	Company Representative
	IND #	Distributor
6. If IND, Give Protocol#	STN#	Other:
	510K# K092710	MEDWATCH
7. Type of Report (Check all that apply)	Combination Yes	
5-day 30-day	Pre-1938 Yes	
10-day Initial	OTC Product Yes	
☐ 15-day ☐ Follow-up#		
9. Manufacturer Report Number 2518897-2013-00004	8. Adverse Event Term(s) n/a	

The public reporting burden for this collection of information has been established to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 Please DO NOT RETURN this form to this address

Investigation is ongoing.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

FORM FDA 3500A (6/10)

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of <u>3</u>

D.J. Describe Lyent	of Flooreni (Continued)				
B.6. Relevant Test/ L	aboratory Data, Including Dates (continued)				
B.7. Other Relevant	History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/ renal dysfunction, etc) (continued)				
Concomitant Medica	Products and Therapy Dates (exclude treatment of event) (For continuation of C.10 and/ or D.11; please distinguish)				
Other Remarks	le 1735 = Infection, Bacterial				
F10 Device Code 1091 =Device Cleaning Issue;					
	2303 = Bacterial contamination of device				
H.6 Evaluation (
_Method	10 = Actual device involved in incident was evaluated				
_Results	204 = Disinfection error;				
	234 = Reuse of device without following disinfection/sterilization instructions				
_Conclusion	46 = Device failure indirectly contributed to event, 54 = Device was out of specification in a manner that relates to event				
	10 Device railure maineary communicated to event, of - Device was out of specification in a manifest triates to event				

PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services Food and Drug Administration

MEDWATCH

FORM FDA 3500A (2/13)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	OTTIB CLARCOTTICITE OTT TO TOTOC.
// Mfr Report #	
JF/Importer Report # 2518897-20	13-00004

Page 1 of

rer reporting		25.	18897-2	013-00004	
f <u>3</u>				EDA Usa Only	
C. SUSPECT PROD	UCT(S)			FDA Use Only	
1. Name (Give labeled stre	ngth & mfr/labele	er)			
#1 					
#2					
2. Dose, Frequency & Ro	ute Used		py Dates (i	lf unknown, give duration) stimate)	
#1		#1	,	,	
#2		#2			
4. Diagnosis for Use (India	cation)			Abated After Use	
#1			#1 Y	ed or Dose Reduced? Tes No Doesn't	
#2				Apply Doesn't	
6. Lot #	7. Exp. Date		#2 L Y	es No Apply	
#1	#1			Reappeared After oduction?	
#2	#2		#1 🗌 Y	es No Doesn't	
9. NDC# or Unique ID] #2 □ Y	Doesn't	
10. Concomitant Medical	Droducte and Ti	harany Data		— — Арріу	
10. Conconitant Medical	rioducts and Ti	петару Басе:	s (Exclude i	realment of eventy	
			(C	ontinue on page 3)	
D. SUSPECT MEDIO 1. Brand Name	CAL DEVICE				
1. Brand Name					
2. Common Device Name			2b. P	rocode	
3. Manufacturer Name, Ci	ty and State				
4. Model#	Lot #			5. Operator of Device	
Catala w #	Freeinatia	Data ((alalánan)	Health Professional	
Catalog #	Expiration	on Date (mm	Lay User/Patier		
Serial #	Unique le	dentifier (UD)I) #	Other:	
6. If Implanted, Give Date	(mm/ddAyay)	7 If Evn	lanted Giv	re Date (mm/dd/yyyy)	
o. Il Implanted, Olive Date	(mm/dd/yyyy)	/: II EXP	iantea, On	e Date (mm/dd/yyyy)	
8. Is this a Single-use Dev	ice that was Re	processed a	and Reuse	d on a Patient?	
9. If Yes to Item No. 8, En	ter Name and A	ddress of Re	nrocessor	-	
o. Il res to tell No. 0, Ell	ter Hume and A	uuress or re	.ргоссээо		
10 Device Available for E	haluation2 (Do.	not cond to F	DAI		
10. Device Available for E Yes No	Returned to				
				(mm/dd/yyyy)	
11. Concomitant Medical	Products and 11	nerapy Dates	s (Exclude	treatment of event)	
E INITIAL DEPONT	·ED		(C	ontinue on page 3)	
E. INITIAL REPORT 1. Name and Address	EK				
Phone #	⊑r	mail Address			
	-				
2. Health Professional?	3. Occupation			nitial Reporter Also Sent Report to FDA	
Yes No]	Yes No Unk.	

A. PATIENT INF	ORMATION			
1. Patient Identifier	2. Age at Time		3. Sex	4. Weight
	of Event:		☐ Female	lbs
	Date			or or
In confidence	of Birth:		Male	kgs
B. ADVERSE E	VENT OR PRODUC	T PROBLE	VI	
1. Adverse Ever	nt and/or Pro	duct Problem (e	.g., defects/malft	unctions)
	ted to Adverse Event			
(Check all that app	ly)	Disability a	r Darmanant Da	
Death:	(mm/dd/yyyy)		r Permanent Dai	-
Life-threatenir			Anomaly/Birth D	
	n - initial or prolonged		ous (Important M	•
	rvention to Prevent Perma			•
3. Date of Event (mi	m/dd/yyyy)	4. Date of This	Report (mm/dd	
5 B	- Door letterer		07/03/2014	
5. Describe Event or	ropiem			
market survei demonstrated record. An ex revealed that detergent and it using clea Medical for r deviation fro potentially of example, whill tri-bristle of that ALGH per	ceived market c llance data for that the produc- tensive review of the hospital will high level dis- ning equipment eprocessing its of the validated contributed to Contributed o Contribute to Contr	PENTAX Mets have an of hospita as not usi infectant recommended duodenosc reprocess RE contamil recommendon-brush, in on-bristle	dical endo excellent l procedur ng validat products, d by PENTA opes. Th ing protoc nation. F ds the use vestigatio d (squeege	scopes safety es ed nor was X is ol or of a n showed e-type)
			(Continuo or	nago 2)
6. Relevant Tests/La	boratory Data, Including	Dates	(Continue or	i page 3)
7. Other Relevant Hi race, pregnancy, si	story, Including Preexis moking and alcohol use, h	ting Medical Co epatic/renal dysi	(Continue or nditions (e.g., a function, etc.)	
Submission of a i	report does not con	stitute an ad	(Continue or	medical
personnel, user fa	acility, importer, dis outed to the event.	tributor, mar	nufacturer or	product

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

11. Report Sent to FDA?

√ Yes

☐ No

√ Yes

☐ No

Address

Email Address

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

30-day

Periodic

✓ Follow-up # 4

___ Initial

9. Manufacturer Report Number

7. Type of Report

5-day

7-day

10-day

15-day

Date User Facility or

Importer Became Aware of Event (mm/dd/yyyy)

> Patient Code Device Code

07/03/2014

(mm/dd/yyyy)

07/03/2014

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

FORM FDA 3500A (2/13) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment

Home

Other: _

12. Location Where Event Occurred

☐ Initial

✓ Follow-up #

Importer

2. UF/Importer Report Number

2518897-2013-00004

5. Phone Number

Date of This Report

Outpatient Diagnostic Facility

Surgical Facility

Ambulatory

(Specify)

2. Phone Number

Foreign
Study
Literature
Consumer

3. Report Source (Check all that apply)

Health Professional
User Facility

Company Representative

Distributor

Other:

(mm/dd/yyyy)

Page 2 of ³

- 2
of <u>3</u>
H. DEVICE MANUFACTURERS ONLY
1. Type of Reportable Event 2. If Follow-up, What Type?
☐ Death ☐ Correction
Serious Injury Additional Information
Malfunction Response to FDA Request
Device Evaluation
3. Device Evaluated by Manufacturer? 4. Device Manufacture Date (mm/yyyy)
Not Returned to Manufacturer
Yes Evaluation Summary Attached
No (Attach page to explain why not) or provide code: 5. Labeled for Single Use?
Yes No
6. Event Problem and Evaluation Codes (Refer to coding manual)
Patient
Code
Device Code
Method
Results
Conclusions
7. If Remedial Action Initiated, Check Type 8. Usage of Device
Recall Notification Initial Use of Device
Repair Inspection Inspection
Patient wormoring 9. If action reported to FDA under
Relabeling Modification/ Adjustment 21 USC 360i(f), list correction/ removal reporting number:
Other:
10. Additional Manufacturer Narrative and / or 11. Corrected Data
B.4, F.11, F.13 Added date;
B.5 Additional information added
F.2 Added UFI/Importer Report Number;
F.7, G.7 Checked Follow up #4;
G.9 Removed Manufacturer Report Number;
H.2 Checked Correction and Additional Information;
H.10 Checked Corrected Data.
Department of Health and Human Services OMB Statement: "An agency may not

FDA USE ONLY

This section applies only to requirements of the Paperwork Reduction Act of 1995.

(A)NDA # _ IND #

BLA#

510(k)#

Pre-1938

Combination

OTC Product

8. Adverse Event Term(s)

Yes

Yes

Yes

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov **OMB Statement:** "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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MEDWATCH

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of 3

	FORW FDA 3500A (2/13) (Continued)
	B.5. Describe Event or Problem (continued)
Back to Item B.5	PENTAX Medical retrained ALGH personnel on both reprocessing and pre-procedural performance check activities for the device on July 17, 2013. In addition, in October 2013, the hospital implemented its own initiative to sterilize its duodenoscopes using ethylene oxide. During our investigation, PENTAX Medical determined that between March and July there had been five specific ED-3490TK duodenoscopes used on patients who either had an active infection or been screened and tested positive for CRE. The serial numbers of those devices are: Al10084, Al10574 and Al10299, Al10086 and Al10471. All of these endoscopes were tested for CRE and only one, Al10084, was found to be positive for CRE. As noted, PENTAX Medical has not received any reports of incidents of CRE infection for model ED-3490TK or any other PENTAX endoscope from any other hospitals. Therefore, PENTAX Medical considers this MedWatch report closed.
	B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
B.6	
Back to Item B.	
Back t	
	B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
n B.7	
Back to Item B.7	
Back	
.10	Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)
Item C.	Constitution of the land of th
Back to Item	
Back to Item D.11	
ack to	Other Remarks
ш	

MEDWATCH	§								FEA USE ONE I
FORM FDA 3500		continued)		Pac	ge 2 of	_{{ 2}			
1. Check One User Facety 3. User Facety or Imp FBNTAX of Amer 3 Paragon Driv Montvale, NJ 0	[] impose porter Name/A ica, Inc.	2. UF/ 2. UF/ 2. 0518 ddreas	imporier R	-		1. Type of Reportable Ev Death Serious Injury Mattunction Citner: 3. Device Evaluated by N	vorit		2. If Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation 4. Device Manufacture Date
4. Contact Person 6. Date User Facility of Importer Secame Awars of Event (mr.		Type of Report	. Phone Nu	8. Date of This Report (mm/ad/yyyy)		Not Returned to 8	danulacturer ation Summa	ry Attached	(mm/ylyy)
09/30/201 9. Approximate Age of Device 3 months	L3 [Fallow-up #				6. Evaluation Codes (Re Method Results Conclusions	3263 3218	manuä)	
11. Report Sent to FD. Yes 10/28 No 13. Report Sent to Ma Yes 10/28 No 14. Manufacturer Name	/2013 Vyyyy) nufacturer? /2013 Vyyyyi	12. Location Wh Hospital Home Nurskig I Cutpality Testility Other.		Culpatient Diagnostic Facility Ambulatory Surgical Facility		7. If Remadial Action Ini Recall Repeir Replace Relabeling Cher:	Notificatio Notificatio Inspectior Patient Mo Modificatio Adjustmen	n onitoring on/	8. Usage of Device [Initial Use of Device [Reuse [Unknown 9. If setton reported to FDA under 21 USC 359(f), list correction/removel reporting number:
Boya Corporati 30~2 Okada Aza Tuskidate, Kur	-Shimomiy ihara-shi	vano , Miyagi,	-	87-2203	***	Advocatë Luthera PENTAX was infor carbapenem-resis	nformation Generated that the General Comment of the General Comment	on: Dur al Hosp t one pa terobac	and/or 11. Corrected Data ing a conference call with itel on Sept. 30, 2013 atient developed teriaceae (CRE) infection es using scope ED-3496TK,
1. Centact Office - Na for Devices; Contact offic Manufacturing	me(Address (a	and Manufacturi F3-above	ng Site	2. Phone Number 3. Report Source (Check all that apply Foreign Study Literature Consumer Health Professions	*	CRE; nine pëtier screened positivinfection. The scope was to culture was four hole of the accoparates are used scopes. The cleaned detergent/cleaned	the screet of Control of the second of the s	the used the electric transfer of transfer of tran	ights were screened for gative and 3 patients did not develop an CRE er facility and positive levator and through the nfirmed that non-PENTAX serocess the PENTAX sed at the facility are Env® is the enzymatic occess the Scopes and is
4. Date Received by Manufacturer (minited of partial o	013 of 8: ') lay odic	5. (A)NDA# NO # STN# PMA/ 510(c) # KG9 Combination Product Pr#-1938 OTC Product	2710 YesYesYes	User Facility Company Representative Distributor Other:		is used for High PENTAX Reprocess (IFU), it specificate all recesse Should be thorout cylinder cleaning detergent solutions H6: Endoscope was	n Level ring/Mai ricelly rd areas ughly ol ng brush ton." as evalu as found	Disinfer ntenance states around eaned wardes, and design are ated by behind evaluate	•

The public reporting burden for this collection of information has been estimated to average 68 minutes per response, including the time for revisiving instructions, searching existing data sources, gathering and maintaining the date needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

8. Adverse Event Term(s)

Department of Health and Human Services
Food and Orug Administration
Office of Chief Information Officer
1355 Piccard Drive, Room 450
Rockville, MD 10850

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13-00307

U.S. Department of Health and Human Services Food and Drug Administration

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MEDWATCH

MEDAAVICH						
FORM FDA 3500A (6/10)	Page 1	of 2			FDA Use Only	
A PATIENT INFORMATION		C SUSPECT PRO	DUCTG		t on pag truly	
1 Patient Identifier 2.		1 Name (Give labeled a				
		*1				
		#2				
In confidence	2	2 Dose, Frequency & F	Paula Head	12 Thanking Bir	88 (If unknown, give duration)	
B ADVERSE EVENT OF PRODUC	TEROBLEM	c. Doss, riequency & r	enate axea	from/to (or be	sej estimate) es (n unknown, gwe ouranon)	
1. Y Adverse Event and/or Prot	tuot Problem (e.g., defects/malfunctions)	#1		#1		
2. Outcomes Attributed to Adverse Event		构		#2		
(Check all that apply)		4: Diagnosis for Use (In	idication)		ent Absted After Usa	
Death: (mmoaryyyy)	Disability or Permanent Damage	#1		{ _	opped or Dose Reduced? Yes No (""Doesn't	
Life-threatening	Congenital Anomaly/Eirth Defect	#2		171 <u> </u>	Apply	
✓ Hospitalization - initial or prolonged	Cither Serious (Important Medical Events)	6. Lot #	7. Exp. Date	#2	☐ Yes ☐ No ☐ Coësn't	
Required intervention to Prevent Perms	sent Impairment/Damage (Devices)	#1	#1	8. Ev	vent Reappeared After	
· · · · · · · · · · · · · · · · · · ·	4. Date of This Report (mm/dd/yyyy)			3	nintroduction?	
Patient Information	09/30/2013	9. NDC# or Unique ID	#2	#1 [Yes No Doesn't Apply	
5. Describe Event or Problem On September 30, 2013 user f.	acility reported an event as	5. MSG# GF UMIQUE ID		#2	Yes No Doesn't	
follows: Patient underwent a	n Endoscopic Retrogradë	10. Concemitant Medic	al Bradinate and The			
Cholangiopancreatography (ERC		To. Concomment mount	ni i i i i i i i i i i i i i i i i i i	phł natás Irvn	wa niidimiid m anand	
and developed an Carbapenem- Enterobacterioaceae (CRE) in:						
received antibiotics. No fur	ther information is					
available at this point about						
found behind elevator on aco	je.	D SUSPECTIVIE	DIGAL DEVIGE			
	***************************************	1. Brand Name. PENT?	. V			
	· · · · · · · · · · · · · · · · · · ·	rented				
		2. Common Davice Name VIDEO DUDODENOSCOPE				
		3. Manufacturer Name, City and State PENTAX of America, Inc.				
		Montvale, NJ	, 1,10.			
		4: Model#	Lot #		5. Operator of Davice	
		E0-3490TK			☐ Flealth Professional	
	Catalog #	Expiration	n Date (mm/dd/y)	Lay User/Patient		
		Serial #	Other #	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Other:	
		A110574	2			
		6. If Implanted, Give Da	ite (mm/dd/yyyy)	7. If Explanted	, Give Date (mm/dd/yyyy)	
6. Relevant Testa/Laboratory Dáta, including	Dates		****			
		8. is this a Single-use I	Sevice that was Repr	ocessed and Re	used on a Patient?	
		3. If Yes to Item No. 8, I	Inter Name and Add	ress of Reproce	SSOF	
	\$				****	
		10. Device Available for		· ·		
		Yes No	Returned to M	aunisciniai.cu: ~	(mm/dd/yyyy)	
		11. Concomitant Medic	al Products and The	rapy Dates (Exc		
7. Other Relevant History, Including Preexist	ling Medical Conditions (e.g., sliergies,					
race, pregnancy, smoking and alconol vise, h	epatic/renal dyskinction, etc.)					
		E NITIAL REPO	71E2			
		1. Name and Address	Phone	å		
				Patient Inforn	nation	
		Patient Information	*	3 6 3		
		Advocate Luther 1775 Dempster S		ispicai		
		Park Ridge, IL				
Submission of a report does not con	editare an approximation that waster?	2. Health Professional?	13 Opposition	••••••	4. Initial Reporter Also Sent	
personnel, user facility, importer, dis caused or contributed to the event.	tributor, manufacturer or product		Other Healthcare	Professional	Report to FDA	
caused or contributed to the event.	•	√ Yes No	Pare: nearingle	i interstottat	S Yes No Unk.	

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U.S. Department of Health and Human Services

Food and Drug Administration

For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Mfr

	Form Approved: OMB No. 10-029 1, Expires 12/31/11 See OMB statement on reverse.
Mfr report #	2518897-2013-00006
UF/Importer R	Leport #

R/I	En	w.	TMU
IVI	EV	AAM	TCH

1. Patient Identifier

FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

Page 1

of <u>3</u>			FDA Use Only
C. SUSPECT PRO	DDUCT(S)		
1. Name (Give labeled stre	ength & mfr/ labeler)		
#1			
#2			_
2. Dose, Frequency,& Rou	ite Used		s (If unknown, give duration) best estimate)
#1		#1	
#2		#2	
4. Diagnosis for Use (India	cation)		t Abated After Use ped or Dose Reduced?
#1		#1 [Yes No Doesn't
#2			Doesn't
6. Lot#	7. Exp Date	8. Even	Yes No Apply 1 Reappeared After duction?
#1	#1	Komuo	Doesn't
#2	#2	— _{#1} □	Yes No Apply
9. NDC# or Unique ID	#2	#2 [Yes No Apply
10. Concomitant Medical F	Products and therapy Da	ates (Exclude tre	atment of event)
To. Concomitant woulder	roddos and alorapy De	LXCIGGE BEI	aunoni or evenir
D. SUSPECT MED	DICAL DEVICE		
Brand Name PENTAX	NOAL BLVIOL		
2. Common Device Name			
VIDEO DUDODE 3. Manufacturer Name, Cit			
PENTAX of Amer Montvale, NJ			
4. Model # ED-3490TK	Lot#		5. Operator of Device
Catalog #	Expiration Date	e (mm/dd/yyyy)	Health Professional
Serial #	Ofher#		Lay User/ Patient
A110299	Outer #		Other:
6. If Implanted, Give Date	(mm/ddhaan)	7 If Evolution	Give Date (mm/dd/yyyy)
o. Il Impianteu, Give Date	(11)111/00/9/9/9/	7. II Explained,	Give Date (ITIIII/OG/yyyyy)
8. Is this a Single-use Devi	ice that was Reprocess	ed and Reused o	n a Patient?
9. If Yes to Item No. 8, Ent	er Name and Address o	of Reprocessor	
40 8 1 1 1 1 1 5 5			
10. Device Available for E	_ `	anufacturer on: _	(mm/dd/yyyy)
11. Concomitant Medical F	Products and Therapy D	ates (Exclude tre	patment of event)
E. INITIAL REPO	RTER		
1. Name and Address		Phone #	Patient Information
Patient Information !			
Advocate Lutheran			
1775 Dempster Stre Park Ridge, IL 6006			
2. Health Professional? 3	. Occupation		Initial reporter Also Sent Report to FDA
Yes No	Other Healthcar	е	Yes No Unk.

■ User Facility

4. Contact Person

 Approximate Age of Device

X Yes

☐ No

X Yes

☐ No

2 yrs

11. Report Send to FDA?

Pentax Medical 3 Paragon Drive Montvale, NJ 07645

 Date User facility or Importer Became Aware of Event (mm/dd/yyyy)

10/18/2013

Patient

Code

Device

Code

11/12/2013

11/12/2013 (mm/dd/yyyy)

30-2 Okada Aza-Shimomiyano

Contact Office = see F.3 above

Manufacturing Site = see F.14 above

Hoya Corporation PENTAX Miyagi Factory

Contact Office - Name/ Address (and Manufacturing Site for devices)

Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturers Name and Address

G. ALL MANUFACTURERS

4. Date Received by Manufacturer

10/18/2013

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

☐ 5-day
☐ 30-day

7-day Periodic

☐ 10-day ☑ Initial
☐ 15-day ☐ Follow-up#
9 Manufacturer Report Number

FORM FDA 3500A (6/10)

3. User facility or Importer Name/ Address

F. FOR USE BY USER FACILITY/ IMPORTER (DEVICES Only)

7. Type of Report

Follow-up #

10. Event Problem Codes (Refer to coding manual)

12. Location Where Event Occurred

Initial

1735

1091

Nursing Home
 Outpatient Treatment Facility

☐ Home

Other:

(A)NDA#

IND#

STN#

Combination Product

Pre-1938

PMA/ K092710 510K#

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

2. UF/ Importer Report Number 2518897-2013-00006

5. Phone Number

2303

 Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Center

(Specify)

Phone Number
 800-431-5880
 Report Source
 (Check all that apply)

☐ Foreign

Consumer

User facility

Company

Distributor

Representative

Health Professional

Study
Literature

 \boxtimes

 \boxtimes

Other:

11/12/2013

Page 2 of 3

			FDA	٩U	SE ONLY		
3							
3							
H. DEVICE MA	NUFACTUR	RERS ONL	Y.				
1. Type of Reportab	le Event			2.	If Follow-up, Wi		уре?
☐ Death					Correction		
Serious Injury	у				☐ Additional		
☐ Malfunction☐ Other					Device Ev		DA Request
				4	Device Manufac		
3. Device Evaluated	•				(mm/dd/yyyy)	, tui C	Date
Not Returne	d to Manufacture	r			08/03/2011		
Yes E			L				
■No (Attach pa provide code:	age to explain wi	ny not) or		5.	Labeled for Sing	gle U	se?
					Yes		□ No
Evaluation Codes	Refer to coding	manual)		_			
	0000		\neg			1	
Method	3263 -			-		-	
Results	3218 -			-		-	
Conclusions	18 -	24	Ħ				
l			ᆜ	_			
7. If Remedial Actio	_		8. U	_ ~	e of Device		
Recall Repair	☐ Notifica			=	Initial Use of De Reuse	vice	
Replace	= '	Monitoring	1 2	=	Unknown		
Relabeling	☐ Modific	ation/			ion reported to I SC 360 I(f), list	-DA	under
Other	☐ Adjustr	nent	re	1 U	SC 360 I(1), list oval reporting nu	come	ection/
10. Additional N	Janufachung Nar	rative	and	/ or	11 🗆	C0	rrected Data
io. 🔼 Additional i	nanulaciuloi Nai	iauvo	anu	, 01		- 00	nected Data
H10 Addition	al Narrative:						
P5: During o	conformed	call with A	dı (O)	201	o Luthoran	C-01	neral Hospital
on October 1							
developed ca	arbapenem-r	esistant E	nter	ob	acteriaceae	(CF	RE) infection
In addition, o							OTK, A110299.
CRE infection		do octoon	Juli	,	OIL DUCAIA	110	(dovolop an
							ture was found
behind the el confirmed tha							
the PENTAX	scopes. The	cleaning	brus	she	es used at the	ne fa	acility are
							rgent/cleaner
of detergents							approved list
According to	the PENTAX	K Reproces	ssin	g/ľ	Maintenance	e Ins	struction For
Use (IFU), it	specifically s	tates that	use	r n	nust "Be awa	are	that all
recessed are cleaned with							
CSC9S) and							(e.g.
H6: Endosco	pe was eval	uated by u	ser	an	d bacterial o	cultu	ure (CRE) was
found behind	l elevator. Th	ie actual s	cop	e h	nas not yet b	eer	n evaluated by
PENTAX. Inv	esugation is	Sun ongoi	ng (CC	impiaint#: i	3-0	0309).
Denortment of Heat	fh and Uumaa C	en ince		784	R Statement		
Department of Heal Food and Drug Adn	ui and Human Si ninistration	al vices			B Statement: agency may not	t con	duct or sponsor,

2518897-2013-00006

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FORM FDA 3500A (6/10)

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of <u>3</u>

B.5. Describe Event of	or Problem (continued)
B.6. Relevant Test/ L	aboratory Data, Including Dates (continued)
B.7. Other Relevant H	listory, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) (continued)
Concomitant Medical	Products and Therapy Dates (exclude treatment of event) (For continuation of C.10 and/ or D.11; please distinguish)
Other Remarks	
	e 1735 = Infection, Bacterial
	e 1091 =Device Cleaning Issue; 2303 = Bacterial contamination of device
H.6 Evaluation C _Method	
_Results	3218 = MICROBIAL CONTAMINATION
_Conclusion	18 = FAILURE TO FOLLOW INSTRUCTIONS; 24 = OFF-LABEL, UNAPPROVED, OR CONTRAINDICATED USE

U.S. Department of Health and Human Services Food and Drug Administration

Medwatch

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For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting Mfr Report # 2518897~2013~00906 UF/Importer Report #

		3	-		************************	
FORM FDA 3500A (2/13) Pag	je 1 o	f 2				FDA Use Only
AND ANIENNAMED AND ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN ANIEN A		A SUSPERIOR	11.10.011100	761		1 CM SECONY
1. Patient identifier 2.		Name (Give lab.	annaman an			
		#1				
		#2			••••••	
		2. Dose, Frequent	ev & Pauta He	ori	3 Thorony Bots	e s (if unknown, give duration)
E ADVERSE EVENT OF PRODUCT PROBLEM			of miterate as		from/to (or be	
1. [2] Advarsa Event and/or [3] Product Problem (e.g., defects/malfunctions)		#1			#1	
2. Outcomes Attributed to Adverse Event		#2			#2	
(Check all that apply)		4. Diagnosis for U	lse (Indication)	}		ent Abated After Use
Desth: Disability or Permanent Cemage		#1				opped or Dose Reduced?
[1] Crudeway Moustakeur haste		#2			}	Yes No Doesn't
[2] Hospitalization - initial or prolonged Other Serious (Important Medical Eve	nts)	5. Lot#		xp. Date		Yes ∷No ∷Doesn't Apply
Required Intervention to Prevent Permanent Impairment/Damage (Devices)		#;	#1	•	<u> </u>	ent Reappeared After
3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy)					Re	introduction?
02/25/2014		*3			#1 [Yes No Dossn't
5. Describe Event or Problem		9. NDC# or Uniqu	810		#2 F	Yes No Doesn't
		16 Consenierat	Sadinal Parde	and The		************
		(G. Concomnant)	eedicai ripgu	icis suo iner	apy nates (cxoc	ide treatment of event)
	, in the same					
						Continue on some 21
		000000000000000000000000000000000000000				(Continue on page 3)
	iiiiii	Brand Name				
×.				*******	***************	
"		2. Common Devic	e Name		{2	b. Procode
	i	3. Manufacturer N	isme, City and	i State		
	od out		•			
	air air	·		Section of the sectio	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	J.J J. J
	9	4. Model#		Cot #		5. Operator of Device
	999	Catalog #		Expiration I	Date (mm/dd/yyy	Health Professional
		-				Lay User/Patient
	***************************************	Serial #		Unique ider	itifier (UOI) #	Other:
	999			ļ.;;		
(Continue on page 3))	6. If Implanted, G	ive Date (mm/	σαγγγγ	/. If Explanted,	Give Date (mm/dd/yyyy)
6. Relevant TestelLaboratory Data, including Dates		8. Is this a Single	-use Device th	at was Repri	cessed and Re	used on a Patient?
Specimen from patient, and cultured for <u>Carbapeness</u> resistant enterobacterieseae (CRE) on Patient Information Test		9 "	No			
results: Parient positive test on [Patient Information]	. 1	If Yes to item N	lo. 8, Enter Na	ms and Addr	ess of Reproces	ssor
<u> </u>						
		10. Device Availa	kia 6au Eustiin	Name of the sect	need to ETAL	
		Yes [Also [7] E	house puo ses Debenados ka kä	omigant nar and	
	i i					(mm/80/yyy)
(Continue on page 3)) [11. Concomitant I	Medical Produ	icts and Ther	apy Dates (Excl	ude treatment of event)
 Other Relevant History, Including Pressisting Medical Conditions (e.g., allergies, race, pregnancy, amuking and alcohol use, hepatic/renal dysfunction, etc.) 						
Sputum, E-Coli metallo-beta-lactamases (MBL), Pleural						(Continue on page 3)
Effusion		ENIMITAL RI	220128222			(comme on page of
		1. Name and Add				
						annon

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Manthau and a		Phone #		Emai	Address	
(Continue on page 3)		2. Health Profess	Linnighininin Langto 191			4. Initial Reporter Also Sent
Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or produc	\$	1	\$5-	сирация		Report to FDA
aused or contributed to the event.		Yes	1422			Yes No Unk.

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FORM FDA 3500	A (2/13)	(continued)	Page	2 of 2			
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1. Check One	****	2. UF/Imparter R	isport Number	1. Type	of Reportable Ev	ent	2. If Follow-up, What Typs?
	theck One User Facility Importer 2. UF/Importer 3. UF/Importer		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Death		(Z) Correction
3. User Facility or Impo	User Facility or Importer Name/Address Contact Person 5. Phone Date User Facility or Importer Became 7. Type of Report Importer Became Awars of Event Imm/dd/yyyy Initial Follow-up # Approximate Age of Device Patient Codes (Refer to a Code Code Code Code Technology) 1. Report Sent to FOA? 12. Location Where Event President Codes (Refer to a Code Code Code Code Code Code Code Code			3: 3	Serious injury		(Z) Additional Information
					Malfunction		Response to FDA Request
							Device Evaluation
				3. Devic	e Evaluated by N	lanufacturer?	4. Device Manufacture Date
			<u> </u>		Not Returned to M	lanufacturer	(mm/yyyy)
4. Contact Person		5. Phone N	umber		Yea ([]) Evalua	ition Summary Attached	
			F		No (Attach page I provide code:	c explain why not) or	5. Labeled for Single Use?
Importer Becamé	}		8. Date of This Report (mm/dd/yyyy)				() Yes [] No
Aware or Event (mill	raceyyyy	territ		Eurani	Denhism and Su	aluation Codes (Refer to	codica magual
		C Follow-up #		1 0 242	Patient		acong manae)
9. Approximate Age of Davice	10. Event	Problem Codes (Refer to code	ng manual)		Code	1930 -	
	: ,	m			Davice Cade	~	-
	• • • • • • • • • • • • • • • • • • • •				(3-036	······································	
		-	"		Method	-	
11. Report Sent to FOA	13	12. Location Where Event	Docurred		Results		-
Yes	S.::::::::::::::::::::::::::::::::::::	}	Outpatient Diagnostic Facility			t	
No (mm/da)	· <i>УУ</i> УУ)	f tour	[] Ambulatory		Conclusions	-	
13. Report Sent to Mar	rufacturer?	1	Surgical Facility	7. If Ren	nedial Action Init	lated, Check Type	5. Usage of Device
Yes	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		"		Recatl	Notification	initial Use of Device
☐ No ())	****	Other:	(Specify)		Repair	Inspection	Reuse
14 Manufacturer Nami	e/Address	1	(Operat)		Replace [Patient Monitoring	Unknown
***					Relabeling [Modification/ Adjustment	3. If action reported to FDA under 21 USC 360i(f), list correction/
8: 8:					Other:	1	removal reporting number:
•					***************************************		
55- 55- 56- 56- 56- 56- 56- 56- 56- 56-				10 [27]		acturer Marrative	and / or 11. 📝 Corrected Date
Kenyanana anda	(MINITE	Ţ.		£ .	dditional N		with the same same
**************************************	ammmmm		2. Phone Number	8		G3, H6: Addition	nal information.
Name	************			8 8			representatives from CDC
S. Addresson	*************		3. Report Source	¥- ¥			entioned by the CDC ional patients who were
Ausress			(Check all that apply)	consi	dered as su	rveillance cultu	are positives (i.s.,
***			Study	posit patie			s), other than the one
***************************************			Literature				orted in the initial . That patient was
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Consumer	consi	dered as a	clinical cass as	s had developed an
cimen Waaress			Health Professional			tion (MBL). Furt additional patis	ther, information was
4. Date Received by			User Facility		that is con	sidered as a su	cveillance culture
· ·		(A)NDA #	Company Representative				information provided on
į			Distributor		/2014 and 0 al Rospital		a hospital (Advocate
6. If IND, Give Protoco	I #	BLA#	☑ Other:	, B31 C	orrected Da	ta:	
7000		***************************************	CDC	A2: £	atient age	was reported in	error, instead of 4
7. Type of Report							
4							
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10-day [] initial		,					
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9. Manufacturer Repor	prizet Person 5. Phore Interest Person 5. Phore Interest Person 7. Type of Report Interest Pecame Interest Pecame Interest Politify or Interest Politify Interes		· · · · · · · · · · · · · · · · · · ·				
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4. all and an incommendation	***************************************	~~~	***************************************	»		·····	

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes par response, including the time for reviewing instructions, searching existing date, sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting 2518897-2013-00006 UF/Importer Report #

PLEASE TYPE OR USE BLACK INK

Page 1 FORM FDA 3500A (2/13) A PARIENTNINGORMATION 1. Patient Identifier | 2. Age at Time 3. Sex 4. Weight SNADVERSEEVENDOR PRODUCTOROGIEW . Adverse Event Product Problem (e.g., defects/malfunctions) and/or Outcomes Attributed to Adverse Event (Check all that apply) Destri: Disability or Permanent Damage (mimidalyyyyy) Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) Hospitalization - initial or prolonged []] Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/t/d/yyyy) 4. Date of This Report (mm/dd/yyyy) 02/25/2014 5. Describs Event or Problem (Continue on page 3) 6. Relevant Tests/Laboratory Data, including Dates (Continue on page 3) Other Relevant History, including Pressisting Medical Conditions (e.g., affergles)
rece, pregnancy, smoking and accordings, hapatic/renal dysfunction, etc.) (Continue on page 3) Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

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	y is nadia asso	•	from/to	(or best e	stimate)	ive duration)
#1			#1	************		***********
#2			#2			
4. Diagnosis for U	se (Indication)				Abated After id or Dosa R	
#1					es []] No	
#2		***********		w ["] v		Doesn'i
6. Lot#	7. Exp	. Date				**********
#1	#1				Reappeared Eduction?	Affer
#2	#2			#1 [] Y	es []] No	Doesn's
9. NDC# or Uniqu) ID			**********		Doesn's
10 Cananatana	Socient Dung.	Ti			*******	
10. Concomitant N	reunus rraaucii	s and thei	ಇಗಿಸಿ ಗಟ್ಟಕ್ಕಳ	(Ex9009)	ceastient of (rvent)
				{C	antinue an	page 3)
n GREPHAT	MEDIOALD	EVIOL				
1. Brand Name						
2. Common Devic	e Name		***********	2b. P	rocode	
3. Manufacturer N	ama City and S	fain			***************************************	
c. menopologis. (ums. om and a	cuto				
4. Model #	······································	2000		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
4. MOGES #	1.	lot #			5. Operator	
Catalog #	E	ixpiration l	Oate (mm/	dd/yyyy)	Lay Us	Professional
8				***********	Other:	Sect. Strass
Serial #		luidne iqei	amer (OD)) 8°	in a contract of	
6. If Implanted, Gi	ve Date (mm/dd/	γγγγ)	7. If Expl	anted, Giv	e Date (mm/	dd/yyyy)
			L			
8. Is this a Single-	use Device that No	was Repr	0005560 8	nd Reusse	on a Patier	nt?
3. If Yes to Item N		and Add:	ess of Re	orocessor		***************************************
10. Device Availat	de for Fysicatio	p3 (On not	sand to EC	141	***************************************	
	2000	umed to Ma		-		
~~~~	~~~~				(mm/dd/y)	
11. Concomitant R	edical Product:	s and Ther	apy Dates	(EXCLUDE	realment of	event)
		Managara.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(C	ontinue on	page 3)
1. Name and Add	.622					
Phone #		Emai	Address	ine initialistic	dililinini.	
2 Magith Denfer	nnaf3 12 . /	airinealainna MacNam	بنبنبنب		nitial Bene-	er Also Sent
Health Professi     Yes	§ .	patteri		} \$	Report to FD	A
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FORM FDA 3500/	a (2/13) <i>(</i>	(continued)		Page	2 of <u>4</u>			
					W		iatėjų: iaitekoji	
1. Check One	inilitationa			eport Number	ay Amminini	of Reportable		2. If Follow-up, What Type?
User Facility	[] impor	į.	rumporter re	aport isamusi	1		24#111	
****					-401 1111	Death		Correction
<ol><li>User Facility or Impr</li></ol>	orter Name//	Address				Serious Injury		Additional Information
						Malfunction		Response to FDA Request
								Device Evaluation
:					1 1 2 2	P	**************************************	
					1. 1	ice Evaluated by 		Device Manufacture Date (mm/yyyy)
			, , , , , , , , , , , , , , , , , , ,		્∦્ } ····	Not Returned to		
4. Contact Person			5. Phone N	mber	£. £		uation Summary Attached	£
						No (Attach page provide code:	a to explain why not) or	5. Labeled for Single Use?
<ol> <li>Date User Facility or Importer Became</li> </ol>	. 7	' Type of Repor	1	<ol> <li>Date of This Report (mm/dd/yyyy)</li> </ol>		provide sade:		☐ Yes ☐ No
Aware of Event (mm	(dalyyyy)	folial		(mare mary 3333)			***************************************	
		The Halland up 4			6. Evai	nt Problem and I	Evaluation Codes (Refer	r to coding manual)
Approximate	~~~~	Follow-up #	*******	yo maxwall	<b></b> [. ]	Patient	1930 ~	
Age of Device			randi su sudii	ng simulatari		Code	<u> </u>	
	Patient		-	an (		Device Code	-	-
l	Code [		<u> </u>	}		0,000	- t	······· pri········ pri·······
	Device Cade	-	-	-		Method	~	-
11. Report Sent to FDA		12. Location W	fhere Event	Docurred	4		1	
		( ) Hospita		["] Cutpatient		Results	~	
Yes(mmydd/	Svervi	Home	•••	C Diagnostic Facility		Dunielies.		
i No	************		v Dame	Ambulatory		Conclusions		
13. Report Sent to Man	ufacturer?	[]] Nursing	g Home ient Treatmer	Surgical Facility	7. If Re	emedial Action in	itiated, Check Type	8. Usage of Device
Tes		Facility	em treamer	K.		Recati	Notification	[]] Initial Use of Device
No (mm/dd/	YSYY)	Other			( ) ····	Repair	Inspection	Reuse
C				(Specify)	B 8 222	Replace	Patient Monitoring	Unknown
14. Manufacturer Name	JAddress .	.::::::::::::::::::::::::::::::::::::::	*************		8 8		****	9. If action reported to FDA under
						Relabeling	Medification/ Adjustment	21 USC 366i(f), list correction/ removal reporting number:
					11 -	Other:		temosa rapaining number.
					1			
		000000000000000000000000000000000000000			] []0. []	Additional Man	ufacturer Narrative	and / or 11. Corrected Data
G ALL MANUFA								
1. Contact Office (and	Manufactur	ing Site for Davi	ices)	2. Phone Number				
Name								
Address	***********			Report Source (Check all that apply)				
- KICK BIDS			:	1				
				Foreign				
				Study				
				Literature				
Email Address		***************************************	;	Consumer				
				Health Professional				
4. Date Received by		S.		User Facility				
Manufacturer (mm/d	(d/yyyy)	(A)NDA#		Company				
			************	Representative Distributor				
6. If IND, Give Protoco	1 #	- and a		} ·····				
		BLA#		(2) Other:				
		PMA		COC				
7. Type of Report (Check all that apply)		510(k) #						
		Combination	س. ۸ رس		-			
tend from	•	Product	Yes					
and the second		Pre-1938	[]] Yes					
E hand	w-up# 2	OTC Product	Yes					
		- B. 6.6.5		ļ	4			
8, Manufacturar Repor		8 Adverse Ev	veut ratus(a)					
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U.S. Department of Health and Human Services Food and Drug Administration

## MEDWATCH

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PLEASE TYPE

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mir Report #	2518897~2014	-00002	
JF/Importer F	Report #:	·	
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FORM FDA 3500A (2/13)	Page 1	1 of 2	<u>}</u>					FDÄ Use	Cabo
A PARIENS INSORMATION  1. Patient Identifier  2.		1.	Nama (Give labeled stre #1 #2 Doss, Fraquency & Ro	ngth & m	b/Jabeler)	3. Thereis	y Date* ///	uiknown, give dura	
B ADVERSE EVENT OF PROBU	PROBLEM			nın nunin		from c	(or basi as	timate)	10.17
1. 🕜 Adverse Event and/or 🗌 Pro	duct Problem (e.g., defects/malfunctions)		<b>\$1</b>			#1	***************************************		
Outcomes Attributed to Adverse Event     (Check all that apply)		1	¥2			#2	***************************************		
	Disability or Permanent Damage		Disgnosis for Use (Indi	ostion)				beted After Use d or Dose Reduced	7
Death: (mm/dd/yyyy) Life-thysatening	Congenital Anomaly/Birth Defect		<b>\$1</b>				#1 [_] Ye	NS □NG □ DG	resn't vige
Hospitalization - initial or prolonged	Other Serious (Important Medical Events)		#Z				#2 [ ] v	173 No. 173 DC	oesn't
Required Intervention to Prevent Perm	1.1	a.	. Lot #	7. Exp.	. Data		~~~~	leappeared After	ply
3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	#		#1			Reintro	duction?	
	03/06/2014	#	***************************************	¥2.			#1 []] Ye		pesn't apiy
5. Describe Event of Problem It was reported by facility	on February 14, 2014;	3.	NDC# or Unique ID				#2 [] Ye	ns No So	cesn't
patient had underwent Endosc	opic retrograde	1 1	3. Concomitant Medical	Products	and Ther	any Dates	(Exclude fr	~~~~	μ,
cholangiopancreatography (SR manuscal) and was tested for CRE. Patentatomatical revealed patient teste resistant Enterobacteriaceae	Test results Patient Information d positive for Carbapenem-		٠			à			
developed an active CRE infe pneumoniae carbapenemase (KP (MBL): New Dëlbi MBL (NDM);	ction e.g., Klebsiella C); metallo-\$-lactamases		N SUSPECTMEDI	CAL DI	VICE		(Cd	ontinue on page	3)
MEL (VIM). Additional inform	ation from the facility		Brand Name PENTAX	VIDE	adona c	NOSCOPE	 E	***************************************	
revealed one more patient positive for CRE, but had no	tested to developed an active	2.	Common Device Name	~~~~~			2b. Pr	ocode	
infection. These both cases	are being reported as they		Manufacturer Name, C	in and &	tata		FDT		
are surveillance culture pos further information provided of 2 reports.	titive cases. There was no		ENTAX Medical, Mo:	ntvale,	#J				
reception of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the s		8 8	Model# :D-3490TK	1.	.ot #			<ol> <li>Operator of Davi</li> </ol>	
-			Catalog #	- E	xpiration i	Date (mm/c	id/yyyy)	Health Profess	
***************************************		-	Serial 8	ย	nique ider	itifier (UDI)	} #	Lay User/Patie	<u> </u>
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6. Relevant Teste/Leboretory Date, Includin	(Continue on page 3)	1 L							
Specimen from patient, and c resistant enterobacteriaceas results: Patient positive të	(CRE) on Patient Information Test		is this a Singla-use Da Yes / No If Yes to Hem No. 8, En						
***************************************								••••	
		1 675	0. Device Available for E			sond to FD anufacturar			
			***************************************					(mm/dd/yyyy)	
Other Relevant History, including Presxis ráce, pregnancy, smoking and akchol use,	(Continue on page 3) sting Medical Conditions (e.g., allergies, hepatichenel dyafunction, etc.)		1. Concomitant Médical	Products	s and Ther	apy Dates		, ,	generation
				-3-25-2000000 -3-25-20000000			(C)	ontinue on page	3)
		1. A	. Rome and Address  Patient Information  dvocate Luthera  775 Dempster St ark Ridge, IL 6	n Gene reet	≋ral Ho	spital		y	
	(fignilians as manifel	ρ.	NONE #			i Address	1.G = ~4.c~	ratabasish ~	~
Submission of a report does not cor	(Continue on page 3)	ال ال	. Health Professional?	3. Occur	and the second	nt Information	4.3	cateheaith.co nilial Reporter Also	
personnel, user facility, importer, di caused or contributed to the event.	stributor, manufacturer or product		Yes No	,		are Pro	1 8	seport to FDA Yes No 🕢	8

## Alenia/avec

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FORM FDA 3500/	4 (2/13) (	continued)		Page :	2 of 2			
F FOR USE BY U		•	-374-3-372	avr/a2	885588556		ACTURERS ONL	
1. Chack One	CI-SAM AND	***************************************		aport Number	900000000000	************************		
User Pacility	[Z] Impor					of Reportable En	uess:	2. If Follow-up, What Type?
houd "			8897~203	. マーーロメcoᲚ	1	Death		Correction
3. User Facility or Impo PENTAX Medical	rter Nameli	Address				Serious Injury		Additional Information
3 Paragon Drive						Malfunction		Response to FDA Request
Montvale, NJ 07								Device Evaluation
					3 5-4	Market Albert	Since of the advantage of	4 Barbardina francis
						ce Evaluated by I		Device Manufacture Date     (mm/yyyy)
					1 -	Not Returned to		06/12/2012
4. Contact Person	-		5. Phone No	imber		Yas Evalu	ation Summary Attached	06/13/2012
			1			No (Affect page	io explain why notj or	5. Labeled for Single Use?
<ol> <li>Date User Facility or Importer Became</li> </ol>	7	. Type of Report	1	8. Date of This Report (mm/dd/yyyy)		provide code:		Yes Z No
Aware of Event (mm/	dd/yyyy)	🕢 irdisəl			*	9T		
02/14/2014	4	Follow-up #		03/06/2014	6. Ever	it Problem and E	reluziton Codes (Refer l	o coding manual)
		*****		***************************************		Patient	1 2020 1	
R. Approximate Age of Device	10. Evant P	roblem Codes (F	tajar ta cadh	ng manusij		Code	1.930 -	
	Patient	1930 -	[ ···		*****	Device:		
-2	Code		L		******	Code	L	
	Device Code			**	200	Method	3263 - 3317	, s
					1			
11. Report Sent to FDA		12. Location W			***	Results	3221 -	-   -
Yes 03/05/		[2] Hospita	1 -	Outpatient Diagnostic Facility				
No (minegae)	5393G	] Homĕ		Ambulatory		Conclusions	67 -	
13. Report Sent to Man	uřacturar?	Nursing	Home	Surgical Facility	7. If Re	medial Action Ini	Hated, Check Type	6. Usage of Device
☐ Yes		Outpatis	ant Treatmen	R.				Initial Use of Device
imm/dd/vyyv)				<u></u>	Recall [	Notification	Reuse	
□ 160		Cither:	***********	(Specify)	L	Repair [	Inspection	
4. Manufacturar Nama	Address		******	***************************************		Replace [	Patient Monitoring	Unknown
Hoya Corporation FENTAX Miyagi Factory						Relabeling [	] Modification/ Adjustment	If action reported to FDA under     21 USC 360kh, list correction/
30-2 Okada Aza~						S Cidence	Notamics.	removal reporting number:
Tuskidate, Kuri	hara-sh	i, Miyagi,	Japan S	87~2203	L	Other:		
						***************************************	~~~~~~~~~~	
					10.	Additional Manu	facturer Narrative :	and / or 11. Corrected Data
G. ALL MANUFAC	ON URBER	S			810	Additional t	Jarrative:	
. Contact Office (and )	Manufacturi	ina Site for Davi	::::::::::::::::::::::::::::::::::::::	2. Phone Number				cently (02/14/2014) made
Name					aware	e of patient	s with CRE orga	anism after undergoing
				3. Report Source	ERCP	procedure v	vith scope (seri	ial number A110471). The
Address			•	(Check all that apply)	\$		, ,	ied by FENTAX Medical and
3 Paragon Drive				Foreign				06/26/2013, and returned
Montvale, NJ 07	543			Study		the scope		B. The facility did not
Hoya Corporatio	n PENTA	X Mivagi Fa	actory	Uterature				History Records (DHR)
30-2 Okada Aza-				, hand	ธกอพ	ed there wer	ce no reports of	f any non-conformance
Email Address				Health Professional				g in-process and final
	***************************************		******************************	User Facility				afactured according to
<ol> <li>Date Received by Manufacturer (mm/de</li> </ol>	t/srzvat	5.		10				evaluate the scope at the
02/14/20		(A)NDA#		Company Representative	Comi	or return :	facility of any	ss there were no reports y adverse events or
		IND#		Distributor				te scope. The scope has
3. If IND, Give Protocol	#	BLA#.		Other:				r user facilities and
								ing out from those
7. Type of Report		PMA/ 510(k) # K0	92710		faci	lities of a	ny CRE cases ass	sociated with this acope.
(Check all that apply)								
5-day 7 30-day	y	Combination Product	Yes					
7-day Period	iic	Pre-1938	Yes					
10-day 📝 tritial		OTC Product	erra.					
15-day Follow	-up#	O L DORGE	Yes					
. Manufacturer Report	Number	5. Adverse Ev	ent Term(s)	ł				
•								
2518897-2014-00	/US &							
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FDA USE ONLY

U.S. Department of Health and Human Services: Food and Drug Administration

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For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #	2518897~2014~00002
Ui-/Importer f	Report #

PLEASE TYPE OR USE BLACK INK

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ORM FDA 3500A (2/13)	Page 1 o	2								rm 4 31 0 -1.
A PATIENT INFORMATION		P338F37F7	33000	21.00		***************************************		***************************************		FDA Use Only
1. Patient identifier Z.		************	***************************************	************	************	***************************************				
1. Panent lugission 2.		1. กลกร	(mine: 191	iensa asser	ngin & n	vistabeter)				
		#1		~~~~~			~			
		\$2								
		2 0000	Francias	cy & Rot	rio I lesos		3 Thoras	w States (f	f unknown, g	isa duration)
B. ADVERSE EVENT OR PRODUCT PROBLEM		w. wwije,	a residentiti	ing in stoc	MO 0001	,	from/to	for best es	simale)	me uzealani
l ☑ Adverse Event and/or ☐ Product Problem (e.a., defects/melfunctio		#1					*:			
	XII 27	#2	~~~~~				.55			***************************************
! Outcomes Attributed to Adverse Event (Check all that apply)							#2		······································	
Control Contro		4. Blagn	ceis for	Use (India	cation)				Abated After od or Dose R	
(mm/od/yyyy)	'] [#1						`	es: No	Dossn't
Life-threatening Congenital Anomaly/Birth Defect		#2						, " L. ' '	24: <u>1</u>	Apply L
Hospitalization - initiation prolonged	al Events)}	6. Lat#			75 2), Date		#2 Y	es: No	Doesn't
Required Intervention to Prevent Permanent Impairment/Demage (Devices)						s, Lense				المراجع السا
3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy	,	#1			#1				Reappassed	Aner
03/06/2014	´	#2.			#2			i	es No	Doesn't
i. Deseriba Event or Problem		9. NDC#	nr Unio	se ID					20 L	Apply L
It was reported by facility on February 14, 2014;	99		27 O					#2 Y	es No	Dossn't
patient had underwent Endoscopic retrograde	3	16 6		DK-sett-s-1			62 - 4	(F		L.J. Apply
cholangiopancrestography (ERCP) procedure on Patient Informati		iu conc	musam	wegicai i	Product	s:sng iner	apy Dates	(Exclude b	restment of a	organ)
testiments and was tested for CRE. Test results Patient Inform										
section revealed patient tested positive for Carbapen	em~									
resistant Enterobacteriaceae (CRE), but had not	5									
developed an active CRE infection e.g., Klebsiælla pnæumoniae cærbapenemase (KPC); metallo-6-lactamase	. 3							(C	ontinué on	page 3)
(MBL): New Delhi MBL (NDM); and Verona integron-enc	5 1	1000 300		Meell		(AV)(A)				
MBL (VIM). This is 2 of 2 reports.	}	1. Brand	Name	************		***************************************	*************	*************		
	-									
		2. Comn	ron Devi	ce Name				Zb. P	rocode	
		G Rannon		Name, Ch	te and s					
		G. INISEES	er inini	rsame, we	ty and a	21.616				
		4. Mode	8			Lot 8			5. Operator	of Davice
	-								T'7 Unash	Professional
		Catak	19 S			Expiration	Date (mm/	da/yyyy)	/ <i>/</i>	}
									Lay Us	ser/Patient
		Sorial	ğ		1	Jnique ide	ntifier (UD	i) #:	Cither:	
								1		
Wastinua an na	on 31	6. If Imp	lanted, C	elsa ović	(mm/dd	(5393)	7. If Expl	anted, Giv	e Date (mm/	(dd/yyyy)
(Continue on pa	ge 3/									
Specimen from patient, and cultured for Carbapenem					rice tha	was Repr	೦೦ಕಾಶಕಾಗ ಕ	nd Rauser	d on a Patier	1 1?
:	est	[]] Y	es [] No						
results: Patient positive test on Patient Information		9. If Yes	to Item !	No. 8, En	ter Nam	e and Add	ress of Re	processor		
^ L										
										÷
		10. Devi	a Availa	able for E	valuatio	n? (Do not	send to FL	34)		
		[]] Y	88 []] No	[]] Re	tirmed to M	anufacture	r on:	····	
									(mm/sid/y)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
(Continué on pa	ge 3)	33. Conc	mana	Medica:	s. roanë	a sua me	rapy Dates	: (EXCHIGE	to inamised	eventi
 Other Relevant History, including Pressisting Medical Conditions (a.g., allergings, pregnancy, smoking and alcoholuse, hapelic/renal dysfunction, etc.) 	ઇ S,									8
and the statement of memoring and management enduring their sharement as it is								10	ontinuë on	1 Carps 21
			33.338 833		7373			,	ommoe di	, မှာရေရှင့် <i>သုံ</i>
		1. Nama	***********	*************	*********					
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28521	(2)	Phone #				Ems	ii Address			
(Continue on pa	in annimous									
ubmission of a report does not constitute an admission that me ersonnel, user facility, importer, distributor, manufacturer or pro	dicai Must	2. Healti	Profes	sional?	3. Occu	pation		4. l	nitial Report Report to FD	ər Also Sənt A
araumer, user reumy, importer, user tourur, menthacterar or pri	envilens k	ΠY	es []	No						No Unk.

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FORM FDA 3500.	A (2/13)	(continued)			Page	2 of .							
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1. Check One-		********************	UF/Importer	***********	***************************************			aportable E			5000000000p	2. If Follow-up, What Type	
User Facility	[] Imp	l l	18897-20	-			Des						
3. User Facility or Impr	*****					-	*****				ĺ	Correction	
S. Some I actuary of impo	(22.622.14064114	2/2/00/16/22					i	ous Injury				Additional informati	
							Man	noitanu				Response to FDA F	₹eques
											İ	Device Evaluation	
						3	. Device Er	raluated by	Manufact	urer?		4. Device Manufacture Dat	ei.
							□ Not	Returned to i	Manufacti	irer :		(mm/yyyy)	
4. Contact Person		***************************************	5. Phone I	Number	·	-	Yes			imary Attache	ส		
							,	(Affach page		,		5. Labeled for Single Use?	,
6. Date User Facility or		7. Type of Rep	nrt	8. Date	of This Report	- 1	prov	ijqe coqe: Musico bode:	itt oxfoar	s westy mosty on	-		
Importer Became Aware of Event (mm			••••		/dd/yyyy)							Yes No	
wasia m resist tum	orsen h h h h	[] Initsi				1 1	Same Ber	thing and C	i confirmation	Codes (Refe		Viza mazuail	
¥ .		Follow-up	#	_			c resistant	Patient				sing manuas)	~~_
3. Approximate	10. Event	Problem Codes	(Refer to co	ling menu	al)			Code		-			
Age of Davice	Patient [I [[7		Device	[F
	Code	1930	-		٠]]]		Code	ļ	j~ [.			
	Device							Method		-			7
	Code	7.10	<u> </u>		<u></u>	4		Common	L			L	
11. Report Sent to FDA	\$7	12. Location				-		Results		-	-		
Yes		Hosp			Outpatient Diagnostic Facility				ļ				٦ ٦
No (mm/dis	77777	Home		П	Ambulatory		(Conclusions			<u> </u> .	~[
13. Report Sent to Man	utacturer		ng Home	; ســا	Surgical Facility	17	. If Remedi	al Action In	itisted, C	heck Type	8. U	Isage of Device	
MYes .		U Ovtpa	atient Treatme	ent			∏ Rec	f	Notifie	×5i		Initial Use of Device	
No (mm/dd)	<i>(</i> 4894)	Other	•				tana					Reuse	
L			·	(\$pec	湖)	-	∏ Rep		Insper			M Unknown	
14. Manufacturer Name	s/Address							lace [∭ Modifi	t Menitoring	3. 19	farting represent to EPLA con	rder
							L. rees	sheling	Adjust	ment	2	in USC 360(f), list correction emoval reporting number:	mi
							[] Oth	er:				emerarispormig namous.	
							••••				-		
					Jacob Company	16		***************************************	*****		=	() () () () () () () () () ()	
	000000000000000000000000000000000000000	~~~~					10. 🔲 Add	itional Manu	macturer	sestanes	ana	/or 11. Correcte	30 2333
G ALL MANUFA	*************	***************************************											
1. Contact Office (and	Manufacti	uring Site for De	ivices)	2. Pho	ine Number			Pt.					
Neme													
Address				3. Ret	ort Source ack all that apply)								
				·	reign								
				[] St	=								
				ł	erature								
Email Address			~~~~	}	insumer salth Professional								
				} ·:									
4. Date Received by	(22) - m = 3	5.		},	er Facility								
Manufacturer (mm/d	киуууу	(A)NDA#		L C	impany spresentative								
		IND#			stributor								
6. If IND, Give Protoco	1#	5											
		§		''									
7. Type of Report	***********					~							
(Check all that apply)	;	Combination											
[] 5-day [[] 30-da		Product	Yes			~							
7-day Perio		Pre-1938	Y62			-							
10-day 📝 Initial		OTC Produc	Country										
15-day Follo	w-up#	-	لسا 'ھ			-							
9. Manufacturer Repor	t Number	8. Adverse l	Event Term(s	3)		7							
2518897-2014-0	0002												
1													
						u L						***************************************	***********

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MEDWATCH

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For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mir Report #

UF@mporter Report # 2018897~2015~60027

ATTACA CONTRACTOR CONT	of 3		\$388077 2047 3002
	***************************************		FDA Use Only
A DANIES NEGOTALIANTEN 1. Patiant Identifier 2. Age at Time \$1.5cc 4.5Weight	CONTRACTOR OF THE CONTRACTOR O		0.00000
of Event:	1. Name (Give labeled strong	in a minap eni j	
75 This Ris	*i		
In confidence of Sinth: Mate was	82		
B ADVERSE EVENT OR PRODUCT PROBLEM	2. Dose, Frequency & Route		herapy Dates (If unknown, give duetion) om/to (or best estimate)
Adverse Event and/or 7 Product Problem (a.g., defects/mailunctions)	#1	#1	
Z. Outcomes Attributed to Adverse Event	#2	#2	
(Chack as that apply)	4: Diagnosis for Use (indical	tion)	5. Event Abaled After Use
Death: Death: Disability or Permanent Damage	#1 ···		Stopped or Dose Reduced?
Congenital Anomaly/Birth Defect	#2		Apply
Hospitalization - initial or prolonged	6, Lot #	7. Exp. Date	#Z Tes Ho Dosent
Required Intervention to Prevent Permanent Impaliment/Damage (Devices)	*1	#1	8. Event Reappeared After
3. Date of Event immissions 4. Date of This Report immissions 97/15/2015	#2	**2	Reintroduction?
5. Describe Event or Problem	9. NDC\$ or Unique ID		Apply Apply
On 07/15/2015 DENTAK Medical received a Maude Event	700 - 100 -	edaes	#2 Tyes No Toom
Report Patient Information from FDA involving a video Dudgenoscope Model ED-3490TK/Serial Number All0592. It	10. Concomitant Medical Pr	oducts and Therapy (Dates (Exclude treatment of event)
stated a user facility had reported that "after	\$		
appropriate cleaning and high level disinfection routine		1	
culturing on the device elevator produced a positival results for carbapenem-resistant enterobacteriaceae		6 600 2000 2000	
(CRE). This patient is at risk for potential exposure to	B SUSPERIMEDIA		(Continue on page 3)
the organism."	1. Srand Stame		
On 07/17/2015 Pentax sent an e-mail to the facility for	FENTAX		
additional information. On 07/21/2015 the facility	2 Common Device Name Video Duadenoscope	:	Zb. Procede
informed PENTAN Medical that it became aware of the positive culture results on Patient Information Additionally,	3. Manufacturer Name, City	and State	
the facility advised that it immediately removed the	HOYA Corporation Takyo, Japan		
scope from service, and ? (two) patients who underwent procedures with the scope were identified. The event	4. Model #	Lot#	S. Operator of Devices
date for use of the scope on the patients was Patient Information	ED-3490TK		[7] Health Professional
The patients were tested for CRE and no patient tested positive. Therefore, the response from factility	Catalog #	Expiration Date	imm/shd/yyyy) Lay UsaniPaliani
indicates there was no patient injury.	Serial #	Unique Identifie	
	A110592		
(Continue on page 3)	5. If implemed, Give Date (ir	anddd yyyy) 7 _. lf	Explanted, Give Date (mm/dd/yyyy)
6. Relevant Teste/Laboratory Data, Including Dates	8. la ffrix a Sicola-van Govic	a that was Benraces	sed and Reused on a Patient?
	Yes Ne		
	9. If Yes to Item No. 8, Enter	Name and Address	of Reprocessor

			**
	10. Device Available for Eva	Justion? (Do not send	to FDA)
	Yes No @	Returned to Manufa	ckweren:08/03/2015
	11 Cancamitant Madical De	nducta and Thorons	(mredd/yyy) Dates (Exclude beelment of event)
(Continue on page 3) 7. Other Relevant Mistory, Including President Sadical Conditions is a alternic			and the state of t
7. Other Relevant Mistory, including Preexisting Medical Consistens (e.g., allergies, race, pregnancy, smoking and alcohol use, sepalichenal dystimction, etc.)			
			(Continue on page 3)
	1. Name and Address		
	Identifying Infor		****
	Lutheran General H	ospital	
	1775 Dempster St. Park Ridge, IL 600	68	:
		~~~~	
(Continue on page 3)	Phone * Identifying Information	Entell Add	Identifying Information
Submission of a report does not constitute an admission that medical		Occupation	4 Initial Reporter Also Sent
personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.	☑ Yes ☐ No O	ther Healthcare	Profess   Report to FDA   Profess

				00000000000	333333333333333333333333333333333333333	EX.29060314.305.397 (0.900000000000000000000000000000000000
MEDWATCH	· · · · · · · · · · · · · · · · · · ·		3	i 8 - 100i		3.54.4.2.5.2.4.5
FORM FDA 3500A (2/13) (0		Pana	2.0	3.	:	
***************************************		200 120 4 100 200			<u></u>	
F FOR USE BY USER FAC			8	H. DEVICE MANUFACTURE	RS ONLY	
1. Check One	2. UF/Importer R			Type of Reportable Event		2. If Follow-up, What Type?
User Facility (2) import		L5-00027	l	Death		Correction
3. User Facility or Importer Name/A SENTAX HEDICAL	ddress	200301 200 37.00		Serious Injury	**	Additional Information
3 Paragun Drive				Malfunction		Response to FDA Request
Montvale, NJ 07645		!		\$ : ** :		Device Evaluation
				3. Davice Evaluated by Manufacture	£7	4. Device Manufacture Date
				Not Returned to Manufacturer		(mm/yyyy)
4, Contact Person	5. Phone N	umber	1	Yes Evaluation Summa		TBD
			l	No (Attach page to explain wi	3	5. Labeled for Single Use?
S. Date User Facility of 7.	Type of Report	8. Date of This Report	1	provide code:	of month of	
Importer Sections Aware of Event (mm/dd/yyyy)	Initial	(mm/dd/yyyy)		11		Yes 📝 No
		08/07/2015	Н	6. Event Problem and Evaluation Co	des (Refer to co	ding manual)
	Follow-up #	normanian and	Į i	Patient 3189		645
Age of Davice	oblem Codes (Refer to codi	ng manuan		C038		
TED Patient Code	3189 - 264	-		Device 1091		•
Device T	~	firming firming		\$	7 [	manner manner
Code	1093			Method 3263	.]-[	· I
11. Report Sent to FDA?	12. Location Where Event (	Decurred	1	Results 3233	1_	- 2
V ves 08/07/2015	(V) Hospital	Outpetient Diagnostic Facility		Annana Maria	ad himmunumid	
No (mm/ad/yyyy)	Moms	[***] Ambulatory		Conclusions 11	-	
13. Report Sent to Manufacturer?	Nursing Home	Surgical Facility		7. If Remedial Action Initiated, Chec	k Type 18.	Usage of Device
₹ ves 08/07/2015	Culpatient Treatment Facility	it :				initial Use of Device
No (mnyad/yyyy)	Coher			Recali Notificatio		Reuse
		(Specify)		Repair Inspection Replace Patient Me		Linknown
14. Manufacturar Name/Address		-000000 V		Relabeling Modification	F	If action reported to FDA under
HOYA Corporation PENTAX Life Care Tokyo	Office	100		Adjustmen	- I	21 USC 366(f), fist correction/ removal reporting number;
2-7-5 Naka-Psjeo, Shinj	ukuku			Other:		:
Tokyo, Japan 161-8525		000				:
: 8		:		10. Additional Manufacturer Nar	rative and	t/or 11.[**] Corrected Data:
G ALL MANUFACTURERS	;	i e	( I	Second 1		4 in printing an arrange a structure size the page 1
1. Contact Office (and Manufacturis		2. Phone Number	1		<b>**</b>	
Name		See F.S				
200		3 Report Source	1			
Address	w 9	(Check all that apply)				
Contact office - See F.	1 abovo	Foreign	200000			
Manufacturing site - Se		Shudy	00000			
		Clerature				
Email Address:		Consumer Health Professional				
		*****				
4. Date Received by Manufacturer (mm/dd/yyyy)	5.	Qser Facility				
07/15/2015	(A)NDA #	Company Representative	90000			
6. If IND, Give Protocol #	IND #	Distributor				
A STATE OF THE PROPERTY OF	SLA#	Cother:	100000			
***************************************	PMA					
7. Type of Report (Check all that apply)	510(k) # K092710			9\$··		
5-day 7 30-day	Combination Product Yes	***************************************	*			*
7-day Periodic			Silvery .			*
10-day Z Initial	Pre-1938 Yes		*******			
15-day Follow-up #	OTC Product Yes		-			
9. Manufacturer Report Number	8. Adverse Event Term(s)	*	4			

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Food and Drug Administration

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FORM FDA 3500A (2/13) (continued)

# (CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of 3

	8.5. Describe Event or Problem (continued)
න න	
Back to Hem B.5	
**************************************	
	S.G. Relevant Tests/Laboratory Data, Including Dates (continued)
22 22 23 24	
Back to item B.6	
00 00 00	
	B.7. Other Relevant History, including Preexisting Madical Conditions (e.g., s/largies, race, pregnancy, smoking and alcohol use, hepatic/ranal dysfunction, etc.) (continued)
s mess o	
Back to Item B.7	
Back to item D.11 Back to item C.19	Concomitant Medical Products and Therapy Dates (Exclude beabness of event) (For continuation of C.10 and/or D.11; please distinguish)
80,80	
ت ش	
o frem	
Back t	Other Remarks Pacient Code 3189 - Not Applicable: Patient Code 2645 - No Patient Involvement
	Davice Code 1091 - Device Cleaning Issue Method Code 3263 - Actual Device Not Evaluated
	Results Code 3233 - Results Pending Completion Of Evaluation Conclusions Code 11 - Conclusion Not Yet Available-Evaluation In Progress

** *** !

666

200

## FDA Home³ Medical Devices⁴ Databases⁵

## MAUDE Adverse Event Report: PENTAX PENTAX PENTAX DUODENOSCOPE

oerSearch

510(k)⁷|DeNovo⁸|Registration & |Adverse

|Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵

Listing⁹

|Radiation-Emitting

Events¹⁰ |X-Ray

Medsun

|CLIA²⁰|TPLC²¹|Inspections²²

2116 Products¹⁷ Assembler¹⁸

Reports¹⁹

### PENTAX PENTAX PENTAX DUODENOSCOPE

CFR Title

Back to Search Results

Model Number ED-3490TK **Event Date** 06/21/2013 **Event Type** Injury **Event Description** 

Pt underwent an ercp procedure using a pentax ed-3490tk -a110084 side viewing duodenoscope. Pt developed a cre infection. Proper cleaning of scope confirmed as per company recommendations. Organism found under elevator on scope.

## Search Alerts/Recalls²³

New Search | Submit an Adverse Event Report²⁴

**Brand Name**PENTAX Type of DevicePENTAX DUODENOSCOPE Manufacturer (Section D)PENTAX

3 Paragon Drive Montvale NJ 07645

MDR Report Key3252445 Report NumberMW5031083

**Device Sequence Number**1

Product CodeFDT25

Report Source Voluntary

Reporter OccupationRISK MANAGER

Type of ReportInitial

**Report Date**07/23/2013

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received07/23/2013

Is This An Adverse Event Report?No

Is This A Product Problem Report?Yes

**Device Operator**Health Professional

Device MODEL NumberED-3490TK

**Device LOT Number**A110084

Was Device Available For Evaluation? Yes

Is The Reporter A Health Professional? No

Is this a Reprocessed and Reused Single-Use Device? Yes

#### **Patient TREATMENT DATA**

Date Received: 07/23/2013 Patient Sequence Number: 1

### Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php

- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
- 12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
- 13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
- 14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
- 15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. /scripts/cdrh/cfdocs/cfPCD RH/classification.cfm
- 18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDT

Page Last Updated: 10/31/2015

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Contact FDA













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U.S. Department of Health & Human Services

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- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
- 12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
- 13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
- 14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
- 15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
- 18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDT

# Allegheny General Hospital Pittsburgh, Pennsylvania

# **OLYMPUS**

March 27, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

## **MEDWATCH**

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	Occ Olain statement on tayetse.
Mfr Report # 2951238-201	5-00127
UF/importer Report #	

	FORM FDA 3500A (2/13)	Page	1 0	f <u>2</u>				EDA Has Only
	A. PATIENT INFORMATION			C. SUSPECT PROD	UCT(S)			FDA Use Only
	1. Patient identifier 2.			1. Name (Give labeled stre				
				#1				
				#2				
	B. ADVERSE EVENT OR PRODUC	CT DDOD! EM		2. Dose, Frequency & Ro	ute Used	3. Thera	py Dates (	f unknown, give duration)
				#1		#1	o (or best e	stimate)
	Adverse Event and/or Prod     Outcomes Attributed to Adverse Event	duct Problem (e.g., defects/maifunctions)	_	#2		#2		
	(Check all that apply)			4. Diagnosis for Use (India	cation)	#2	5. Event	Abated After Use
	Death:	Disability or Permanent Damage		#1	,		Stoppe	ed or Dose Reduced?
	✓ Life-threatening	Congenital Anomaly/Birth Defect		#2			#1 ∐ Y	es No Doesn't
	Hospitalization - initial or prolonged	Other Serious (Important Medical Event	s)	6. Lot#	7. Exp. Date		#2 🔲 Y	es No Doesn't
	Required Intervention to Prevent Perma			#1	#1		8. Event	Reappeared After
	3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	7				Reintro	oduction?
	02/23/2015  5. Describe Event or Problem	03/09/2015	41	#2 9. NDC# or Unique ID	#2		#1	es No Doesn't
	Olympus received a Voluntary		Ш	o. Noon of offique ib			#2 🗌 Y	es No Doesn't
	patient's blood culture test Klebsiella Pneumonia after u			10. Concomitant Medical	Products and The	rapy Dates	s (Exclude :	
	Retrograde Cholangio-Pancrea							
	user facility noted that the	patient had no history of						
INK	the this organism.		Ш					
Ή	Olympus has made multiple at	tempts to contact the user		D. SUSPECT MEDI	CAL DEVICE		(C	ontinue on page 3)
BLACK	facility for additional inforwriting with no results. No			1 Brand Nama			_	
BI	available at this time.			Olympu	s EVIS EXER	A II Du		
OR USE				2. Common Device Name Duodenvideoscope	!		FDT	rocode
RI				3. Manufacturer Name, C OLYMPUS MEDICAL SYS	ity and State	TON		
				2951 Ishikawa-cho,			192-850	)7, Japan
PLEASE TYPE				4. Model#	Lot#			5. Operator of Device
ΕI				TJF-Q180V Catalog #	N/A	D-4- (	felel ( a a a à	
AS				TJF-Q180V	Expiration	Date (mm N/A	/Ga/yyyy)	Lay User/Patient
PLE				Serial #		entifier (UE	)) #	Other:
_				UNK 6. If Implanted, Give Date	N/A	7 If Eve	lanted Ch	re Date (mm/dd/yyyy)
		(Continue on page 3)	┛	N/A	(IIIIIIuuwyyyy)	N/A	iamed, Giv	re Date (mm/dd/yyyy)
	6. Relevant Tests/Laboratory Data, Including	g Dates		8. Is this a Single-use De	vice that was Rep	rocessed	and Reuse	d on a Patient?
				Yes No 9. If Yes to Item No. 8, En	tor Name and Ad	drage of B		
				5. II 165 to Itelli No. 6, Eli	iter Ivallie allu Au	u1855 01 K	shi ocessoi	
					IO TOMPONIAL			
				10. Device Available for E	_		-	
				Yes V No	Returned to I	vianutaciur	эr on:	(mm/dd/yyyy)
		(Continue on page 3)		11. Concomitant Medical	Products and Th	erapy Date	s (Exclude	treatment of event)
	<ol> <li>Other Relevant History, Including Preexis race, pregnancy, smoking and alcohol use, h</li> </ol>	ting Medical Conditions (e.g., allergies, nepatic/renal dysfunction, etc.)						
							(0	Continue on page 3)
				E. INITIAL REPORT	ΓER			
				1. Name and Address			-	
				Allegheny Genera	-			
				320 East North A Pittsburgh, PA 1				
		(Continue on nece 2)		Phone #	Em	ail Address	i	
	Submission of a report does not con	(Continue on page 3)	_	2. Health Professional?	3. Occupation		4.	nitial Reporter Also Sent
	personnel, user facility, importer, dis caused or contributed to the event.	stributor, manufacturer or product		✓ Yes No	Risk Manage	r	!	Report to FDA  Yes No V Unk.
	or oomerwated to the evelit						1 '	<u>W</u>

### MEDWATCH

Page.	2 of	2
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FORM FDA 3500.	A (2/13)	(continue	1)	Page	2 of 2	_						
F. FOR USE BY	JSER FA	CILITY/IM	PORTER	(Devices Only)	H. D	EVICE MAN	UFACTU	RERS ONLY	1			
1. Check One		2	. UF/Impo	rter Report Number	1. Ty	pe of Reportable	Event		2. If F	ollow-up	, What Typ	e?
User Facility  3. User Facility or Imp	Impo				ן ן	Death Serious Injury Malfunction				Respo	ction onal Informa onse to FDA e Evaluation	Request
					11 _	vice Evaluated by	•		4. Dev	vice Man n/yyyy)	ufacture Da	ate
4. Contact Person			5. Pho	ne Number	1   1			mary Attached	Unk			
O Data Hans Facilities	- T				]   [	No (Attach pag provide code:	ge to explain	why not) or	5. Lab	eled for	Single Use	3
<ol> <li>Date User Facility of Importer Became Aware of Event (mm)</li> </ol>	- 1	7. Type of Re	port	8. Date of This Report (mm/dd/yyyy)					_  [	Yes	<b>√</b> No	
		Follow-u	p#		6. Ev	ent Problem and	Evaluation	Codes (Refer to	o coding ma	anual)		
9. Approximate Age of Device	10. Event F			coding manual)	11	Patier Code	nt 17	35 -		7-[		
Age of Device	Patient Code		7-	]-[		Device Code	1 10	91 -	2303	<u> </u>		=
	Device Code	·	٦-٢	-		Method	d	7-	7-[		-	<u> </u>
11. Report Sent to FDA	17	12. Locatio	n Where Ev	vent Occurred	1	Result	s	7-	٦	二.		<u></u>
Yes(mm/dd/	Anand	Hos	•	Outpatient Diagnostic Facility			[	7=	$\exists \vdash$			
∐ No		Hor Nur	ne sing Home	Ambulatory		Conclusion	s 67	92				
13. Report Sent to Man	nufacturer?	=	patient Trea	Surgical Facility	7. If F	Remedial Action I	Initiated, Ch	eck Type	8. Usage	of Device	a	
Yes(mm/dd/	(yyyy)	Fac	ility			Recall	Notifica	ation	=		of Device	
∐ No ,		Oth	er:	(Specify)	ַן ן	Repair	Inspec		_	Reuse Unknown		
14. Manufacturer Name	e/Address				1   Լ	Replace Relabeling	Patien	t Monitoring			ed to FDA u	nder
						Other:	☐ Adjust	nent	remova	al reporti	list correcti ing number:	
G. ALL MANUFA	CTURER	98			┛╏╴╴	Additional Ma			and / or	11. [	_	ted Data
Contact Office (and			Devices)	2. Phone Number		device ref urned to Ol						
Name				· _	info	ormation be	comes a	vailable t				
Address				3. Report Source (Check all that apply)	sup	plemented a	ccordin	gly.				
				Foreign	11							
OLYMPUS AMERICA 2400 Ringwood A	•			Study		part of our mpus Endosc						od an
San Jose, CA 95				Literature		Service and						
Email Address				Consumer		user facil						that
				Health Professional	rep	rocessing o	of duode	nvideoscop	pes cor	rectly	. Fresh	water
4. Date Received by Manufacturer (mm/d	IdAnna)	5.		User Facility		not being		-	-	•		
03/09/20		(A)NDA#		Company Representative		e being use ms were not						
6. If IND, Give Protoco		IND#		Distributor	eaci	h use. Addi	tionall	y, this ac	ccount	uses a	third	party
•		BLA#		Other:	scor	repairs an pe.	ıd was u	nsure or t	tne ser	ial nu	mber of	the
7. Type of Report		PMA/ 510(k) #	K080403	3		•						
(Check all that apply)		Combinati	on		.							
5-day	•	Product	Y	es								
☐ 7-day ☐ Perio ☐ 10-day ☑ Initial		Pre-1938		es	11							
	w-up#	OTC Prod	uct Y	es	$\cdot   \cdot  $							
9. Manufacturer Repor	t Number	8. Adverse	Event Ter	m(s)								
2951238-2015-0	0127											
,												
		_l			J L							

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# Boca Raton Regional Hospital Boca Raton, Florida

MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting Mfr Report #: 2951238-2015-00184

UF/Importer Report #:

Form Code:

MEDVAICH	for MANDATOI	and manufacturers	- Thisperior rep				
FDA eSubmitter Generated Form 3500A	IOI MANDATOI	XI reporting	Form Code:				
A. PATIENT INFORMATION							
1. Patient Identifier (In confidence)				4. Weight			
B. ADVERSE EVENT OR PRODUCT PROBLEM	<del></del> .						
1. [X] Adverse Event and/or [ ] Product Problem	em (e.g., defects/malfun	ctions)					
2. Outcomes Attributed to Adverse Event (Checked all t			<del></del>				
[ ] Death		[ ] Disability	or Permanent D	Damage			
[ ] Life-threatening [ ] Hospitalization - initial or prolonged	[ ] Congenital Anomaly/Birth Defect [x] Other Serious (Important Medical Events)						
[ ] Required Intervention to Prevent Permanent	impairment/Damage (D	. [X] Other Se	rious (important	Medical Events)			
3. Date of Event (mm/dd/yyyy)	, , , , , , , , , , , , , , , , , , , ,	4. Date of this Report (n	m/dd/mm/				
06/11/2014	• •	04/14/2015					
5. Describe Event or Problem		<u> </u>					
Olympus was informed that a total of nine p Klebsiella pneumoniae, after having undergr However only six of those patients used an underwent a procedure using either a Fuji o Olympus followed up with the user facility ar disfectant in the AER disinfection process for they began to monitor and randomly culture	Olympus duodenovider Pentax duodenovider duodenovider duodenovider du duodenovider du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovide du duodenovid	they have implement	ed a double (2	y (ERCP) procedure, ures. The other three patients x's) with high level (HLD)			
they began to monitor and randomly culturer ranging from August 08, 2014 to December Infections with CRE-KP were confirmed utilized the patients were treated with antibiotics. It positive until a sixth patient tested positive ERCP procedure using the same duodenov positive, with the same ESBL strain. The du (2x's)HLD in the AER disinfection cycle. The duodenovideoscope was placed back in ser complete random testing to control the issue	12, 2014 after each raing test methods ran to was reported that the properties of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer of the transfer	neoscopes after cominad undergone a ERC ging from sputum, billere were no further is an Beta-Lactamase (E 101). On March 21, 2 s then sequestered, a was re-cultured and the comination of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequester of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent of the sequent	Thing tive patter.  Procedure.  Od, urine, live issues with the cases.  SBL) strain follouse the duode re-cleaned and cases.	The initial five patient rapprate, and bile drainage. duodenovideoscopes testing lowing the March 16, 2015 enovideoscope cultured i underwent double			
This is the first of six reports.				•			
6. Relevant Tests/Laboratory Data, Including Dates Blood and urine test on 12/12/2014							
<ol> <li>Other Relevant History, Including Preexisting Medica Pancreatic carcinoma</li> </ol>	al Conditions (e.g., allergie	s, race, pregnancy, smokir	g and alcohol use,	hepatic/renal dysfunction, etc.)			
C. SUSPECT PRODUCT(S)							
Section C is not applicable to devices.			• • •				
D. SUSPECT MEDICAL DEVIÇE	· · · · · · · · · · · · · · · · · · ·						
1. Brand Name		2. Common Device Nam	е				
Olympus EVIS EXERA II DUODENOVIDEOSCOP	E	Duodenovideoscope,		FDT			
3. Manufacturer Name, City and State		4. Model #	To	Catalog #			
OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho,		TJF-Q180V		TJF-Q180V			
Hachioji-shi, Tokyo, 192-8507, Japan, JA		Serial # 2102101	1	Lot#			
·		Expiration Date (mm/dd/	<i>(</i>	Other#			
5. Operator of Device		6. Implanted Date (mm/c	ld/yyyy)	7. Explanted Date (mm/dd/yyyy)			
Health Professional							
8. Is this a Single-Use Device that was reprocessed and	Reused on a Patient?						
( ) Yes ( • ) No ( ) No Information							
9. Reprocessor Name and Address		10. Device Available for  ( ) Yes  (•) No  ( ) No information  [ ] Returned to Ma	·	not send to FDA)			

MEDWATCH

For use by user-facilities, for MANDATORY reporting

Mír Report #:	2951238-2015-00184
UF/Importer Report #:	
Farm Carles	

importers, distributors and manufacturers FDA eSubmitter Generated Form 3500A 11. ConComitant Medical Products and Therapy Dates (Excludes treatment of event) Medivator DSD-Edge Pentax Duodenovideoscope Fuji Duodenovideoscope E. INITIAL REPORTER 1. Name and Address 2. Health Professional? (*) Yes ( ) No ( ) No Information Boca Raton Regional Hospital, Inc. 3. Occupation 800 Meadows Road Boca Raton, FL 33486-2368, US Physician 4. initial Reporter Also Sent Report to FDA? ( ) Yes ( ) No ( • ) Unknown ( ) No Information F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) 1. User Facility or Importer 2. User Facility/importer Number ( ) User Facility ( ) Importer 3, 4, and 5. User Facility or importer Name/Address, Contact Person, and Phone Number 6. Date UF/Importer Became Aware of Event (mm/dd/yyyy) 7. Type of Report ( ) Initial ( ) Follow-up 8. Date of This Report (mm/dd/yyyy) 9. Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) 14. Manufacturer Name/Address Patient Code(s): 1735 CA, US Device Code(s): 2303 11. Report Sent to FDA? ( ) Yes ( ) No ( ) No Information 12. Location Where Event Occurred 13. Report Sent to Manufacturer? ( ) Yes ( ) No ( ) No Information G. ALL MANUFACTURERS 1, 2. Contact Office - Name/Address/Phone Number 1, 2. (Continued) Manufacturing Site Address/Phone for Devices Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) 4. Date Received by Manufacturer (mm/dd/yyyy) [ ] Foreign [X] Health Professional [ ] Study [X] User Facility 5. PMA/510(k) [ ] Literature [X] Company Representative K080403 [ ] Consumer [ ] Distributor [ ] Other 6. If IND, Give Protocol # 7. Type of Report 9. Manufacturer Report Number 8. Adverse Event Term(s) [ ] 5-day [x] Initial [ ] Follow-up 2951238-2015-00184 H. DEVICE MANUFACTURERS ONLY 2. If Follow-up, What Type? 1. Type of Reportable Event 3. Device Evaluated by Manufacturer? () Death [ ] Correction [ ] Not Returned to Manufacturer (•) Serious Injury [ ] Additional Information ( ) Yes [ ] Evaluation Summary Attached ( ) Malfunction [ ] Response to FDA Request (•) No ( ) No Information [ ] Device Evaluation

[ ] No Information

For use by user-facilities,

Mfr Report #:	2951238-2015-00184
UF/Importer Report #:	
Form Code:	

MEDWATCH	importers, distributors and n		UF/Importer R	eport #:
FDA eSubmitter Generated Form 3500A	for MANDATORY re	porting	Form Code:	
4. Device Manufacture Date (mm/dd/yyyy)		/aluation Codes (Rethod Code(s): 332		nual)
5. Labeled for Single Use?	Re	sult Code(s):		
( ) Yes ( ) No ( ) No Information	. Co	nclusion Code(s):	20 - 67	
7. If Remedial Action Initiated, Check Type  [ ] Recall [ ] Notification [ ] Repair [ ] Inspection [ ] Replace [ ] Patient M. [ ] Relabeling [ ] Modification [ ] Other	on (	) Unknown		9. If action reported to FDA under 21 USC 360l(f), list correction/removal reporting number
10. [X] Additional Manufacturer Narrative and/ The device referenced in this report has independent laboratory for further testing exact cause of the user's experience couladditional and significant information bed As part of our investigation with this reportacility's reprocessing practices. During the pre-cleaning, manual cleaning w/HLD, Riusing a Medivator DSD-Edge AER. It was removing from the AER. The customer worked that the user facility was not using Please cross-reference the associated of 2951238-2015-00185, 2951238-2015-00	been returned to Olympus for Once returned a physical end on the conclusively determined a physical end on the conclusively determined as a conclusively determined as a conclusively determined on the constant of the customatic of the conclusion of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic of the customatic o	valuation will be nined at this time ecialist (ESS) v cessing practice not demonstra mer sometimes need to be hung dapter), as reco	performed or e. A supplement isited the use es were discusted as the cus lay down the g immediately mmended in	n the referenced device. The ental report will be submitted if refacility to observe the user used such as manual cleaning, stomer stated that they are ir scopes coiled up after after the HLD process. It was the instruction manual.
File Attachments				
No files attached.			·	· · · · · · · · · · · · · · · · · · ·

# **Carolinas Medical Center, Charlotte North Carolina**

### **MEDWATCH**

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00254
UF/Importer Report #:	
Form Code:	

FDA eSubmitter Generated Form 3500A	IOI WIANDATORI	Toporting	rorm Code:		
A. PATIENT INFORMATION					
1. Patient Identifier (In confidence)					4. Weight
			<b>.</b>		
B. ADVERSE EVENT OR PRODUCT PROBLEM					
1. [X] Adverse Event and/or [ ] Product Problem	(e.g., defects/malfunct	tions)			
2. Outcomes Attributed to Adverse Event (Checked all that	t apply)				
[x] Death		[ ] Disability	or Permanent D	)amage	
[ ] Life-threatening			al Anomaly/Birth		
<ul><li>[ ] Hospitalization - initial or prolonged</li><li>[ ] Required Intervention to Prevent Permanent im</li></ul>	nairment/Damage (De)		rious (Important	iviedicai Ev	/ents)
	·				··
3. Date of Event (mm/dd/yyyy)	'	4. Date of this Report (mi 05/14/2015	n/aa/yyyy)		
	<u> </u>	03/14/2013			
5. Describe Event or Problem			ton diad in OO	10 00 0 70	nult of annhancement
In an article published on May 15, 2015, it was resistant Enterobacteriacaea (CRE) infection	s reported that a pati following an ERCP p	rocedure using an C	lympus duode	noscope.	suit of carbapenem-
Olympus followed up with the user facility in a results after multiple inquiries.	n effort to obtain add	litional information re	garding the re	ported ev	ent, but with no
6. Relevant Tests/Laboratory Data, Including Dates					
7. Other Relevant History, Including Preexisting Medical	Conditions (e.g., allergies	, race, pregnancy, smokin	g and alcohol use	, hepatic/ren	al dysfunction, etc.)
C. SUSPECT PRODUCT(S)					
Section C is not applicable to devices.					
D. SUSPECT MEDICAL DEVICE					
1. Brand Name		2. Common Device Nam	е		
EVIS EXERA II Duodenovideoscope		Duodenoscope, Prod	uct Code: FDT		
3. Manufacturer Name, City and State		4. Model #		Catalog #	
Olympus Medical System Corporation		TJF-Q180V		TJF-Q180	V
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, JA	ļ l	Serial #		Lot#	
11d61li0ji-31li, 10kyo 192-0007, 0A.		Unk		N/A	
		Expiration Date (mm/dd/	yyyy)	Other#	
5. Operator of Device		6. Implanted Date (mm/d	d/yyyy)	7. Explante	d Date (mm/dd/yyyy)
Health Professional		·			
8. Is this a Single-Use Device that was reprocessed and F	Reused on a Patient?				
( ) Yes ( • ) No ( ) No Information					
9. Reprocessor Name and Address		10. Device Available for	Evaluation? (Do	not send to	FDA)
•		() Yes			4
		(•) No			
		( ) No Information			
		[ ] Returned to Ma	nufacturer		
11. ConComitant Medical Products and Therapy Dates (E	xcludes treatment of even	t)			
E. INITIAL REPORTER					
1. Name and Address		2. Health Professional?		<u>.</u>	
Carolinas Madisal Carola		(●) Yes ( ) No	( ) No Inform	mation	
Carolinas Medical Center 1000 Blythe Blvd.	Ţ	3. Occupation			
Charlotte, NC 28203-5871, US		Risk Manager			
		4. Initial Reporter Also S	Sent Report to FI	 DA?	
Email:Unk		() Yes () No			o Information
F. FOR USE BY USER FACILITY/IMPORTER (Devi	ces Only)				
1. User Facility or Importer	,	2. User Facility/Importer	Number		
	1	• •			

#### **MEDWATCH**

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00254
UF/Importer Report #:	
Form Code:	

### FDA eSubmitter Generated Form 3500A

( ) User Facility ( ) Importer 3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number 6. Date UF/Importer Became Aware of Event (mm/dd/yyyy) 7. Type of Report () Initial () Follow-up 8. Date of This Report (mm/dd/yyyy) 9. Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) 14. Manufacturer Name/Address Patient Code(s): 1735 - 1802 Device Code(s): 2303 11. Report Sent to FDA? ( ) Yes ( ) No ( ) No Information 12. Location Where Event Occurred 13. Report Sent to Manufacturer? ( ) Yes ( ) No ( ) No Information **G. ALL MANUFACTURERS** 1, 2. Contact Office - Name/Address/Phone Number 1, 2. (Continued) Manufacturing Site Address/Phone for Devices Olympus America, Inc. 2400 Ringwood Avenue San Jose, CA 95131, US 3. Report Source (Check all that apply) 4. Date Received by Manufacturer (mm/dd/yyyy) [ ] Foreign [ ] Health Professional 05/14/2015 [ ] Study [ ] User Facility 5. PMA/510(k) [X] Literature [ ] Company Representative K080403 [X] Consumer [ ] Distributor [ ] Other 6. If IND, Give Protocol# 7. Type of Report 8. Adverse Event Term(s) 9. Manufacturer Report Number [ ] 5-day [x] Initial [ ] Follow-up 2951238-2015-00254 H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event 2. If Follow-up, What Type? 3. Device Evaluated by Manufacturer? (•) Death [ ] Correction [ ] Not Returned to Manufacturer ( ) Serious Injury [ ] Additional Information ( ) Yes [ ] Evaluation Summary Attached ( ) Malfunction [ ] Response to FDA Request (•) No ( ) No Information [ ] Device Evaluation [ ] No Information 4. Device Manufacture Date (mm/dd/yyyy) 6. Evaluation Codes (Refer to coding manual) Method Code(s): Result Code(s): 5. Labeled for Single Use? Conclusion Code(s): 67 - 92 ( ) Yes ( • ) No ( ) No Information 7. If Remedial Action initiated, Check Type 9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number 8. Usage of Device [ ] Recall-[ ] Notification ( ) Initial Use of Device [] Repair [ ] Inspection (•) Reuse [] Replace [ ] Patient Monitoring ( ) Unknown [ ] Relabeling [ ] Modification/Adjustment ( ) No Information [] Other 10. [X] Additional Manufacturer Narrative and/or 11. [ ] Corrected Data No device was returned to Olympus for evaluation. The exact cause of the source of the infection is unknown and the exact cause of death is unknown. This report will be updated accordingly if additional information becomes available at a later time.

### **MEDWATCH**

FDA eSubmitter Generated Form 3500A

# For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00254
UF/Importer Report	#:
Form Code:	

 $Please\ cross\ reference\ MFR.\ Report\ Numbers:\ 2951238-2015-00258,\ 2951238-2015-00259,\ and\ 2951238-2015-00281.$ 

#### File Attachments

No files attached.

### **MEDWATCH**

For use by user-facilities, importers, distributors and manufacturers

Mfr Report #:	2951238-2015-00281
UF/Importer Report #:	
Form Code:	

DA eSubmitter Generated Form 3500A	for MANDATOR	Y reporting	Form Code:	
A. PATIENT INFORMATION				
1. Patient Identifier (In confidence)	2. Age at Time of Event, D	ate of Birth	3. Sex No Information	4. Weight
B. ADVERSE EVENT OR PRODUCT PROBLEM	Л			
1. [x] Adverse Event and/or [ ] Product Pro	oblem (e.g., defects/malfun	ctions)		
2. Outcomes Attributed to Adverse Event (Checked	all that apply)			
<ul> <li>[x] Death</li> <li>[ ] Life-threatening</li> <li>[ ] Hospitalization - initial or prolonged</li> <li>[ ] Required Intervention to Prevent Permane</li> </ul>	ent impairment/Damage (Do	[ ] Congenita [ ] Other Ser	or Permanent Damage Il Anomaly/Birth Defect ious (Important Medical E	vents)
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (mn 05/14/2015	n/dd/yyyy)	
5. Describe Event or Problem				
Olympus became aware of a news article carbapenem-resistant Enterobacteriacae hospital; three acquired it in the hospital, how the three became infected in the hosinformation regarding the reported event, In an article published on May 15, 2015, result of CRE infection following an ERCI an Olympus product was allegedly associated as a report for the three CRE cases of duodenoscope may have been associated earlier this year.	a (CRE) in the first mon- and one died. The causipital. Olympus followed but with no results after it was reported that a para procedure using an Olated with CRE infection discussed in the Februa	ths of 2015. Of those, se of death was not read up with the user facility multiple inquiries.  Intient at the same med ympus duodenoscope at the medical center by 2015 article based of	15 had CRE upon adnorted. No details were ty in an effort to obtain ical center had alleged. Because the May 15 in 2013, Olympus has on the possibility that a	nission to the e reported about additional  ly died in 2013 as a article reports that determined to n Olympus
6. Relevant Tests/Laboratory Data, including Dates				
7. Other Relevant History, Including Preexisting Me	dical Conditions (e.g., allergio	es, race, pregnancy, smoking	g and alcohol use, hepatic/rer	nal dysfunction, etc.)
C. SUSPECT PRODUCT(S)				
Section C is not applicable to devices.				
D. SUSPECT MEDICAL DEVICE				
1. Brand Name		2. Common Device Name		
EVIS EXERA II Duodenovideoscope		Duodenoscope, Produ		
3. Manufacturer Name, City and State Olympus Medical System Corporation		4. Model # Unk	Catalog # Unk	
2951 Ishikawa-cho,				
Hachioji-shi, Tokyo 192-8507, JA		Serial # Unk	Lot #	
		Expiration Date (mm/dd/y	yyy) Other#	
5. Operator of Device		6. Implanted Date (mm/de	d/yyyy) 7. Explante	d Date (mm/dd/yyyy)
Health Professional		<u></u>		
8. Is this a Single-Use Device that was reprocessed  ( ) Yes ( ● ) No ( ) No Information	and Reused on a Patient?			
9. Reprocessor Name and Address		10. Device Available for	Evaluation? (Do not send to	FDA)
		( ) Yes ( • ) No ( ) No Information [ ] Returned to Mar	nufacturer	
11. ConComitant Medical Products and Therapy Da	tes (Excludes treatment of eve	ent)		
E. INITIAL REPORTER				
1. Name and Address		2. Health Professional?		-
Carolinas Medical Center		(•) Yes () No	( ) No Information	
1000 Blythe Blvd.		3. Occupation		

### **MEDWATCH**

### For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00281
UF/Importer Report #:	
Form Code:	

FDA eSubmitter Generated Form 3500A	IOFMANDATOR	1 reporting	Form Code:	
Charlotte, NC 28203-5871, US		Risk Manager		
Email:Unk		4. Initial Reporter Also S  ( ) Yes ( ) No	="	A? n () No Information
F. FOR USE BY USER FACILITY/IMPOR	TER (Devices Only)			
User Facility or Importer		2. User Facility/Importer	Number	
3, 4, and 5. User Facility or Importer Name/Ad Phone Number	dress, Contact Person, and	6. Date UF/Importer Bec	ame Aware of Ev	rent (mm/dd/yyyy)
•		7. Type of Report		
		() Initial () Fo	llow-up	
		8. Date of This Report (r	mm/dd/yyyy)	9. Approximate Age of Device
10. Event Problem Codes (Refer to coding mar Patient Code(s): 1735 - 1802 Device Code(s): 2303	nual)	14. Manufacturer Name/	Address	
11. Report Sent to FDA?				•
( ) Yes ( ) No ( ) No Information	on		•	
12. Location Where Event Occurred				
				•
13. Report Sent to Manufacturer?		•		
( ) Yes ( ) No ( ) No Information	on			
G. ALL MANUFACTURERS  1, 2. Contact Office - Name/Address/Phone N		101011		dress/Phone for Devices
Olympus America, Inc. 2400 Ringwood Avenue San Jose, CA 95131, US				
3. Report Source (Check all that apply)		4. Date Received by Ma	nufacturer (mm/c	dd/yyyy)
	alth Professional	05/14/2015		
	npany Representative	5. PMA/510(k)		
	ributor	Unk		
[ ] Other		6. If IND, Give Protocol	#	
7. Type of Report		8. Adverse Event Term(	(e)	9. Manufacturer Report Number
[ ] 5-day [x] Initial [ ] Follow-u	p	o. Autoroo Eterni fermi	(0)	2951238-2015-00281
H. DEVICE MANUFACTURERS ONLY				
1. Type of Reportable Event       2. If         (●) Death       [         ( ) Serious Injury       [         ( ) Malfunction       [         ( ) No Information       [	Follow-up, What Type?  Correction  Additional Information  Response to FDA Request  Device Evaluation  No Information	3. Device Evaluated by  [ ] Not Returned to  ( ) Yes [ ] Evaluated by	o Manufacturer	ary Attached
4. Device Manufacture Date (mm/dd/yyyy)		6. Evaluation Codes (R	efer to coding ma	nual)
		Method Code(s):		
5. Labeled for Single Use?		Result Code(s):	67 00	
( ) Yes (•) No ( ) No Information	on	Conclusion Code(s):	b/ - 92	
7. If Remedial Action Initiated, Check Type		8. Usage of Device		9. If action reported to FDA under 21 USC 360i(f), list correction/removal
[ ] Recall [ ] Noti	ification pection	() Initial Use of Do (●) Reuse	evice	reporting number

# For use by user-facilities,

Mfr Report #:	2951238-2015-00281
UF/Importer Report #:	
Form Code:	
Tomicode.	

MEDWATCH FDA eSubmitter Generated Form 3500A	importers, distributors and manufactur for MANDATORY reporting	rers UF/Importer Report #:
[ ] Replace [ ] Patient N	Monitoring ( ) Unknov tion/Adjustment ( ) No Info	
cause of death is unknown. This report	evaluation. The exact cause of the sou will be updated accordingly if additiona	arce of the infection is unknown and the exact Il information becomes available at a later time. 2015-00258, and 2951238-2015-000259.
File Attachments		
No files attached.		

# Cedars-Sinai Medical Center Torrance, California



March 20, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

U.S. Department of Health and Human Services

Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

MEDWATCH

BLACK

USE

PLEASE TYPE OR

Page 1 of 2 FORM FDA 3500A (2/13) A. PATIENT INFORMATION 1. Patient identifier | 2. Age at Time 3. Sex 4. Welght Female 01 Date 出つ Male In confidence of Birth: kgs B. ADVERSE EVENT OR PRODUCT PROBLEM Adverse Event and/or Product Problem (e.g., defects/maifunctions) #2 **Outcomes Attributed to Adverse Event** (Chack all that apply) Death: unk Disability or Permanent Damage (mm/ad/yyyy) Life-threatening Congenital Anomaly/Birth Defect #2 Other Serious (Important Medical Events) Hospitalization - initial or prolonged 6. Lot# Required intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 08/01/2014-02/28/2015 03/04/2015 9. NDC# or Unique ID 5. Describe Event or Problem Olympus was informed that four patient's may have been infected by a "drug resistant organism" of Carbapenemresistant enterobacteriaceae (CRE) from one Olympus duodenoscope in use from August 2014 to mid-February 2015. It was further reported that one of the four infected patient's expired. The cause of death is unknown. However, it was reported that the death was unrelated to a CRE infection. Olympus made multiple attempts to obtain additional information via telephone and in writing, but with no success. This is one of four reports. Ünk Catalog # Unk Serial# Unk (Continue on page 3) 6. Relevant Tests/Laboratory Data, including Dates (Continue on page 3) Other Refevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

FDA Use Only C. SUSPECT PRODUCT(S) Therapy Dates (If unknown, give duration) from/lo (or best estimate) 2. Dose, Frequency & Route Used #1 #2 4. Diagnosis for Use (Indication) 5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't Doesn'i #2 Yes No 7. Exp. Date 8. Event Reappeared After Reinfroduction? #1 Yes No Doesn' Apply #2 #2 Yes No 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) D. SUSPECT MEDICAL DEVICE 1. Brand Name Olympus Duodenovideoscope 2b. Procode 2. Common Device Name Duodenovideoscope KOG 3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Lot# 5. Operator of Device N/A ✓ Health Professional Expiration Date (mm/dd/yyyy) Lay User/Patient n/A Unique Identifier (UDI)# Other: 7. If Explanted, Give Date (mm/dd/yyyy) 6. If Implanted, Give Date (mm/dd/yyyy) N/A 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes V No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude trealment of event) (Continue on page 3) E. INITIAL REPORTER 1. Name and Address Cedars-Sinai Medical Center 4100 W. 190th Street Torrance, CA 90504-5513 Emall Address Phone# 2. Health Professional? 3. Occupation

Risk Manager

Yes No

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

(Continue on page 3)

OCA 0001227

Yes No V Unk

			FDA USE ONLY
MEDWATCH			_
FORM FDA 3500A (2/13) (cc	ontinued)	Page 2	2 of 2
F. FOR USE BY USER FACE	LITY/IMPORTER_(D	evices Only)	H. DEVICE MANUFACTURERS ONLY
1. Check One	2. UF/Importer R		1. Type of Reportable Event 2. If Follow-up, What Type?
User Facility Importe	r		☑ Death ☐ Coπection
3. User Facility or Importer Name/Ad	dress		Serious injury Additional Information
			Malfunction Response to FDA Request
			Device Evaluation
			3. Davice Evaluated by Manufacturer?  4. Device Manufacture Date
, ·			✓ Not Returned to Manufacturer (mm/yyyy)
4. Contact Person	5. Phone N	umber	Yes Evaluation Summery Attached Unk
			No (Attach page to explain why not) or provide code:
6. Date User Facility or 7.	Type of Report	8. Date of This Report	provide code:
Importer Became Aware of Event (mm/dd/yyyy)	Initial	(mm/dd/yyyy)	
1	Follow-up#	l	6. Event Problem and Evaluation Codes (Refer to coding menual)
	blem Codes (Refer to codi	nn menuel)	Patient 1802 - 1735 -
9. Approximate 10. Event Pro			Code
Code			Code 1120 - 2303 -
Device	]_		Method ————————————————————————————————————
Code	O A continuity		
	2. Location Where Event    Hospital	Occurred  Oulpatient	Results
Yes(mm/dd/yyyy)	Hospital Home	Diagnostic Facility	Conclusions 20 - 92 -
□ No	Nursing Home	Ambulatory	001000010
13. Report Sent to Manufacturer?	Outpatient Treatme	Surgical Facility	7. If Remedial Action Initiated, Check Type 8. Usage of Device
Yes	Facility		Recall Notification Initial Use of Device
No .	Other:	(Specify)	Repair Inspection Viknown
14. Manufacturer Name/Address		(0,000,0)	1 Replace   Pallett Worldown
			Relabeling Modification/ Adjustment Relabeling Modification/ Adjustment Relabeling Photography States Relabeling Photography States Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Relabeling Photography Photography Relabeling Photography Photography Photography Photography Photography Photography Photography Photography Photography Photography Photography Photography
			Other:
			10.
G. ALL MANUFACTURERS			The device referenced in this report has not been
1. Contact Office (and Manufacturin		2. Phone Number	returned to Olympus for evaluation. The exact cause of
Name			the reported event could not be conclusively determined
		3. Report Source (Check all that apply)	at this time. However, an Olympus Endoscopy Support Specialist (ESS) has been scheduled to visit the site to
Address		1	perform a demonstration of Olympus recommended
OLYMPUS AMERICA, INC		Foreign	reprocessing practice.
2400 Ringwood Avenue San Jose, CA 95131		Study	If additional information becomes available at a later
om 0000\ 08 30121		Literature  Consumer	time, this report will be supplemented.
Email Address		Consumer    Consumer	
		User Facility	Please cross reference mfr. report numbers: 2951238-2015-00095, 2951238-2015-00140, and
4. Date Received by Manufacturer (mm/dd/yyyy)	5.	Company	2951238-2015-00095, 2951238-2015-00140, and 2951238-2015-00141.
03/04/2015	(A)NDA#	Representative	
6. If IND, Give Protocol#	IND#	Distributor	
	BLA#	Other:	
7. Type of Report	PMA/		
(Check all that apply)	510(k)#	-	· ·
5-day	Combination Yes		_
7-day Perfodic	Pre-1938 Yes		-
10-day Initial	OTC Product Yes		_
15-day Follow-up#			]1
9. Manufacturer Report Number	8. Adverse Event Term(s	3)	11
2951238-2015-00094	1		I I

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and meinteining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Heelih and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@ida.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

# Charite-Universitatsmedizin Berlin, Germany



Date: April 25, 2013

Report Type: Manufacturer Report

8010047-2013-00092

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

### Sincerely,



For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	See OMB statement on	revers
Mfr Report# 8010	0047-2013-00092	
UF/Importer Report	#	

#### **MEDWATCH**

FORM FDA 350	0A (1/09)		Page 1	of 15				
A. PATIENT INF	<b>(</b> ,			C. SUSPECT PROD	UCT/S)		FDA	Use Only
1. Patient Identifier		3. Sex	4. Weight	Name (Give labeled street				
Unk	of Event: Unk		1 1	#1 N/A	G maridoolorj	,		
	or	Female	or lbs					
In confidence	of Birth: Unk	☐ Male	Unk kgs	#2 N/A	uto line d	la Therman	W1	,
B. ADVERSE EV	VENT OR PRODUCT P	ROBLEM		2. Dose, Frequency & Rou	Tre 0290	3. Therapy Dates ( from/to (or best e	ii unknown, give d istimate)	turation)
1. Adverse Even	t and/or Product F	Problem (e.g., defects/mall	unctions)	#1 N/A		#1		
2. Outcomes Attribut		·		#2 N/A		#2		
(Check all that appl	_	Disability or Permanent Da	mana	4. Diagnosis for Use (India	cation)		Abated After Use ed or Dose Reduc	
=	(mm/dd/yyyy)	-	, I	#1 N/A			es No	Doesn't
Life-threatenin		Congenital Anomaly/Birth I Other Serious (Important M		#2 N/A				Apply
	vention to Prevent Permanent			6. Lot#	7. Exp. Date	#2 🗀 Y	es No	Doesn'i Apply
3. Date of Event (mn		ate of This Report (mm/do		#1N/A	#1 N/J		Reappeared Afte	r
1	Unk	3/27/2013		#2N/A	#2 N/3		es No	Doesn't
5. Describe Event or				9. NDC# or Unique ID				Apply
	evice was returned r repair purpose. (					#2 🔲 Y		Doesn't Apply
repaired the	subject device as r	outine work. Aft	er that,	10. Concomitant Medical S	Products and The	rapy Dates (Exclude	treatment of event	i)
	the information tha			N/A				
	with the subject de cording to informat							
the same bact	eria was not detect	ed from the subj						
device. There	was no additional	information.		D. SUSPECT MEDIC	CAL DEVICE			
				1. Brand Name	YERA II DUO	DENOVIDEOSCOPI		
			)					
			Ì	2. Common Device Name		SCOPE		
				3. Manufacturer Name, Cit OLYMPUS MEDICAL SYS 2951 Ishikawa-cho H	TEMS CORPORAT	TION. , Tokyo, 192-850	07 Japan	
				4. Model #	Lot #		5. Operator of D	evice
			- 1	TJF-Q180V	N/A		Health Profe	essional
				Catalog # N/A	Expiratio	n Date (mm/dd/yyyy)	Lay User/Pa	atient
			- 1	Serial #	Other#		Other:	
			- 1	2000700	N/A			
				6. If implanted, Give Date	(mm/dd/yyyy)	7. If Explanted, Giv	e Date (mm/dd/yy	(YY)
6. Relevant Tests/Lal	boratory Data, Including Date	es		8. Is this a Single-use Dev	ice that was Rep	rocessed and Reuse	d on a Patient?	
				9. If Yes to Item No. 8, Ent	er Name and Add	ress of Reprocessor		
				10. Device Available for E	valuation? (Do	it send to EDA		
					Returned to M	,	form (ddf	
				11. Concomitant Medical F	Products and The	erapy Dates (Exclude	(mm/dd/yyyy) treatment of even	t)
7. Other Relevant His	story, including Preexisting N	Medical Conditions (e.g., a	flergies,	N/A		,	3. 4.3/1	-
unk	noking and alcohol use, hepatic	orenai dysfunction, etc.)	- 1					
				E. INITIAL REPORT	ER			
				1. Name and Address	Phone	#		
				Charite-Universit	atsmedizin	Berlin		
			1	Campus Virchow-Kl	inikum Humb			
				Universitat zu Be Augustenburger Pl				
				13353 Berlin Germ				
	eport does not constitu			2. Health Professional?	B. Occupation	4. [	nitial Reporter Al Report to FDA	lso Sent
caused or contrib	uted to the event.	noi, manufacturer or	product	Yes No		i 1	Yes No	Unk.

MEDWATCH				FDA USE ONLY
	entinued)	Page 2	of 15	
ORM FDA 3500A (1/09) (co F. FOR USE BY USER FACIL			H. DEVICE MANUFACTURERS ONL	Υ
F. FOR USE BY USER FACIL	2. UF/Importer Re		1. Type of Reportable Event	2. If Follow-up, What Type?
User Facility Importer			Death	Correction
3. User Facility or Importer Name/Ade	dress		Serious Injury	Additional Information
		i	Malfunction	Response to FDA Request  Device Evaluation
		ļ	Other: Potential Infection	
		j	3. Device Evaluated by Manufacturer?	4. Device Manufacture Date (mm/yyyy)
	15.51		✓ Not Returned to Manufacturer     ✓ Yes	August/2010
4. Contact Person	5. Phone Nur	nber	No (Attach page to explain why not) or	5. Labeled for Single Use?
6. Date User Facility or 7. 7	Type of Report 8	. Date of This Report	provide code:	Yes 🖓 No
Importer Became	Initial	(mm/dd/yyyy)		
-	Follow-up #		6. Evaluation Codes (Refer to coding manual)	
, _	blem Codes (Refer to coding	menual)	Method	
Age of Device			Results	
Code	1735 -			
Device Code	3190 -	!-	Conclusions 67 92	<u>-</u>
11. Report Sent to FDA?	2. Location Where Event O		7. If Remedial Action Initiated, Check Type	8. Usage of Device
Yes	Hospital	Outpatient Diagnostic Facility	Recall Dotification	Initial Use of Device
No (mm/dd/yyyy)	Home	Ambulatory	Repair Inspection	Unknown
13. Report Sent to Manufacturer?	Nursing Home Outpatient Treatment	Surgical Facility	Replace Patient Monitoring  Relabeling Modification/	
Yes(mm/dd/yyyy)	Facility		Relabeling Modification/ Adjustment	9. If action reported to FDA under 21 USC 360I(f), list correction/ removal reporting number:
□ No (///////////////////////////////////	Other:	(Specify)	Other:	-
14. Manufacturer Name/Address			10. Additional Manufacturer Narrative	and / or 11. Corrected Data
G. ALL MANUFACTURERS			Since the subject device had repaired, OLYMPUS MEDICAL SYS evaluate it. Thus, OMSC canno the cause of this event. Howe as a possible cause of this p	TEMS CORP. (OMSC) could not t conclusively determine ver, it can be considered henomenon that patients
Contact Office - Name/Address (a for Devices)	and Manufacturing Site	2. Phone Number	infected from other than the such as environmental factor the same bacteria was not det	in the facility, because
OLYMPUS MEDICAL SYSTEM 2951 Ishikawa-cho, Hac		Report Source (Check all that apply)	device.	
192-8507, Japan	chioji dhi, idhiya	Foreign	This report is being submitte	d as a medical device
İ		Study	report in an abundance of car	icion.
		Literature Consumer		(
		Health Professional	11	
4. Date Received by	5,	User Facility	<b>\</b> \	
Manufacturer (mm/dd/yyyy)	(A)NDA#	Company Representative		
3/28/2013	IND#	Distributor	1 1	
6. If IND, Give Protocol #	STN#	Other:		
	PMA/		.	
7. Type of Report (Check all that apply)	510(k) #	!		
5-day	Combination Yes			
7-day Periodic	Pre-1938 Yes		-	
☐ 10-day ☐ Initial	OTC Product Yes		-	
9. Manufacturer Report Number	8. Adverse Event Term(s)		<del> </del>	
B010047-2013-00092				
0010041-2012-00032			11	
The public reporting burden for this commutes per response, including the till sources, gathering and maintaining the collection of information. Send communications are communications of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communication of the communi	me for reviewing instructions	, searching existing data ng and reviewing the timate or any other aspect o	Office of Chief Information Officer (HFA-710)	OMB Statement: "An agency may not conduct or spons and a person is not required to respon to, a collection of information unless it displays a currently valid OMB control number."

OCA_0001697



Date: July 5, 2013

Report Type: Manufacturer Report

8010047-2013-00092

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is a supplemental report for a previously reported 30-Day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

(



For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

JF/Importer Report #	//ir Report#	8010047-2013-00092	
	JF/Importer I	Report#	

#### **MEDWATCH**

FOR

Page 1 of 15

FORM FDA 350	UA (1/09)			raye i			<u> </u>	FDA Use On
A. PATIENT IN					C. SUSPECT PRO			
1. Patient Identifier	of Event:		3. Sex	4. Weight	1. Name (Give labeled str #1 N/A	rength & mfr/labeler)		
	or		Female	or	#2 N/A			<u></u>
in confidence	of Birth:		Male Male	kgs	2. Dose, Frequency & R	oute Used	3. Therapy Dates	(If unknown, give duration
_	VENT OR PRODU		• •	6	#1 N/A		from/to (or best #1	estimate)
1. Adverse Ever	ited to Adverse Event	oduct Problem (é	.g., aerects/mail	unctions)	#2 N/A		#2	
(Check all that app					4. Diagnosis for Use (In	dication)		t Abated After Use
Death:	(mm/dd/yyyy)	_ Disability of	r Permanent Da	amage	#1 N/A		i	ped or Dose Reduced? Yes No Does
Life-threateni	•	_	Anomaly/Birth i	1	#2 N/A			— Apply
1 - '	n - initial or prolonged	_	ous (Important N	1	6. Lot#	7. Exp. Date	#2 🗌	Yes No Does
	ervention to Prevent Perm				#1N/A	#1 N/F		t Reappeared After troduction?
3. Date of Event (m	m/aa/yyyy)	4. Date of This	Report (Innivo	uryyyy)	#2N/A	#2 N/A		Yes No Does
5. Describe Event o	r Problem				9. NDC# or Unique ID			
	oplemental repor- -00092 to provid						#2 []	Yes No Apply
BfArM, Compet A patient who pneumoniae was the subject	report from the tent Authority : o had been diagon as examined on lidevice was used ation on twenty	in Germany. nosed with February 8t to carry c	Klebsiella h 2013. In ut another	n total, r twenty-	10. Concomitant Medica			•
February 8th	and March llth repair. Subseque	before it	was sent t	to	D. SUSPECT MED  1. Brand Name	ICAL DEVICE		
found 5 of the	nese patients.'	Two of the	five pation	ents have	2. Common Device Nan			
^ !	OLYMPUS MEDICAL cause of the p			ot been				
5					3. Manufacturer Name,	City and State		
2					4. Model#	Lot#		5. Operator of Device
-								Health Profession
35					Catalog #	Expiration	on Date (mm/dd/yyy	Lay User/Patient
Trease of the					Serial #	Other#		Other:
					6. If Implanted, Give Da	ite (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
6. Relevant Tests/L	aboratory Data, Includi	ng Dates			8. Is this a Single-use I	Device that was Rep	processed and Reu	sed on a Patient?
					9. If Yes to Item No. 8,	Enter Name and Ad	dress of Reproces	sor
					10. Device Available fo	•	-	
					Yes No	Returned to	Manufacturer on:	(mm/dd/yyyy)
					11. Concomitant Medic	al Products and Th	erapy Dates (Exclu	<del></del>
7. Other Relevant I race, pregnancy,	listory, Including Preex smoking and alcohol use	isting Medical C , hepatic/renal dy	onditions (e.g., sfunction, etc.)	allergies,				
					E. INITIAL REPO	RTER		
ļ					1. Name and Address	Phor	ne #	
					ļ			
	report does not co				2. Health Professional	? 3. Occupation		4. Initial Reporter Also S Report to FDA
caused or contr	ibuted to the event				Yes No			● Yes ☐ No ☐ L

### **MEDWATCH** FORM FDA 3500A (1/09) (continued) F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) 1. Check Оле User Facility 3. User Facility or Importer Name/Address

4. Contact Person

9. Approximate Age of Device

Yes

☐ No

☐ No

11. Report Sent to FDA?

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

5-day 30-day

7-day Periodic

15-day 🔽 Follow-up # 1 9. Manufacturer Report Number

8010047-2013-00092

10-day Initial

Contact Office - Name/Address (and Manufacturing Site for Devices)

mporter

7. Type of Report nitial Follow-up # 10. Event Problem Codes (Refer to coding manual)

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

Page 2

2. UF/Importer Report Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility

Company Representative

Distributor

Other:

1 F		
15	TURERS ON	,
H. DEVICE MANUFAC , Type of Reportable Event		2. If Follow-up, What Type?
. Type of Reportable Event		Correction
Serious Injury		Additional Information
Malfunction		Response to FDA Reques
Other:		Device Evaluation
Device Evaluated by Man	uto aturar?	4. Device Manufacture Date
Not Returned to Man		(mm/yyyy)
□ '	Summary Attached	
No (Attach page to e.	-	5. Labeled for Single Use?
provide code:	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Yes No
. Evaluation Codes (Refer t	to coding manual)	
Method	-	
Results		
Results		
Conclusions		
. If Remedial Action Initiate	ed, Check Type	8. Usage of Device
Recali 1	Notification	Initial Use of Device
Repair I	nspection	Reuse
Replace F	Patient Monitoring	Unknown
	Modification/ Adjustment	If action reported to FDA under     21 USC 360i(f), list correction/
Other:		removal reporting number:
	turer Narrative	and / or 11. Corrected Dat
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eight led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely than the subject device.
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
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EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resure SYSTEMS CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely
EUROPA disassemble with personnels from each device for culture facility brought test. Subsequently were tested negat. Based on the resurverse CORP. this	request from ed the subjection the user part dismant e test. The pthem back and y, all sample ive.  It of the culnks that this	the user facility, OLYMPI t device in conjunction facility. They took eigh led from the subject ersonnels from the user performed the culture s collected from the par ture test, OLYMPUS MEDIC event was most likely

The public reporting burden for this collection of information has been estimated to average 65 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

STN#

510(k)# Combination Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, MD 20857

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

# Clinique De Bercy Charenton-le-Pont, France

FR



Date: December 20, 2012 Report Type: Manufacturer Report

8010047-2012-000452

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,



For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

UF/Importer Report #	

### **MEDWATCH**

TERMOR TITE ON OUR DENOMBLY

FORM FDA 3500A (1/09)

Page 1 of 15

A. PATIENT INF	OPMATION			C. SUSPECT PROD	UCT/S)		PDA USE Only
		0.0	4 101-1-14				
1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight	Name (Give labeled stre	ngtn & mtr/labeler)		
	or	Female	ibs	#1			
	Date	Male	or	#2			
In confidence	of Birth: VENT OR PRODUCT PROBLE	ì	kgs	2. Dose, Frequency & Ro	ute Used	3. Therapy Dates	(If unknown, give duration)
		181		#1		from/to (or best of	estimate)
1. Adverse Even		g., defects/mail	unctions)	#2		#2	
<ol><li>Outcomes Attribut (Check all that appl)</li></ol>				4. Diagnosis for Use (Indi	cation1		Abated After Use
Death:		or Permanent Da	mage		cationy		ped or Dose Reduced?
Life-threatenin	(mm/dd/yyyy)	l Anomaly/Birth	Defect	#1		#1 🗀 `	Yes No Doesn't Apply
=		ous (Important N		#2			— Doesn't
_	vention to Prevent Permanent Impairment	, .	1	6. Lot #	7. Exp. Date		Yes No Apply
3. Date of Event (mn	·			#1	#1		Reappeared After roduction?
-		11/21/201		#2	#2	_	Yes No Doesn't
5. Describe Event or				9. NDC# or Unique ID	1		— Doesn't
	lity reported to identifi 3 patients that underwen					#2 LJ`	Tes   No   Apply
-,	tested positive for Esche			10. Concomitant Medical	Products and The	rapy Dates (Exclude	treatment of event)
•	of infections or other p			N/A			
			l				-
			į	1			
				D. SUSPECT MEDI	CAL DEVICE		
				1. Brand Name EVIS E	XERA II DUO	ENOVIDEOSCOP	E
				2. Common Device Name	DUODENOENDO	DSCOPE	
				3. Manufacturer Name, C			
				OLYMPUS MEDICAL SY	STEMS CORPORAT		
				2951 Ishikawa-cho 1		токуо, 192-850	
			1	4. Model #	Lot#		5. Operator of Device
			l	TJF-Q180V Catalog #	Expiratio	n Date (mm/dd/yyyy)	Health Professional
							Lay User/Patient
İ				Serial #	Other#	,	Other:
				2101357		12 1/2 1/2 1/2	J
				6. If Implanted, Give Date	(mm/aaryyyy)	7. If Explanted, G	ive Date (mm/dd/yyyy)
vant Tests/La	boratory Data, Including Dates			8. Is this a Single-use De	vice that was Repr	ocessed and Reus	ed on a Patient?
				Yes No			
				9. If Yes to Item No. 8, En	iter Name and Add	ress of Reprocesso	or
				10. Device Available for B	Evaluation? (Do no	t send to FDA)	····
				Yes V No	Returned to M	lanufacturer on:	
				11. Concomitant Medical	Products and The	rany Dates (Evolud	(mm/dd/yyyy)
7. Other Belggert Hi	stant Including December & Madical Co		-//	11. Conconituit medical	rioddola did i iic	tapy bates (Excise)	c treatment or eveny
race, pregnancy, si	story, Including Preexisting Medical Co moking and alcohol use, hepatic/renal dys	sfunction, etc.)	allergies,				
ļ				E. INITIAL REPOR			
]				Name and Address	Phone	#	
				Clinique De Bero	-		
				Charention Le Po	int, 94, Fra	ance	
Submission of a	report does not constitute an ad	mission tha	t medical	2. Health Professional?	3. Occupation	4.	Initial Reporter Also Sent Report to FDA
personnel, user to caused or contrib	acility, importer, distributor, ma	nutacturer c	r product	Yes No	Other Healthcare F	Professional	Yes No Unk.

#### **MEDWATCH**

User Facility

4. Contact Person

9. Approximate Age of Device

☐ No

Yes _

No

6. Date User Facility or

Importer Became Aware of Event (mm/dd/yyyy)

rt Sent to FDA?

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1,02-8507, Japan

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND. Give Protocol #

7. Type of Report (Check all that apply)

☐ 10-day 🗸 Initial

15-day Follow-up # 9. Manufacturer Report Number

8010047-2012-00452

5-day

7-day

11/21/2012

√ 30-day

Periodic

Contact Office - Name/Address (and Manufacturing Site for Devices)

2951 Ishikawa-cho, Hachioji-shi, Tokyo

OLYMPUS MEDICAL SYSTEMS CORP.

(mm/dd/yyyy)

(mm/dd/yyyy)

Patient

Code Device

Code

FORM FDA 3500A (1/09) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Home

Other;

12. Location Where Event Occurred

Outpatient Treatment Facility

nitial [ Follow-up #

2199

1091

Importer

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number

✓ Foreign

Company

Distributor

Other:

Representative

Study Literature Consumer Health Professional ✓ User Facility

3. Report Source (Check all that apply)

Page 2'd	of 1	5
----------	------	---

		FDA USE ONLY
• • •		
of 15		
H. DEVICE MANUFAC		
Type of Reportable Event		2. If Follow-up, What Type?
Death		Correction
Serious Injury		Additional Information
Malfunction		Response to FDA Request
Other: Potential		Device Evaluation
Device Evaluated by Mana		4. Device Manufacture Date (mm/yyyy)
✓ Not Returned to Manu		01/2011
	Summary Attached	
No (Attach page to exprevide code:	xplain why not) or	5. Labeled for Single Use?
,		Yes No
6. Evaluation Codes (Refer to	o coding manual)	
· –		
Method		
Results		
Conclusions	67 - 92	
7. If Remedial Action Initiate	d, Check Type 8. I	Usage of Device
Recall N	lotification	Initial Use of Device
Repair Ir	nspection	Reuse
Replace P	atient Monitoring	Unknown
	fodification/ 9. I	f action reported to FDA under 21 USC 360i(f), list correction/
Other:	iojustitient i	removal reporting number:
10. Additional Manufact	uror Norrethia	I/or 11. Corrected Data
1 —		facility to obtain
		this report, and was
informed that the		
negative for growt		
The subject device evaluation, and wi		
		biological testing. At
the present time,		
		however insufficient nnot be ruled out as
contributory facto		mior be ruled out as
If significant add	itional informa	tion is received, a
supplemental repor	t will follow.	
This report is bei	ng submitted as	a Medical Device
Report in an abund		
C Me	Damanti 2010	047 0010 00453
8010047-2012-00454		047-2012-00453, and ted reports.
	202 001102 2021	100 1001100

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

STN# PMA/

510(k)# Combination Product

Pre-1938

OTC Product

8. Adverse Event Term(s)

Yes Yes

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane

Rockville, MD 20857

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # 8010047-2013-00595	
UF/Importer Report #	

#### **MEDWATCH**

FORM FDA 3500A (1/09)

A. PATIENT INFORMATION

ANDAIC	KY reporting	OF/Insporter K	epuit #			
Page 1	of 15					
	C. SUSPECT PRO	DUCT(S)				FDA Use Only
Weight	1. Name (Give labeled str	ength & mfr/labeler)				
jnk lbs	#1 N/A					
or Jnk kgs	#2 N/A					
J <u>nk</u> kgs	2. Dose, Frequency & Ro	oute Used	3. Thera	py Dates (i	f unknown, stimate)	give duration)
in and	#1 N/A		#1	, (or 2004 or	Jumotoy	
ons)	#2 N/A		#2			
	4. Diagnosis for Use (Ind	lication)			Abated Afte	
e	#1 N/A			#1 TY	ed or Dose es ∏ No	Doesn't
at Events)	#2 N/A					Apply Doesn't
al Events)	6. Lot#	7. Exp. Date		#2 🗆 Y	es 🗌 No	Apply
l	#1N/A	#1 N/I	A		Reappeared	d After
″	#2N/A	#2 N/	4	#1 🗆 Y	_	Doesn't
	9. NDC# or Unique ID					— Dosen'i
hat				#2 Y		☐ Apply
y	10. Concomitant Medical	Products and The	rapy Dates	s (Exclude I	reatment of	event)
er						
the						
	D. SUSPECT MEDI	CAL DEVICE				
	1. Brand Name EVIS I	EXERA II DUO	DENOVID	EOSCOPE	2	
1	2. Common Device Name	DUODENOENDO	SCOPE			
	3. Manufacturer Name, C	ity and State			_	
1	OLYMPUS MEDICAL SY 2951 Ishikawa-cho			192-850	7 Japan	
	4. Model #	Lot#				or of Device
	TJF-Q180V	N/A				h Professional
	Catalog #	Expiration	n Date (mr	n/dd/yyyy)		Jser/Patient
	Serial #	Other#			Other	r.
	2101336	N/A				
	6. If Implanted, Give Date	e (mm/dd/yyyy)	7. If Exp	lanted, Giv	e Date (mn	v/dd/yyyy)
	8. Is this a Single-use De	vice that was Rep	rocessed a	and Reuse	on a Patio	ent?
	Yes V No					
	9. If Yes to Item No. 8, E	nter Name and Ad	dress of Re	processor	•	
- 1	10. Device Available for	_				
-	Yes V No	Returned to I	vanutacture	er on:	(mm/dd/)	(ייייי)
	11. Concomitant Medica	Products and The	erapy Date:	s (Exclude	treatment o	f event)
ies,	· · · ·					
-						
	E. INITIAL REPOR					
- 1	Name and Address	Phon	C #			
	Clinique de Bero	-			_	
	9 Quai de Bercy,	94220 Char	enton-l	e-Pont,	France	•
- 1	1					

2. Health Professional? 3. Occupation

Yes No

	1. Patient Identifier			3. Sex	4. Weigh	ıt
	Unk	of Event: Unk		☐ Female	Unk	lbs
		or			or	
	In confidence	of Birth:	Unk	Male Male	Unk	kgs
	B. ADVERSE EV	VENT OR PROD	JCT PROBLE	M		
	1. Adverse Even	t and/or P	roduct Problem (e	.g., defects/maif	unctions)	
	2. Outcomes Attribut	ted to Adverse Event	· ·	-		_
	(Check all that appl	V)				
	Death:	(mm/dd/yyyy)	[_] Disability o	r Permanent Da	mage	
	Life-threatenin			l Anomaly/Birth D		
		- initial or prolonged		ous (Important M		ents)
		vention to Prevent Per	manent Impairmen	/Damage (Devic	es)	
ا	3. Date of Event (mn		4. Date of This	Report (mm/dd		
ί.,		08/2013		11/21/2013	3	
	5. Describe Event or	Problem				
	Olympus Medica	al Systems COF	P. (OMSC) w	as informe	d that	
	after endosco	pic retrograde	cholangiop	ancreatogr	aphy	ļ
		the subject de				
ایی		ere detected f the same bact				
ź۱		annel and the				
2	subject device	e, too. The ou				
OR USE BLACK INK	unknown.					
B,						
ĕ						
5						
종						
ğ.						
TYPE						
EΙ						
₹SI						
Ē						
ᆈ						
. '						
٠- ١	6. Relevant Tests/Lal	horatory Data, Includ	ing Dates			_
	Unk	boratory bata, merae	ing Dates			
-						
	7 611 6 1		1-11		ri	
	<ol><li>Other Relevant His race, pregnancy, sn</li></ol>	story, including Preex moking and alcohol use	tisting Medical Co , hepalic/renal dys	nditions (e.g., a function, etc.)	liergies,	
	Unk	-		-		
Ì						
Į	Submission of a re	eport does not co	nstitute an ad	mission that	medica	
	personnel, user fa					

4. Initial Reporter Also Sent Report to FDA Yes No Unk.

MEDWATCH							FDA OSE ONLY
FORM FDA 3500	A (1/09) (	continued)		Page 2	2 of 15		
F. FOR USE BY U		CILITY/IMPOI		evices Only) eport Number	H. DEVICE MANUFAC		2. If Follow-up, What Type?
User Facility  3. User Facility or Impo	☐ Impo				Death Serious Injury Maifunction Other: Potential Device Evaluated by Manu	ufacturer?	Correction Additional Information Response to FDA Request Device Evaluation  4. Device Manufacture Date (mm/yyyy)
4. Contact Person			5. Phone Nu	mber	✓ Not Returned to Manu  Yes ☐ Evaluation  No (Attach page to ex	n Summary Attached	01/2011 5. Labeled for Single Use?
Date User Facility or Importer Became Aware of Event (mm	- 1	7. Type of Repor		8. Date of This Report (mm/dd/yyyy)	6. Evaluation Codes (Refer to		☐ Yes ☑ No
9. Approximate Age of Device	Patient Code Device Code	1735 - 3190 -	Refer to codin	g manual)	Method Results Conclusions	67 - 92	]-[
11. Report Sent to FD/  Yes	nufacturer?	12. Location W Hospita Home Nursing Cutpati Facility Other:	d Home ient Treatmer	Outpatient Diagnostic Facility Ambulatory Surgical Facility	Repair In Replace F	Notification Inspection Patient Monitoring	. Usage of Device   Initial Use of Device   Reuse   Unknown   If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
G. ALL MANUFA 1. Contact Office - Na for Devices) OLYMPUS MEDIC 2951 Ishikawa 192-8507, Jaj	CAL SYST	s (and Manufacte		2. Phone Number  3. Report Source (Check all that apply)  ✓ Foreign  Study  Literature  Consumer  ✓ Health Professional	the facility. The instrument channel instrument channel which Olympus does instruction manual the specific clear instrument channel cleaning brush use suction channel. Could not determine	facility brush  1, the suction  1 opening with  s not recommend  1 of the subject  ning brush for  1 opening, which  ed for the inst  Olympus Medical  ne the root can  reprocessing	the same cleaning brush,  I. In addition, the  the device directs to use the distal end and the ch is different from the trument channel and the is Systems CORP (OMSC) use of this event.  could not be ruled out as-
10-day Initi	2013  col #  day riodic ial low-up # ort Number	5.  (A)NDA#  IND#  STN #  PMA/ 510(k) #  Combination Product  Pre-1938  OTC Product  8. Adverse E	Yes Yes	Company Representative Distributor Other:	-		
minutes per response,	including the I maintaining In. Send com	e time for reviewing the data needed, nments regarding t	ig instructions , and complet this burden e	stimate or any other aspect of	Office of Chief Information Of	on officer (HFA-710)	OMB Statement: "An agency may not conduct or sponso and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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OCA_0001724



Date: March 16, 2015

Report Type: Manufacturer Report (30day)

#8010047-2015-00210

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



# For use by user-facilities, importers, distributors and manufactur

Fo	rm Ap	proved	: OMB	No, 0916 See C	0-0291 DMB st	, Expires: atement o	6/30/20 n rever:
Mfr Report #	801	0047	-201	5-00:	210	4 (C. E.	
UF/Importer I	Repor	t#.	-:-	,	7 .	'4.5° .	
Arme a la la la la	. * *	A				471.00	

FLEADE 1 1 FE UN UDE BEAUN INN

MEDV	VATCH	iii poi		ORY reporting	UF/Importer R	Report #	Control Service
FORM FDA 35	t Maria Carlos and a fine con-		Page 1	of 2	1 1	300 J J 1	FDA Use C
A. PATIENT IN	FORMATION			C. SUSPECT PRO	DUCT(S)	_	FDA 05# C
1. Patient Identifie		3. Sex	4. Weight	1. Name (Give labeled st		)	4 /4 **
	of Event:	Fem	ale ibs	#1			
	Date	) =	or [	#2			
In confidence	of Birth:	☐ Male	kgs	2. Dose, Frequency & R	oute Used	3. Therapy Dates	(If unknown, give duration
B. ADVERSE	EVENT OR PROD	UCT PROBLEM				fromito (or best	estimate)
1. Adverse Ev	ent and/or F	Product Problem (e.g., defectsin	maifunctions)	#1		#1	<del></del>
2. Outcomes Attrib (Check all that ap	outed to Adverse Event	t		#2		#2	
Death:		Disability or Permanent	Damage	4. Diagnosis for Use (Inc	dication)		t Abated After Use ped or Dose Reduced?
Life-threater	(mmiddlyyyy)	Congenital Anomaly/Bia	_	#1		#1 []·	Yes No Doe:
	ion - initial or prolonged	Other Serious (Importa	I	#2			
1 -		rmanent Impairment/Damage (D	-[	6. Lot #	7. Exp. Date	#2 📙	Yes No Appl
3. Date of Event (n		4. Date of This Report (mn		#1	#1		t Reappeared After roduction?
	/08/2013	11/21/20		#2	#2		Yes No Does
5. Describe Event	or Problem			9. NDC# or Unique ID			Appl Does
Madi	cal Systems CO	RP. (OMSC) was infor	mad that			#2 [	Yes No Appl
after endosc	opic retrograde	e cholangiopancreato	graphy	10. Concomitant Medica	Products and The	erapy Dates (Exclude	treatment of event)
(ERCP) using	the subject de	evice, Enterobacteri	es and				
		from two patients. T teria were detected					
		suction channel of					0.4
subject devi unknown.	ce, too. The or	utcome of the patien	nts is	D. SUSPECT MED	ICAL DEVICE		Continue on page 3)
unknown.				1. Brand Name			
				EVIS		DENOVIDEOSCOP	
				2. Common Device Nam DUODENOENDOSCOPI		26.	Procode
				3. Manufacturer Name, ( OLYMPUS MEDICAL SY 2951 Ishikawa-cho	STEMS CORPORA		607 Japan
l				4. Model #	Lot#		5. Operator of Device
				TJF-Q180V	N/A		Health Profession
				Catalog #	Expiration	Date (mm/ddlyyyy)	Lay User/Patient
			i	TJF-Q180V Serial#	I Inlana Id	N/A entifier (UDI) #	Other:
				2101336	N/A	entitler (ODI) #	
		(0		6. If implanted, Give Dat		7. If Explanted, Gi	ive Date (mmlddlyyyy)
evant Tests/L	aboratory Data, includ		on page 3)	N/A		N/A	
	,,	ang Dates	ļ	8. Is this a Single-use D	evice that was Rep	rocessed and Reuse	ed on a Patient?
			Ì	9. If Yes to Item No. 8, E	nter Name and Ad	dress of Reprocesso	
			ĺ				•
1							
			1				
				10. Device Available for		,	
				Yes V No	Returned to I	Manufacturer on:	(mm/ddiyyyy)
		(Continue	on page 3)	11. Concomitant Medica	Products and The	erapy Dates (Exclude	treatment of event)
7. Other Relevant H	listory, Including Prees	xisting Medical Conditions (e.g., hepaticIrenal dysfunction, etc.)	., allergies,				
		., eye.circuon, etc.)				10	Continue on page 3)
				E. INITIAL REPOR	TER		, and the property
				1. Name and Address			
				Clinique de Bero 9 Quai de Bercy,		enton=le-Pont	France
				y guar de Bercy	Jaces Char	chech-re-ront	, stance
				Phone #	IEm	all Address	
		(Continue	on page 3)				
		onstitute an admission th distributor, manufacturer		2. Health Professional?	3. Occupation	4.	Initial Reporter Also Se Report to FDA
	buted to the event		or product	Yes No			Yes No U

### MEDWATCH

EODM EDA SESSA	A (2(42) /-	antinuad)		Page 2	of 2					
FORM FDA 3500A						- 			the state of the state of the state of the	
F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)  H. DEVICE MANUFACTURERS ONLY										
1. Check One			F/Importer Re	port Number	434	of Reportable Ev	/ent		2. If Follow-up, What Type?	
User Facility	Importe	<u></u>				Death			Correction	
3. User Facility or Impo		l		Serious Injury			Additional Information			
						Malfunction			Response to FDA Request	
				l					Device Evaluation	
				į	3. Devi	ce Evaluated by I	Manufacturer?		4. Device Manufacture Date	
			lr	Not Returned to I	Manufacturer		(mmlyyyy)			
4. Contact Person 5. Phone Nu			mber	1 =	Yes ∏ Evalu	ation Summary Atta	ched			
					No (Attach page	to explain why not)	or	5. Labeled for Single Use?		
			8. Date of This Report		provide code:			Yes No		
Importer Became Aware of Event (mmlddlyyyy)   Initial			(mmlddlyyyy)							
wram (mm)		_			6. Eve	nt Problem and E	valuation Codes (R	Refer to co	oding manual)	
9. Approximate 10. Event Problem Codes (Refer to codin					Patient	1735	_			
9. Approximate Age of Device	10. Event Pro	oblem Codes (i	Refer to codin	g manuai)	[	Code	1735	_		
•	Patient		- [			Device Code	3190	-	-	
	Code [			<b>=  ===</b>		0000				
	Device Code	-	•	]-[]		Method	LL		-L	
11. Report Sent to FDA	7	12. Location W	here Event C	ccurred		Results				
_ `	1	Hospita	al	Outpatient		Resuits	<u></u>			
(mmlddlysov)		Diagnostic Facility		Conclusions	67 -	92	-   -			
No No Nursing Home  13. Report Sent to Manufacturer? Nursing Home				Ambulatory Surgical Facility	7 15 0	amedial Action In	itiated, Check Type	ı A	Usage of Device	
_ `	iuracturerr	Outpati	ent Treatment		_		_	.  0,	Initial Use of Device	
Yes Facility				I I ⊑	Recall	Notification		Reuse		
No (Ministry)			(Specify)	_	Repair [	Inspection		Unknown		
14. Manufacturer Name/Address						Replace [	Patient Monitorin		If action reported to FDA under	
						Relabeling	Modification/ Adjustment		21 USC 360i(f), list correction/	
						Other:	•		removal reporting number:	
							Factories - No.		d/or 11 Coverated Date	
					1 -	,	ıfacturer Narrative		d/or 11. Corrected Data	
G. ALL MANUFACTURERS  This report is being submitted upon further review of the MDR complaint filed on December 17, 2013 (Mfr#										
1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number						047-2013-00	595). It has	been	determined that one	
Nome				2. Book Books	addi	additional MDR is needed to account for the reported				
Address			3. Report Source (Check all that apply)	numb	er of patie	nts allegedl	y infe	ected by the scope.		
				Foreign		ea cross so	ference the	A 200/	ociated complaints:	
OLYMPUS MEDICAL SISTEMS CORP.				Study	1 1	047-2013-00		- 4550		
192-8507, Japan			Literature	1 1				$\mathcal{O}$		
			Consumer					reprocessing practice in		
Email Address				Health Professional					ed the distal end, the channel, and the	
4. Date Received by		5.		✓ User Facility	inst	rument chan	nel opening	with 1	the same cleaning brush,	
4. Date Received by Manufacturer (mm/o	ddlyyyy)	5. (A)NDA#		Company	Whic	h Olympus d	loes not reco	mmend.	. In addition, the	
11/25/20	013	( · · · –		Representative Distributor	inst	ruction man	ual of the s	ubject	t device directs to use the distal end and the	
6. If IND, Give Protoco	1#	IND#_		Other:	inet	specific cl rument char	eaning brush mel opening.	which	h is different from the	
		BLA#		LJ Ciner:	clea	ining brush	used for the	inst	rument channel and the	
		PMA			suct	ion channel	. Olympus Me	edical	Systems CORP (OMSC)	
7. Type of Report (Check all that apply)		510(k) #		1	coul	could not determine the root cause of this event. However, improper reprocessing could not be ruled out a				
5-day 🗸 30-da		Combination Product	Yes		Howe	ontributory	er reprocess factor to th	e ren	orted event.	
7-day Perio		Pre-1938	Yes		" "	y		р		
10-day 📝 initial	1	OTC Product	_		1					
15-day Follo	w-up #				] [					
Manufacturer Report Number 8. Adverse Event Term(s)				1 [						
8010047-2015-0	0210									
					₃ ∟					

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@ida.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

FDA USE ONLY

# **Erasmus Medical Center Rotterdam, Netherlands**



Date: May 25, 2012 Report Type: Manufacturer Report 8010047-2012-000157

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,



2. Age at Time

of Event:

Unk

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	Form Approved: OMB No. 09 10-029 1, Expires 12/31/1 See OMB statement on reverse
Mfr Report #	8010047-2012-00157
UF/Importer	Report #

Mfr

### **MEDWATCH**

1. Patient Identifier

Unk

FORM FDA 3500A (1/09) A. PATIENT INFORMATION Page 1 o

4. Weight

3. Sex

	-			<u> </u>		
15						FDA Use Only
C. SUSPECT	PRODUCT	(S)				
1. Name (Give label	led strength &	mfr/labeler)				
#2 NT / 2						
#2 N/A 2. Dose, Frequency	& Pouts He	nd .	3 There	ny Dates /h	Funkasum -	ive duration)
#1 N/A	y a noute os		from/t	o (or best es	stimate)	ive duration)
#2 N/A						
. Diagnosis for Us	en (Indication)		#2	6 Event	Abated After	
#1 N/A	·				d or Dose R	
#2 N/A				". 🚨 ,		L_J Apply
6. Lot#	7. E	xp, Date		#2 🗆 Y	es 🔲 No	Doesn'i
#1N/A	#1	N/A			Reappeared	After
#2N/A	#2	N/A		#1 \ Y		☐ Doesn'
9. NDC# or Unique	ID			1 <del></del>		Apply Doesn's
				#2 N	es No	Apply
D. SUSPECT I	MEDICAL	DEVICE				
1. Brand Name	IS EXERA		PHOUT	TOCOOD		
2. Common Device		11 DOOL	ENOVI	DEUSCOPE	· 	
	DOC	DENOENDO	SCOPE			
3. <b>Manufacturer N</b> a OLYMPUS MEDICA 2951 Ishikawa-	AL SYSTEMS	CORPORAT		192-8507	Japan	
4. Model #		Lot#			5. Operator	of Device
TJF-Q180V		N/A			✓ Health	Professional
Catalog # N/A		Expiration	n Date (m	m/dd/yyyy)	Lay Us	ser/Patient
Serial #		Other#			Other:	
2101363 6. If Implanted, Giv	to Data (mar/	N/A	17 45	lantad Ob	- D-4- (	
o. It impianted, GN	re Date (mm/	<i>aa/yyyy)</i>	/. IT EX	lanted, Giv	e Date (mm)	(dd/yyyy)
8. Is this a Single-		at was Repr	ocessed	and Reused	on a Patie	nt?
9. If Yes to Item No	o. 8, Enter Na	me and Add	ress of R	eprocessor		
10. Device Availab	le for Evalua	tion? (Do co	sand to	ED 41		
Yes 7		Returned to M		,		
					(mm/dd/y	
11. Concomitant N N/A	iedicai Produ	icts and The	rapy Date	s (Exclude	treatment of	event)
E. INITIAL RE						
1. Name and Addr	ess	Phone	#			
Process Madd	anl Cant					
Erasmus Medi Rotterdam Ne						
2. Health Professi	L				nitial Repor Report to FD	ter Also Sen
Yes 🔲 I	No Physic	ПВП		} {	Yes ■	No 🗌 Unk

caused or contributed to the event.

#### **MEDWATCH**

User Facility

4. Contact Person

Approximate
 Age of Device

Yes _

∏ No

Yes

☐ No

6. Date User Facility or Importer Became

11. Report Sent to FDA?

Aware of Event (mm/dd/yyyy)

Patient

Code Device

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

192-8507, Japan

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

7. Type of Report (Check all that apply)

10-day 📝 Initial

15-day Follow-up#_____

9. Manufacturer Report Number

8010047-2012-00157

5-day

7-day

4/26/2011

√ 30-day

Periodic

1. Contact Office - Name/Address (and Manufacturing Site

2951 Ishikawa-cho, Hachioji-shi, Tokyo

(A)NDA#

IND#

STN#

510(k) # ___

Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)

OLYMPUS MEDICAL SYSTEMS CORP.

1. Check One

FORM FDA 3500A (1/09) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

| Initial | Follow-up # _____ | 10. Event Problem Codes (Refer to coding manual)

1735

3190

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

Importer

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Date of This Report (mm/dd/yyyy)

> Outpatient Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

Foreign

☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☑ User Facility

Company

Distributor

Yes

Yes Yes

Other:

Representative

3. Report Source (Check all that apply)

Page 2 of 15

## DEVICE MANUFACTURERS ONLY  Type of Reportable Event			FUA USE ONLY
H. DEVICE MANUFACTURERS ONLY  Type of Reportable Event	15		
Desirous Injury			
Death   Serious Injury   Additional Information   Additional Information   Additional Information   Device Evaluated by Manufacturer?   Yes   Evaluation Summary Attached   No (Attach page to explain why not) or provide code:   Yes   Evaluation Codes (Refer to coding menual)   Sevential Use of Device   Tyes   No			
Serious Injury   Additional Information   Response to FDA Request   Device Evaluated by Manufacturer?   Vict Returned to Manufacturer?   Yes   Evaluation Summary Attached   No (Attach page to explain why not) or provide code:   Yes   Ves   Sevaluation Summary Attached   Sevaluation Codes (Refer to coding menue)   January /2011   S. Labeled for Single Use?   Yes   No   No   No   No   No   No   No   N			
Maifunction   Device Evaluated by Manufacturer?   Not Returned to Manufacturer   Yes   Evaluation Summary Attached   No (Attach page to explain why not) or provide code:   Patent Monitoring   Adjustment   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes   Notes	<u> </u>		_
Other: Potential Infection	₩		
Device Evaluated by Manufacturer?   Not Returned to Manufacturer   Yes		1 Infection	
Not Returned to Manufacturer   Yes   Evaluation Summary Attached   No (Attach page to explain why not) or provide code:   Stabled for Single Use?   Yes   No			- I Britis Manufacture Britis
Yes   Evaluation Summary Attached   No (Attach page to explain why not) or provide code:   Yes   No			
No (Attach page to explain why not) or provide code:   Yes   No	_		January /2011
Yes   No	= -	-	
Method	provide code:	Apidin Wily 1000 or	□ Ves □ □ No
Results			
Results	. Evaluation Codes (Refer	to coding menual)	
Conclusions    Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   C	Method	-	
Conclusions    Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   Conclusions   C	<u></u>		
Remedial Action Initiated, Check Type   Recall   Notification   Repair   Inspection   Replace   Patient Monitoring   Relabeling   Modification/ Adjustment   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Lowerection   Reuse seal   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Reuse   Unknown   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   State of Device   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Interest   Inter	Results		
Recall   Notification   Replace   Patient Monitoring   Relabeling   Modification/ Adjustment   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unkn	Conclusions	67 - 92	<b>-</b>
Recall   Notification   Replace   Patient Monitoring   Relabeling   Modification/ Adjustment   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unknown   Street   Unkn	7. If Remedial Action Initiate	ed. Check Type	8. Usage of Device
Repair   Inspection   Reliabeling   Modification/ Adjustment   Other:   Station reported to FDA under 21 USC 360iff, list correction/ removal reporting number:   Other:   Station reported to FDA under 21 USC 360iff, list correction/ removal reporting number:   Other:   Station reported to FDA under 21 USC 360iff, list correction/ removal reporting number:   Other:   Station reported to FDA under 21 USC 360iff, list correction/ removal reporting number:   Other:   Oth			
Replace Patient Monitoring Modification/ Adjustment Patient Monitoring Other:  10. Additional Manufacturer Narrative and/or 11. Corrected Data The device was not returned to OYMPUS MEDICAL SYSTEMS (OMSC) for evaluation because the device was being investigated by independent organization. However, the photograph of the distal end of the device which was sent from OLYMPUS NEDERLAND showed the debris around the objective lens. In addition there is no abnormal record in it manufacturing history record.  From the above information only, OMSC can not conclusively determine the cause this event. However, i can be considered as a possible cause of this phenomeno that the patient infected from other than the endoscope and procedure such as environmental factor in the facility.  This report is being submitted as a medical device report in an abundance of caution.			Reuse
Relabeling   Modification/ Adjustment   Station reported to FDA under 21 USC 360iff), list correction/ removal reporting number:  10.  Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Additional Manufacturer Narrative   Add			Unknown
Other:  10. Additional Manufacturer Narrative and/or 11. Corrected Data The device was not returned to OYMPUS MEDICAL SYSTEMS (OMSC) for evaluation because the device was being investigated by independent organization. However, the photograph of the distal end of the device which was sent from OLYMPUS NEDERLAND showed the debris around the objective lens. In addition there is no abnormal record in it manufacturing history record. From the above information only, OMSC can not conclusively determine the cause this event. However, i can be considered as a possible cause of this phenomeno that the patient infected from other than the endoscope and procedure such as environmental factor in the facility.  This report is being submitted as a medical device report in an abundance of caution.	Relabeling	Modification/	9. If action reported to FDA under
The device was not returned to OYMPUS MEDICAL SYSTEMS (OMSC) for evaluation because the device was being investigated by independent organization. However, the photograph of the distal end of the device which was sent from OLYMPUS NEDERLAND showed the debris around the objective lens. In addition there is no abnormal record in it manufacturing history record.  From the above information only, OMSC can not conclusively determine the cause this event. However, i can be considered as a possible cause of this phenomeno that the patient infected from other than the endoscope and procedure such as environmental factor in the facility.  This report is being submitted as a medical device report in an abundance of caution.		Adjustment	removal reporting number:
The device was not returned to CYMPUS MEDICAL SYSTEMS (OMSC) for evaluation because the device was being investigated by independent organization. However, the photograph of the distal end of the device which was sent from OLYMPUS NEDERLAND showed the debris around the objective lens. In addition there is no abnormal record in it manufacturing history record. From the above information only, OMSC can not conclusively determine the cause this event. However, i can be considered as a possible cause of this phenomeno that the patient infected from other than the endoscope and procedure such as environmental factor in the facility.  This report is being submitted as a medical device report in an abundance of caution.	Other:		
The device was not returned to CYMPUS MEDICAL SYSTEMS (CMSC) for evaluation because the device was being investigated by independent organization. However, the photograph of the distal end of the device which was sent from OLYMPUS NEDERLAND showed the debris around the objective lens. In addition there is no abnormal record in it manufacturing history record. From the above information only, CMSC can not conclusively determine the cause this event. However, i can be considered as a possible cause of this phenomeno that the patient infected from other than the endoscope and procedure such as environmental factor in the facility.  This report is being submitted as a medical device report in an abundance of caution.			
report in an abundance of caution.	The device was not (OMSC) for evaluation investigated by in photograph of the sent from OLYMPUS objective lens. It in it manufacturi. From the above in conclusively detecan be considered that the patient and procedure sucfacility.	t returned to tion because to dependent organization of NEDERLAND shows a ddition the neghistory reformation only mine the causes a possible infected from has environment.	OYMPUS MEDICAL SYSTEMS the device was being ganization. However, the f the device which was owed the debris around the ere is no abnormal record cord. y, OMSC can not se this event. However, i e cause of this phenomeno other than the endoscope ental factor in the

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, MD 20857

OMB Statement:
"An agency may not conduct or sponsor
and a person is not required to respond
to, a collection of information unless it
displays a currently valid OMB control
number."

Please DO NOT RETURN this form to this address.



Date: May 26, 2015

Report Type: Manufacturer Report (30day)

#8010047-2012-00157

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is a supplemental 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



4. Initial Reporter Also Sent Report to FDA Yes No Unk.

2. Health Professional? 3. Occupation

Yes No

U.S. Department of Health and Human Services Food and Drug Administration

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

## MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfc	Report #	8010	047	-2012	-001	57	
UF/I	mporter	Report	#		-	+ , I	_
162				u.,	1. 24	_ fixed to selections.	
. <del>7</del> 5.	7 75 7	11	•	A 2 4	1997	FDÁ Úse C	only

	FORM FDA 3500A (2/13)	Pag	e 1 ot <u>-</u>			- ',		FDA Use Only
	A. PATIENT INFORMATION  1. Patient identifier   2. Age at Time	2 0		SUSPECT PRODUC				
	of Event:	3. Sex 4. Weight	1 !	ame (Give labeled strengti	n & mfriiabeler)	,		the distrib
	or	Female or	ibs #1					
	In confidence of Birth:	☐ Male	(gs #2					
	B. ADVERSE EVENT OR PRODUCT PROBLE		2. Do	ose, Frequency & Route	Used	3. Therapy Dates fromito (or best	(if unknown, ç estimate)	ive duration)
	1. Adverse Event and/or Product Problem (	(e.g., defects/malfunctions)	#1			#1		
	Outcomes Attributed to Adverse Event     (Check all that apply)		#2			#2		
	1 —	or Permanent Damage	4. Di	agnosis for Use (Indicatio	on)		Abated Afte	
	(mmlddlyyyy)	_	#1				res No	Doesn't
		al Anomaly/Birth Defect fous (Important Medical Ever	(s) #2					Apply Doesn't
	Required Intervention to Prevent Permanent Impairmer	• •	6. Lo	t# 7.	Exp. Date	#2 📙	Yes ∐ No	Apply
		s Report (mmlddlyyyy)	<u> </u>	#*	1		Reappeared roduction?	After
	1/4/2012		#2	#2	2	· · ·	Yes No	Doesn't
	5. Describe Event or Problem		9. NO	C# or Unique ID				Apply Doesn't
	This supplemental report is being submadditional information based on the me						Yes   No	L Apply
	article that Olympus found on April 27		10. C	oncomitant Medical Proc	ducts and The	rapy Dates (Exclude	treatment of (	event)
	From January to April 2012, 30 patient	ts with a VIM-2-						
м	producing Pseudomonas aeruginosa were	identified. 22 ou	t					
K	of 30 patients had undergone an endosc cholangiopancreatography (ERCP) using					(0	Continue on	page 3)
ÇK	device. 8 out of 30 patients had not u		D. 8	SUSPECT MEDICAL	L DEVICE	1		pigo o,
BLA	7 out of 8 patients without a history		1. Br	and Name				
SEB	history of ICU stay. The device was in user facility in February 2011. No inf		2. Co	mmon Device Name	<del></del>	2b. F	rocode	
$\Box$	the device was involved occurred until	l January 2012. Th		inufacturer Name, City a				
OR	device was withdrawn from clinical use 2012.	e on March 14,	J 3. 1818	indiacturer Name, City a	no State			
TYPE			1			···	,	
$\succeq$	The first patient underwent an ERCP on with the device, and subsequently the			del #	Lot#	•	5. Operator	
SE	isolated from patient's blood culture			talog#	Expiration	Date (mmlddlyyyy)	_	Professional
PLEASE	2012.						Lay Us	
$\mathbf{F}$			Se Se	rial#	Unique Ide	ntifier (UDI) #	Other:	
		(0/	6. If !	mplanted, Give Date (mn	niddiyyyy)	7. If Explanted, Gi	/e Date (mm/	ddlyyyy)
	6. Relevant Tests/Laboratory Data, Including Dates	(Continue on page 3)	-					
	•		1 1	this a Single-use Device Yes	that was Repr	ocessed and Reuse	d on a Patier	117
			1 —	es to Item No. 8, Enter N	lame and Add	ress of Reprocesso	r	
i								
			10.0	evice Available for Evalu	ation? /Do not	rend to EOA)		
					•	anufacturer on:		
			44.0				(mm/dd/yy	
	7 Other Delayant History Laborator Description Health Co.	(Continue on page 3)		oncomitant Medical Prod matic cleaner for			treatment of	eveni)
	<ol> <li>Other Relevant History, Including Preexisting Medical Corace, pregnancy, smoking and alcohol use, hepaticirenal dys.</li> </ol>	functions (e.g., allergies, function, etc.)	ETD-	3 in combination	with pera	cetic acid as	a disinf	ectant
i			L			(C	ontinue on	page 3)
				VITIAL REPORTER me and Address				
			'' ''	Alla Addiess			1	i
ļ								
			Di-			L Classic		, <u>-</u>
- 1		(Continue on page 3)	Phone	s #	Emai	l Address		ļ

#### FOA USE ONLY MEDWATCH Page 2 of 2 FORM FDA 3500A (2/13) (continued) H. DEVICE MANUFACTURERS ONLY F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) Type of Reportable Event 2. If Follow-up, What Type? 2. UF/Importer Report Number 1. Check One User Facility Importer Death Correction . . . 3. User Facility or Importer Name/Address Additional Information Serious Injury Malfunction Response to FDA Request Device Evaluation 4. Device Manufacture Date (mm/yyyy) 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer 5. Phone Number Yes Evaluation Summary Attached 4. Contact Person 5. Labeled for Single Use? No (Altach page to explain why not) or provide code: 8. Date of This Report (mmlddlyyyy) 6. Date User Facility or Importer Became Aware of Event (mmlddlyyyy) 7. Type of Report T Yes ___ Initial 6. Event Problem and Evaluation Codes (Refer to coding manual) Follow-up # Patient 10, Event Problem Codes (Refer to coding manual) 9. Approximate Age of Device Code Device Patient Code Code Device Method Code 12. Location Where Event Occurred 11. Report Sent to FDA? Results Outpatient Diagnostic Facility Hospital Yes . (mmiddlyvyy) ☐ Home Conclusions ☐ No Ambulatory Surgical Facility Nursing Home 13. Report Sent to Manufacturer? 7. If Remedial Action Initiated, Check Type 8. Usage of Device Outpatient Treatment Facility Initial Use of Device Recall Notification Yes (mmlddlyyyy) Reuse ☐ No Other: Repair Inspection (Specify) Patient Monitoring Unknown Replace 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: 14. Manufacturer Name/Address Modification/ Relabeling Other: 10. Additional Manufacturer Narrative and / or 11. Corrected Data According to the journal, the user facility cultured the G. ALL MANUFACTURERS subject device, and clonal relatedness of the VIM-2 P. 2. Phone Number 1. Contact Office (and Manufacturing Site for Devices) aeruginosa was confirmed for 22 cases and for the VIM-2 Name strain isolated under the forceps elevator of the 3. Report Source (Check all that apply) device. Enterococcus faecium was also isolated from this Address site. Environmental sampling was performed, and revealed Foreign the VIM-2 P. aeruginosa in four sinks at the Study Gastroenterology and Hepatology (GEH) department and in a water recipient in the endoscopy suite. In addition, ✓ Literature the VIM-2 is known to be present at the ICU at a low Consumer endemic level. Email Address Health Professional User Facility Repair history of the device was reviewed by an Olympus 4. Date Received by Manufacturer (mmiddlyyyy) subsidiary in Europe. The record showed that the device Company Representative (A)NDA# was repaired one time in November 2011. The device Distributor passed all inspection items of final inspection after IND# 6. If IND, Give Protocol # the repair. Other: BLA# It could not be identified that the device or **PMA** 7. Type of Report 510(k)# environment such as the GEH department and the ICU (Check all that apply)

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Combination Product

OTC Product Yes

8. Adverse Event Term(s)

Pre-1938

Yes

Yes

√ 30-day

9. Manufacturer Report Number

Periodic

5-day

7-day

10-day | initial

Department of Health and Human Services Food and Drug Administration Office of Chief Information Office Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

related to the patient infection. The cause of the

infection could not be conclusively determined.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

No

# Evangelisches Waldkrankenhaus Spandu Berlin, Germany



Date: July 10, 2014

Report Type: Manufacturer Report

#8010047-2014-00393

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,

(



U.S. Department of Health and Human Services Food and Drug Administration

**MEDWATCH** 

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #	8010047-2014-00393	
UF/Importer	Report #	

	FORM FDA 3500A (1/09)	Page 1	of	15					ſ	FDA Use Only
	A. PATIENT INFORMATION  1. Patient Identifier   2.			C. SUSPECT		UCT(S)				PDA OSE ONLY
	R. R.			#1	Desec 30 es	igur & miinabelerj				
	in confidence		_	#2 . Dose, Frequer	nev & Pou	to Used	3 Theren	Dates (II	/ unknown a	rive duration)
	B. ADVERSE EVENT OR PRODUC	CT PROBLEM			icy a nou	te daed	from/to	(or best es	timate)	ive duradony
		duct Problem (e.g., defects/malfunctions)		#1			#1			
	Outcomes Attributed to Adverse Event    (Check all that apply)			#2 Diagnosis for	Han Andia	notical	#2	F 611	Abated After	
	Death:	Disability or Permanent Damage	- 1	#1	USB (INVIC	alion)	l		d or Dose R	Reduced?
	(mm/dd/yyyy)  Life-threatening	Congenital Anomaly/Birth Defect						#1 🗌 Ye	es 🗌 No	Doesn't Apply
	☐ Hospitalization - initiat or prolonged	Other Serious (Important Medical Events)	⊢	#2 . Lot #		7. Exp. Date		#2 Ye	es No	Doesn't Apply
	Required Intervention to Prevent Perma	anent Impairment/Damage (Devices)		f1		#1		8. Event F	Reappeared	
	3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	-	12		#2		Reintro	duction?	Doesn't
	05/26/2014 5. Describe Event or Problem	06/12/2014		. NDC# or Uniqu	ue ID	1#2		#1 Ye	es No	Apply
				. Haran ar anna				#2 🗌 Ye	es 🗌 No	Doesn't Apply
	Olympus was informed that for for carbapenem resistant Kle.		11	0. Concomitant	Medical	Products and The	apy Dates	(Exclude to	reatment of e	event)
-	having undergone an endoscop	ic retrograde								
	cholangiopancreatography (ER were examined with the same									
Z		-								
Š	The user facility conducted endoscope on Jun 3, 2014, an			D. SUSPECT	MEDIO	CAL DEVICE				
$\Gamma$ V	found. The last routine samp	ling of the endoscope on	1	. Brand Name	EVIS E	KERA II DUOI	ENOVID	EOSCOPE		
EВ	April 29, 2014 did not indic	ate anything abnormal.	2			DUODENOENDOS				
$_{ m OSE}$				. Manufacturer			SCOPE			
PLEASE TYPE OR			10	NEW SURFER	CAL SYS	TEMS CORF.	m-lui-	. 00 6165		
PE		İ	⊢∟		a-che,	Hachioji-shi,	токуо .	<del></del> ,		
7				. Model# :JF-Q180V		Lot#			5. Operator	
SE			-	Catalog #		Expiration	n Date (mm	Vdd/yyyy)	_	Professional ser/Patient
ĚΑ			1	Serial#		Other#	N/A		Other:	
H			2	202615		N/A		ļ		
			6	. If Implanted, 0	Give Date	(mm/dd/yyyy)		anted, Giv	e Date (mm/	(dd/yyyy)
	6. Relevant Tests/Laboratory Data, Including	g Dates	, i	N/A	enise Der	rice that was Repr	N/A	nd Reuser	on a Patie	nt?
					No No					
				. If Yes to Item	No. 8, Ent	ter Name and Add	ress of Re	processor		
				·, ·.						
			1		able for E	valuation? (Do no	send to Fi	DA)	06/12/2	014
				✓ Yes	_ No	Returned to M	lanufacture	r on:	(mm/dd/y)	
			1	1. Concomitant	t Medical	Products and The	rapy Dates	(Exclude	treatment of	event)
	<ol> <li>Other Relevant History, Including Preexistance, pregnancy, smoking and alcohol use, in</li> </ol>	sting Medical Conditions (e.g., allergles, hepatic/renal dysfunction, etc.)								
		•								
				E. INITIAL R			,,			
				. Name and Ad	aress	Phone	#			
			ļ							
				Evangelisc	hes Wai	ldkrankenhau	ıs Spane	dau		
						555, 13589 E			·Y	
	Submission of a report does not con	stitute an admission that medical	'   ₂	. Health Profes	sional?	3. Occupation		4. [	nitial Report	ter Also Sent
	personnel, user facility, importer, dis caused or contributed to the event.	stributor, manufacturer or product		Yes [	] No	Physician				No Unk.

### MEDWATCH

TILDITA I OII				_				
ORM FDA 3500	A (1/09) (	continued)		Page	2 of 15			
F. FOR USE BY U	JSER FAC	ILITY/IMPOR	TER (De	vices Only)	H. DE	VICE MANU	IFACTURERS ONLY	
1. Check One				port Number	1. Type	of Reportable I	Event	2. If Follow-up, What Type?
User Facility	impor	ter				Death		Correction
3. User Facility or Impo	orter Name/A	Address				Serious Injury		Additional Information
						Malfunction		Response to FDA Request
						Other:		Device Evaluation
					3. Devi	e Evaluated by	Manufacturer?	4. Device Manufacture Date
					II	Not Returned to		(mm/yyyy)
4. Contact Person			. Phone Nur	mber	1		luation Summary Attached	03/2012
		ľ					e to explain why not) or	5. Labeled for Single Use?
6. Date User Facility of	r  7	. Type of Report	[8	. Date of This Report	┧╽╶	provide code:	o to oxplain trily they at	∵ Yes ☑ No
Importer Became Aware of Event (mm		Initial	İ	(mm/dd/yyyy)				_
		_			6. Eval	uation Codes (F	Refer to coding manual)	
0. 4	110 5	Follow-up#_	ofor to and!	manuall	-	Method	10 - 38	
9. Approximate Age of Device	10. Event P	roblem Codes (Re	erer to coaing	manuaij	_	Micaio		
	Patient Code	1735 -		-		Results	142 -	
	Device			= = =	뒤 [			
	Code	2303	<u> </u>		<u> </u>	Conclusions		
11. Report Sent to FD/	A?	12. Location Wh	ere Event O		7. If Re	medial Action 1	nitiated, Check Type	8. Usage of Device
Yes		✓ Hospital		Outpatient Diagnostic Facility		Recall	Notification	Initial Use of Device
□ No (mm/dd	(yyyy)	☐ Home		Ambulatory		Repair	Inspection	Reuse (
13. Report Sent to Mar	nufacturer?	Nursing H		Surgical Facility		Replace	Patient Monitoring	Unknown
Yes		U Outpatier Facility	nt Trealment			Relabeling	Modification/ Adjustment	If action reported to FDA under     21 USC 360i(f), list correction/     removal reporting number:
No (mm/did	(YYYY)	Other:			_	Other:	710,001110111	removal reporting number:
14. Manufacturer Nam				(Specify)	<b>⊣</b>			
G. ALL MANUFA  1. Contact Office - Nat for Devices)			ng Site	Phone Number     Report Source	SE & confinst on t	CO. KG (O irmed brow rument cha he suction exact caus lusively d	EKG) for evaluation stain and black nnel. In addition channel.	s time. A supplemental
OLYMPUS MEDIO 2951 Ishikawa 192-8507, Jay	a-cho, H	achioji-shi	, Tokyo	(Check all that apply Foreign Study Literature Consumer Health Professiona User Facility	info Plea othe	rmation be se cross-r r three pa	comes available	lowing reports for the 2014-00407,
4. Date Received by Manufacturer (mm/	(dd/yyyv)	5.		Company				(
07/01/2		(A)NDA#		Representative				
6. If IND, Give Protoco		ND#		✓ Distributor				
o. II IND, GIVE PROTOCO	O1#	STN#		Other:				
7. Type of Report		PMA/ 510(k) #			-			
(Check all that apply		Combination			-			
5-day 30-d		Product	Yes					
7-day Pen		Pre-1938	Yes		_			
I — · —	ow-up#	OTC Product	Yes Yes		-			
9. Manufacturer Repo		8. Adverse Eve	ent Term(s)		<b>⊣</b>			
8010047-2014-0					]			
0010047-2014-0	00223							
L							and Human Be-Jees	OMB Statement
The public reporting but minutes per response, a sources, gathering and	including the	time for reviewing	instructions,	en estimated to average searching existing data g and reviewing the	Food a	nd Drug Admini	and Human Services stration tion Officer (HFA-710)	OMB Statement: "An agency may not conduct or sponso and a person is not required to respons to, a collection of information unless it.

collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

5600 Fishers Lane Rockville, MD 20857

to, a collection of information unless it displays a currently valid OMS control number."

FDA USE ONLY

Please DO NOT RETURN this form to this address.

# Fox Chase Cancer Center, Philadelphia, Pennsylvania

# MEDWATCH

JE BLACK INK

PLEASE TYPE O.

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	See Civid a	Esternera orrieverse.
Mfr Report #	2431293-2015-00007	
UF/importer i	Report #	
		EDA Has Only

FORM FDA 350	0A (2/13)			Page 1	ot <u>~</u>						1	FDA Use Only
A. PATIENT INF	ORMATION				C. SUSPE	CT PRO	DUCT(S	6)				
1. Patient  dentifier			3. Sex	4. Weight	1. Name (Give	labeled str	ength & m	fr/labeler)				
	of Event:		☐ Female	lbs	#1							
	or Date			or	#2							
In confidence	of Birth:		Mate	kgs	2. Dose, Freq	uency & Ro	oute Used	<u> </u>	3. Therapy	Dates (#	unknown, g	ive duration)
B. ADVERSE E	VENT OR PRODU	ICT PROBLE	M			,			from/to (d	or best ès		•
1. Adverse Even	t and/or 📝 Pr	oduct Problem (e	.g., defects/malf	unctions)	#1				#1			
	ted to Adverse Event				#2				#2			
(Check all that appl	y)	Disabeting.			4. Diagnosis	for Use (Inc	tication)	•	5		Abated Affer d or Dose R	
Death:	(mm/dd/yyyy)		or Permanent Da	· I	#1						s No	☐ Doesn't
Life-threatenin	-		I Anomaly/Birth D	- 1	#2				-			☐ Apply
,	n - initial or prolonged	i	ous (Important M	1	6. Lot#		7. Exp	. Date	#	2 Ye	s 🗌 No	Doesn't Apply
<u></u>	vention to Prevent Pem				#1		#1		8		Reappeared	After
3. Date of Event (mn	1/dd/yyyy)	1	Report (mm/dd		#2		#2			,,,,,,,	duction?	☐ Doesn't
		<u>.                                    </u>	06/05/2019	3	9. NDC# or U	niaue ID	#2			-1 re	es No	☐ Apply
<ol> <li>Describe Eventor</li> <li>As reported b</li> </ol>	Problem y the customer	:			3. NOON 01 01	iique iib			#	2 🗌 Ye	es No	Doesn't Apply
Sometime betw	een 04/21/2015 cultured and	and 05/06/		subject	10. Concomit	ant Medica	Product	s and The	erapy Dates (i	Exclude to	reatment of e	
Klebsiella Pn	eumoniae.											
					D. SUSPE	CT MED	ICAL D	EVICE		(Co	ontinue on	page 3)
					1. Brand Nam	Fujin						
					2. Common D Endoscope					2b. Pn 78F~	ocode DT	
					3. Manufactus Fujifilm C 4112 Tono,	ptics Co	., Ltd.	Mito		224		
					4. Model # ED-530XT		/L	.ot #			5. Operator	
					Catalog #		E	xpiration	Date (mm/dd	(yyyy)	Lay Us	Professional er/Patient
					Serial# ND102A064		U	nique Ide	entifler (UDI) #	ŧ	Other:	
			(Continue or	page 3)	6. If Implanted	f, Give Date	e (mm/dd/)	(YYYY)	7. If Explan	ted, Give	Date (mm/c	id/yyyy)
6. Relevant Tests/Lat	boratory Data, includin	ig Dates	,	, , ,	8. is this a Sir	igle-use De	vice that	was Rep	rocessed and	Reused	on a Patien	t?
					Yes	✓ No		·				
					9. If Yes to Ite	m No. 8, Er	nter Name	and Add	ress of Repr	ocessor	•	
•					10. Device Av	ailable for F	Evaluation	n2 (Do 40	I send to FDA	<u> </u>		
					√ Yes	∏ No		-	tanufacturer o		05/22/20	)15
					<u> </u>						(mm/dd/yy	
			(Continue on		11. Concomita	int Medical	Products	and The	rapy Dates (	Exclude tr	reatment of a	vent)
<ol><li>Other Refevant His race, pregnancy, sn</li></ol>	story, including Preexist toking and alcohol use,	sting Medical Cor hepatic/renal dysf	nditions (e.g., ai unction, etc.)	lergies,								
										(Co	ntinue on	page 3)
				l	E. INITIAL	REPORT	TER					
					1. Name and A	Address						
					Fox Chase	Cancer	Cente	r				
					333 Cottm	an Ave.						
					Philadelp	hia, PA	19111					
					Phone #			Ema	il Address			
	<u></u>	····	(Continue on									
Submission of a re ersonnel, user fa	eport does not con cility, importer, dis	nstitute an adr	mission that	medical product	2. Health Prof	1					itial Reports sport to FDA	er Also Şent N
aused or contrib	uted to the event.	annumber; male	windling Of	p. 0000E	✓ Yes [	No	Physic	ian		1 [	Yes 🗍 N	lo 🕢 Unk.

### MEDWATCH

. Check One

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

Yes

No

Address

Email Address

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

5-day

7-day

10-day

05/06/2015

√ 30-day

___ Initial

2431293-2015-00007

Periodic

Follow-up # 9. Manufacturer Report Number

□ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient. Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Fujifilm Medical Systems USA Inc.

10 High Point Drive, Wayne, NJ 07470

Fujifilm Optics Co., Ltd, Mito Factory 4112 Tono, Hitachiomiya City, Japan

FORM FDA 3500A (2/13) (continued)

3. User Facility or Importer Name/Address

Importer

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

Follow-up #

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Home

Other:

12. Location Where Event Occurred

Outpatient Treatment Facility

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

3. Report Source

Foreign

Consumer

✓ Health Professional ✓ User Facility

Company Representative

Distributor

Other

Study Literature

(Check all that apply)

(mm/dd/yyyy)

Page	2	of	2

		FDA USE ONLY	
_	1		
2		•	
H. DEVICE MANUF	ACTURERS ONLY		
. Type of Reportable Ev		2. If Follow-up, What Type?	-
	2,11	Correction	
Death		=	
Serious Injury		Additional Information	
Malfunction		Response to FDA Request	
		Device Evaluation	
Device Evaluated by M	lanufacturer?	4. Device Manufacture Date	
Not Returned to M		(mm/yyyy)	
<u> </u>		12/21/2011	
Yes Evalua	ition Summary Attached		
No (Attach page to provide code:	o explain why not) or	5. Labeled for Single Use?	
provide code.		Yes 🗸 No	
Event Problem and Ev	aluation Codes (Refer to	coding manual)	
Patient	3190 -	]_[	
Code			
Device Code	2895 -	2303 - 1091	
Code			
Method	10 -	<u> - </u>	
Results	142 -		
Conclusions	18 - 61		
Concacions	15 - 72		
If Remedial Action Initi		8. Usage of Device	
II I COMPANIA PROGRAMMA	iated, Check Type	b. daage of Device	
Recall	iated, Check Type  Notification	Initial Use of Device	
	_ ' '		
Recall	Notification	Initial Use of Device	
Recall Repair Replace	Notification Inspection Patient Monitoring	☐ Initial Use of Device ☐ Reuse ☐ Unknown  9. If action reported to FDA under	
Recall Repair	Notification Inspection Patient Monitoring	☐ Initial Use of Device ☑ Reuse ☐ Unknown	
Recall Repair Replace	Notification Inspection Patient Monitoring Modification/	☐ Initial Use of Device ☐ Reuse ☐ Unknown  9. If action reported to FDA under 21 USC 360I(f), list correction/	
Recall Repair Replace Relabeling	Notification Inspection Patient Monitoring Modification/	☐ Initial Use of Device ☐ Reuse ☐ Unknown  9. If action reported to FDA under 21 USC 360I(f), list correction/	
Recall Repair Replace Relabeling Other:	Notification Inspection Patient Monitoring Modification/ Adjustment	☐ Initial Use of Device ☐ Reuse ☐ Unknown  9. If action reported to FDA under 21 USC 360l{f), list correction/ removal reporting number:	
Recall Repair Replace Relabeting Other:	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:  and / or  11. Corrected Data	
Recall Repair Replace Relabeting Other:  Additional Manuf.	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical	
Recall Repair Replace Relabeting Other:  Additional Manufing 05/07/2015, rystems Endoscop	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visi	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a	
Recall Repair Replace Relabeling Other:  Additional Manuf. 05/07/2015, r ystems Endoscop	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visi is time patient	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical	
Recall Repair Replace Relabeling Other:  OS/07/2015, rystems Endoscoppillow up. At thisk Management	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visitis time patient is still invest	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360HI), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed	
Recall Repair Replace Relabeling Other:  Other:  Additional Manuf.  05/07/2015, republic with the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of th	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visi is time patient is still invest which had multipreviously been	Initial Use of Device Reuse Unknown  9. Maction reported to FDA under 21 USC 360MM, list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed drug resistant exposed to the endoscope	
Recall Repair Replace Relabeling Other:  Other:  Additional Manuf.  O5/07/2015, rystems Endoscop bllow up. At the lisk Management aree patients, lebsiella, had a question. It	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visitis time patient is still invest which had multipreviously been is unknown if to	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360HI), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed drug resistant	- 1
Recall Repair Replace Relabeling Other: Other: Others Endoscopollow up. At this k Management have patients, lebsiella, had n question. It	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visitis time patient is still invest which had multipreviously been is unknown if to	Initial Use of Device Reuse Unknown  9. Maction reported to FDA under 21 USC 360MM, list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed drug resistant exposed to the endoscope	- 1
Recall Repair Replace Relabeling Other:  Other:  Additional Manufication of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the c	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visi is time patient is still invest which had multi previously been is unknown if ti	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed drug resistant exposed to the endoscope he patients were infected	- 1
Recall Repair Replace Relabeling Other:  Additional Manuf O5/07/2015, r ystems Endoscop pllow up. At th lask Management have patients, lebsiella, had had question. It y the endoscope	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visi is time patient is still invest which had multip previously been is unknown if ti	Initial Use of Device Reuse Unknown  9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed drug resistant exposed to the endoscope he patients were infected ts on 05/19/2015,	- 1
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Recall Repair Replace Relabeling Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other: Othe	Notification Inspection Patient Monitoring Modification/ Adjustment  acturer Narrative epresentatives y Division visities time patient is still invest, which had multipreviously been is unknown if ties contact attempt 5/26/2015 were reacted with the subject d with the subject formation has in the subject endos Systems Endosce the customer state film, the subject and subsequent the was then EO ga	Initial Use of Device Reuse Unknown  9. Maction reported to FDA under 21 USC 360MB, list correction/ removal reporting number:  and/or 11. Corrected Data from Fujifilm Medical ted the facility as a status is unknown and igating. It is believed drug resistant exposed to the endoscope he patients were infected ts on 05/19/2015, made to the facility's rding condition of ect endoscope. As of been provided by the  scope was received at opy Division and placed tes that prior to et endoscope was high tly tested negative on	

This section applies only to requirements of the Paperwork Reduction Act of 1996. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

Combination

OTC Product

Product

Pre-1938

510(k) # K042076

8 Adverse Event Term(s)

Yes

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Please DO NOT RETURN this form to the above PRA Staff email address.

# Froedtert Hospital Milwaukee, Wisconsin



August 15, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mir Report#	2951238-2014-00023	
UF/Importer I	Report #	· · · · · · · · · · · · · · · · · · ·

### **MEDWATCH**

FORM FDA 3500A (1/09)

Page 1 of 2

FORM FDA 3500A (1/09)	Page 1			FDA Use Only
A. PATIENT INFORMATION		C. SUSPECT PROD		
Patient identifier     2. Age at Time     of Event:	3. Şex 4. Welght	1. Name (Give labeled street	ngth & mfr/labeler)	
or	Female ibs	#1		
In confidence of Birth:	Male kgs	#2 2. Dose, Frequency & Ros	ita Ilead	3. Therapy Dates (If unknown, give duration)
B. ADVERSE EVENT OR PRODUCT PROBLE	M		110 0360	from/to (or best estimate)
. Adverse Event and/or Product Problem (	e.g., defects/malfunctions)	#1		#1
2. Outcomes Attributed to Adverse Event		#2		#2
(Check all that apply)  Death: Disability	or Permanent Damage	4. Diagnosis for Use (India	cation)	5. Event Abated After Use Stopped or Dose Reduced?
(mm/dd/yyyy)	il Anomaly/Birth Defect	#1		#1 Yes No Doesn
	ious (Important Medical Events)	#2 8. Lot#	7. Exp. Date	#2 Yes No Doesn
Required intervention to Prevent Permanent impairmen	nVDamage (Devices)	#1	#1	8. Event Resppeared After
3. Date of Event (mm/dd/yyyy) 4. Date of This	Report (mm/dd/yyyy)	·		Reintroduction?
		#2 9. NDC# or Unique ID	#2	#1 Yes No Doesn
5. Describe Event or Problem		8. NDC# Of Offique ID		#2 Yes No Doesn
		10. Concomitant Medical	Products and Ther	apy Dates (Exclude trealment of event)
		D. SUSPECT MEDI	CAL DEVICE	
		1. Brand Name		
		2. Common Davice Name	•	
		3. Manufacturer Name, C	Ity and State	<del></del>
		4. Model#	Lot#	5. Operator of Device
		Catalog #	Evolvation	n Date (mm/dd/yyyy)
		Catalog #	Expiration	Lay User/Patient
		Serial #	Other#	Other:
		8. If Implanted, Give Date	e (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
6. Relevant Tests/Laboratory Data, Including Dates				
o. Adipatilit leater Laboratory Data, moldaring Datas		8. Is this a Single-use De	ivice that was Repi	rocessed and Reused on a Patient?
		9. If Yes to Item No. 8, E	nter Name and Add	ress of Reprocessor
		10. Davice Available for	Evaluation? (Do no	t send to FDA)
		Yes No	Returned to N	Manufacturer on:
		11. Concomitant Medica	l Products and The	prapy Dates (Exclude frealment of event)
7. Other Relevant History, including Preexisting Medical	Conditions (e.g., allergies,			
race, pregnancy, smoking and alcohol use, hepatic/renal d	resumann, acc.)			
		E. INITIAL REPOR		
	ļ	1. Name and Address	Phon	e #
			L	
	ļ			
Submission of a report does not constitute an a	dmission that medical	2. Health Professional?	3. Occupation	4. Initial Reporter Also Se
personnel, user facility, importer, distributor, m	anufacturer or product	☐ Yes ☐ No		Report to FDA

MEDWATCH				FDA USE ONLY	
	A (1/09) (continued)	Page 2	of ²		
	JSER FACILITY/IMPORTER (E		H. DEVICE MANUFACTURERS ONLY	,	
1. Check One	2. UF/Importer F		1. Type of Reportable Event	2. If Follow-up, What Type?	
User Facility	Importer Importer		Death	X Correction	
3. User Facility or Imp	orter Name/Address		Serious injury	Additional Information	
			Malfunction	Response to FDA Request	
			Other:	Device Evaluation	
			3. Device Evaluated by Manufacturer?	4. Device Manufacture Date (mm/yyyy)	
			Not Returned to Manufacturer		
4. Contact Person	5. Phone N	umber	Yes Evaluation Summary Attached	5 t sholed for Clark the C	
6. Date User Facility o	r 7. Type of Report	8. Date of This Report	No (Attach page to explain why not) οτ provide code:	5. Labeled for Single Use?	
Importer Became Aware of Event (mm		(mm/dd/yyyy)		Yes No	
			6. Evaluation Codes (Refer to coding manual)		
O. Assessimate	Follow-up #  10. Event Problem Codes (Refer to code	, , , , , , , , , , , , , , , , , , ,	Method 10 - 23	37 - 3264	
9. Approximate Age of Davice		ng manuari	mentod 10		
	Patient Code -		Results 3251 -		
	Device		Conclusions 75 -	<u> </u>	
11. Report Sent to FD/	Code	Occurred	7. If Remedial Action Initiated, Check Type	8. Usage of Device	
Yes	Hospital	Oulpatient	Recall Notification	Initial Use of Device	
No (mm/dd	//////// Home	Diagnostic Facility	Repair Inspection	Reuse	
13. Report Sent to Mar	nufacturer? Nursing Home	Ambulatory Surgical Facility	Replace Petient Monitoring	Unknown	
□Yes	Outpatient Treatme	nt	Relabeling Modification/	9. If action reported to FDA under 21 USC 3601(f), list correction/	
□ No (mm/dd			Adjustrion	removal reporting number:	
14. Manufacturer Nam	a/A ddsann	(Specify)			
14. managacturer Ham	UMULIUS .		10. Additional Manufacturer Narrative	and / or 11. ✓ Corrected Data	
		-	This supplemental report is be		
			the incorrect MFR Report number	=	
			The correct MFR Report number : 2951238-2014-00023. See section		
G. ALL MANUFA	CTURERS		2331230-2014-00023. See Section	511 G5.	
1. Contact Office - Nar	meiAddress (and Manufacturing Site	2. Phone Number	As part of our investigation in was sent to an independent off		
for Devices)	•		microbiological testing and Es	4	
		3. Report Source (Check all that apply)	recovered from the device. The device was then forwarded		
		Foreign	to Olympus for physical evalua	tion.	
	i	Study	The device was returned to Oly		
		Literature	device passed the leak test. T issues that could contribute o		
· ·		Consumer	phenomenon. There was no sign	of bio-materials in the	
		Health Professional User Facility	device. The device was refurbiuser facility.	shed and returned to the	
4. Date Received by Manufacturer (mm/c	fd/vvvv) 5.	Company	14001 14001140,		
08/11/2	014 (A)NDA#	Representative			
8. If IND, Give Protoco		Distributor Other:			
	STN#	·   Outen	<b> </b>		
7. Type of Report	PMA/ 510(k) #				
(Check all that apply)	Combination				
5-day	odle		1 1		
10-day Initia	1 Pre-1938				
,	w-up#2 OTC Product Yes				
9. Manufacturer Repo	rt Number 8. Adverse Event Term(s	)			
2951238-2014-0	0023				
			<b> </b>		
The public reporting bur	den for this collection of information has b	en estimated to average 66	Department of Health and Human Services	OMB Statement:	

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Heafth and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, 420A Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.



January 28, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.



Copies:

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report#	2951238-2014-00023
UF/Importer F	Report #

#### MEDWATCH

PLEASE TYPE OR USE BLACK INK

MEDITATOR	Dama 4 as 2				····
FORM FDA 3500A (1/09)	Page 1 of 2	_			FDA Use Only
A. PATIENT INFORMATION	C. 8	SUSPECT PROD	UCT(S)		
1. Patient Identifier 2.	1. Na	me (Give lebeled stre	ngih & mfr/labeler)		
	#1				
	#2				
In confidence	2. Do	se, Frequency & Ro	ute Used	3. Therapy Dates	(if unknown, give duration)
B. ADVERSE EVENT OR PRODUCT PROBLEM	#1			from/to (or best	estimate)
1. Adverse Event and/or Product Problem (e.g., defects/melfunction)	ons) —				· · · · · · · · · · · · · · · · · · ·
2. Outcomes Attributed to Adverse Event	#2			#2	
(Check all that apply)  Death: Disability or Permanent Demage		ignosis for Use (Indi	cation)		t Abated After Use ped or Dose Reduced?
(mm/aa/yyyy)	#1				Yes Mo Mo Doesn't
Life-threatening Congenital Anomaly/Birth Defec	#2			<del>-</del>	Apply
Hospitalization - Initial or prolonged Other Serious (Important Medic	6. Lo	t#	7. Exp. Date	#2 🗀	Yes No Doesn't
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1		#1		t Reappeared After
3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyy)			#2	1 -	roduction?
05/19/2013 01/06/2014	#2	Off on Holoup ID	#4	# ¹ L.	Yes No Apply
5. Describe Eventor Problem Olympus was informed that five patients tested posi	1 1	IC# or Unique ID		#2	Yes No Doesn't
for Carbenepenum Resistant Enterbacteriaceae contai	-t   L	oncomitant Medical	Denducts and The	Dates (Evelude	Apply
New Delhi Metallo-beta-lactamase (CRE-NDM) after ha	ving 10.0	oncomitant medical	Products and the	lapy Dates (Excitor	a dealine in Or dvorry
undergone an endoscopic retrograde					
cholangiopancreatography (ERCP) procedure. The pati were examined with the same duodenovideoscope.	ents				
Hara avenue aren ena anna anadena radoccada.	11				
On April 25, 2013, resistant E.coli was found in th		SUSPECT MEDI	CAL DEVICE		
first patient's blood. On May 19, 2013 that patient					
underwent an ERCP with stone extraction subsequentle developing cholangitis. On May 20, 2013 resistant E	·     " - "	and Name	s EVIS EXER	A II Duodeno	rideoscope
coli was found in the patient's bile duct fluid. The	2. Co	mmon Device Name	Duodenovide	DSCODE	
patient was hospitalized for an unspecified amount	V-	nufacturer Name, C			
time. The patient was discharged went back to India	OLYN 2951	PUS MEDICAL SY: I Ishikawa-cho,	STEM CORPORATI		07, Japan
An Endoscopy Support Specialist was dispatched to t user facility. A reprocessing in-service has not be		del#	Lot#		5. Operator of Device
scheduled to date.		-Q180V	N/A		Health Professional
	Ci	talog#	Expiratio	n Date (mm/dd/yyy)	Lay User/Patient
		-Q180V		Unk	Other:
	1 1	riai# 1529	Other#		
	1 1	mplanted, Give Date		7. If Explanted, G	live Date (mm/dd/yyyy)
		/A	,	N/A	,
6. Relevant Tests/Laboratory Data, Including Dates	8. Is	this a Single-use De	vice that was Rep	rocessed and Reus	ed on a Patient?
		Yes ☑ No			
	9. If '	Yes to Item No. 8, En	ter Name and Add	iress of Reprocess	or
	"/"				
	[ ]				
	10.0	evice Available for I	valuation? (Do no	t send to FDA)	
1		Yes 📝 No	Returned to N		
					(mm/dd/yyyy)
		oncomitant Medical pe Buddy Model		orapy Dates (Exclud	de treatment of event)
<ol> <li>Other Relevant History, including Pressisting Medical Conditions (e.g., aflerg race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)</li> </ol>	les, Med	ivators scope		/sn# unk	
Non-Hodgkin's Lymphoma, chemo, S/P autologous perir		•			
stem cell transplant (4/18/13), prior cholecystecto		NITIAL REPOR	TER		
CBD dialation, MRCP shows some biliary stone		me and Address	Phon	e#	
			L		
	F	edert Hospita	1		
1		0 W. Wisconsi			
		waukee, WI 53			
	] <b>[</b>				
		the Market Land	9 Constant		Initial Reporter Also Sent
Submission of a report does not constitute an admission that me personnel, user facility, importer, distributor, manufacturer or pro-	idical [2. H	ealth Professional?	,	ľ	Report to FDA
personnel, user facility, importer, distributor, manufacturer or pricaused or contributed to the event.	Q	Yes No	Risk Manager		Yes No Unk.

OCA_0000831

#### "FOA USE ONLY **MEDWATCH** Page 2 of 2 FORM FDA 3500A (1/09) (continued) F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) H. DEVICE MANUFACTURERS ONLY 2. UF/Importer Report Number 1. Type of Reportable Event 2. If Follow-up, What Type? 1. Check One User Facility [ ] Importer Correction ☐ Death 3. User Facility or Importer Name/Address Serious injury Additional Information Response to FDA Request Matfunction Device Evaluation Other: 4. Device Manufacture Date 3. Davice Evaluated by Manufacturer? Not Returned to Manufacturer 5. Phone Number 4. Contact Person Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: 5. Labeled for Single Use? 6. Date User Facility or 7. Type of Report 8. Date of This Report Yes Yes **√** No Importer Became Aware of Event (mm/dd/yyyy) (mm/dd/yyyy) Initial 6. Evaluation Codes (Refer to coding menual) Follow-up # Method 9. Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) Patient 1735 Results Code Davice 2993 Conclusions 20 Code 7. If Remedial Action Initiated, Check Type 8. Usage of Device 11. Report Sent to FDA? 12. Location Where Event Occurred Outpatient Initial Use of Device Hospital Notification Recall Yes Diagnostic Facility (mm/dd/yyyy) Reuse Home Repair Inspection ☐ No Ambulatory Surgical Facility Unknown Nursing Home Patient Monitoring 13. Report Sent to Manufacturer? Replace If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number: Outpatient Treatment Modification/ Relabeling Yes . (mm/dd/yyyy) ☐ No Other: Other: (Specify) 14. Manufacturer Name/Address 10. 📝 Additional Manufacturer Narrative and / or 11. Corrected Data The device has not been yet returned for evaluation. The exact cause of the user's experience could not be conclusively determined at this time. A supplemental report will be submitted if additional and significant information becomes available later. G. ALL MANUFACTURERS Contact Office - Name/Address (and Manufacturing Site for Devices) 2. Phone Number Please cross-reference the following reports for the other four patients: 2951238-2014-00024, Report Source (Check all that apply) OLYMPUS AMERICA, INC 2951238-2014-00025, 2951238-2014-00026, and 2400 Ringwood Avenue 2951238-2014-00027. Foreign San Jose, CA 95131 Sludy OLYMPUS MEDICAL SYSTEM CORPORATION Literature 2951 Ishikawa-cho, Hachioji-shi, Tokyo Consumer 192-8507, Japan Health Professional User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 01/06/2014 Distributor IND# 6. If IND, Give Protocol # Other: STN# 7. Type of Report (Check all that apply) 510(k) # Combination Product √ 30-day Yes Yes 5-day Periodic 7-day Pre-1938 ☐ Yes 10-day 📝 Initial OTC Product Yes 15-day Follow-up# 9. Manufacturer Report Number 8. Adverse Event Term(s) 2951238-2014-00023 OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Department of Health and Human Services Food and Drug Administration The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of

Office of Chief Information Officer 1350 Piccard Drive, 420A

Please DO NOT RETURN this form to this address.

Rockville, MD 20850

this collection of information, including suggestions for reducing this burden to:

OCA 0000832

# Hartford Hospital Hartford, Connecticut

# **OLYMPUS**

May 22, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

**U.S. Department of Health and Human Services**Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Vifr Report #	2951238-2014-00174	
UF/Importer I	Report #	

### **MEDWATCH**

FORM FDA 3500A (1/09)

A. PATIENT INFORMATION

Patient Identifier 2. Age at Time of Event:

Page 1 of ²

4. Weight

3. Sex

RY reporting	UF/Importer Re	port#			
2					FDA Use Only
C. SUSPECT PRODU	JCT(S)				DA ON ONLY
t. Name (Give lebeled stren					
#1					
#2					
2. Dose, Frequency & Rou	te Used	3. Therapy from/to (o			ive duration)
#1		#1			
#2		#2			
4. Diagnosis for Use (Indica	stion)	5.		lbated After d or Dose F	
#1		*	1 🗌 Ye	es 🔲 No	Doesn't Apply
#2	7 Fra Data		2   Ye	es No	Doesn't Apply
5. Lot#	7. Exp. Date #1	8.	Event F	Reappeared	
#1		1	Reintro	duction?	r Doesn't
#2 9. NDC# or Unique ID	#2	<del></del> -  <u>*</u>	1   Y	es No	Apply
Wilder of Builds in		#	2 [] Y	es No	Doesn't Apply
0. Concomitant Medical P	roducts and The	rapy Dates (E	xclude t	reatment of	event)
D. SUSPECT MEDIC	AL DEVICE				
Daniel Maria	EVIS EXER	II Duoc	ienovi	deoscop	е
Common Device Name	Duodenovide				
Manufacturer Name, Cit	y and State				
OLYMPUS MEDICAL SYS 2951 Ishikawa-cho,	TEM CORPORATI		2-8507	, Japan	
. Model #	Lot #				r of Device
TJF-Q180V	N/A				Professional
Catalog #	Expiration Date (mr		kd/yyyy)		ser/Patient
TJF-Q180V Serial#	Other#			Other	:
2304031	N/A				
<ol> <li>If Implanted, Give Date</li> <li>N/A</li> </ol>	(mm/dd/yyyy)	7. If Explan	ited, Giv	e Date (mm	/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?					
Yes No					
9. If Yes to Item No. 8, Ent N/A	er Name and Add	iress of Repr	OCOSEOI	•	
10. Device Available for E					
Yes V No	_			(mm/dd/)	
11. Concomitant Medical I Custom Ultrasonics			(Exclude	treatment o	f event)
COSCOM CICAGOUITCE		-			
l					
E. INITIAL REPORT	ER				
1. Name and Address	Phon	- "			
n					
Hartford Hospita: 80 Seymour Street					
Hartford, CT 061					
2. Health Professional?			4.	Initial Repo Report to F	rter Also Sent DA
Yes No	Administrator/Su	pervisor			No 💽 Unk.

		or		Female	<u>-</u>	lbs	
	In confidence	Oate of Birth:		Male Male	or	kgs	
		VENT OR PRODUC	T PROBLE	И			
	1. 🕢 Adverse Even	t and/or Pro-	duct Problem (e.	a defects/math	unctions)		
	2. Outcomes Attribut		adet i resioni (e	g., dorotto mane		$\dashv$	
(Check all that apply)							
	Death:	(mm/dd/yyyy)	`	r Permanent Da	-		
	Life-threatenin			Anomaly/Birth C			
		- initial or prolonged vention to Prevent Perms	Œ.	ous (Important M		ונבויוי	
	3. Date of Event (mm		4. Date of This		· · · · · · · · · · · · · · · · · · ·		
		7/2014		05/02/2014			
	5. Describe Event or					_	
		nformed that two Escherichia col					
		trum Beta Lacta					
	undergone an e	endoscopic retr	ograde				
	cholangiopanc	reatography (ER isolated from	CP) proced:	ure. The p	ositiv	e	
Ě۱		nd bile. The par			with		
7	four different	t duodenovideos	copes. The	se			
AC.		copes were cult		by the us	er		
OR USE BLACK INK	racility. No (	organisms were	1901ated.				
岡		, 2014, the fir					
5		he procedure, t	-		y test	ed	
8	information wa	resistant E. co as available.	II. NO EGG	rtionar			
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L							
Ξ							
ASE							
PLE							
-							
			.,-				
	6. Relevant Tests/Lat	boratory Data, Including	g Dates				
- {							
	7. Other Relevant His	story, including Preexis	ting Medical Co	nditions (e.g., a	llergies,		
	race, pregnancy, sn	noking and alcohol use, i	nepatic/renal dys	function, etc.)			
	Pite andt opst	truction stents					

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

MEDWATCH	ı					FDA USE ONLY
FORM FDA 3500		ued)	Page	2 of ²		
F. FOR USE BY			evices Only)	H. DEVICE MANUFAC	TURERS ONLY	
1. Check One		2. UF/Importer F		Type of Reportable Event		2. If Follow-up, What Type?
User Facility	mporter [			☐ Death		Correction
3. User Facility or Imp	orter Name/Address	.1		Serious Injury		Additional Information
				Matfunction		Response to FDA Request
i				Other:		Device Evaluation
				3. Device Evaluated by Manu	ufacturer?	4. Device Manufacture Date
				✓ Not Returned to Manu	sfacturer	(mm/yyyy)
4. Contact Person		5. Phone N	umber			unk
				☐ No (Attach page to ex	xplain why not) or	5. Labeled for Single Use?
6. Date User Facility o Importer Became	7. Type o	f Report	8. Date of This Report (mm/dd/yyyy)	provide code:		☐ Yes ☑ No
Aware of Event (mm	n∕dd∕yyyy) 🗀 Initia	t	(11111111111111111111111111111111111111			
	Follo	w-up#		6. Evaluation Codes (Refer to	o coding manual)	
9. Approximate	10. Event Problem C		ng manual)	Method	-	-   -
Age of Device	Patient C					
	Code 1735			Results		J [*] L
	Device 2993	-	_	Conclusions	20 -	]-[
11. Report Sent to FDA		ation Where Event	Occurred	7. If Remedial Action Initiate	d, Check Type 8.	Usage of Device
I _ `		Hospital	C Outpatient	II		Initial Use of Device
Yes(mm/dd	,   <u></u>	Home	Diagnostic Facility	1 1 2 2	lotification	Reuse
13. Report Sent to Mar	nufacturer?	Nursing Home	Ambulatory Surgical Facility	! I = ' = =	atient Monitoring	Unknown
l _ '		Outpatient Treatmen	at		Indification/ 9.	if action reported to FDA under
Yes(mmi/dd	/yyyy)	Facility Other:			djustment	21 USC 360i(f), list correction/ removal reporting number:
L	"	Office.	(Specify)	Other:		
14. Manufacturer Name	e/Address	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
ļ				10. 📝 Additional Manufactu	urer Narrative an	d / or 11. Corrected Data
					oort has not yet been	
				returned to Olympus	s for evaluation	on.
				As part of our inve	estigation with	ı this report, Olympus
G. ALL MANUFA	CTURERS					facility to observe the
Contact Office - Nan     for Devices)	ne/Address (and Mar	nufacturing Site	2. Phone Number			ctices. There were minor ocessing of the device.
				It was noted that	the user facili	ty had no suction in
OLYMPUS AMERI			3. Report Source (Check all that apply)	the reprocessing room and the staff were not using a syringe to flush around the forceps elevator riser area.		
2400 Ringwood San Jose, CA			Foreign	Syringe to riush a.	Today the folle	.po erevetor riser ared.
1			Study	The exact cause of the user's experience could not be		
	AL SYSTEM COR		Literature	· ·		ime. A supplemental
192-8507, Jap		,,	Consumer	information becomes available later.		
			Health Professional	Diama current	ones the faller	ilna unnauta for the
Date Received by Manufacturer (mm/d)	5.		User Facility	other eleven cases		ving reports for the -00211,
05/02/20	(A)ND	A #	Company Representative	2951238-2014-00212	, 2951238-2014-	-00213,
6. If IND, Give Protoco	{N	D#	Distributor	2951238-2014-00219 2951238-2014-00221		
S. II IIID, GIVE PROTOCO		N#	Other:	2951238-2014-00221		
7.7	РМА			2951238-2014-00225	and 2951238-20	014-00226.
7. Type of Report (Check all that apply)	510(1					
5-day (7) 30-da	l Comb	ination ct Yes				İ
7-day Perio	Pre-19	938				İ
10-day 🗸 Initial	1 0101	Product Yes				
<u> </u>	w-up #			<u> </u>		
9. Manufacturer Repor		erse Event Term(s)				
2951238-2014-0	0174					
				]		
The public reporting burg	ten for this collection of	f information has be	en estimated to average 66	Department of Health and Hum	nan Services	OMB Statement:

The nie public reporting durden for this collection of information has been estimated to average to minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

Umis Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



February 13, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is a supplemental report for a previously reported 30-day MDR reportable event. Any further correspondence may be directed to my office.





Copies:

For use by user-facilities, rters, distributors and manufacturers for MANDATORY reporting

Form Approved: UMB No. 09	10-0291, Expires: 6/30/201
286	OMB statement on reverse

See OMB state	xpires: 6/30/20 ment on rever
Mfr Report # 2951238-2015-00001	

UF/Importer Report #

Food and Drug Administration	For use by user- importers, distributors a
MEDWATCH	for MANDATOR

FORM FDA 3500A (2/13)

Page 1 o

2	-			<u></u>	·	
	ODUCT	(6)				FDA Use Only
C. SUSPECT PF  1. Name (Give labeled)		· ·				
#1	-	·				
#2						
2. Dose, Frequency &	Route Us	sed	3. Therap	y Dates (1	f unknown, g	ive duration)
#1			#1	(or best e	stimate)	
#2			#2		<del></del>	
4. Diagnosis for Use	(Indication	)	#2	5. Event	Abated Afte	rllee
#1	•	,		Stoppe	ed or Dose F	Reduced?
#2				#1   Y	es No	Doesn't Apply
6. Lot#	7. F	Exp. Date		#2 🔲 Y	es No	Doesn't Apply
#1	#1	·		8. Event I	Reappeared	
#2	—   #2			#1 Y	oduction?	┌── Doesn't
9. NDC# or Unique II				\ <u>"</u> "	es   No	Apply
				#2 🔲 Y	es 🗌 No	Doesn't Apply
10. Concomitant Me	dical Prod	ucts and The	rapy Dates	Exclude (	reatment of	event)
				(C	ontinue on	. noro 21
D. SUSPECT M	EDICAL	DEVICE		()	Ontinue on	paye 3)
1. Brand Name				_		
2. Common Device	Name			2b. P	rocode	
0.11	- 01	. 1 04-4-				
3. Manufacturer Nar	ne, City an	id State				
	<del> </del>	· · · · · · · · · · · · · · · · · · ·				
4. Model #		Lot#			5. Operator	of Device
Catalog #		Expiration	n Date (mm	n/dd/yyyy)		Professional
	· · · · · · · · · · · · · · · · · · ·					ser/Patient
Serial #		Unique Id	entifier (UI	)) #	Other:	
6. If Implanted, Give	Date (mm	/dd/yyyy)	7. If Exp	planted, GIV	ve Date (mm/	/dd/yyyy)
8. Is this a Single-u	se Device Vo	that was Rep	processed	and Reuse	d on a Patie	nt?
9. If Yes to Item No.		lame and Ad	Idress of R	eprocesso	r	
10. Device Available	e for Evalu	ation? (Do n	ot send to i	FDA)		
✓ Yes		Returned to		-	01/29/2	:015
11. Concomitant Me	adlest Dre	duate and Th	ovenu Dat	on (Evolude	(mm/dd/y	
71. Conconnant wi	Julcai Piol	aucts and Th	lerapy Date	as (Exclude	treatment of	event)
E INITIAL DE	ODTE			(0	Continue or	page 3)
E. INITIAL REP		K				
I Hambana Adare						
Dhara #		Te:	mail Addres			<u> </u>
Phone #		E	maii Addres	18		
2. Health Profession	onal?  3. C	Occupation		4.		ter Also Sent
Yes N	lo				Report to FE	

A. PATIENT INF				
1. Patient Identifier	2. Age at Time of Event:		3. <b>S</b> ex	4. Weight
	or		Female	lbs
	Date		☐ Male	or
In confidence	of Birth:			kgs
B. ADVERSE EV	/ENT OR PRODU	CT PROBLE	VI	
1. Adverse Even	t and/or 🔲 Pro	oduct Problem (e	.g., defects/maif	unctions)
2. Outcomes Attribut			***	
(Check all that apply	v)			
Death:	(mm/dd/yyyy)	Disability o	r Permanent Da	mage
Life-threatenin	g	Congenita	Anomaly/Birth D	)efect
· ·	- initial or prolonged	learned .	ous (Important M	
Required Inter	vention to Prevent Pern	nanent Impairmen	l/Damage (Devic	es)
3. Date of Event (mm	ı/dd/yyyy)	4. Date of This	Report (mm/do	Vуууу)
5. Describe Event or	Problem			
*				
		•		
1			<b>(0</b>	
6. Relevant Tests/Lal	horatoni Data Includi	na Datos	(Continue o	n page 3)
O. Nelevant Tests/Ear	Joiatory Data, Iliciaul	ing Dates		
			(Onulinus -	
7. Other Relevant His	tone Including Prope	leting Madical C	(Continue o	
race, pregnancy, sn	noking and alcohol use	, hepatic/renal dys	sfunction, etc.)	meryles,
1				
1				
	· · · · · · · · · · · · · · · · · · ·		(Continue o	
Submission of a r	eport does not co	nstitute an ac	imission tha	t medical
personnel, user fa caused or contrib	scility, importer, d	istributor, ma	nufacturer o	r product

MEDWATCH FORM FDA 3500A (2/13) (	_
F. FOR USE BY USER FAC	CILITY/IMPORTER (Devices Only)
1. Check One	2 HElimportor Donort Number

3. User Facility or Importer Name/Address

[ Importer

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

[ Initial Follow-up #

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

No

Yes Yes

No

Name

Address

Email Address

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

7. Type of Report

5-day

7-day

01/23/2015

√ 30-day

Periodic

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Page	2	of	2
_			

2. UF/importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

Foreign Study Literature Consumer

3. Report Source (Check all that apply)

Health Professional User Facility

Company Representative

Distributor

Other:

				i	DA US	SE ONI	Υ		
. າ									
2							_		
H. DEVICE MANUF	ACTURE	RS	ONL	1					
1. Type of Reportable Eve	int				2. If F	ollow	up	, What Type?	
Death					[		Tec		
Serious Injury					[			onal information	
Malfunction					. !			nse to FDA Re	quest
					L	<b>√</b> De	vice	Evaluation	
3. Device Evaluated by M	anufacturer	?			4. De	vice N	lani	ufacture Date	
Not Returned to M	anufacturer				(iii	m/yyyy	,		
Yes Evalua	tion Summai	y At	tached						
No (Attach page to provide code:	explain wh	y noi	) or		5. La	beled	for	Single Use?	
provide dead.						Ye	s	☐ No	
6. Event Problem and Eve	dustles Co.	4	(D-4)		-U				
Patient		169	Treier i	0 60	ung n	ianuai)	·		,
Code			J-L			]-	L		
Device			1_			٦.			i
Code [			J L		_		느		J
Method	10	-	26		-	37	_ -	38	
Results .	3218	LΓ	180		_[		Ē		
results .	3210		100	_	_		٦-		
Conclusions	63	<u> -</u> [	19		_		_ -		
7. If Remedial Action Initi	ated, Checi	(Ту	pe	8.	Usage	of De	vice	,	
Recall	Notification	1				initial	Use	of Device	
Repair	Inspection					Reuse	•		
Replace	Patient Mo	nito	ring			Unkno	wn		
Relabeling	- ☐ Modificatio	n/	•	9.	f action	on rep	orte	d to FDA und	er
	⁻ Adjustmer	ıt			remov	/al rep	ortir	ist correction ng number:	′
Other:		-		1					
				L					
10. 📝 Additional Manuf					d / or		11. [		
This supplementa							ıe.	laborator	У
results, and dev	ice eva	lua	tion	re	sult	s.			
Based on the mic	robiolo	aic	al t	est	ina	con	duc	ted by an	,
off-site laborat	ory, the	e s	cope	te	ste	og k	sit	ive for	•
Microbacterium 1	acticum	. M	licro	bac	ter	ium :	is	not	
considered clini environmental or	carry s	ւցր ሞհ	e or	ant	ano	l 18 was	of	ten an	
the forceps elev	ator re	ces	s.	9				covered I	LOIN
ma a deservición es	<b></b>								
The device was E before returning	TO ster	ili	.zed	by bo	the	off	-si	te labora	tory
examine the inte	rnal in	str	umen	to	hani	nels	an	s usea to d found n	) 
foreign material	. A vis	ual	. ins	pec	tio	n wa	s p	erformed	on
the forceps elev	ator an	d f	ound	no	fo:	reig	n m	aterial	
inside. The devi	ce pass	ed	leak	t e	est.	The	re	were mino	r
damages noted on likely cause the	report	eq ATC	phen	OWE	ver	, Եռ . Մհ	18 4	would not	
serviced and ret	urned t	o t	he u	sei	fa	cili	ty.	evice was	•
							-		
L									

Pre-1938 Yes [ ] Initial OTC Product Yes 9. Manufacturer Report Number 8. Adverse Event Term(s) 2951238-2015-00001 This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection

of information. Send comments regarding this burden estimate or any other aspect of this

collection of information, including suggestions for reducing this burden to:

(A)NDA #

IND#

BLA# PMA

510(k)#

Combination Product

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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# Massachusetts General Hospital, Boston, Massachusetts

U.S. Department of Health and Human Services Food and Drug Administration

### MenWateu

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mir Report #	
UF/Imponer Report #	2518897-2014-00012
***************************************	***************************************

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500				Page 1	nf 3						***************************************	***************************************
					000000000000000000000000000000000000000			***************************************		***********		FBA Use Only
1. Patient identifier	***************************************		). Sex	4. Weight		***************************************	***************************************	***************************************				
	of Event ONK		3.3968	* 8	t. Name (GA	un needenber 2d	angn a	umusosseri				
	24		Female	UNK BS	#1 							
	Date	INK	Male	ONK kos	#2							
in confidence	555 BSKK*CCC:		}	7/8/K #gs	2. Dose, Fra	quency & Re	oute ties	ď	3. Therapy (	Jetes (i	i unknown,	give duration)
	VENT OR PROBLE				#1				irom/to (ar	`D856 83	simale)	
1. 🛛 Adverse Event	t and/or 🏻 Pro	dust Problem (e.,	,, defects/mañu	nctions)	*:			***************************************	#1 	**********		~~~
2. Quicomes Attribut		***************************************	······································		#2				<b>#2</b>			
(Check sti that apply	<i>1)</i>	£	m		4. Diagnosis	for Use (inc	ficetion)				Abotod Aft	
Death:	(snm/00/yyyy)	"[] rissossiv or	Permanent Dan	nage	#1				5		ed or Dose es () No	
Ufe-threatenin		Congenital /	knomaly/Birth D	efact	#2			***************************************		, , , , , , , , , , , , , , , , , , ,	ez ("'! 146	Doesn't Apply
Mospitalization	e initial or prolonged	Other Serior	skí inshoqmi) zu	edicai Eventa)	6. Lot#			p. Date		Y   "   Y	es () No	Doesn't
Required inter	vention to Prevent Perm	anent impalmenti	Jamaga (Device	ss)	8			hr mana	ļ	·····	~~~	
3. Date of Event (mm	V0C/3333)	4. Date of This F	leport (mm/dd/	1/2/2//	#1		. }*1				Resposse Resilant	3 6438.889
2	1014	1	1/17/2018	٠	#2		#2		#1	Y	es [] No	Doesn't Apply
5. Describs Event or	Problem	<u>.</u>	***************************************	·····	9. NDC# or L	Inique ID		••••••	······································			
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increased inc	idence in post-	procedure d	rug-resist	tant E.	l							
	ia. The Duoden											
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					20-34901	, <u>k.</u>		N/A			√ Head	h Professional
					Catalog #			Expiration i	Data (mm/dd/)	Lay UseriPatient		
					N/A Serial #			S Realization Medicare	N/A ntiffer (UDI) #			
					A110428			n/a	sessee, despite		load "	
					55. If implant	ed, Give Dat			7. If Explant	ad, Giv	a Data (mr	2/8/3//////
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8. Retevant Tests/Lat	borstory Data, including	S cuses			8. is this a S		wica tha	i was Rapn	යෙනගෙනස් නහල්	Reuses	on a Patie	ent?
20,7 20					Yes	[Z] M:			************************			
					9. If Yes to It	10M HG. 8, E	niar Nan	18 සහස් එ.රජා	අපය හැ ලිපවාහ	COSSCI		
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					<b>?</b>		-	•			12-01-	2014
					[ℤ] Yes	[] No	KI KE	BUTTER TO NA	anufacturer on	·	(mm/dd/)	
			(Continue on	2808 3)	11. Concomi	tant Medica	Produc	ts and Ther	epy Dates (E	sciuds.	èrééimeni o	f svent)
7. Other Relevant His	story, including Presxis	ting Madical Con	ditions (e.g., sil		N/A							
гасе, ргедлежсу, ал №/А	noking and alcohol usa, l	hopsiichenal dysfu	nction, etc.)									
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Submission of a n	aport does not con	***************************************		***************************************	2. Health Pro	riessinner?	3. Occ					rise Also Sent
personnel, user fa	icility, importer, dis uted to the event.	stributor, man	Macturer or	product	š		Nurse			8	leport to F	DA.
caused or contrib	uted to the event.				Yes	∭ No	140836				_J ¥e≴ [_]	No 🛭 Unk

900 900 900 90	300				660600000000000000000000000000000000000	
MEDW			Page 2	2 e 3		
	0A (2/13) (continue 80:53:85:(a)863(i)		·-·	vonnonnon.	PACTURES ONL	
1. Check One	,	2. UF/Importer F	· *	1. Type of Reportable E	ivant	2. If Follow-up, What Type?
User Facility or Imperior Facility or Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior Imperior I	ze	2518897-20	14-00012	Death Serious injury Adathmetion		Correction Additional Information Response to FDA Reques Device Evaluation
***************************************			0.000	Device Evaluated by     Not Returned to	* •	4. Device Manufacture Date (mm/yyy)
4. Contact Person		5. Phone N	umber	1 To 1	uation Summary Attached	04/2012
6. Date User Facility of Importer Secame Aware of Event (mo		Report	8. Date of This Report (mm/dd/yyyy)	His (Affach page provide code;	i to explain why not) or	5. Lebeled for Single Use?  Yes White
11/17/20	LELI MADE	.i	12/15/2014	6. Event Problem and E	valuation Codes (Refer )	o coding menuel)
9. Approximate Age of Device	16. Event Problem Co.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ng menusi)	Patient Code	1735	-
37 years	Patient 1735			Device Code	3190 -	-
14 Parad Factor C	Device 3190 Code 3190			Method	TBD ~	
11. Report Sent to FD  Yes 12/15  No minus	/2014   [7] H		Oscurred  Cutpatient Disgnosite Facility  Ambulatory Surgical Facility	Results Candusians	3233 -	]-[
13. Report Sent to Ma Yes 12/15 Mo	/2014	apalient Trestmer cility	.~ 1 8	7. If Remedial Action in Recall	Motification Inspection	Wasge of Device     Millal Use of Device     Peuse     Unknown
ō	ion are Tokyo Office jao, Shinjuku∞ku			Replace Relabeling	Adjustment	9. If action reported to FDA under 21 USC 360(f), Ret correction/ removed reporting number: N/A
Contact Office (am	Genelicasco d Manutacturing Site for	Devices)	2. Phone Hismber	10. 🔲 Additional Ward N/A	ifacturer Herrative	i. and for 11. Corrected Data
Pierne	······	***************************************	200 F.S	8		
Audress			3. Report Source (Check of their apply) Foreign	000000000000000000000000000000000000000		
8	e - See F.3 abov site - See F.14		Study Likerature	***************************************		
Email Address			Consumer  Health Professional	XX		
4. Data Received by Manufacturer (mm/ 11/17/2  8. WIND. Give Protect	1014 (A)MUA	***********************	User Facility Company Representative Distributor			
N/A	BLA	***************************************	Coner:			
7. Type of Report (Cinck all that appl)	51Ω(k):	K092710		000		

This section applies only to requirements of the Paperwork Reduction Act of 1985. The public reporting burden for this collection of information has been estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gethering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Combination Product

OTC Product Yes

8. Adverse Event Term(s)

Pre-1938

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(<u>√</u>) 30-4×y

Periodic

S-day

N/A

7-day Period

15-day [Follow-up#. 3. Manufacturer Report Number

> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff information unless it display
> PRAStaff@Ms.hbs.gov valid CMB control number."
> Plasse DC NOT RETURN this form to the above PRA Staff email address.

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(CONTINUATION PAGE)
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Page 3 of 3

	B.S. Describe Event or Problem (continued)
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	B.6. Relevant Tests/Laboratory Data, including Datas (continued)
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CANCA SC 538008 55.78	
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	2.2.40
	B.7. Other Relevant History, including Pressisting Medical Conditions (a.g., sterglas, race, pregnancy, smoking and alcohol use, hepetic/renal dystruction, etc.) (continued)
3	N/A
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Carca sc seems co.	
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2	Consomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)
۶ ا	Someonessan manusa Frontino and analog bases (exclude assuman in evall) (Fix complication of C. 10 angulo D. 11, please distinguists)  N / N
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2 }	
Š	N/A  Other Remarks
ž }	Patient Code 1735 - Bacterial infection. Device Code 3190 - No Information, Method Code - To be
8	Determined Beauty Code 2332 Intertion bevile Come 3150 - 80 Intermstion, Method Code - 70 De
3	Determined. Results Code 3233 - Results Pending Completion of Svaluation. Conclusions Code 11 -
8	Conclusion not yet available, Evaluation in Progress.
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U.S. Department of Health and Human Services Food and Drug Administration

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Mir Report 8	
UF/kinpaner Report #	2518897~2015~00003
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FORM FDA 3500A (2/13)  ###################################		***************************************						FBA Use Only
	be consisted	1. Name /Circles	***************************************					
1. Patient Identifier 2. Age at Time 3. Sex of Event: UNK 8/1/8	4. Weight	1. Name (Give lei	balad saangus	i grandapanan				
07 [ Fe:		<i>\$</i> 1		A			33303	······································
In confidence of Birth: UNK Ma	ale UNK kas	#2				-		A
Environmence of States	UNK_ kgs	2. Dose, Frequer	ncy & Route !	Used	3. Thorapy	Dates (If ur	пкложп, д	give duration)
			•	1	source (c	or best estim	18(9)	// <del>-</del>
1. [] Adverse Event and/ar [] Product Problem (e.g. defects	s/melfunctions)	#1 	***************************************		81	000000000000000000000000000000000000000	*************	~~~~~
Curicomes Attributed to Adverse Event (Check of that apply)		#2			<b>#</b> 2			
pm,		4. Diagnosis for	Use (Indicatio	m)	5	i. Event Abs		
(mine SOLYYYY)		#1			١,	Stopped o		Reduced? (***; Doesn'i
Life-threatening Congenital Anomaly/E	8	#2		***************************************		1 11100	[_] 140	Apply
Hospitalization - Initial or protonged Other Serious (Import		6 Lot 8	37.	Exp. Date		×2  Yes	□ No	Doesn't
Required intervention to Prevent Permanent Impairment/Damage ()	(Devices)	}	1					Lui Apply
3. Date of Event (mm/dd/yyyy) 4. Date of This Report (m	nm/dd/yyyy)	#1		 		Event Rea Reintrodu	uerzeggy Yngitau	After
2014		#2	<b>#</b> 2	å	#	10000		Choesen's
5. Describe Evant or Problem		9: NEDC\$ or Uniqu	(ue ID				00000	Apply Sonse's
PENTAX Medical contacted the Initial Reporter					<b> </b> *	₹2 ☐ Yes	☐ No	Doesn't
on 01/05/2015 and 01/20/2015. Responses were from the facility on 01/23/2015 indicating >	, received	10. Concomitant	i Medical Prov	ducts and Ther	acv Dates (f	Exclude tres	staneat of s	
<pre>trom the lacitity on 01/23/2015 indicating ? tested positive for a single strain type of c</pre>	patients	5	÷		Olege was	P-0-2	J. 1. 2	Fung
resistant E.coli post-ERCP procedure performe	ed with		•					
Video Duodenoscope Model ED-3490TK/Serial All	10328.							
Strain types 5A-H are related to each other.	Patient					le na	· · · · · · · · · · · · · · · · · · ·	·
met the case of "Immediate bacteremis p	ost-ERCP"			***************************************		(Luin	JAME ON BOOKS	1 page 3)
meaning pattent had (+) blood culture post-ER 72 hours. The facility protocol for infection	CP within	1. Brand Name						
part of the hospital surveillance plan, which	n includes							
bacteremias, is that the department leadershi	ip and the	2: Common Davi	ice Name			2b. Proce	ode	200000
provider are notified of the infection; any t	trends			***************************************	***************************************			
identified and a review of the infection (roo		3. Manufacturer i	Name, City ar	tel State				
manalysis) is completed. The group of patients ERCP was being treated for a range of pancrea	undergoing	- N						
principle of parties of the property of the principle of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the p	stormine	4. Model #		Lot 8	~~~00000000000000	<b>15</b>	maratar	of Device
specific signs and symptoms other than fever/	/chills and					! <u></u>		: De Device : Professional
malaine that would be related to the post-pro	ecedare	Catalog #	***************************************	Expiration (	Date (mm/dd/	ilwwy 🗀		
bacteremias. Patient was treated for bacterem							Lay Use	
appropriate antibictics. Patient was not reca further screening as the marker for this outb		Serial #	***************************************	Unique Iden	stiffer (UDI) #	/ T L	] Other:	
investigation was a (+) blood culture for	reas							**************
8	ue on page 3)	6. If Implemed, G	Alve Date (mm	happhilih)	7. If Explant	ied, Give D	one (mm/c	delryyyy)
6. Relevant Tests/Laboratory Date, including Dates	***************************************	* * Ahle a Cloud	- M 4 n.m.	~~~			~~~~	***************************************
Strain type as determined by pulsed-field	***************************************	8. Is this a Single Yes	le-use Davice i Ti No	hai was napro	/603866 ana	ម្តីមួយមន្តិ បុក	i a Patien	X?
electrophoresis) - 5A		2. If Yes to Item ?	~~~	*~~~ mad hildi	A Bassel	area 1995.	***************************************	
mine of land and and and a state of the same of		35. 10 P GFG Me source .	1890 Dy Saverno 1.	Sine issue ones,	MA OI TOPEN	ACRESON.		
Time of lat(+) culture - + (within 72 hours of	procedure;							
Date of Scope Use ~ Patient Information	***************************************							
	•	10. Device Avails	ahin toe Eugli	allows IPso Bot	and to FOA'	······	***************************************	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Site of(+)culture - Blood	******	l	<b>~</b>		•	•		
		☐ Yess ☐	JNo 🗌	Returned to Ma	Statacturer on		mm/dd/yyy	NV)
(Continu	ue on page 3)	11. Concomitant	Modical Prod	jucts and Therr	apy Dates (f	~~~~~~~~~~	~~~ ·~~	
7. Other Relevant History, Including Pressisting Medical Conditions (e.	D.G., Stiercles.			-		**		
rece, pregnency, smoking and alcohol use, hapstichenel dystynction, alc	2)							
			~~~~			(Conti	tinue on ,	page 3)
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anners.		1. Name and Add	eest		-		West	M74
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for more than		Phone 8		Email	Address		***************************************	30000aaaaaaa
	ue on page 3)						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Submission of a report does not constitute an admission to personnel, user facility, importer, distributor, manufacture	inat medicai ~r ~r ~roduct	2. Health Profess	. 1	eupstion		Rapa	an ta FDA	
caused or contributed to the event.	of the fact accommen	☐ Yes ☐	No					No Una

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FORM FDA 3500		•	Page	***************************************		
1. Check One		2. UF/Import	er Raport Number	1. Type of Reportable Even		2. if Follow-up, What Type?
User Facility			2015-00009	C Death		Correction
3. User Facility or im	nsM sproc	o/Address		Serious Injury		Additional Information
				Mathunction		Response to FDA Request
			y'			Orvice Evaluation
				3. Davice Evaluated by Mar	niesturer?	4. Davice Manufacture Date (mm/yyy)
4. Cuntact Person	··········	78 34	on filtransky at	Mot Returned to Mar		
4. Complete Reserv		S. PRION	e Mumber	,,	n Summary Attached	5. Labeled for Single Use?
6. Data User Facility (>r	7. Type of Report	8. Date of This Report	No (Altach page to a provide code:	ssbjæw myk volj ox	
Importer Became Aware of Event (m	n/dd/yyyy)	[Z] Initial	(mm/dd/yyy)			☐ Yes ☐ No
		Follow-up #	06/23/2015	6. Event Problem and Evelu	ation Codes (Refer :	lo coding manual)
9. Approximate	10. Event	Problem Codes (Refer to) redine menueli	Patient	1735 -	
Age of Device	Patient	minimum binim	annamik (annaminimus)	Code (Device E'''		
÷.	Code	1735 -		Code		
	Device Code	-	~	basised	-	
11. Report Sent to FD	1 A?	12. Location Where Eve	ant Occurred			and parameter, grammer,
(7) Yes 05/23		Haspital	Outpatient	Results [
140 (mm/ok	l'yyyyi	Mome :	Olognostic Facility (```) Ambulatory	Consiusions	-	
13. Report Sent to Ma		Nursing Home	"" Surgical Facility	7. If Remedial Action Initiate	ed, Check Type	8. Usage of Device
V Yes 05/23	/2015	Outpatient Treat Facility	men!	TRecall Til	Votification	Initial Use of Device
☐ No Immot	ranari	Cither:			nspection	Reuse
14 Manufacturer Nam	e/Address		(3),60,13)	(Replace F	Patient Monitoring	Usknown
				(Relabeling)	dodification/ Vojustment	9. If action reported to FDA under 21 USC 36641), list correction removal reporting number:
				Cther.		temans reporting number:
				10 Additional Manufact	uror Namativa	and/or 11. Corrected Date
GRADOWALIUS/	OT UE	15		" "		111111111111111111111111111111111111111
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Manufacts	sing Site for Devices)	2 Phone Mumber			
Name						
Address		······································				
			C Foreign			
			☐ Shudy			
.•			Literature			
Emsii Address	<b>W</b>		Consumer  Health Professional			
A. Pharman			User Facility			
4 Date Received by Renulacturer (nurse	kd/yyyyy)	5. (A)NDA #	Company			
01/23/3	015	***************************************	Representative Distributor			
6: If IND, Give Protoce	d <b>8</b>	W0#	Cither:			
		BLA #	·····			
7. Type of Report			·····			
(Check all that apply)		Combination				
7-day Perio	*	Product Yes	1			
10-day 📝 Initia		Pre-1838 Yes				
15-day Troic	w-nb	OTC Product [] Yes				

This section applies only to requirements of the Paperwork Reduction Act of 1885. The public reporting burden for this callection of information has been selimeted to average 6% minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other espect of this collection of information, including suggestions for reducing this burden to:

8. Adverse Event Term(s)

Cepartment of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASISREITA his gov valid OMB control numbers DO NOT RETURN this form to the above PRA Staff email address.

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9. Manufacturar Report Number

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Page 3 of 3

FORM FDA 3500A (2/13) (continued)

	8.5. Describe Event or Problem (continued)	
	ceftriaxone-resistant E.coli: all(+)blood cultures are reviewed daily by infection preventionists.	
	30 day Initial MDR 2518897-2014-00012 was filed on 12/15/2014 which included Initial information regarding this event. Follow up#1 MDR 2518897-2014-00012 includes additional information received fro the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID	m
483		
œi E	Initial MDR 2518897-2015-00009 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID	
2	Initial MDR 2518897-2015-09010 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID	
88 28 28 28	Initial MDR 251 <b>8897~2</b> 015~00011 includ <mark>es additi</mark> onal information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID	
	Initial MDR 2518897-2015-00012 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID	
	Initial MDR 2518897-2015-00013 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID	
	Initial MDR 2518897-2015-00014 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID :	
	3.6. Relevant Testsit. aboratory Data, including Datas (continued)	
163		
83 83		
Back to Item		
8		
000	3.7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnency, smoking and alcohol use, hepaticirenal dysfunction, etc.) (continued)	,
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ack to frem 8.7		
Back to Nom 8.7		
Back to Nem B		
.10 Back to Hom B	Concomitant Medical Preducts and Therapy Dates (Exclude treatment of event) (For continuation of C 10 and/or D.11; please distinguish)	
.10 Back to Hom B	Concernitant Medical Preducts and Therapy Dates (Exclude treatment of event) (For continuetion of C 10 and/or D 11; please distinguish)	
.10 Back to Hom B	Concomitant Medical Preducts and Therapy Dates (Exclude treatment of event) (For continuation of C 10 and/or D 11; please distinguish)	
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Back to from C.10 Back to from B	Consomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C 10 and/or D 11; please distinguish)	
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U.S. Department of Health and Human Services Food and Drug Administration

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Mfr Report # UF/Importer Report # 2518897-2015-00018

FORM FDA 3500A (2/13) Page 1 c	§ 3		FDA Use Only	
A. PATIENT INFORMATION	C. SUSPECT PROD	JCT(S)	, , , , , , , , , , , , , , , , , , ,	
1. Patient identifier 2. Age at Time 3. Sex 4. Weight	1. Name (Give labeled stren	gth & mfr/labeler)		
of Event:	#1			
Date Of Mala	#2	Carrier and the second	and the second of the second	
in confidence of Birth:	2. Dose, Frequency & Rou	te Used 3. The	rapy Dates (If unknown, give duration)	
B. ADVERSE EVENT OR PRODUCT PROBLEM	#1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	#1	/to (or best estimate)	
1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)				
2. Outcomes Attributed to Adverse Event (Check all that apply)	#2 4. Diagnosis for Use (Indic.	#2	5. Event Abated After Use	
Death: Disability or Permanent Damage	#1		Stopped or Dose Reduced?  #1 Yes No Doesn't Apply	
(mm/dd/yyyy)  Life-threatening Congenital Anomaly/Birth Defect				
Hospitalization - Initial or prolonged Other Serious (Important Medical Events)	#2		#2 Yes No Doesn't	
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	6. Lot #	7. Exp. Date	— — rpm	
3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy)	#1 «мениментиминаминаминана	#1	B. Event Reappeared After     Reintroduction?	
Patient Information 01/23/2015	#2	#2	#1 Yes No Doesn't	
5. Describe Event or Problem	9. NDC# or Unique ID		- Dagge	
PENTAX Medical received a report on 01/23/2015 indicating 1 patient tested positive for a single strain			#2 Tes No Apply	
type of ceftriaxone-resistant E. coli post-ERCP	10. Concomitant Medical F	roducts and Therapy Dat	es (Exclude treatment of event)	
procedure. No information on the Medical Device used				
during the ERCP procedure was received at the time of this report. Patient met the case definition of	The Same of the Same			
"Delayed bacteremia post-ERCP" meaning patient had (+)				
blood culture post-ERCP after 72 hours but within 30	D. SUSPECT MEDICAL DEVICE (Continue on page 3)			
days post-procedure. The facility protocol for infections that are part of the hospital surveillance	1, Brand Name			
plan, which includes bacteremias, is that the department			2b. Procode	
leadership and the provider are notified of the infection; any trends identified and a review of the	2. Common Device Name 2b. Procode			
infection (root cause analysis) is completed. The	3. Manufacturer Name, City and State			
facility also indicated that patients undergoing ERCP		many and and a	and the state of the state of the state of the state of the state of the state of the state of the state of the	
are being treated for a range of pancreatic and biliary diseases; it would be difficult to determine specific	4. Model #	Lot #	5. Operator of Device	
signs and symptoms other than fever/chills and malaise	•		✓ Health Professional	
that would be related to the post-procedure bacteremias.	Catalog #	Expiration Date (m		
Patient was treated for bacteremias with appropriate antibiotics. Patient was not recalled for further	Serial #	Unique Identifier (I	Iniva Other	
screening as the marker for this outbreak investigation		a sound man a man constant Co		
was a (+) blood culture for ceftriaxone-resistant	6. If Implanted, Give Date	(mm/dd/yyyy) 7, If E	cplanted, Give Date (mm/dd/yyyy)	
(Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates				
Strain type as determined by pulsed-field	Yes No	ice that was Reprocesse	d and Reused on a Patient?	
electrophoresis - 8	9. If Yes to Item No. 8, Ent	er Name and Address of	Reprocessor	
Time of lst(+)culture - Delayed(>72 hours but <30 days)				
	And the second			
Date of Scope Use - Patient Information	10.00	-1110 /P111	FRAI	
Site of (+) culture - Blood	10. Device Available for Evaluation? (Do not send to FDA)  Yes No Returned to Manufacturer on			
	(min/dd/yyyy)			
(Continue on page 3)	11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatichenal dysfunction, etc.)				
i way, pi aynanay, amaning ana mauna asa, napanaranana aysunction, aw.)		Section 1	(Continue on page 3)	
	E. INITIAL REPORT	er <u> </u>		
	1. Name and Address			
	MGH Gastroentero			
	Boston, MA 02114-	-2696		
	Phone #	, Firmil Addo		
(Continue on page 3)	Patient Information	······································		
Submission of a report does not constitute an admission that medical	2. Health Professional?	,	4. Initial Reporter Also Sent Report to FDA	
personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.	Yes No	Physician	Yes No Unk	

### MEDWATCH

FORM FDA 3500	A (2/13)	(continued)		Page 2	of 3			
F. FOR USE BY U	JSER FA		RTER (Device F/Importer Report		H. DEVICE MANUE	ACTURERS ONLY	2. If Follow-up, What Type?	
User Facility	☑ Imp	1	18897-2015-0					
3. User Facility or Imp	······································	ococano — — — — — — — — — — — — — — — — — — —	70031-5017-00	, v = 0	☐ Death		Correction	
PENTAX Medical	oner Name	NAGGress			Serious Injury		Additional Information	
3 Paragon Drive	e				Malfunction		Response to FDA Request	
Montvale, NJ 0	7645				Device Evaluation			
					3. Device Evaluated by N	Kanufacturer7	4. Device Manufacture Date	
A STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STATE OF THE STA			Z		Not Returned to N	and the second second	(mm/yyyy)	
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Anastasia Vlam	is	and the second of	201-571-230	0- x2066	-		5. Labeled for Single Use?	
6. Date User Facility o	******	7. Type of Repo	1	te of This Report	provide code:	to explain why not) or		
Importer Became	-			n/dd/yyyy)		and the second of the second	Yes No	
Aware of Event (mm	vaavyyyyj	✓ Initial		07/02/2015				
		Follow-up #	ameannements			valuation Codes (Refer to c	coing manual)	
9. Approximate	10. Event	Problem Codes	(Refer to coding mai	ual)	Patient Code	1735 -	-	
Age of Device	Patient [		F		Device		THE REPORT OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE	
	Code	1735	-	-	Code	3190 -		
Samuel and the	Device [	2100						
	Code	3190	-		Method			
11. Report Sent to FDA	4?	12. Location V	Yhere Event Occur	ed	Results			
Yes 07/02/	2015	✓ Hospit	al [	Outpatient	Neaulia		J bassassassassas lamanasassassas	
No (mm/dd	<i>'</i> אַצאַצו'	Home		Diagnostic Facility	Conclusions	-	_	
13. Report Sent to Mar	n.,6mmt,,eme*	Nursin	g Home	Ambulatory Surgical Facility			al Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Commence of Com	
		. 1	lient Treatment		7. If Remedial Action Init	liated, Check Type	Usage of Device	
Yes 07/02/		Facility	Mary Larry		Recall	Notification	Initial Use of Device	
☐ No !'''''	וצענעי	Other:	***************************************		Repair	Inspection	Reuse	
14. Manufacturer Nam		1	(Sp	ecify)	Replace	Patient Monitoring	Unknown	
Hoya Corporati					Relabeling	Modification/ 9.	If action reported to FDA under	
PENTAX Life Ca		o Office				Adjustment	21 USC 360i(f), list correction/ removal reporting number:	
2-7-5 Naka-Psj	ao, Shi	njuku-ku			Other:	***************************************		
Tokyo, Japan 1	61-8525	and the second second					and the second of the second of the	
The state of the state of		Name of the Co			10. Additional Manu	facturer Narrative ar	nd / or 11. Corrected Data	
G. ALL MANUFA	CTUDE!	7.0				and the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of t	or or training Corrected Date	
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1. Contact Office (and	Manuracti	tring Site for Dev		ione Number				
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Address			3 R	port Source heck all that apply)				
	San Page			oreign				
Contact office	- See	F.3 above						
Manufacturing :			nove -	Study				
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Email Address	1			Consumer				
		And the second		fealth Professional				
4. Date Received by	·····	5.		Iser Facility				
Manufacturer (mm/c	id/yyyy)	(A)NDA#		Company				
01/23/2	015	(617) 44		Representative Distributor				
6. If IND, Give Protoco	of #	IND#_		Other				
		BLA#	L.J.	Julei,				
		PMA/						
7. Type of Report (Check all that apply)	, s. 16.	510(k)#						
5-day 30-da		Combination Product	☐ Yes —					
7-day Pend	1000		in the second	#PERSONAN				
10-day 7 Initial	The same of	Pre-1938	Yes					
Land bearing	w-up#	OTC Product	Yes					
		9 84						
9. Manufacturer Repoi	r wamber	8. Adverse E	vent telm(s)					
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff Please DO NOT RETURN this form to the above PRA Staff email address.

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## MEDWATCH

FORM FDA 3500A (2/13) (continued)

# (CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of 3

Back to item B.5	B.5. Describe Event or Problem (continued)  E.coli; all(+) blood cultures are reviewed daily by infection preventionists. PENTAX Medical contacted the Initial Reporter via email on 05/05/2015, 05/21/2015, 06/12/2015 and 06/23/2015 to confirm the Medical Device used during the ERCP procedure. Also, the Initial Reporter was contacted via email on 05/21/2015 and 06/23/2015 in regards to current patient status. No information on the Medical Device involved in this event or current patient status information for Patient ID ERCP2 have been received from the facility to date.
	B.S. Relevant Tests/Laboratory Data, Including Dates (continued)
B./ Back to nem B.5	B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
Dack to Hem D./	
Back to item D.11 Back to Item C.10	Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)
Ded	Other Remarks Patient Code 1735 - Bacterial infection. Device Code 3190 - No Information.

U.S. Department of Health and Human Services Food and Drug Administration

### MEDWATCH

PLEASE TYPE OR USE BLACK INK

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mir Report # UF/Importer Report # 2518897-2015-00031

FORM FDA 3500	0A (2/13)		Page 1	of 3					000 6 11 6
A PATIENT NE	ORMATION				M 27 (0) 0) 8)	21(S)			FDA Use Ont
1. Patient Identifier		3. Sex	4. Wolght	200000000000000000000000000000000000000	*********************	h & mir/labeler)	***************************************		200000000000000000000000000000000000000
UNK	of Event: UNK	Female	UNK ibs	#1					
	Date	Male	or	#2		***************************************	·····	***************************************	***************************************
in confidence	of Sirth: VIII #817#227601818		UNK kgs	2 Dose, Frequ	ancy & Route	Used	3. Therapy Dat	es (Il unknown, g	jive deration)
***************************************	**********************************			#1			from/to (or be	ist estimate)	
1. 🕢 Adverse Evens		duct Problem (e.g., defects/mat	functions)	**************************************				nnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnn	
<ol><li>Outcomes Attribut (Check all that appl)</li></ol>				4: Diagnosis fo	se i kas (tentisoti		#2   #2	ent Abated Afte	e liek
Death:	(mmvda/yyyy)		mage	81	ar 324 (mossis)	n.c.		opped or Dose F	₹ <b>ಀ</b> ಚಟದಿಗೆ?
Ulfe-threatening		Congenital Anomaly/Birth	Defect		•••••••••••••••••••••••••••••••••••••••			∭Yes	Coesn' Apply
Hospitalization	- initial or prolonged	Citizer Serious (Important 8	Aedical Events)	6. Lot#		Eur Pair		Yes No	Doesn
Pequired Interv	vention to Prevent Perm;	anest Impairment/Damage (Cevi	ces)	#1	-	Exp. Date	70000000	ant Reappeared	Apply L
3. Date of Evant_imm		4. Date of This Report (mm/d	\$/yyy)	mmmaaaaaa	#	***************************************		antroduction?	
<u> </u>		07/20/201	5	#2	#	<b>?</b>	*1 {	∏Yes ∏Ns	Ocean Apply
5. Describe Event or ! PENTAX Medica!		e of an event on Pati	ent Information	9: NDC# or Un	Gi supi		82 (	Yes No	Doesn'
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		ere made via e-mail the facility to con		10.503928	10 (10 (10 (10 (10 (10 (10 (10 (10 (10 (			(venmae on	, hade a
		obtain a facility of		1. Brand Name		888888888888888888888888888888888888888		***************************************	***************************************
to receive inf	formation on th	e 3 patients.	3000	2: Common De				b Procode	**************************************
Wo information	n has been rece	ived from the facili	ty to	Video Buo	ianoscape			FOT	
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				ED-34907K	******************			[7] Health	Professional
			8	Catalog #		Expiration	Date (mm/dd/yyy	y)	seriPattent
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				B110743			, , , , , , , , , , , , , , , , , , ,	OULUNDOODAAAAAA	************
		(Cantinue o	n naos 3i	6. If implanted,	Give Data (mr	n/dd/yyyy;	7. If Explanted,	Give Date (mm)	dd/yyyy)
6. Relevant Tests/Lab	oratory Data, Including	***************************************		A sa thia a Sia	via una finuira	Ohat was Base	rearry and the	used on a Patier	
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arsonnel, user fa	cility, importer, dis	stitute an admission that Aributor, manufacturer o		2. Health Profe		•		4. Initial Report Report to FD.	A
aused or contribu	uted to the event.	,	•	Yes 🖫	∄No NA			MYes Me	vo Zi Unk

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FORM FDA 3500			ıd)	Page 2	? of <u>3</u>	***************************************	
1. Check One	USBER 7			Picturge: serill Report Number	1. Type of Reportable Ev		2. If Follow-up, What Type?
User Facility	[S] Imp	etter.	2518897~20	i i	Death	******	Correction
3. User Facility or imp PENTAX MEDICAL 3 Paragon Oriv Montvale, NJ 6	· ·	e/Address			Serious Injury Mailunction		Additional information Response to FDA Request
4. Contact Parson	0000***********************************		S. Phone	kh sm fror	3. Device Evaluated by No Returned to No February (7) Yes Evalue		4. Davice Manufacture Date (mm/yyyy)
Date User Facility of Importer Became Aware of Event (mr.		7. Type of R	lapon .	(mm/sd/yyyy)	1-743	la explain why nol) or	5. Labeled for Single Use?  Yes Z No
07/28/201			46	03/11/2015	6. Event Problem and Ev	aluation Codes (Refer (	lo coding menual)
9. Approximate Age of Device		*****	ip# les (Refer la coc	ling menusily	Patient Ceds	1735	•
•	Pattent [ Code [	1735	<b>]-</b>	***	Device Code	2379 -	-
	Davide [ Code	2379		•	Method	10 -	•
Yes 38/11.  No (mar/do  13. Report Sent to Ma  [Yes 98/11.  No (mar/do  14. Manufacturer Nam  HOYA Corporat;  PENTAX Life Ca 2-7-5 Naka-2*;  Tokyo, Japan 1  Costact Office (and  Name	nufacturer? /2015 ////////////////////////////////////	o Office	ime rsing Home dpatient Treatme cility her:	2. Phone Number See F.S. 3. Report Source	Replace	Notification Inspection Patient Monitoring Modification/ Adjustment	8. Usage of Device   Initial Use of Device   Reuse   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unknown   Unk
Contact office Manufacturing: Email Address  4. Data Received by Manufacturer (mm/c 07/20/20  7. Type of Report (Check of that apply)	site ~	5. (A)NDA *	above	(Check all that apply) Foreign Study Literature Consumer Health Professional User Facsity Company Representative Distributor Other			

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 88 minutes per response; including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Stand comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to.

Combination Product

OTC Product Yes

8. Adverse Event Yerm(s)

Pre-1938

Yes

Yes

Department of Health and Human Services Food and Crug Administration Office of Chief Information Officer Paperwark Reduction Act (PRA) Staff PRAStangida.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

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☑ 30-day ☐ Periodic ☑ Initial ☐ 5-day ☐ 30-day ☐ 7-day ☐ Pariodic ☐ 10-day ☑ Initial ☐ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number

# NEDWATCH FORM FDA 3500A (2/13) (continued)

(CONTMUATION PAGE)

For use by user-facilities,
importers, distributors, and manufacturers
for MANDATORY reporting

Page 3 of 3

	S.5. Describe Event or Problem (continued)
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	8.6. Relevant Tests/Laboratory Data, Including Dates (continued)
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Back to Item B.5	
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	6.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, racs, pregnancy, amoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
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	Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C 10 and/or D 11; please distinguish)  Other Remarks Patient Code 1735 - Bacterial Infection
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	Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.16 and/or D.11; please distinguish)  Other Remarks Partient Code 1735 - Bacterial Infection Device Code 2379 - Device Issue Method code 10 - Actual Device Evaluated
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## New York-Presbyterian/Weill Cornell Medical Center New York City, New York



June 7, 2013

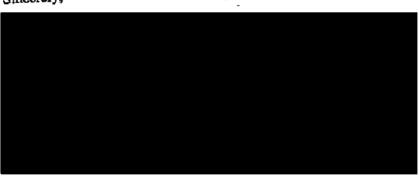
Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting P.O. Box 3002
Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



PLEASE TYPE OR USE BLACK INK

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers

Mfr Report#	8010047-2013-00176
UF/Importer	Report #

MEDWATCH for MANDA			MANDAT	ORY reporting UF/Importer Report #					
FORM FDA 3500A	A (1/09)			Page 1	of 2			FDA Use Only	
A. PATIENT INFO	RMATION				C. SUSPECT PROD	UCT(S)			
1. Patient Identifier 2.			3. <b>S</b> ex	4. Weight	1. Name (Give labeled strer	ngth & mfr/labeler)			
	of Event:		Female	lbs	#1				
	Date			or	#2				
In confidence	of Birth:		Male Male	kgs	2. Dose, Frequency & Rou	ite I Ised	3. Therapy Dates (	if unknown, give duration)	
B. ADVERSE EVE	ENT OR PRODUC	CT PROBLE	VI		2. Dose, Frequency & Rou	ite Oseu	from/to (or best e	stimate)	
1. 🕢 Adverse Event	and/or ✓ Pro	duct Problem (e	.g., defects/malf	functions)	#1		#1		
2. Outcomes Attributed					#2		#2		
(Check all that apply) Death:		□ Diochilibe o	or Permanent Da	maaa	4. Diagnosis for Use (India	cation)		Abated After Use ed or Dose Reduced?	
	(mm/dd/yyyy)				#1		1 —	es No Doesn't	
Life-threatening			Anomaly/Birth (		#2			Apply Apply	
Hospitalization -	initial or prolonged	Other Serie	ous (Important M	Medical Events)	6. Lot#	7. Exp. Date	#2 🔲	∕es ☐ No ☐ Doesn't Apply	
Required Interve	ention to Prevent Perm	anent Impairment	t/Damage (Devi	ces)	#1	#1	8. Event	Reappeared After	
3. Date of Event (mm/d	id/yyyy)	4. Date of This	Report (mm/do	d/yyyy)	#1			oduction?	
Ur	nk		05/09/2013	3	#2	#2	#1 🔲 Y	res No Doesn't	
5. Describe Event or Pr	roblem				9. NDC# or Unique ID			- Doesn't	
Olympus was inf							#2 L	res No Apply	
of their duoder TJF-Q180V, with	•	-			10. Concomitant Medical I	Products and The	rapy Dates (Exclude	treatment of event)	
2101853, 210189				.1010507	1				
disinfection an				ive for					
the following b									
Pseudomonas aer	-			er, the					
user facility r duodenovideosco					D. SUSPECT MEDIC	CAL DEVICE			
it was a mix.		-	-		1 Brand Name				
one of the 160		_	-		Olympu		A Duodenovide	oscope	
Klebsiella pneu			-		2. Common Device Name Duodenovideoscope				
reported that t		_		fection	3. Manufacturer Name, City and State				
and they believed duodenovideosco		related t	o the		OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan				
daodenovideosco	opes.				2951 Ishikawa-cho,	Hachioji-shi	, Tokyo 192-850	7, Japan	
					4. Model #	Lot#		5. Operator of Device	
					TJF-160VF	N/A		Health Professional	
					Catalog #	Expiration	on Date (mm/dd/yyyy)	Lay User/Patient	
					TJF-160VF Serial#	Other#	Unk	Other:	
					2802210	N/A			
					6. If Implanted, Give Date		7. If Explanted, G	ive Date (mm/dd/yyyy)	
					N/A	(	N/A	( <b>,,,,,</b>	
6. Relevant Tests/Labo	oratory Data, Includin	g Dates			8. Is this a Single-use De	vice that was Rep	rocessed and Reus	ed on a Patient?	
					Yes No				
					9. If Yes to Item No. 8, En	ter Name and Ad	dress of Reprocess	or	
					N/A				
					10. Device Available for E	_ `	•	06/04/2013	
					Yes No	Returned to I	Manufacturer on:	(mm/dd/yyyy)	
					11. Concomitant Medical	Products and Th	erapy Dates (Exclud		
7. Other Relevant Histo	ony Including Pressi	sting Medical Co	anditions /e a	allemies					
race, pregnancy, smo	king and alcohol use,	hepatic/renal dys	function, etc.)	anorgrou,					
1									
					E. INITIAL REPOR				
					1. Name and Address	Phon	1e #		
					Infection Contro	l Nurse			
					NYP Weill Cornel		enter		
					512 E. 71th Stre				
					New York, NY 100	21			
Submingles of a ser	nort door	natituta an -	Iminal 4	t madical	2. Health Professional?	3 Occupation		. Initial Reporter Also Sen	
Submission of a repersonnel, user fac	port aces not col ility, importer. di	nstitute an ad stributor. ma	iniission tha Inufacturer o	n medical or product			- 1	Report to FDA	
personnel, user fac caused or contribut	ted to the event.	,			Yes No	Administrator/S	upervisor	Yes No 📵 Unk.	

MEDWATCH	l						FDA USE ONLY
FORM FDA 3500		ontinued)		Page	2 of ²		
F. FOR USE BY			RTER_/D		H. DEVICE MANUFACT	URERS ONLY	
1. Check One	002/(1/10/			eport Number	1. Type of Reportable Event		2. If Follow-up, What Type?
User Facility	importe	r			☐ Death		Correction
<ol><li>User Facility or Imp</li></ol>	orter Name/Ad	ldress			Serious Injury		Additional Information
					Malfunction		Response to FDA Request
					Other: patient in	fection	Device Evaluation
					3. Device Evaluated by Manufa		4. Device Manufacture Date (mm/yyyy)
1 C-1-1 D			5. Phone N	·mbor	Not Returned to Manufac		unk
4. Contact Person			o. Filolie IVI	iiiiDei	✓ Yes ✓ Evaluation Su  No (Attach page to expla	•	5. Labeled for Single Use?
6. Date User Facility o	or 7.	Type of Report	t	8. Date of This Report	provide code:	an way non o	Yes ✓ No
Importer Became Aware of Event (mn	n/dd/yyyy)	Initial		(mm/dd/yyyy)			. 100 140
	-	⊐ ☐ Follow-up#			6. Evaluation Codes (Refer to co	oding manual)	
9. Approximate		blem Codes (f		ng manual)	Method 1	0 - 37	38 -
Age of Device	Patient	1725			Results 10	)0 -	
	Code	1735 -	<u> </u>		Results 10	<u></u>	
	Device Code	1091 -	2303	3 -	Conclusions 5	1 -	-
11. Report Sent to FDA	A? 1	2. Location W	here Event (	Occurred	7. If Remedial Action initiated,	Check Type 8.	Usage of Device
Yes		Hospita	i	Outpatient Diagnostic Facility	Recall Noti	fication	initial Use of Device
No (mm/dd	VYYYY)	Home	Han-	☐ Ambulatory		ection	Reuse
13. Report Sent to Mar	nufacturer?	☐ Nursing	Home ent Treatmen	Surgical Facility	1 1 '	ent Monitoring	Unknown
Yes	(Anna)	Facility	DIR TIOURIO	•		lification/	If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
☐ No	-,,,,,,	Other:		(Specify)	Other:		Total Survey of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of th
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101 Devices)	,			484-896-5688			
OLYMPUS AMERI				3. Report Source (Check all that apply)			
San Jose, CA				Foreign			
OT VMDITE MEST	TAT GUGGE	1 CODDOD3"	TON	Study			
OLYMPUS MEDIO 2951 Ishikawa				Literature			
192-8507, Jap	pan			Consumer Health Professional			
4 Data Basebad for	<del></del>	5.		✓ User Facility			
4. Date Received by Manufacturer (mm/c	(dd/yyyy)	6. (A)NDA#		Company			
05/09/2	013	IND#		Representative Distributor			
6. If IND, Give Protoco	ol#	STN#		Other:			
		PMA/			<u>.</u>		
7. Type of Report (Check all that apply	,	510(k) #	· · · · · · · · · · · · · · · · · · ·				
5-day		Combination Product	Yes		-		
7-day Peri		Pre-1938	Yes		-		
☐ 10-day ☑ Initia	al ow-up#	OTC Product	Yes		-		
9. Manufacturer Repo		8. Adverse Ev	rent Term(s)		<del> </del>		
8010047-2013-0							
The public reporting bur	rden for this col	lection of inform	nation has be	en estimated to average 66	Department of Health and Huma	n Services	OMB Statement;
minutes per response, i sources, gathering and	including the tin maintaining the	ne for reviewing data needed, a	instructions, and completi	searching existing data	Food and Drug Administration Office of Chief Information Office	er	"An agency may not conduct or sponsor and a person is not required to responsor a collection of information unless it
collection of information this collection of information	n. Send comme ation, including	nts regarding th suggestions for	is burden es reducing thi	timate or any other aspect o s burden to:	of 1350 Piccard Drive, 420A Rockville, MD 20850		to, a collection of information unless it displays a currently valid OMB control number."

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Manufacturer Report # 8010047-2013-00176

Section H10.

The user facility returned one TJF-Q180V with serial number 2101850 along with two TJF-160VFs with serial numbers: 2802210 and 2802201 to Olympus for evaluation. The two TJF-160VFs was received with a torn bending section cover.

All returned duodenovideoscopes were sent to an offsite laboratory for microbiological testing. The TJF-Q180V with serial number 2101850 was tested positive for Klebsiella pneumonia. The two TJF- 160VFs did not grow any microorganisms.

Following the microbiological testing the duendovideoscope (subject) was returned to Olympus for physical evaluation. The biopsy port, biopsy channel, suction cylinder and suction channel of the duodenovideoscope were examined with a boroscope and no residue or debris was found. However, a tear in the bending section was noted, which caused the device to fail the leak test. In addition, the subject device had deep scratches on the edge of the distal end cover. The device was recommended for major repair.

As part of our investigation with this report, an Olympus Endoscopy Support Specialist (ESS) visited the user facility to observe the user facility's reprocessing practices and provided reprocessing training per the user facility's request. During the onsite visit the ESS observed that the user facility staff was not pre-cleaning, leak testing, and pressurizing the endoscope before submerging the device in the water. Additionally, the staff was not using the air/water cleaning adapter, nor using the correct suction cleaning adapter.

Please cross reference Mfr. Report# 8010047-2013-00172, 8010047-2013-00173, 8010047-2013-00174, 8010047-2013-00175, and 8010047-2013-00177.

### FDA Home³ Medical Devices⁴ Databases⁵

#### MAUDE Adverse Event Report: OLYMPUS OLYMPUS ERCP ENDOSCOPE

|X-Ray

oersearch

510(k)⁷|DeNovo⁸|Registration & |Adverse

|Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵

Listing⁹ Events¹⁰

CFR Title |Radiation-Emitting

Medsun |CLIA²⁰|TPLC²¹|Inspections²²

2116 Products¹⁷ Assembler¹⁸ Reports¹⁹

#### **OLYMPUS OLYMPUS ERCP ENDOSCOPE**

Back to Search Results

Model Number J180 **Event Date** 12/20/2012 **Event Type** Malfunction **Event Description** 

This pt and 15 subsequent pts developed klebsiella pneumoniae infections after having undergone endoscopic retrograde cholangiopancreatogram (ercp) procedures. The problem was thought to be related to difficulty in reliably cleaning and disinfecting the mechanically complex 'elevator' at the distal end of the endoscope. In response, the method of reprocessing was changed from automated high-level disinfection (hld) to gas sterilization. In addition, all staff was re-trained in scope pre-cleaning, cleaning, and high-level disinfection. The re-training and hdl was assessed by obtaining brush specimens of the elevator after hld of 10 ercp scopes that had been used on pts with known infection of the biliary tract. All of these cultures were negative.

#### Search Alerts/Recalls²³

New Search | Submit an Adverse Event Report²⁴

**Brand Name**OLYMPUS Type of DeviceERCP ENDOSCOPE Manufacturer (Section D)OLYMPUS Center Valley PA 18034

MDR Report Key3413223 Report NumberMW5032234

**Device Sequence Number**1

Product CodeKOG²⁵

Report Source Voluntary

Reporter OccupationATTORNEY

Type of ReportInitial

**Report Date**10/09/2013

2 DeviceS WERE Involved in the Event:12 0 PatientS WERE Involved in the Event:

Date FDA Received 10/10/2013

Is This An Adverse Event Report?No Is This A Product Problem Report?Yes

**Device Operator**Health Professional

**Device MODEL Number**J180

Is The Reporter A Health Professional?No

Is this a Reprocessed and Reused Single-Use Device?No

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- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=KOG

Page Last Updated: 09/30/2015

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U.S. Department of Health & Human Services

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- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=KOG

## Thomas Jefferson University Hospital, Philadelphia, Pennsylvania

#### U.S. Department of Health and Human Services Food and Drug Administration

**MEDWATCH** FDA eSubmitter Generated Form 3500A

### For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00249
UF/Importer Report #:	
Form Code:	

A. PATIENT INFORMATION							
1		4. Weight					
B. ADVERSE EVENT OR PRODUCT PROBLEM							
1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfun	ctions)						
. Outcomes Attributed to Adverse Event (Checked all that apply)  [ ] Death [ ] Life-threatening [ ] Hospitalization - initial or prolonged [ ] Required Intervention to Prevent Permanent impairment/Damage (Devices)							
3. Date of Event (mm/dd/yyyy)       4. Date of this Report (mm/dd/yyyy)         04/18/2013       05/17/2015							
5. Describe Event or Problem							
Olympus was informed that a patient contracted a carbapenement three different ERCP procedures. It was reported that two TJF -C perform the patient's procedures on February 28, 2013, April 18, procedure on May 21, 2013, the patient began to experience synhospital for observation. The patient was later discharged on May	2180V and one TJF-160V Duod 2013 and May 21, 2013 at diffe optoms of infection with epigastr 1/25, 2013.	envideoscopes were used to rent user facilities. After, the ic pain and was admitted to the					
betalactamases (ESBL)-producing Gram-negative bacteria and v	On or about May 30, 2013 the patient returned to the user facility and cultured positive for E.Coli -Extended-spectrum betalactamases (ESBL)-producing Gram-negative bacteria and was medically treated with antibiotics. It was reported that the patient continues to experience reoccurring pneumonia, kidney, bladder and urinary tract infections which caused the patient to have repeated hospital admissions.						
Olympus followed up with user facility to obtain additional information with no results. The exact serial numbers of the duodenvideosco	ation regarding the reported eve pes used in the procedure are u	ent by telephone and in writing but unknown at this time.					
6. Relevant Tests/Laboratory Data, Including Dates							
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergic Pancreatitis	es, race, pregnancy, smoking and alcoho	l use, hepatic/renal dysfunction, etc.)					
C. SUSPECT PRODUCT(S)	·						
Section C is not applicable to devices.							
D. SUSPECT MEDICAL DEVICE							
1. Brand Name EVIS EXERA II Duodenovideoscope	Common Device Name     Duodenovideoscope, Product Co	ode: FDT					
3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION	4. Model # Unknown	Catalog # Unknown					
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA	Serial # Unknown	Lot# N/A					
	Expiration Date (mm/dd/yyyy)	Other#					
5. Operator of Device Health Professional	6. Implanted Date (mm/dd/yyyy)	7. Explanted Date (mm/dd/yyyy)					
8. Is this a Single-Use Device that was reprocessed and Reused on a Patient?  ( ) Yes (•) No ( ) No Information							
9. Reprocessor Name and Address  10. Device Available for Evaluation? (Do not send to FDA)  ( ) Yes  ( •) No  ( ) No Information  [ ] Returned to Manufacturer							
11. ConComitant Medical Products and Therapy Dates (Excludes treatment of ever	ent)						
E. INITIAL REPORTER							
1. Name and Address	2. Health Professional?						
	() Yes (•) No () No	nformation					

## **U.S. Department of Health and Human Services**Food and Drug Administration

### **MEDWATCH**

FDA eSubmitter Generated Form 3500A for N

## For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	Mfr Report #:	2951238-2015-00249
UF/Importer Report #:	UF/Importer Report #:	

FDA eSubmitter Generated Form 35	500A for MANDATO	Form Code:			
123 Sount Broad Street		3. Occupation			
Suite 2250 Philadelphia, PA 19109, US		Attorney			
. Tilladolphia, 177 10100, 00		4. Initial Reporter Also Sent Report to FDA?			
	74	( ) Yes ( ) No (•) Unk	nown ( ) No Information		
F. FOR USE BY USER FACILITY/IM	IPORTER (Devices Only)				
1. User Facility or Importer		2. User Facility/Importer Number			
( ) User Facility ( ) Importer					
3, 4, and 5. User Facility or Importer Nar Phone Number	me/Address, Contact Person, and	6. Date UF/Importer Became Aware	of Event (mm/dd/yyyy)		
		7. Type of Report			
		( ) Initial ( ) Follow-up			
		8. Date of This Report (mm/dd/yyyy)	9. Approximate Age of Device		
10. Event Problem Codes (Refer to codin	ng manual)	14. Manufacturer Name/Address			
Patient Code(s): 1735 - 1994	-				
Device Code(s): 2303					
11. Report Sent to FDA?		•			
( ) Yes ( ) No ( ) No Infor	mation				
12. Location Where Event Occurred					
13. Report Sent to Manufacturer?					
( ) Yes ( ) No ( ) No Infor	mation				
G. ALL MANUFACTURERS  1, 2. Contact Office - Name/Address/Pho	ana Numbar	4 0 40 41 1100			
1, 2. Contact Office - Name/Address/File	one Number	1, 2. (Continued) Manufacturing Site	e Address/Phone for Devices		
Olympus America					
2400 Ringwood Ave San Jose, CA 95131, US					
Jan 1036, 0A 33131, 03					
3. Report Source (Check all that apply)  [ ] Foreign [ ]	Health Professional	4. Date Received by Manufacturer (	mm/dd/yyyy)		
	User Facility	05/17/2015			
	Company Representative	5. PMA/510(k) K080403			
[ ] Consumer [ ] [x] Other: Attorney	Distributor				
,		6. If IND, Give Protocol #			
7. Type of Report		8. Adverse Event Term(s)	9. Manufacturer Report Number		
[ ] 5-day [x] Initial [ ] Folk	ow-up		2951238-2015-00249		
H. DEVICE MANUFACTURERS ONL	_Y				
1. Type of Reportable Event	2. If Follow-up, What Type?	3. Device Evaluated by Manufacture			
() Death (◆) Serious Injury	[ ] Correction [ ] Additional Information	[ ] Not Returned to Manufacto			
( ) Malfunction	[ ] Response to FDA Request	()Yes []Evaluation Sur (●)No	nmary Attached		
( ) No Information	[ ] Device Evaluation	(*/ 110			
	[ ] No Information				
4. Device Manufacture Date (mm/dd/yyyy	)	6. Evaluation Codes (Refer to coding	g manual)		
P Labeled Service 1 11 2		Method Code(s):			
5. Labeled for Single Use?  ( ) Yes (•) No ( ) No Infor	motion	Result Code(s): Conclusion Code(s): 67 - 92			
		, ,			
7. If Remedial Action initiated, Check Ty [ ] Recall [ ]	•	8. Usage of Device	9. If action reported to FDA under 21 USC 360I(f), list correction/removal		
[ ] Necall [ ]	Notification	( ) Initial Use of Device	reporting number		

## **U.S. Department of Health and Human Services** Food and Drug Administration

# For use by user-facilities,

Mfr Report #:	2951238-2015-00249
UF/Importer Report	#:
Form Code:	
 · · · · · · · · · · · · · · · · · · ·	

MEDWATCH	i	mporters, distributors		UF/Importer R	leport #:		
FDA eSubmitter Generated Fo	rm 3500A	for MANDATOF	RY reporting	Form Code:			
[ ] Repair [ ] Replace [ ] Relabeling [ ] Other	[ ] Inspection [ ] Patient Monito [ ] Modification/A		<ul><li>(●) Reuse</li><li>( ) Unknown</li><li>( ) No Information</li></ul>				
10. [X] Additional Manufacture	er Narrative and/or	11. [ ] Corrected Data	a				
The device referenced in this report has not yet been returned to Olympus for evaluation. The exact cause of the patient's coutcome could not be conclusively determined at this time. If additional and significant information becomes available at a later time these reports will be supplemented.  As part of our investigation into this report, Olympus dispatched an endoscopy support specialist (ESS) to the user facility on May 29, 2015 to observe their reprocessing practices. There was no reprocessing deviations noted, but it was observed that the user facility did not have a flushing pump in the reprocessing room.							
new protocol for the TJF-	Q180V.	domine to reprocess	men endoscopes. Th	e Loo dellio	onstrated all steps as per the		
Please see associated me	edical device repor	ts: 2951238-2015-00	248 and 2951238-20	15-00253.			
File Attachments							
No files attached.							

## THA HODE 3 Medical Devices 44 Databases 55 Tt. OLYMPUS MEDICAL SYSTEM CORPORATION DUODENOVIDEOSCOPE

510|DeNovo⁸⁸|Registration| Adverse |Recalls¹¹¹¹|PMA¹²¹²|HDE¹³¹³|Classification¹⁴¹⁴|Standards¹⁵¹⁵
66k) & Listing⁹⁹ Events¹⁰¹⁰

CDRH 77

CFR Title | Radiation-Emitting | X-Ray | Medsun |CLIA²⁰²⁰|TPLC²¹²¹|Inspections²²²²
21¹⁶¹⁶ Products¹⁷¹⁷ Assembler¹⁸¹⁸ Reports¹⁹¹⁹

#### OLYMPUS MEDICAL SYSTEM CORPORATION DUODENOVIDEOSCOPE

Back to Search Results

Lot Number N/A

Device Problem No Known Device Problem

Event Type Injury

Event Description

Olympus received a news article which reported that eight patients tested positive for carbapenem-resistant enterobacteriaceae (cre) infections after undergoing a procedure using a duodeno videoscope (model/serial number unspecified) at the user facility. In addition, it was stated the hospital cultured its scopes and found no bacteria matching the strain causing the patient's infections. The exact cause of the patient's outcome cannot be conclusively determined at this time. Originally, (b)(6) 2015 olympus was informed of one patient infection in which the patient was medically treated with antibiotics. Based on the new information received olympus will submit seven mdrs to account for the eight patients. (cross reference: 2951238-2015-00388, 2951238-2015-00389, 2951238-2015-00390, 2951238-2015-00391, 2951238-2015-00392, and 2951238-2015-00393) olympus followed up with the user facility to obtain additional information regarding the reported events by telephone and in writing but with no result.

#### **Manufacturer Narrative**

The user facility has not provided the specific model and serial number of the scopes involved into the reported events. Therefore, it is unknown if the user facility has returned the scope to olympus for service or evaluation. As part of our investigation in this report, olympus dispatched an endoscopy support specialist (ess) to the user facility to observe their reprocessing practices. At this time the user facility has not yet scheduled a date for the in-service. If additional and significant information becomes available at a later time these reports will be supplemented please see original associated medical device report: 2951238-2015-00249.

Search Alerts/Recalls²³²³

New Search²⁴ | Submit an Adverse Event Report²⁵²⁴

Brand NameDUODENOVIDEOSCOPE
Type of DeviceDUODENOVIDEOSCOPE
Manufacturer (Section D)OLYMPUS MEDICAL SYSTEM

CORPORATION 2951 Ishikawa-Cho, Hachioji-Shi Tokyo 192-8 507 JAPAN 192-8507

Manufacturer ContactNoemi Schambach

2400 Ringwood Avenue San Jose , CA 95131 (408) 408 -4089 40893550 4089355002

MDR Report Key5030603

Report Number 2951238-2015-00387 **Device Sequence Number**1

Product CodeFDT²⁶²⁵

Report Source Manufacturer

Source TypeLITERATURE, OTHER, USER FACILIT

Reporter OccupationOther

Type of ReportInitial

**Report Date**08/05/2015

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received08/25/2015

Is This An Adverse Event Report? Yes

Is This A Product Problem Report?No

**Device Operator**Health Professional

**Device LOT NumberN/A** 

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA?

**Event Location**No Information

**Date Manufacturer Received**08/05/2015

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Is The Device Single Use?No

Is this a Reprocessed and Reused Single-Use

**Device?** 

Type of Device UsageReuse

**Patient TREATMENT DATA** 

Date Received: 08/25/2015 Patient Sequence Number: 1

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- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
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- 14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
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- 17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

- 18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm
- 7. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
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- 12. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
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Page Last Updated: 09/30/2015

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U.S. Department of Health & Human Services

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## UCLA Medical Center Los Angeles, California



February 17, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:		
( '044400'		
Connes		
CODICO.		

Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #	2951238-2015-00064	_
UF/importer i	Report #	_
		_

MEDWATCH

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500	OA (2/13)			Page 1	of 2						FDA Use Only
A. PATIENT INF	ORMATION				C. SUSPE	CT PROD	UCT(S)				
1. Patient Identifier			3. Sex	4. Weight	1. Name (Give	labeled stre	ngth & mfr/labele	7)			
	of Event:		☐ Female	lbs	#1						
	Date	-		or	#2						
In confidence	of Birth:		Male	kgs	2. Dose, Frequ	iency & Roi	ute Used	3. Thera	py Dates (//	f unknown, g	ive duration)
B. ADVERSE EV	ENT OR PRODUC	CT PROBLE	VI			,		from/to	o (or best es	stimate)	,
1. 🕢 Adverse Event	t and/or 🗌 Pro	duct Problem (e	.g., defects/malf	unctions)	#1			-   <del>#1</del>			
<ol><li>Outcomes Attribut (Check all that appl)</li></ol>					#2	H dadi		#2	E Event	Abated Afte	-1100
Death:	01/XX/2015	☐ Disability o	r Permanent Da	mage	4. Diagnosis f	or Use (Indi	cation)			d or Dose F	
Life-threatenin	(mm/dd/yyyy)		Anomaly/Birth [	•	#1				#1 🗆 Y	es 🗌 No	Doesn't Apply
	ย ı - initial or prolonged		ous (Important N		#2				#0 🗆 V		Doesn't
	r-milial or prolonged vention to Prevent Perm				6. Lot#		7. Exp. Date		#2   Y		L Apply
3. Date of Event (mm			Report (mm/do		#1		#1			Reappeared oduction?	After
	1- 01/24/2015	4. Date of this	01/28/2015		#2		#2		1 —	es No	Doesn't
5. Describe Event or			01/10/101		9. NDC# or Ur	nique ID			1		☐ Apply
Olympus was i	nformed that a	-							#2 N	es No	Doesn't Apply
	resistant organ trograde Cholan		-		10. Concomit	ant Medical	Products and Ti	nerapy Date	s (Exclude I	treatment of	event)
	October 3,2014.		<i>-</i> ·								
patient who h	ad the ERCP on	October 3,	2014 was	not							
~	he user facilit	-									
	copes as a prec confirmed to b								. (C	ontinue or	ı page 3)
	ated all their		-	or			CAL DEVICE				
laboratory te investigation	sting, as part	of their i	nternal		1. Brand Nam	evis e	XERA II DU	ODENOVII	EOSCOP	3	
_					2. Common D				2b, P KOG	rocode	
	ater informed t				Doudenovi  3. Manufactu				ROG		
patients expi	red. The cause	of death 1	s unknown.		OLYMPUS ME	DICAL SY	STEM CORPORA		102-05	07 7222	
Olympus has b	een in ongoing	communicat	ion with t	he user		awa-cno,	Hachioji-sh	1, Tokyo,	192-03		
	telephone and i	_			4. Model #	,	Lot#			5. Operato	
detailed into	rmation regardi	ing the rep	ortea ever	nts.	TJF-Q180V	·		on Date (mm	/dd/vvvv)		h Professional
					TJF-Q180	J		N/A	,,,,,	Lay U	lser/Patient
					Serial #					<b>:</b>	
					2405047		(	7 45	landed Ob		(dd ( to a a a )
			(Continue o	n page 3)	N/A	a, Give Date	(mm/dd/yyyy)	N/A		ve Date (mm	raaryyyy)
6. Relevant Tests/La	boratory Data, Includin	g Dates				ngle-use De	vice that was Re			d on a Patie	nt?
					☐ Yes	✓ No					
					9. If Yes to Ite	em No. 8, Er	nter Name and A	ddress of R	eprocesso	r	
	,				H						
					10. Device Av	ailable for	Evaluation? (Do	not send to I	FDA)		
					Yes	✓ No	Returned to		-		
									- (F -1 -1	(mm/dd/y	
			(Continue o		11. Concomit	ant Medical	Products and T	nerapy Date	is (Exclude	treatment of	r event)
7. Other Relevant Hi race, pregnancy, si	story, including Preexi moking and alcohol use,	sting Medical Co hepatic/renal dys	onditions (e.g., a sfunction, etc.)	allergies,	<b> </b>						
					'				(0	Continue o	n page 3)
l					E. INITIAL		TER				
					11 Name and	Addrose					
1					The Reger	nts Univ	ersity of	Californ	nia		
					200 UCLA						
					Los Ange	les, CA	90095				
					Phone #		TE	mail Addres	5		
			(Continue o	n page 3)			Į.				1
Submission of a	report does not co	nstitute an ac	lmission tha	t medical	2. Health Pro	fessional?	3. Occupation		4.	Initial Repor	rter Also Sent
caused or contrib	acility, importer, di outed to the event.	stributor, ma	nutacturer o	r product	✓ Yes	☐ No	Nurse				No ☑ Unk.

### SenW/Ateu

ORM FDA 3500				Page 2	2 of 2			
F. FOR USE BY L			RTER (D	evices Only)	H. DE	VICE MANUE	ACTURERS ONL	Υ
. Check One	27-11-11			eport Number		of Reportable Ev		2. If Follow-up, What Type?
User Facility	Impo				I	Death		Correction
User Facility or Impo	orter Name/	Address		· · · · · · · · · · · · · · · · · · ·	1 =	Serious Injury		Additional Information
,						Malfunction		Response to FDA Request
						·		Device Evaluation
								Device Evaluation
					3. Devic	e Evaluated by N	lanufacturer?	4. Device Manufacture Date
						Not Returned to M	Manufacturer	(mm/yyyy)
Contact Person			5. Phone No	ımber		Yes Evalua	ation Summary Attached	Unk
						No (Attach page )	to explain why not) or	5. Labeled for Single Use?
Date User Facility or	r 7	7. Type of Repor	t	8. Date of This Report		provide code:	,,	☐ Yes 📝 No
Importer Became Aware of Event (mm.	/dd/yyyy)	[ ] Initial		(mm/dd/yyyy)				163 410
•					6. Even	Problem and Ev	aluation Codes (Refer	to coding manual)
		Follow-up#				Patient	1725	1000
Approximate Age of Device	10. Event P	roblem Codes (F	Refer to codir	ng manual)		Code	1735 -	1802 -
	Patient					Device	1120 -	2303 -
	Code					Code		
	Device Code	-		-		Method	-	-   -
1. Report Sent to FDA		12. Location W	here Event	Occurred				
		Hospital		Outpatient		Results	<b>-</b>	
Yes(mm/dd/	(1111)	Home		Diagnostic Facility		Conduciona	20 - 92	
∐ No		Nursing	Home	☐ Ambulatory		Conclusions	20 - 32	
3. Report Sent to Man	ufacturer?	I = -	ent Treatmen	Surgical Facility	7. If Rei	nedial Action Ini	tiated, Check Type	8. Usage of Device
Yes		Facility	one readings	ı.		Recall	Notification	Initial Use of Device
☐ No (mm/dd/	<i>(YYYY)</i>	Other:				Repair	Inspection	✓ Reuse
				(Specify)		Replace	Patient Monitoring	Unknown
4. Manufacturer Name	e/Address				ΙΙÄ	Relabeling	Modification/	9. If action reported to FDA under
							Adjustment	21 USC 360i(f), list correction/ removal reporting number:
						Other:		-
					10. 📝	Additional Manu	facturer Narrative	and / or 11. Corrected Data
G. ALL MANUFA	CTURER	S						ed to Olympus for
. Contact Office (and			ras)	2. Phone Number				py Support Specialist
Name	manadada	ing one for both		E THOMS NUMBER				ss the reprocessing
				3. Report Source	l 1°		-	and provided training and
Address				(Check all that apply)				staff. The ESS noted
LYMPUS AMERICA	TNC			Foreign	repro	cessing ind	consistencies d	uring the site visit.
400 Ringwood A				Study	The c	ause of the	e patient death	is unknown at this time.
an Jose, CA 95				Literature				mes available at a later
					time	this report	t will be suppl	emented.
Email Address				Health Professional			meu ususut	whoma
. Date Received by		16		√ User Facility			mfr. report nu 065.2951238-201	mbers: .5-00066,2951238-2015-00067
. Date Received by Manufacturer (mm/de	d/yyyy)	5. (A)NDA #		Company				015-00069, and
01/28/20	015	(A)NDA #		Representative		38-2015-000		
. If IND, Give Protocol	I #	- IND#		Distributor				
	,	BLA#		Other:		-	-	not an admission that the
		PMA/			aevic	e nas cause	ed or contribut	ed to the reported event.
. Type of Report (Check all that apply)		510(k) # KO	24033					
		Combination						
5-day 30-da	-	Product	Yes					
7-day		Pre-1938	Yes					
	w-up #	OTC Product	Yes					
		8 Advance For	ant Tarmic'	<u> </u>				
. Manufacturer Report		8. Adverse Ev	eitt ierm(S)					
951238-2015-00	0064							
		I			·			

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff information unless it displays a currently PRAStaff@fda.hhs.gov valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of

FDA USE ONLY

## UMass Memorial Medical Center, Worchester, Massachusetts



September 17, 2013

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

U.S. Department of Health and Human Services
Food and Drug Administration

For use by user-facilities,

Mfr Report #	2951238-2013-00017
UF/Importer I	Report #

PLEASE TYPE OR USE BLACK INK

ood and Drug Adi	_		importer	MANDAT	ORY reporting	UF/Importer R	Report #		
MEDWATCH	1		101						
FORM FDA 3500	0A (1/09)			Page 1	of 2	1			FDA Use Only
A. PATIENT INF	ORMATION				C. SUSPECT PRODU				
	2. Age at Time		3. Sex	4. Weight	Name (Give labeled strength	gth & mfr/labeler	)		
UNK	of Event: UNK	UNK	Female	UNK lbs	#1				
	Date	NK	☐ Male	or UNK kas	#2				
In confidence	of Birth: VENT OR PRODUC			UNK kgs	2. Dose, Frequency & Rou	te Used	3. Therap	oy Dates (la ) (or best es	f unknown, give duration) stimate)
					#1		#1		
1. Adverse Even		luct Problem (e	.g., defects/maif	unctions)	#2		#2		
<ol><li>Outcomes Attribut (Check all that applied)</li></ol>	ted to Adverse Event (y)				4. Diagnosis for Use (Indic	ation)			Abated After Use
Death:	(mm/ddhaaa)	Disability o	r Permanent Da	mage	#1				ed or Dose Reduced?
Life-threatenin	( <i>mm/dd/yyyy)</i> ng	Congenital	Anomaly/Birth I	Defect	#2				Apply
	n - initial or prolonged		ous (Important N		6. Lot#	7. Exp. Date		#2 🗌 Y	'es
Required Inter	rvention to Prevent Perma				#1	#1			Reappeared After
3. Date of Event (mr		4. Date of This	Report (mm/de		#2	#2			oduction? 'es No Doesn't
	Unk		8/28/2013		9. NDC# or Unique ID	1		ا	Арріу
<ol><li>Describe Event or Olympus was i</li></ol>	nformed that the	ere were m	ultiple pa	atients				#2 🗌 Y	'es No Doesn't Apply
infected with	an unspecified	bacteria	that was t	raced	10. Concomitant Medical F	Products and TI	herapy Date	s (Exclude	treatment of event)
back to using duodenovideos	the duodenovidecope was reproc	eoscope. T essed usin	ne g Cidex OI	PA with					
an automated	endoscope repro-	cessor. Th	ere was no						
reported issu	e with reprocess	sing of th orts of ob	e structions	or					
difficulty pa	ssing the clean	ing brush	through th	ne	D. SUSPECT MEDIC	CAL DEVICE	:		
duodenovideos	cope. Prior to cope had not be	this event	, the	rv 2013.	1 Brand Name				
					Olympu	s EVIS EXE		lodenov:	laeoscope
	cted the user f				2. Common Device Name	Duodenovid	leoscope		
informed that	rmation regardi there were 20	plus patie	nts infect	ted with	3. Manufacturer Name, Cit OLYMPUS MEDICAL SYS	ty and State			
the unspecifi	ed bacteria. Th	e same bac	teria was	said to	2951 Ishikawa-cho,			192-850	7, Japan
	lated from the further informa			nowever,	4. Model #	Lot#			5. Operator of Device
			÷		TJF-Q180V	N/A			Health Professional
					Catalog # TJF-Q180V	Expirat	tion Date (m	m/dd/yyyy)	Lay User/Patient
					Serial #	Other#			Other:
					2102040				L
1					<ol> <li>If Implanted, Give Date N/A</li> </ol>	(mm/dd/yyyy)	7. If Exp	olanted, Giv	ve Date (mm/dd/yyyy)
6. Relevant Tests/La	aboratory Data, Including	g Dates			8. Is this a Single-use Dev	vice that was Re		and Reuse	ed on a Patient?
				-	Yes No				
					<ol><li>If Yes to Item No. 8, En N/A</li></ol>	ter Name and A	ddress of R	eprocesso	r
					N/A				
					10. Device Available for E	valuation? (Do	not send to F	EDA)	0.400.405.5
					✓ Yes   No	✓ Returned to	o Manufactur	er on:	8/28/2013 (mm/dd/yyyy)
1					11. Concomitant Medical	Products and T	herapy Date	s (Exclude	
7. Other Relevant H	listory, Including Preexis	sting Medical Co	onditions (e.g.,	allergies,	Cidex OPA Custom Ultrasonic	Machine			
race, pregnancy, s	smoking and alcohol use,	hepatic/renal dys	sfunction, etc.)		Custom Offrasonic	naciilile			
					E. INITIAL REPORT	TER			
					1. Name and Address		one#		
1									
1					UMASS Memorial M	edical Cen	iter		
1					55 Lake Avenue N	orth			
1					Worcester, MA 00	1655			
	report does not con				2. Health Professional?	3. Occupation		4.	Initial Reporter Also Sen Report to FDA
caused or contri	facility, importer, di buted to the event.	actibutor, Ma	muracturer (	or product	✓ Yes  No	Nurse			Yes No Unk

OCA_0001669

#### **MEDWATCH**

Check One
 User Facility

4. Contact Person

Approximate
 Age of Device

Yes

Yes

☐ No

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient

Code Device

Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

OLYMPUS AMERICA, INC.

2400 Ringwood Avenue

San Jose, CA 95131

192-8507, Japan

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

7-day

10-day 📝 Initial

15-day Follow-up # ____

9. Manufacturer Report Number

2951238-2013-00017

08/28/2013

Periodic

1. Contact Office - Name/Address (and Manufacturing Site

OLYMPUS MEDICAL SYSTEM CORPORATION

2951 Ishikawa-cho, Hachioji-shi, Tokyo

(A)NDA#

IND#

STN# PMA/

510(k) # ___

Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

FORM FDA 3500A (1/09) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

| Initial | | Follow-up # _____ |
| To. Event Problem Codes (Refer to coding manual)

1735

2303

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

Importer

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

Foreign

Literature

Consumer

Study

3. Report Source (Check all that apply)

☐ Health Professional

✓ User Facility

Company Representative

Distributor

Other:

Page	2	of	2
------	---	----	---

		FDA USE ONLY
f ²		
H. DEVICE MANUFA	CTURERS ONLY	
Type of Reportable Ever		2. If Follow-up, What Type?
Death		Correction
✓ Serious Injury		Additional Information
Malfunction		Response to FDA Request
Other:		Device Evaluation
3. Device Evaluated by Ma		4. Device Manufacture Date (mm/yyyy)
Not Returned to Ma  ✓ Yes ☐ Evaluation	nufacturer on Summary Attached	XX/2011
□ No (Attach page to	•	5. Labeled for Single Use?
provide code:		☐ Yes ☑ No
6. Evaluation Codes (Refer	to coding manual)	
Method	10 - 23	37 - 38
Method	10 - 23	]
Results	115 -	]-[]
Conclusions	51 -	]-[
7. If Remedial Action Initia	ted, Check Type 8	. Usage of Device
Recall	Notification	Initial Use of Device
Repair	Inspection	Reuse
Replace	Patient Monitoring	Unknown  If action reported to FDA under
Relabeling	Modification/ Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:		removal reporting number.
10. 📝 Additional Manufa	cturer Narrative a	nd / or 11. Corrected Data
		port has been sterilized
and was returned		evaluation. The using a borescope and
		substances and debris
		nels, channel mount, and
		astic cover was cracked failed the leak test,
		am of the control body
unit and at the d		bending section glue
was cracked.		
		o this report, an
		list has been dispatched the reprocessing
practices.	.rcy to reassess	the reprocessing
mha ausat assu		and and b
The exact cause of conclusively dete		
		device could not be
ruled out as a co	ntributory fact	or to the reported
event. This repor information becom		emented if additional
·		
L		

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, 420A Rockville, MD 20850

OMB Statement:
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## Universitair Medisch Centrum Utrecht, Netherlands

Food and Drug Administration

#### **MEDWATCH**

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	8010047-2015-00816
UF/Importer Report #:	
Form Code:	

FDA eSubmitter Generated Form 3500A	IOT MANDATOR	CY reporting	Form Code:				
A. PATIENT INFORMATION							
1. Patient Identifier (In confidence)	2. Age at Time of Event, D	ate of Birth	3. Sex No Informa	tion	4. Weight		
B. ADVERSE EVENT OR PRODUCT PROBLEM	ĺ						
1. [X] Adverse Event and/or [ ] Product Prol	blem (e.g., defects/malfun	ctions)					
Outcomes Attributed to Adverse Event (Checked at Death     I Death     I Life-threatening     Hospitalization - initial or prolonged	,	[ ] Congenita [x] Other Ser	or Permanent al Anomaly/Birt ious (Importan	th Defect	vents)		
[ ] Required Intervention to Prevent Permaner	nt impairment/Damage (De	·					
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (mn 08/19/2015	1/dd/yyyy)				
5. Describe Event or Problem Olympus was informed that eight patients cholangiopancreatography (ERCP) proced The facility is recalling patients. The hospital informed olympus that all TJF No detailed information is available at this	dure using a TJF-Q180 F-Q180V scopes were o	V between 1st Jan 20	r undergoing 15 and 15th /	an endoso Aug 2015.	copic retrograde		
6. Relevant Tests/Laboratory Data, Including Dates							
7. Other Relevant History, Including Preexisting Medi	ical Conditions (e.g., allergie	es, race, pregnancy, smoking	and alcohol use	e, hepatic/rena	al dysfunction, etc.)		
C. SUSPECT PRODUCT(S)							
Section C is not applicable to devices.							
D. SUSPECT MEDICAL DEVICE							
1. Brand Name		2. Common Device Name					
EVIS EXERA II DUODENOVIDEOSCOPE		DUODENOVIDEOSCO	)PE, Product (	Code: FDT			
Manufacturer Name, City and State     OLYMPUS MEDICAL SYSTEMS CORPORATION     OF A Lability of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company	DN	4. Model # TJF-Q180V		Catalog #			
2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA		Serial # unk		Lot#			
		Expiration Date (mm/dd/yyyy)					
		Unique Identifier (UDI) #					
5. Operator of Device Health Professional		6. Implanted Date (mm/dd	/уууу)	7. Explanted	Date (mm/dd/yyyy)		
8. Is this a Single-Use Device that was reprocessed a	and Reused on a Patient?						
9. Reprocessor Name and Address  10. Device Available for Evaluation? (Do not send to FDA)  ( ) Yes  (•) No  ( ) No Information  [ ] Returned to Manufacturer							
11. ConComitant Medical Products and Therapy Date	es (Excludes treatment of eve	nt)					
E. INITIAL REPORTER							
1. Name and Address		2. Health Professional?  (•) Yes ( ) No	( ) No Infor	mation			
Universitair Medisch Centrum Heidelberglaan 100 3584 CX UTRECHT		3. Occupation Physician					
NL		4. Initial Reporter Also Se	-		Information		

Food and Drug Administration

#### **MEDWATCH**

FDA eSubmitter Generated Form 3500A

# For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	8010047-2015-00816
UF/Importer Report #:	
Form Code:	

F. FOR USE BY USER FACILITY/IM	PORTER (Devices Only)						
1. User Facility or Importer		2. User Facility/Importer Number					
( ) User Facility ( ) Importer							
3, 4, and 5. User Facility or Importer Na Phone Number	me/Address, Contact Person, and	6. Date UF/Importer Became Aware of Event (mm/dd/yyyy)					
		7. Type of Report					
		( ) Initial ( ) Follow-up					
		8. Date of This Report (mm/dd/yyyy)	9. Approximate Age of Device				
10. Event Problem Codes (Refer to coding	ig manual)	14. Manufacturer Name/Address					
Patient Code(s):							
Device Code(s):							
11. Report Sent to FDA?		1					
( ) Yes ( ) No ( ) No Infor	mation						
12. Location Where Event Occurred		1					
12. Location where Event Occurred							
		-					
13. Report Sent to Manufacturer?							
( ) Yes ( ) No ( ) No Infor	mation						
G. ALL MANUFACTURERS							
1, 2. Contact Office - Name/Address/Pho	one Number	1, 2. (Continued) Manufacturing Site Ac	Idress/Phone for Devices				
OLYMPUS MEDICAL SYSTEMS C	ORP.						
2951 Ishikawa-cho,							
Hachioji-shi, Tokyo 192-8507, JA							
2 Benerit Severe (Check all that and the		4 Data Basalisad by Manufactures (com	(ddf, a - a d				
3. Report Source (Check all that apply)	Health Professional	4. Date Received by Manufacturer (mm/dd/yyyy) 08/19/2015					
	Health Professional User Facility	06/19/2015					
	Company Representative	5. PMA/510(k) K080403 6. If IND, Give Protocol #					
I .	Distributor						
[ ] Other							
7. Type of Report		8. Adverse Event Term(s)	9. Manufacturer Report Number				
[ ] 5-day [x] Initial [ ] Foll	ow-up	.,	8010047-2015-00816				
H. DEVICE MANUFACTURERS ON	•						
Type of Reportable Event	2. If Follow-up, What Type?	3. Device Evaluated by Manufacturer?					
( ) Death	[ ] Correction	Device Evaluated by Manufacturer?     Not Returned to Manufacturer					
(•) Serious Injury	[ ] Additional Information						
( ) Malfunction	[ ] Response to FDA Request	( ) Yes [ ] Evaluation Summary Attached (•) No					
( ) No Information	[ ] Device Evaluation	(-) 110					
	[ ] No Information						
4. Device Manufacture Date (mm/dd/yyy)	<i>(</i> )	6. Event Problem and Evaluation Codes	s (Refer to coding manual)				
		Patient Code(s): 1930 - 1735					
5. Labeled for Single Use?		Device Code(s): 1120					
( ) Yes ( • ) No ( ) No Infor	rmation	Method Code(s): 3263					
( ) 165 (*) NO ( ) NO IIIIOIIIauoii		Result Code(s): 3221					
		Conclusion Code(s): 92					
7. If Remedial Action initiated, Check Ty		` '	9 If action reported to EDA under 24				
	Notification	8. Usage of Device 9. If action reported to FDA under 21 USC 360(f), list correction/removal					
[ ] Recall [ ]		(•) Reuse	reporting number				
[] Replace []		(•) Reuse () Unknown					
	Modification/Adjustment	( ) No Information					
[ ] Other	-						

Food and Drug Administration

#### **MEDWATCH**

FDA eSubmitter Generated Form 3500A

#### For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	8010047-2015-00816
UF/Importer Report #:	
Form Code:	

10. [X] Additional Manufacturer Narrative and/or 11. [ ] Corrected Data

The subject devices have not been returned to Olympus Europia SE&Co .KG(OEKG) for evaluation.

The exact cause of user's report could not be conclusively determined at this time.

A supplemental report will be submitted if significant and additional information becomes available later.

Please cross-reference the following reports for the other seven patients: 8010047-2015-00817,8010047-2015-00818,8010047-2015-00819,8010047-2015-00820,8010047-2015-00821,8010047-2015-00822, and 8010047-2015-00823.

#### **File Attachments**

No files attached.

## University of Pittsburgh Medical Center Presbyterian Hospital Pittsburgh, Pennsylvania

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #	8010047-2012-00481	
UF/Importer	Report #	

#### **MEDWATCH**

PLEASE TYPE OR USE BLACK INK

FORM FRA AFOR				Page 1	of 2					
FORM FDA 3500				ı aye i					F	DA Use Only
A. PATIENT INF					C. SUSPEC		, ,			
Patient Identifier		3.	Sex	4. Weight	1. Name (Give	labeled streng	th & mfr/labeler)			
	of Event:		Female	lbs	#1					
	Date			or	#2			•••		
In confidence	of Birth:	[	Male	kgs		P Doule	Hand	Thomas D	ates (if unknown, giv	o dustinal
B. ADVERSE EV	ENT OR PRODU	CT PROBLEM			2. Dose, Frequ	iency & Route	usea	from/to (or	best estimate)	re duration)
1  Advance Suppl	andine [] Per	alvet Backlers (c.c.	dafaata/maif	antiana)	#1			#1		
1. Adverse Event		duct Problem (e.g.,	aerects/mairui	nctions)	#2			#2		
<ol><li>Outcomes Attribute (Check all that apply</li></ol>					4. Diagnosis fo	or Hea (Indica)	lion		Event Abated After	lise
Death:		Disability or Pe	rmanent Dam	age	_	or pac involved	1019		Stopped or Dose Re	
[ ] Life threetening	(mm/dd/yyyy)	Consenite An	analy/Dieth Ca		#1			#1	Yes No	Doesn't
Life-threatening		Congenital And			#2					Doesn't
	- initial or prolonged	Other Serious		1	6. Lot#	7	. Exp. Date	#2	Yes No	Apply
Required Interv	renlion to Prevent Perm	anent Impairment/Da	mage (Device	s)	#1	],	#1		Event Reappeared A	After
3. Date of Event (mm		4. Date of This Rep		(3737)					Reintroduction?	□ Doesn't
Unk	nown	11	/19/2012		#2		#2	#1	∐ Yes ∐ No	Apply
<ol><li>Describe Event or 8</li><li>The user facil</li></ol>		hat 10-13 mas	ients th	at had	9. NDC# or Uni	ique ID		#2	☐ Yes ☐ No	Doesn't
been examined		-								☐ Apply
infected with	-		-		10. Concomita	nt Medical Pr	oducts and The	rapy Dates (Ex	clude treatment of ev	vent)
information pr	•									
had been provi	ded to the pat	ients.								
					D. SUSPEC	CT MEDICA	AL DEVICE			
					1. Brand Name	Olumnus	ente eve	DOUG IT 44	DENOVIDEOSCOP	F
1					3. Camara a Da				- LNOVIDEOUCOI	
				İ	2. Common De	Nice Name Di	iodenoscop	e		
					3. Manufacture	r Name, City	and State			
							EM CORPORATI		-8507, Japan	
					2951 Ishika	iwa-cho, H	acniaji-smi,	, токуо 192	-esu/, Japan	
					4. Model #		Lot#		5. Operator of	of Device
					TJF-Q180V		N/A	. B		Professional
					Catalog # TJF-0180V		Expiratio	n Date (mm/dd/ N/A	Lay Use	er/Patient
					Serial #		Other#	N/A	Other:	
					2001160		N/A			
					6. If Implanted.	, Give Date (n		7. If Explante	ed, Give Date (mm/d	d/yyyy)
					N/A			N/A	,	
6. Relevant Tests/Lab	oratory Data, Includin	g Dates			8. Is this a Sing	gle-use Devic	e that was Rep	rocessed and F	Reused on a Patient	t?
					Yes	√ No				
					9. If Yes to Item	n No. 8, Enter	Name and Add	Iress of Repro	essor	
					1		luation? (Do no.	,	12/11/20	112
					✓ Yes	∐ No [✓	Returned to M	fanufacturer on:	(mm/dd/yyy	
					11. Concomita	nt Medical Pr	oducts and The	rapy Dates (E)	xclude treatment of e	-
7. Other Relevant Hist	tony Including Presult	ting Medical Condi	ions/e a all	amies						.,
race, pregnancy, sm	oking and alcohol use,	hepatic/renal dysfunc	tion, etc.)	grea,						
					E. INITIAL	REPORTE	R			
					1. Name and A	ddress	Phone	#		
						_	L			
-										
					UPMC Prest	oyterian				
					200 LOTHRO	•	•			
					Pittsburgh	h, PA 152	:13			
Submission of a re	port does not cor	istitute an admis	sion that r	nedical	2. Health Profe				4. Initial Reporte Report to FDA	r Also Sent
personnel, user fac caused or contribu	ited to the event.	stributor, manura	acturer or	product	✓ Yes	_No Oth	ner Healthcare	Professional	I — —	lo 🔳 Unk.

#### **MEDWATCH**

Check One
 User Facility

4. Contact Person

Approximate Age of Device

11. Report Sent to FDA?

Yes

☐ No

Yes

No

for Devices)

 Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

FORM FDA 3500A (1/09) (continued)

3. User Facility or Importer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

12. Location Where Event Occurred

☐ Initial ☐ Follow-up #

1735

2993

Hospital

] Home

Other:

Nursing Home

Outpatient Treatment Facility

Patient

Code Device

Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

OLYMPUS AMERICA, INC. 2400 Ringwood Avenue

San Jose, CA 95131

192-8507, Japan

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

5-day

7-day

10-day

11/19/2012

√ 30-day

Periodic

✓ Initial

15-day Follow-up#_____

9. Manufacturer Report Number

8010047-2012-00481

1. Contact Office - Name/Address (and Manufacturing Site

OLYMPUS MEDICAL SYSTEM CORPORATION

2951 Ishikawa-cho, Hachioji-shi, Tokyo

(A)NDA#

IND#

STN#

510(k) # __ Combination

Pre-1938

OTC Product

8. Adverse Event Term(s)

Yes Yes

Yes

Yes

[ ] Importer

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

Foreign

Literature

Consumer

Study

 Report Source (Check all that apply)

☐ Health Professional

☐ User Facility

Company Representative

Distributor

Other:

Page	2	of	2
------	---	----	---

ı		FDA USE ONLY
- 2		
f <u>2</u>		
H. DEVICE MANUFAC	TURERS ONLY	
Type of Reportable Event		2. If Follow-up, What Type?
Death		Correction
Serious Injury		Additional Information Response to FDA Request
Malfunction		Device Evaluation
Other: Klebsiell		-
3. Device Evaluated by Manu		<ol> <li>Device Manufacture Date (mm/yyyy)</li> </ol>
Not Returned to Manu		
	Summary Attached	5. Labeled for Single Use?
No (Attach page to ex provide code:	piain wny not) or	
		Yes 📝 No
6. Evaluation Codes (Refer to	coding manual)	
Method	10 - 38	-
		<u> </u>
Results	3233	
Conclusions	11 -	
7. If Remedial Action Initiate		. Usage of Device
l	, , , .	Initial Use of Device
	olification	Reuse
	atient Monitoring	Unknown
Relabeling M	lodification/	. If action reported to FDA under 21 USC 360i(f), list correction/
	djustment	removal reporting number:
Other:		
10. 📝 Additional Manufact		ind / or 11. Corrected Data
Olympus followed-u	p with the use	r facility to obtain this report. The user
facility reported	that all poter	tially affected patients
had undergone ERCP		
patients. The user endoscopes were cu		of the endoscopes which
is the subject dev	ice reference	in this report was
		nia on two separate es. Nevertheless, the
user facility repo	rted that the	e was no direct evidence
of the infection b	eing tied to	ny particular endoscope.
As part of our inv	estigation in	to this report, two
Olympus representa	tives had been	dispatched to the user
facility to assess	the facility	's reprocessing practices ion. Additionally, the
		i in the investigation.
		ection of the device
		no major observation ocessing practices was
assessed with no m	ajor risk fac	or for K. pneumonia
transmission obser	ved.	
The device was sen	t to an indep	endent testing laboratory
for microbiologica	l testing. Th	e results of the testing
Olympus for a comp	ne device nas Olete evaluati	not yet been returned to on. This report will be
supplemented when		
This report is bei	ng submitted	as a Medical Device
Report in an abund		
Department of Health and Hun	C	OMB Statement:

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, 420A Rockville, MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.



January 29, 2013

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is a supplemental report for a previously reported 30-day MDR reportable event. Any further correspondence may be directed to my office.

## Sincerely,



Copies:

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #	8010047-2012-00481	
UF/Importer	Report #	
	<u></u> -	

## **MEDWATCH**

FORM FDA 3500A (1/09)

Page 1 of 2

FORM FDA 3500A (1/09)	Page 1	<u> </u>			FDA Use Only
A. PATIENT INFORMATION		C. SUSPECT PRODU	ICT(S)		
1. Patient identifier 2. Age at Time of Event:	3. Sex 4. Weight	Name (Give labeled streng #1	ith & mfr/labeler)		
or	or	#2			
In confidence of Birth:	Male kgs	2. Dose, Frequency & Route	B Used	3. Therapy Dates (/	funknown, give duration)
B. ADVERSE EVENT OR PRODUCT PROBLE		#1		from/to (or best ea	stimate)
Adverse Event and/or Product Problem (4     Outcomes Attributed to Adverse Event	.g., defects/malfunctions)	#2		#2	
(Check all that apply)		4. Diagnosis for Use (Indice	tion)	5. Event	Abated After Use
Death: Disability (	or Permanent Damage	#1		l <u></u> ''	ed or Dose Reduced? es
	l Anomaly/Birth Defect	#2		#1 []	Apply
	ous (Important Medical Events)	8. Lot #	7. Exp. Date	#2 🗖 Y	es ☐ No ☐ Doesn' Apply
Required intervention to Prevent Permanent Impairmen		#1	#1		Reappeared After
3. Date of Event (mm/dd/yyyy) 4. Date of This	Report (mm/dd/yyyy)	#2	#2	l	oduction? es
5. Describe Event or Problem		9. NDC# or Unique ID			— Арріу
				#2 □ Y	es 🗌 No 🔲 Doesn' Apply
		10. Concomitant Medical Pr	oducts and The	rapy Dates (Exclude I	realment of event)
TLEASE LIFE OK USE BLACK INK		D. SUSPECT MEDIC.	AL DEVICE		
Fr		1. Brand Name			
<u>a</u>		2. Common Device Name			
5		3. Manufacturer Name, City	and State		
		4. Model#	Lot#	· <u>·</u>	5. Operator of Device
		Catalog #	Expiratio	on Date (mm/dd/yyyy)	Health Professional Lay User/Patient
		Serial#	Other#		Other:
		6. If Implanted, Give Date (	nm/dd/yyyy)	7. If Explanted, Giv	e Date (mm/dd/yyyy)
6. Relevant Tests/Laboratory Data, including Dates		8. is this a Single-use Devi	ce that was Rep	rocessed and Reuse	d on a Patient?
		9. If Yes to Item No. 8, Ente	r Name and Add	iress of Reprocesso	
		10. Device Available for Ev	aluation? (Do no	ot send to FDA)	
	i	Yes No [	Returned to N	vianufacturer on:	(mm/dd/yyyy)
		11. Concomitant Medical P	roducts and The	erapy Dates (Exclude	
7. Other Relevant History, Including Preexisting Medical Corace, pregnancy, smoking and alcohol use, hepatic/renal dys	onditions (e.g., allergies, function, etc.)				
		E. INITIAL REPORTE	R		
		1. Name and Address	Phone	e #	
					•
Submission of a report does not constitute an ac personnel, user facility, importer, distributor, ma caused or contributed to the event.	mission that medical nufacturer or product	2. Health Professional? 3	. Occupation		initial Reporter Also Sen Report to FDA Yes No Unk

#### FDA USE ONLY **MEDWATCH** FORM FDA 3500A (1/09) (continued) Page 2 of 2 F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) H. DEVICE MANUFACTURERS ONLY 1. Check One 2. UF/Importer Report Number 1. Type of Reportable Event 2. If Follow-up, What Type? User Facility mporter [ Death Correction 3. User Facility or importer Name/Address Serious Injury X Additional Information Maifunction Response to FDA Request Other: ☐ Device Evaluation 3. Device Evaluated by Manufacturer? 4. Device Manufacture Date (mm/yyyy) Not Returned to Manufacturer 4. Contact Person 5. Phone Number Yes Evaluation Summary Attached 5. Labeled for Single Use? No (Attach page to explain why not) or provide code: 8. Date of This Report 6. Date User Facility or 7. Type of Report Importer Became Aware of Event (mm/dd/yyyy) Yes [ ] No (mm/dd/yyyy) [ ] Initial 6. Evaluation Codes (Refer to coding manual) Follow-up # 9. Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) Method Patient Results Code Device Conclusions Code 11. Report Sent to FDA? 12. Location Where Event Occurred 7. If Remedial Action Initiated, Check Type 8. Usage of Device Oulpatient Diagnostic Facility Yes Hospital Initial Use of Device Recall Notification (mm/dd/yyyy) Home ∏ No Reuse Repair Inspection Ambulatory Surgical Facility Nursing Home Unknown 13. Report Sent to Manufacturer? Replace Patient Monitoring Outpatient Treatment Facility Modification/ If action reported to FDA under 21 USC 380(f), list correction/ removal reporting number; Retabeling Yes (mm/dd/yyyy) Adjustment ☐ No Other: Other: (Specify) 14. Manufacturer Name/Address 10. 📝 Additional Manufacturer Narrative 11. Corrected Data and / or This is a supplemental report for MFR Report # 8010047-2012-00481 to provide the initial results for the microbiological testing. The initial results from the independent laboratory shown no growth. The final results are pending, and this report will be G. ALL MANUFACTURERS supplemented as the final results become available. Contact Office - Name/Address (and Manufacturing Site for Devices) 2. Phone Number 3. Report Source (Check all that apply) D Foreign Study Literature Consumer Health Professional User Facility 4. Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# IND# Distributor 6. If IND, Give Protocol# Other: STN# PMA/ 7. Type of Report (Check all that apply) 510(k)# Combination 30-day 5-day Yes Periodic 7-day Pre-1938 Yes 10-day Initial OTC Product Yes 15-day Follow-up#1 9. Manufacturer Report Number B. Adverse Event Term(s) 8010047-2012-00481 Department of Health and Human Services

The public reporting burden for this collection of information has been estimated to average 68 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

OMB Statement:
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Please DO NOT RETURN this form to this address.

1350 Piccard Orlve, 420A

Rockville, MD 20850

## ome³ Medical Devices⁴ Databases⁵ IDE Adverse Event Report: OLYMPUS OLYMPUS 160/180 SERIES ENDOSCOPE ERCP

510(k) DeNovo8 CFR Title |

**21**¹⁶

Registration & Listing⁹ Radiation-Emitting Products¹⁷

Adverse |Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵ Events¹⁰ X-Ray Assembler¹⁸

Medsun Reports¹⁹

|CLIA²⁰|TPLC²¹|Inspections²²

OLYMPUS OLYMPUS 160/180 SERIES ENDOSCOPE ERCP SCOPE 1160

Back to Search Results

**Lot Number** 2001160 **Event Date** 02/27/2013 **Event Type** Malfunction **Event Description** 

Over a 2 year period, there was an increase in the number of kp resistant microbiology (kpc) reported results. During investigation, it was determined that a small percentage of involved patients had undergone endoscopic procedures. Endoscopes were cultured by microbiology department. One endoscope tested positive for kpc following disinfection. The endoscope was removed from use. (b)(6) was consulted. A review of endoscope cleaning, disinfection and related processes was documented by (b)(6). Staff were interviewed, reprocessing documents reviewed, audits completed. The subject endoscope was tested by third party laboratory, (b)(4). Third party laboratory culture results were negative for kpc. Investigation and analysis of kpc is ongoing and sources of kpc remains undetermined at this time. Official olympus report received, root cause unknown. Dates of use: (b)(6) 2011 - (b)(6) 2012.

### Search Alerts/Recalls²³

New Search | Submit an Adverse Event Report²⁴

Brand NameOLYMPUS 160/180 SERIES ENDOSCOPE Type of DeviceERCP SCOPE 1160

Manufacturer (Section D)OLYMPUS

2400 Ringwood Ave. San Jose CA 95131

MDR Report Key2999629

Report NumberMW5029305

Device Sequence Number 1

**Product CodeFDS**²⁵

Report Source Voluntary

Reporter OccupationNurse

Type of ReportInitial

Report Date 03/04/2013

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received03/04/2013

Is This An Adverse Event Report?No

Is This A Product Problem Report?Yes

**Device Operator**Health Professional

**Device LOT Number**2001160

OTHER Device ID NumberTJF-Q180V

Was Device Available For Evaluation? Device Returned To Manufacturer

**Date Returned to Manufacturer**01/08/2013

Is The Reporter A Health Professional? Yes

Is this a Reprocessed and Reused Single-Use Device?No

**Patient TREATMENT DATA** 

Date Received: 03/04/2013 Patient Sequence Number: 1

#### Links on this page:

http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain

- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
- 12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
- 13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
- 14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
- 15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
- 18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDS

Page Last Updated: 09/30/2015

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Contact FDA



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U.S. Department of Health & Human Services

Links on this page:

# Virginia Mason Hospital and Medical Center Seattle, Washington



August 22, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

U.S. Department of Health and Human Services Food and Drug Administration

# **MEDWATCH**

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report# 2951238-2014-00364	
UF/Importer Report #	

F	ORM FDA 350	0A (2/13)			Page 1	OT 2				FDA	Use Only
	A. PATIENT INF	ORMATION				C. SUSPECT PRODU	JCT(S)				ood Oilly
ſ	I. Patient Identifier			3. Sex	4. Weight	1. Name (Give labeled stren	gth & mfr/labeler)				
- 1		of Event:		☐ Female	lbs	#1					
- 1		Date			or	#2					
.	In confidence	of Birth:		Male Male	kgs	2. Dose, Frequency & Rout	to Head	3 Therany	Dates (If	unknown also	dunatio -1
Ì	B. ADVERSE E	VENT OR PRODUC	CT PROBLE	VI		2. Dose, Frequency & Rout	e Oseu	from/to (	or best est	unknown, give ( imate)	uration)
	1. Adverse Even	t and/or Pro	duct Problem (e.	.g., defects/malf	unctions)	#1		#1			
L	2. Outcomes Attribut				, , , , , ,	#2		#2			
	(Check all that appl	y)	_			4. Diagnosis for Use (Indicate	ation)	15	5. Event A	bated After Us	e
- 1	Death:	(mm/dd/yyyy)	Disability o	r Permanent Da	mage	#1				or Dose Redu	uced? Doesn't
- 1	Life-threatenin		Congenital	Anomaly/Birth [	Defect	#2			#1 Ye:	s No [	Apply
- 1	Hospitalization	- initial or prolonged	Other Serie	ous (Important N	fledical Events)	6. Lot#	7. Exp. Date		#2 🔲 Ye:	s No	Doesn't Apply
ı	Required Inter	vention to Prevent Perma	anent Impairment	/Damage (Device	ces)	#1	#1		8. Event R	eappeared After	
1	3. Date of Event (mn	n/dd/yyyy)	4. Date of This	Report (mm/de	d/yyyy)				Reintro	duction?	
		x/2013		07/25/201	4	#2	#2		#1 🗌 Ye	s No [	☐ Doesn't Apply
	5. Describe Event or		llowed inf			9. NDC# or Unique ID			#2   Ye	s No F	Doesn't
		nformed of 37 a involving mult	-								Apply
	series/180ser		apas aasas		, , ,	10. Concomitant Medical F	Products and The	rapy Dates	(Exclude tr	eatment of ever	nt)
. 1	_	the Washington ven cases of ca	-		Health						
		aceae (CRE) cul			ent by	i					
	the user faci	lity. There wer	e no speci	fic endos	cope	D. CHICDECT MEDIC	CAL DEVICE		(Co	ontinue on pa	ige 3)
		ial numbers pro ere identified				D. SUSPECT MEDIC					
		ent deaths is u		LIACILIC	y, ine	Olympu:	s Duodenovi	deoscope	9		
USE	-					2. Common Device Name Duodenovideoscope			2b. Pr KOG	ocode	
		Olympus was no sed on culture				3. Manufacturer Name, Ci			INOG		<u>-</u> -
		od, bile, urine				OLYMPUS MEDICAL SYS	TEM CORPORAT		102 050		
阅	Olympus conta	cted the user f	acility vi	a telepho	ne and in	2951 Ishikawa-cho,		, Tokyo,	192-850	/, Japan	
TYPE		tain more detai				4. Model# TJF-160VF	Lot#		ľ	<ol><li>Operator of</li></ol>	Device
	provided.	events but no f	urtner ini	ormation	was	Catalog #		n Date (mm/	(dd/yyyy)	✓ Health Pro	ofessional
AS						TJF-160VF	Zapirado	, , , , , , , , , , , , , , , , , , , ,	,,,,,	Lay User/	Patient
PLEASE						Serial #	Unique Id	entifler (UD	l) #	Other:	
P.						UNK					
				(Continue o	on page 3)	6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Expl	lanted, Giv	e Date (mm/dd/	YYYY)
	6. Relevant Tests/La	boratory Data, Includin	g Dates		, , ,	8. Is this a Single-use De	vice that was Re	processed a	and Reuse	d on a Patient?	
						Yes No	vioo tiiat tras ito	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		on a rationer	
						9. If Yes to Item No. 8, En	ter Name and Ad	dress of Re	processor		
						10. Device Available for E	_ ·		-		
						Yes 🕢 No	Returned to	Manufacture	er on:	(mm/dd/yyyy	<del>,                                    </del>
				(Continue	on page 3)	11. Concomitant Medical			s (Exclude	treatment of ev	ent)
	7. Other Relevant H	story, Including Preexi	sting Medical C	onditions (e.g.,		TJF-Q180V Serial	Number (Unk	nown)			
	race, pregnancy, s	moking and alcohol use,	nepatic/renal dy	sfunction, etc.)		1 1			ır	`an#/ma am m	21
						E. INITIAL REPOR	TER		Į	Continue on p	age 3)
	1					1. Name and Address	1211				
	İ					Virginia Mason N	Medical Cen	ter			
	ĺ					1100 9th Avenue Seattle, WA 9810	)1				
	1										
	l			(O- :!!	<b>_</b> _	Phone #	E	mail Address	S		
	Submississ of		ma4144		on page 3)	0.110.111.7	10.00		- 17	lable Committee	. A le - C
	personnel, user	report does not co acility, importer, d	nstitute an a istributor. m:	amission the	at medical or product	2. Health Professional?				Initial Reporter Report to FDA	
	caused or contri	buted to the event.			p	Yes No	Physician			✓ Yes ☐ No	D Unk.

					FDA USE ONLY
<b>MEDWATCH</b>					
FORM FDA 3500A (2/13) (co	ntinued)	Page 2	of 2		
F. FOR USE BY USER FACIL	ITY/IMPORTER (De	vices Only)	H. DEVICE MANUFA	CTURERS ONLY	
1. Check One	2. UF/Importer Re		1. Type of Reportable Even		2. If Follow-up, What Type?
User Facility Importer			☐ Death		Correction
3. User Facility or Importer Name/Add	dress		Serious Injury		Additional Information
			Malfunction		Response to FDA Request
1		·			Device Evaluation
1					
+ 1			3. Device Evaluated by Ma	nufacturer?	4. Device Manufacture Date (mm/yyyy)
			✓ Not Returned to Man	nufacturer	1
4. Contact Person	5. Phone Nur	nber	Yes Evaluation	on Summary Attached	UNK
			No (Attach page to	explain why not) or	5. Labeled for Single Use?
	ype of Report 8	B. Date of This Report	provide code:		☐ Yes ✓ No
Importer Became Aware of Event (mm/dd/yyyy)	Initial	(mm/dd/yyyy)			
_			6. Event Problem and Eval	luation Codes (Refer to	coding manual)
	Follow-up#		Patient	1735 -	1930 -
9. Approximate 10. Event Prob	olem Codes (Refer to coding	manuai)	Code L		1330
Patient Code	1735 - 1930	7-	Device Code	2993 -	-
Device			1 0000		7
Code	2993 -		Method		_]-[]-
11. Report Sent to FDA? 12	2. Location Where Event O	ccurred	Danista [		
☐ Yes	Hospital	Outpatient	Results		
No (mm/dd/yyyy)	Home	Diagnostic Facility	Conclusions	67 -	
13. Report Sent to Manufacturer?	Nursing Home	Ambulatory Surgical Facility	7 1/2 1/-1 4 -1/ 1-1/1/-		O Horse of Barrier
	Outpatient Treatment	* '	7. If Remedial Action Initia	sted, Check Type	8. Usage of Device
Yes(mm/dd/yyyy)	Facility		Recall	Notification	☐ Initial Use of Device ✓ Reuse
□ No	Other:	(Specify)	Repair	Inspection	
14. Manufacturer Name/Address		,,,,,	Replace	Patient Monitoring	Unknown
			Relabeling	Modification/ Adjustment	If action reported to FDA under 21 USC 360i(f), list correction/
			Other:	, 10,0001110111	removal reporting number:
1					
			10. 🗸 Additional Manufa	acturer Narrative	and / or 11. Corrected Data
G. ALL MANUFACTURERS					mpus for evaluation.
1. Contact Office (and Manufacturing	Site for Devices)	2. Phone Number			t to the user facility to
Name		4			ices, but the user cause of the patient
Address		3. Report Source (Check all that apply)			ely determined. If
OLYMPUS AMERICA, INC		Foreign			rmation becomes available
2400 Ringwood Avenue		Study	at a later time,	this report wi	ll be supplemented.
San Jose, CA 95131		=	Cross Reference	mfr Benert num	hare
OLYMPUS MEDICAL SYSTEM O	CORPORATION #		2951238-2014-003	-	
Email Address		Consumer  Health Professional	2951238-2014-003	-	
		I <i>=</i>	2951238-2014-003		
Manufacturer (mm/dd/man)	5.	User Facility	2951238-2014-003 2951238-2014-003		
	(A)NDA #	Company Representative	2951238-2014-003	- · · · · · · · · · · · · · · · · · · ·	
07/25/2014	IND #	Distributor	2951238-2014-003		
6. If IND, Give Protocol#	BLA#	Other:	2951238-2014-003	61, 2951238-20	14-00362,
1	DMA		2951238-2014-003	-	
7. Type of Report	PMA/ 510(k) # K024033		2951238-2014-003 2951238-2014-003		
(Check all that apply)	Combination		2951238-2014-003		
5-day 30-day	Product Yes		2951238-2014-003		
7-day Periodic	Pre-1938 Yes		2951238-2014-003		
☐ 10-day ☑ Initial ☐ 15-day ☐ Follow-up#	OTC Product Yes		2951238-2014-003		
15-day Follow-up#			2951238-2014-003	J.O, 2331230-20	44-000131

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

8. Adverse Event Term(s)

9. Manufacturer Report Number

2951238-2014-00364

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Food and Drug Administration

Office of Chief Information Officer

Paperwork Reduction Act (PRA) Staff

PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

2951238-2014-00380, 2951238-2014-00381,

2951238-2014-00382, and 2951238-2014-00383

OMB Statement: "An agency may not

#### U.S. Department of Health and Human Services Food and Drug Administration

### **MEDWATCH**

### For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00230
UF/Importer Report	#:
Form Code:	

FDA eSubmitter Generated Form 3500A A. PATIENT INFORMATION 4. Weight B. ADVERSE EVENT OR PRODUCT PROBLEM 1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions) 2. Outcomes Attributed to Adverse Event (Checked all that apply) [X] Death: 08/20/2013 (mm/dd/yyyy) [ ] Disability or Permanent Damage [ ] Life-threatening [ ] Congenital Anomaly/Birth Defect [ ] Hospitalization - initial or prolonged [ ] Other Serious (Important Medical Events) [ ] Required Intervention to Prevent Permanent impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 05/13/2015 5. Describe Event or Problem Olympus received a video clip which reported that 39 patients allegedly contracted E.coli after undergoing a procedure at the user facility. It was reported that 18 of those patients had expired and seven patients had expired within 30 days after undergoing their procedures. In addition, it was stated that one of the 18 patients who expired, underwent an endoscopic retrograde pancreatography (ERCP) procedure which used an Olympus duodenoscope (model/serial number unspecified) and the patient reportedly contracted a drug-resistant strain of E.coli. The exact cause of the patient's outcome cannot be conclusively determined at this time. Originally, Olympus was informed of 37 alleged patient infections in which 11 patients had expired. Based on the new information received Olympus will submit two initial MDRs to account for the 39 patients, (Please cross reference 2951238-2015-00230 and 2951238-2015-00231) Olympus followed up with the user facility to obtain additional information regarding the reported events by telephone and in writing but with no result. 6. Relevant Tests/Laboratory Data, Including Dates 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Pancreatic cancer and blocked bile duct C. SUSPECT PRODUCT(S) Section C is not applicable to devices D. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name Duodenovideoscope Duodenovideoscope, Product Code: FDT 3. Manufacturer Name, City and State 4. Model # Catalog # **OLYMPUS MEDICAL SYSTEM CORPORATION** Unk Unk 2951 Ishikawa-cho, Serial # Lot# Hachioii-shi N/A Tokyo 192-8507, JA Expiration Date (mm/dd/yyyy) Other# 5. Operator of Device 6. Implanted Date (mm/dd/yyyy) 7. Explanted Date (mm/dd/yyyy) 8. Is this a Single-Use Device that was reprocessed and Reused on a Patient? ( ) Yes ( • ) No ( ) No Information 9. Reprocessor Name and Address 10. Device Available for Evaluation? (Do not send to FDA) () Yes ( ) No ( ) No Information [ ] Returned to Manufacturer 11. ConComitant Medical Products and Therapy Dates (Excludes treatment of event) E. INITIAL REPORTER 1. Name and Address 2. Health Professional? ( ) Yes ( ) No ( ) No Information Virginia Mason Medical Center 3. Occupation 1100 9th Avenue

U.S. Department of Health and Human Services Food and Drug Administration

## **MEDWATCH**

## For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report #:	2951238-2015-00230
UF/Importer Report	#:
Form Code:	

FDA eSubmitter Generated Form 3500A	Form code.			
Seattle, WA 98101-2756, US	Other Health Care Professional			
Telephone:	4. Initial Reporter Also Sent Report to FDA?			
3000 and 30	( ) Yes ( ) No ( • ) Unknow	n ( ) No Information		
F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)	Shemos title 1			
1. User Facility or Importer	2. User Facility/Importer Number			
( ) User Facility ( ) Importer				
<ol> <li>4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number</li> <li>CA, US</li> </ol>	6. Date UF/Importer Became Aware of E	event (mm/dd/yyyy)		
57, 55	7. Type of Report			
	( ) Initial ( ) Follow-up			
	8. Date of This Report (mm/dd/yyyy)	9. Approximate Age of Device		
10. Event Problem Codes (Refer to coding manual)	14. Manufacturer Name/Address			
Patient Code(s): 1735 - 1802				
Device Code(s): 2303				
11. Report Sent to FDA?				
( ) Yes ( ) No ( ) No Information  12. Location Where Event Occurred				
12. Location Where Event Occurred				
13. Report Sent to Manufacturer?				
( ) Yes ( ) No ( ) No Information	la de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de			
G. ALL MANUFACTURERS	macross del			
1, 2. Contact Office - Name/Address/Phone Number	1, 2. (Continued) Manufacturing Site Ad	ddress/Phone for Devices		
2400 Ringwood Avenue				
San Jose, CA 95131, US				
3. Report Source (Check all that apply)	4. Date Received by Manufacturer (mm	/dd/yyyy)		
[ ] Foreign [ ] Health Professional [ ] Study [ ] User Facility	05/13/2015			
[X] Literature [ ] Company Representative	5. PMA/510(k)			
[ X] Consumer [ ] Distributor	6. If IND. Give Protocol #			
	G. II IND, GIVE PIOLOCOI #			
7. Type of Report	8. Adverse Event Term(s)	9. Manufacturer Report Number		
[ ] 5-day [x] Initial [ ] Follow-up		2951238-2015-00230		
H. DEVICE MANUFACTURERS ONLY				
1. Type of Reportable Event 2. If Follow-up, What Type?	3. Device Evaluated by Manufacturer?			
( • ) Death [ ] Correction [ ] Additional Information	[ ] Not Returned to Manufacture			
( ) Serious Injury [ ] Additional Information [ ] Response to FDA Request	( ) Yes [ ] Evaluation Summ (•) No	ary Attached		
( ) No Information [ ] Device Evaluation	38(4) 434)			
[ ] No Information				
4. Device Manufacture Date (mm/dd/yyyy)	Evaluation Codes (Refer to coding management Method Code(s):	anuai)		
E I shalad far Cinula Has?	Result Code(s):			
5. Labeled for Single Use?  ( ) Yes (•) No ( ) No Information	Conclusion Code(s): 67 - 92			
7. If Remedial Action initiated, Check Type	8. Usage of Device	9. If action reported to FDA under 21		
[ ] Recall [ ] Notification	( ) Initial Use of Device	USC 360i(f), list correction/removal reporting number		
[ ] Repair [ ] Inspection	(•) Reuse			
L	I			

#### U.S. Department of Health and Human Services Food and Drug Administration

## MEDWATCH

## For use by user-facilities, importers, distributors and manufacturers

Mfr Report #:	2951238-2015-00230
UF/Importer Report	t#:
Form Code:	

DA eSubmitter Genera	ted Form 3500A for MAND.	ATORY reporting	Form Code:	
[ ] Replace [ ] Relabeling [ ] Other	[ ] Patient Monitoring [ ] Modification/Adjustment	( ) Unknown ( ) No Information	on	
40 522 Additional \$4	· · · · · · · · · · · · · · · · · · ·			

10. [X] Additional Manufacturer Narrative and/or 11. [ ] Corrected Data

The user facility has not provided the specific model and serial number of the scopes involved into the reported events. Therefore, it is unknown if the user facility has returned the scope to Olympus for service or evaluation. As part of our investigation into this report, Olympus dispatched an endoscopy support specialist (ESS) to the user facility to observe their reprocessing practices. There was no reprocessing deviations noted, but the user facility was found to be using a non-Olympus automated endoscope reprocessor (AER) and a non-Olympus flushing pump. The exact cause of the reported events could not be conclusively determined at this time, but pre-existing condition of the patients could not be ruled out as a contributory factor to the reported events. If additional and significant information becomes available at a later time these reports will be supplemented. the reported events. If additional and significant information becomes available at a later time these reports will be supplemented.

The following five reports will be supplemented to change the report type from serious injury to deaths: 2951238-2014-00352, 2951238-2014-00353, 2951238-2014-00354, 2951238-2014-00355 and 2951238-2014-00357

Please cross reference the remaining mfr. report numbers: 2951238-2014-00347, 2951238-2014-00348, 2951238-2014-00350, 2951238-2014-00351, 2951238-2014-00356, 2951238-2014-00358, 2951238-2014-00359, 2951238-2014-00360, 2951238-2014-00361, 2951238-2014-00362, 2951238-2014-00363, 2951238-2014-00364, 2951238-2014-00365, 2951238-2014-00366, 2951238-2014-00367, 2951238-2014-00368, 2951238-2014-00369, 2951238-2014-00370, 2951238-2014-00371, 2951238-2014-00372, 2951238-2014-00373, 2951238-2014-00374, 2951238-2014-00375, 2951238-2014-00376, 2951238-2014-00377, 2951238-2014-00378, 2951238-2014-00379, 2951238-2014-00380, 2951238-2014-00381, 2951238-2014-00382, 2951238-2014-00383

#### File Attachments

No files attached.