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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

January 13, 2016

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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.
    - FDA quickly evaluate the design of closed-channel duodenoscopes and implement a phased recall to fix or modify the devices if necessary.
    - 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.[1] 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 patients worldwide. Because some of the identified infections had unique markers that made the

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.

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 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.

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

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]

[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 estimates only.

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	**13**[5]	**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	**9**[6]	**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.[7] Doctors in the United States performed more than 660,000 potentially lifesaving ERCP procedures in 2014.[8] 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.[9]

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 multi-step cleaning procedure to ensure the device is safe for re-use.[11] There are generally three steps to duodenoscope reprocessing:

1) Point-of-use Processing: 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) Thorough Cleaning: 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) High Level Disinfection: 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.[16] Duodenoscopes are classified as Class II devices, which pose a medium level of risk.[17] 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.[18] It is the manufacturer's responsibility to determine when a 510(k) submission to FDA is required.[19]

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.[23] 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.[24] 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.[25] 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.

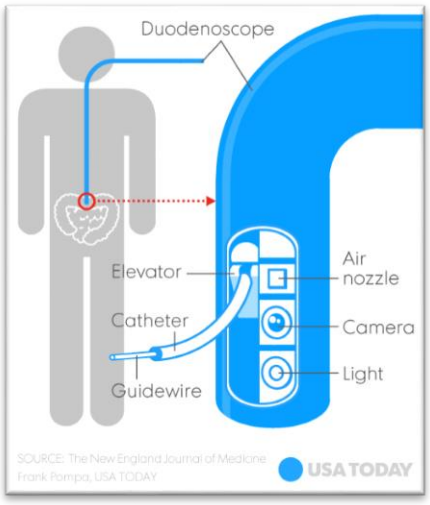
Olympus knew in 2012 that the design of its closed-channel duodenoscope could prevent effective cleaning.

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."[43]

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 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]

> "Reliable sealing by means of the O-ring cannot be guaranteed."
> *–Dr. Ario Loeve*

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.[47] The RIVM report agreed with Dr. Loeve that "the construction of the endoscope hinders optimum manual cleaning."[48] 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."[54] 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."[63] 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.[65] 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.[66] It is the manufacturer's responsibility to determine if and when a 510(k) application should be submitted to FDA.[67]

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."[68] 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."[72] 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 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.[74] After requesting Olympus's validation data in April 2014, FDA reached the same conclusion –

> [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*

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."[80] 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.[81] 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."[91] 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."[92] Meanwhile, Fujifilm lacked procedures for "receiving, reviewing, and evaluating complaints."[93]

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.[94] 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.[95] Fifty percent of Fujifilm duodenoscopes are sold in Europe, 22 percent in Asia, and 18 percent in Latin and South America.[96] 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.[98] 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.[99] 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.[100]

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:

- *Never validated the compatibility of its AERs with closed-channel models of duodenoscopes*;

- 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.[103] 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 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.

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.

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.[106] 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.[107] When a team from Olympus evaluated Virginia Mason's reprocessing procedures in the fall of 2013, the hospital never mentioned the infections.[108] 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.[109] Pentax MDRs also documented difficulty obtaining information from Massachusetts General Hospital, receiving no response after multiple requests for information.[110]

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, Pittsburgh, PA	**Late**	**Late**	**No**	**Unk**	**Yes**
NYP Weill/ Cornell Medical Center NYC, NY	**Late**	**Late**	**No**	**Unk**	**Yes**
UMass Memorial Hospital, Worchester MA	**No**	**No**	**No**	**Yes**	**Yes**
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."[113] 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.[114] Virginia Mason also filed a MedWatch report but did so in May 2014, at least five months after connecting patient infections to duodenoscopes.[115] No hospital that identified clusters of antibiotic-resistant infections linked to closed-channel duodenoscopes reported those infections to CDC until May 2013.[116]

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.[117] 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.[118] 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.[119] 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.[120] 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.[132] 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.[138] 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.[139] 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.[140] 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.[141] 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.[142] 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.[146] 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.[147] 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 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

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

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 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.

In contrast to the surveillance system for drugs, the device surveillance system relies almost exclusively on the self-reporting of manufacturers and hospitals.

The failure of FDA's device surveillance system to rapidly identify and respond to duodenoscope-related 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 device-related 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.

[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),

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

[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),
www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

[13] *Id.*

[14] *Id.* at 10.

[15] FDA Executive Summary at 32-40.

[16] FDA, "Classify Your Medical Device,"
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=876.1500.

[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),
www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

[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),
www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

[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.

[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).

[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.

[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), www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

[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.*

[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.

[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/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/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.*

[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.

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.[4] 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]

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[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 Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee, 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.
[5] Id.

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."[6] 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

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[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.[9] 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.[12] Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.[13]

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.

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[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.

[11] 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 Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee 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,

Patty Murray

Senator Patty Murray
Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee

United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

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 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, 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]

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[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 Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee, pp.14-15.
[3] Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.
[4] Id.

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.[5] 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."[6] 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.[7]

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.[8] 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.[9]

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

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[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 Gastroenterology-Urology Devices Panel of the Medical Devices Advisory 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,

Patty Murray

Senator Patty Murray
Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee

United States Senate

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 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, Fujifilm and your company.[4]

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[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 Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee, pp.14-15.
[3] Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.
[4] Id.

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.[5] 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.[6] 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."[7] 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.[9] 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.[10]

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[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 Gastroenterology-Urology Devices Panel of the Medical Devices Advisory 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,

Patty Murray

Senator Patty Murray
Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee

PATTY MURRAY
WASHINGTON

COMMITTEES:
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HEALTH, EDUCATION, LABOR, AND PENSIONS
RULES AND ADMINISTRATION
VETERANS' AFFAIRS

United States Senate
WASHINGTON, DC 20510–4704

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

Patty Murray
United States Senator

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United States Senate

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

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&
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Table of Contents

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
Henk Braat	Managing Director	Olympus Nederland B.V.
Knut Burmester	Section Manager Service Engineering	Olympus Europa Holding GMBH
Viktor Tran	Production Support Specialist MSD	Olympus Europa Holding GMBH
Kees Verdouw	Service Engineer Flexible Instruments	Olympus Nederland B.V.
Marcel Vonk	Sales Support Manager CDS Unit Head	Olympus Nederland B.V.
Leo Abel	Gastroenterology & Liver Diseases Dept.	Erasmus Medical Center
Jolanda Buijs-Hegeman	Staff Advisor Medical Devices	Erasmus Medical Center
Leo Groenendaal	Unit head of Medical Technology	Erasmus Medical Center
Johan de Kat	Hospital Hygienist	Erasmus Medical Center
Annelies Poth	Expert Medical Devices Hospital Hygienist	Erasmus Medical Center
Annette Sandijck		Erasmus Medical Center
Arjo Loeve	Researcher Biomechanical Engineering	Delft University of Technology

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:

1 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.

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).

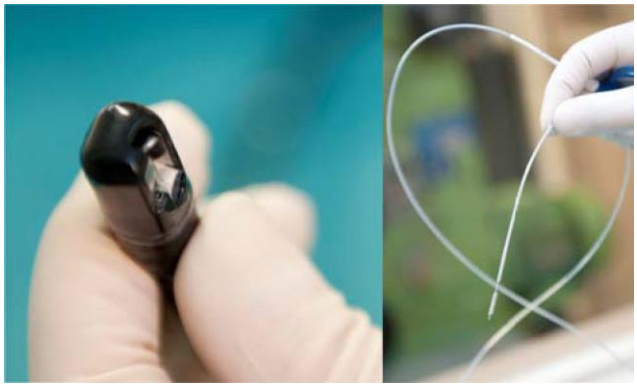


Figure 1: Tip of Scope G-206 and the cytology brush used.

- 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.

- Biopsy / instrumentation channel {5396} and biopsy port {5401} (Figure 3).

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 cross-contamination (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.

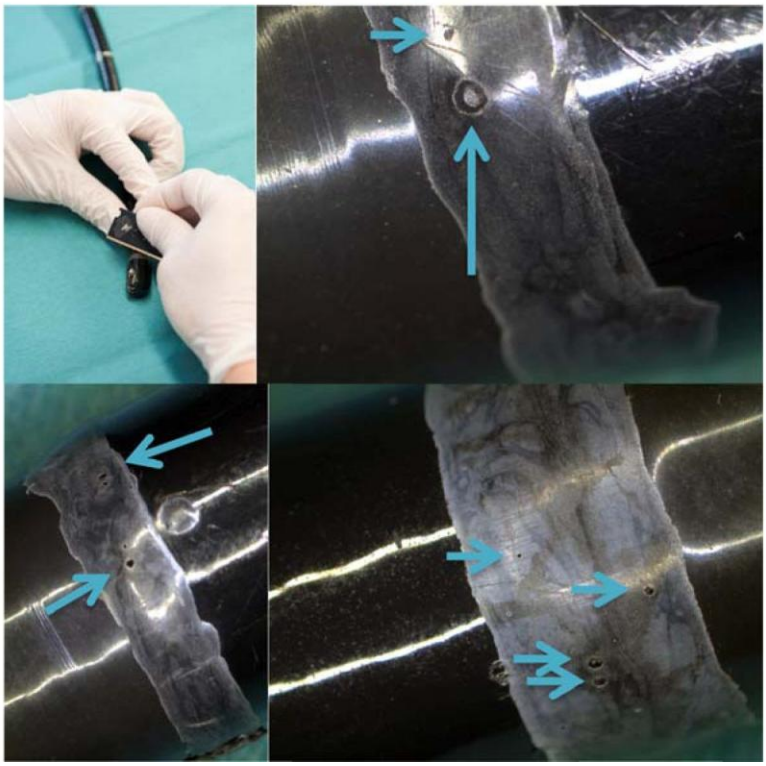


Figure 4: Cutting the sealant of cardan rubber open and microscope photos of the air bubbles (some of them are open) in the still untouched parts of the sealing. The air bubbles are indicated with arrows.

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)

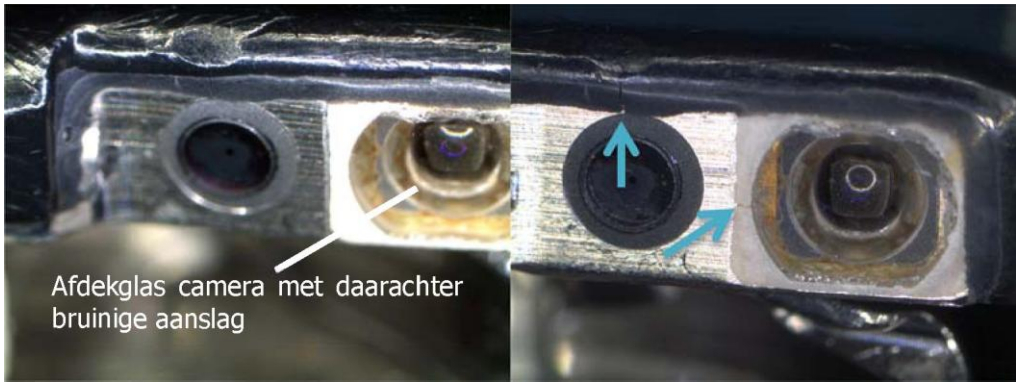


Figure 5: Visual inspection camera housing. On the left and right, it is clearly visible that the scale is located behind the glass covering of the camera. On the right, a vertical arrow points to the tear in de sealing of the housing. Furthermore, on the right another tear can be seen in de sealing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

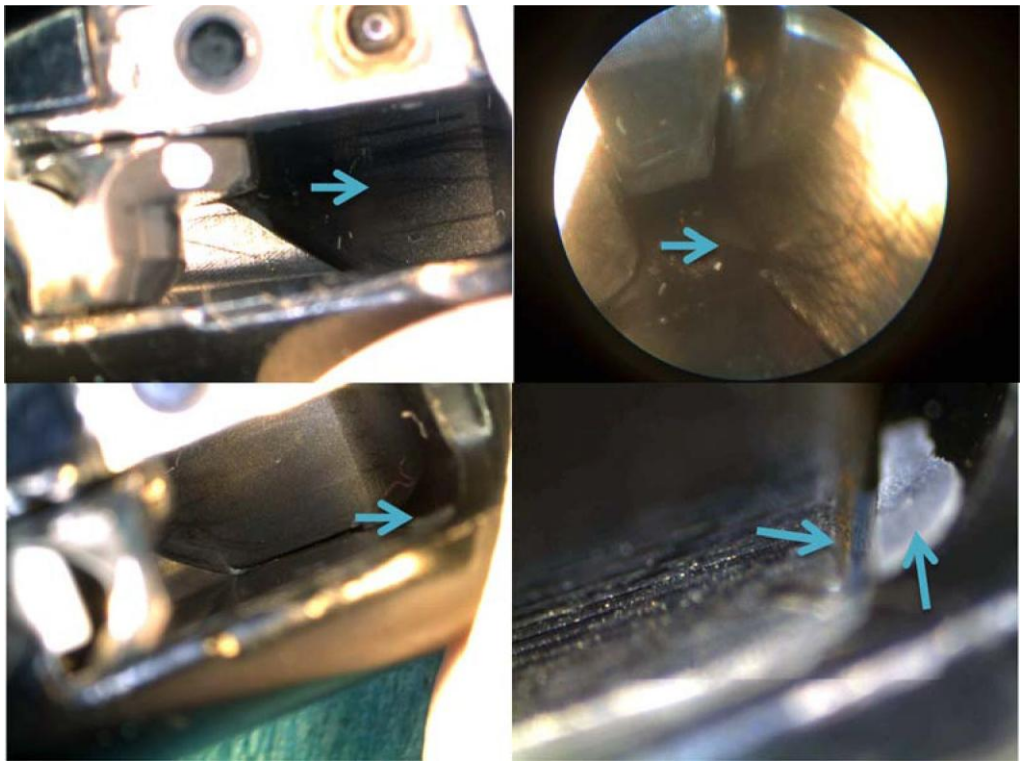


Figure 6: Visual inspection of the tip around the forceps elevator. Above: scratches and grooves well below the forceps elevator; the arrows point to the scratches. Below: whitish and brownish scale (arrow) on the surface where along the forceps elevator moves.

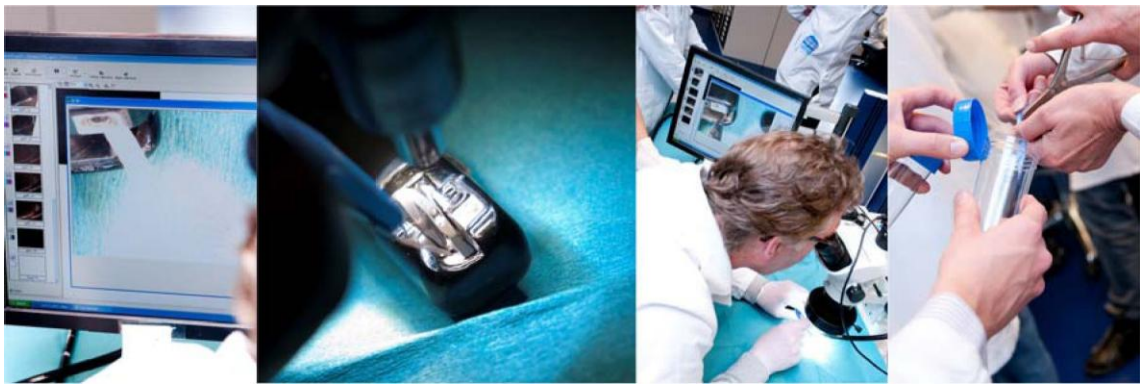


Figure 7: From left to right: sampling of the space around the forceps elevator with swab; scraping sample of white and brown scale; overview of work setting, cutting of scalpel point for packaging.

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).

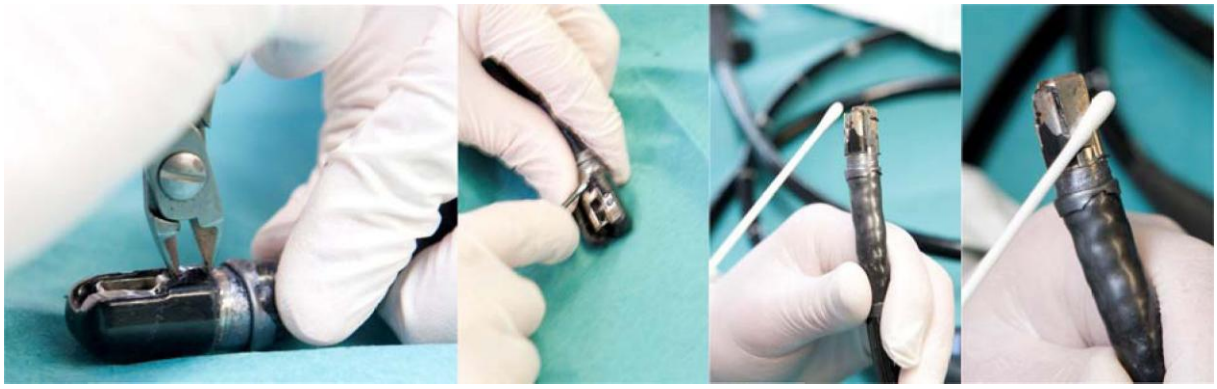


Figure 9: (First two photos on the left) Cutting open and prying loose of the hard plastic cap on the tip. (Two photos on the right) Sampling interior under the removed hard plastic cap.

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).

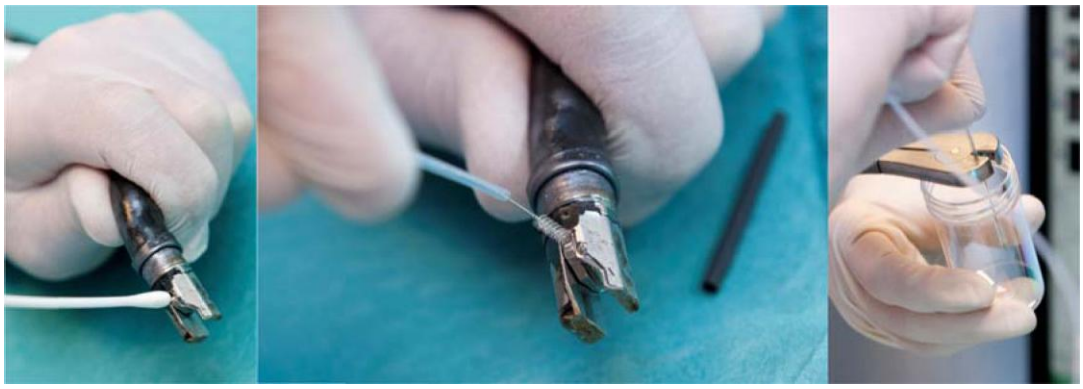


Figure 10: Sampling behind the forceps elevator with swabs and cytology brush.

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}.

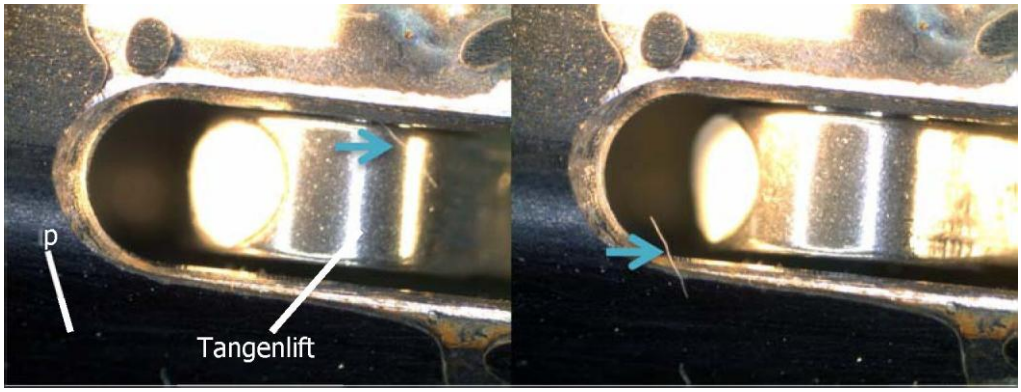


Figure 11: Microscope images of the forceps elevator hinge and the fiber that emerged from it. The axial shifting of the forceps elevator due to room for maneuvering is clearly visible in the two photos. Arrows point to the location of the fiber

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.

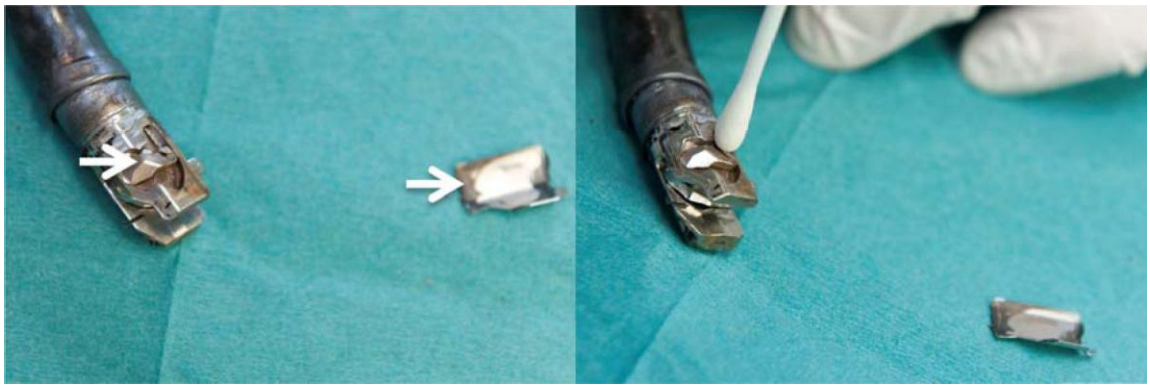


Figure 12: (Left) Verwijdering afdekplaat (rechter piji) van actuator area forceps elevator (linker piji). (Right) Sampling propulsion cable forceps elevator.

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).

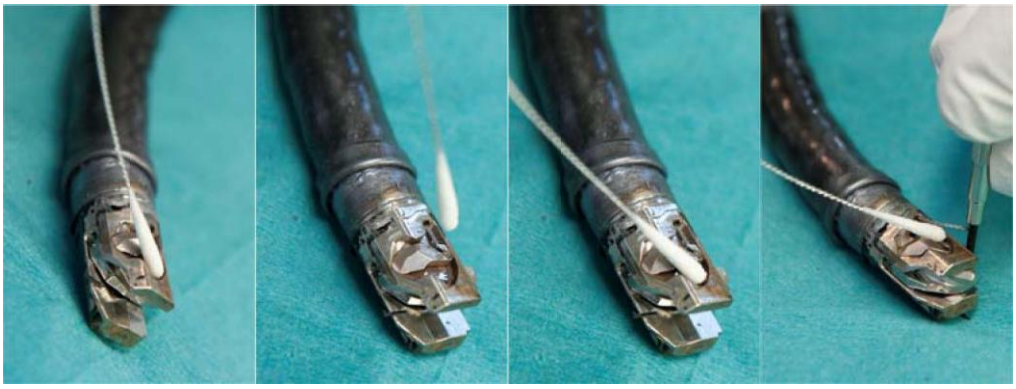


Figure 13: (First three photos on the left) Sampling of the deep area in which the lever of the forceps elevator moves back and forth. (Far right) Sampling under the propulsion cable of the forceps elevator.

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.

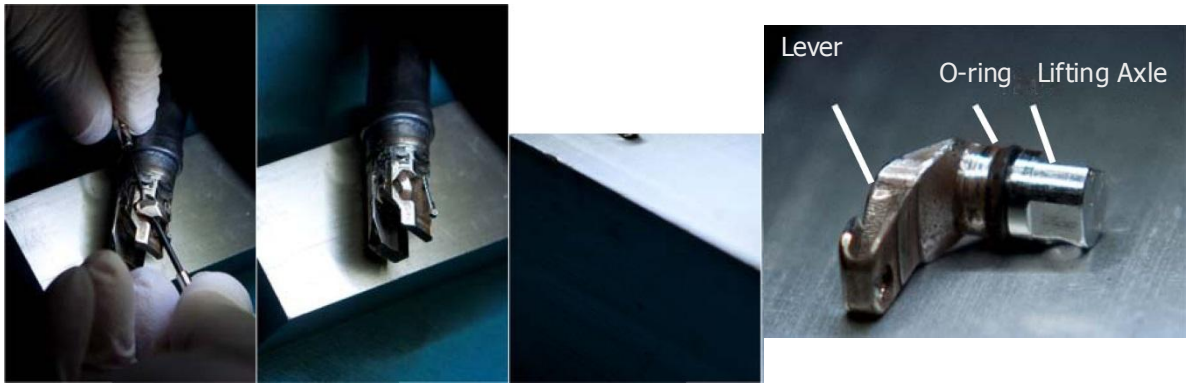


Figure 14: From left to right: lifting away of the lever with lifting axle; actuator area from where the lever was removed; lever with lifting axle and O-ring photographed from the side that was in the actuator area; lever with lifting axle and O-ring photographed from the side of the lifting axle.
The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

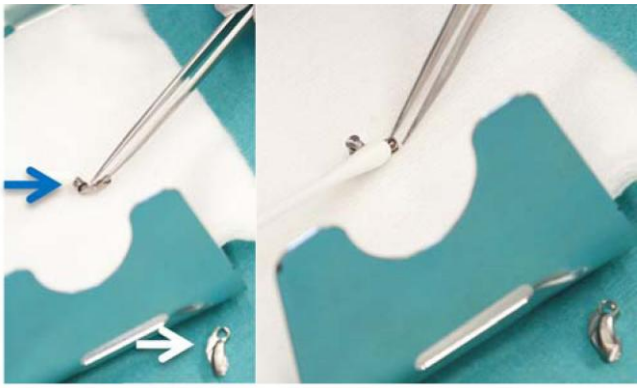


Figure 15: Lever with lifting axle and O-ring (dark blue arrow) and the forceps elevator (white arrow).

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.

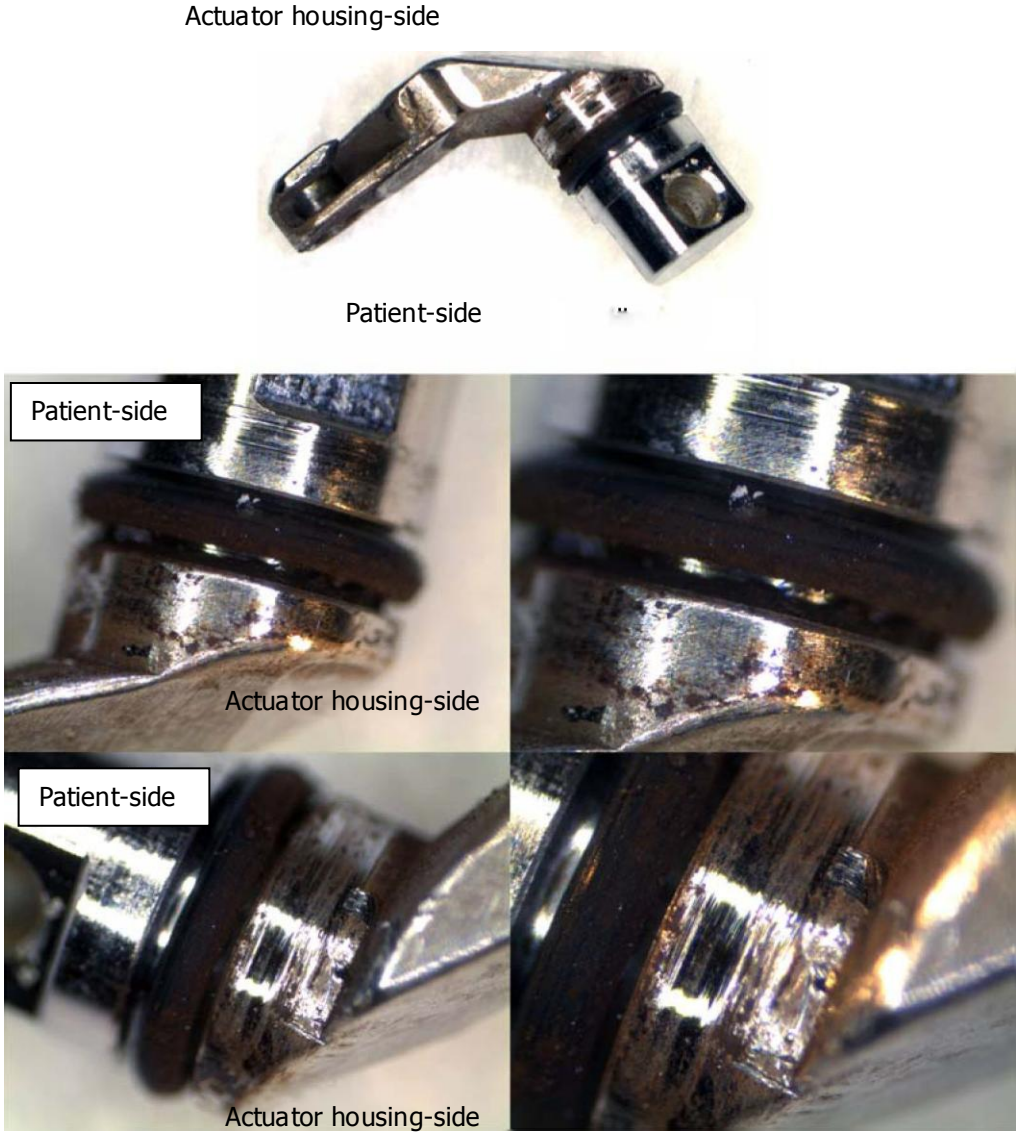


Figure 16: Microscope images of the lever with lifting axle and O-ring. In each of the bottom four photos, there is an enlargement of the central part of the photo on the left.

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).

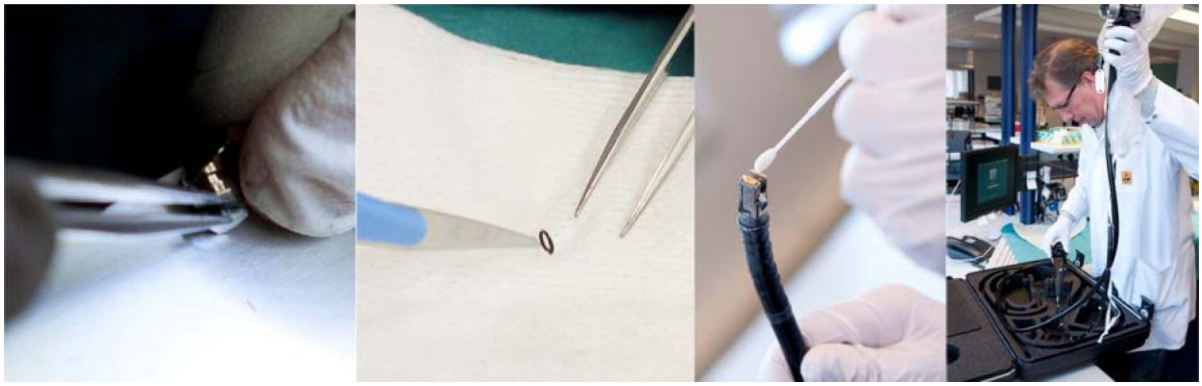


Figure 17: From left to right: removing the O-ring; cutting the O-ring in half; virological sample from water suction channel; packaging of Scope G-206.

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 O-ring 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	Type	Date	Result
5379	Handed to Annelies Poth for DNA Investigation			
5388	Handed to Annelies Poth for DNA Investigation			
5396	Handed to Annelies Poth for DNA Investigation			
5401	Handed to Annelies Poth for DNA Investigation			
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 DNA Investigation			
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 future cultures and / or 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 future cultures and / or counter-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.

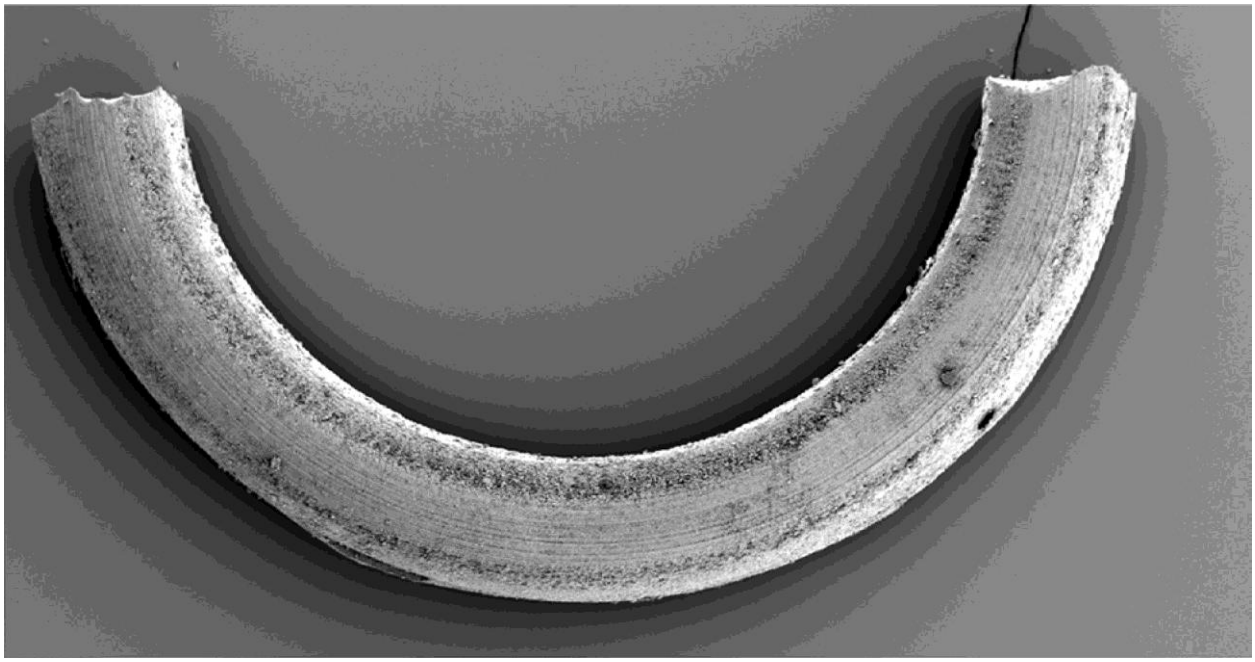


Figure B. 1: Photo of the O-ring which clearly shows that the surface of the O-ring is rough and fibrous, contains scale and was torn at the left bottom.

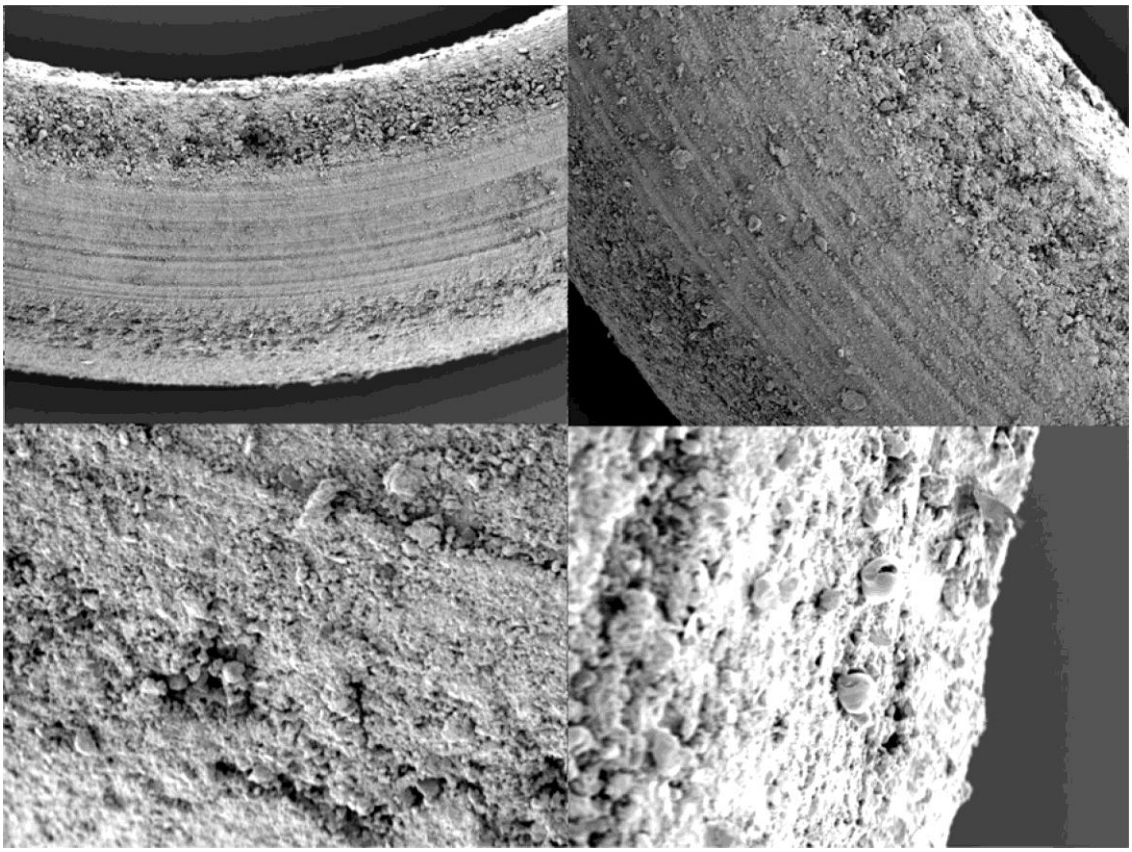


Figure B.2: a few more enlargements of the surface of the O-ring.

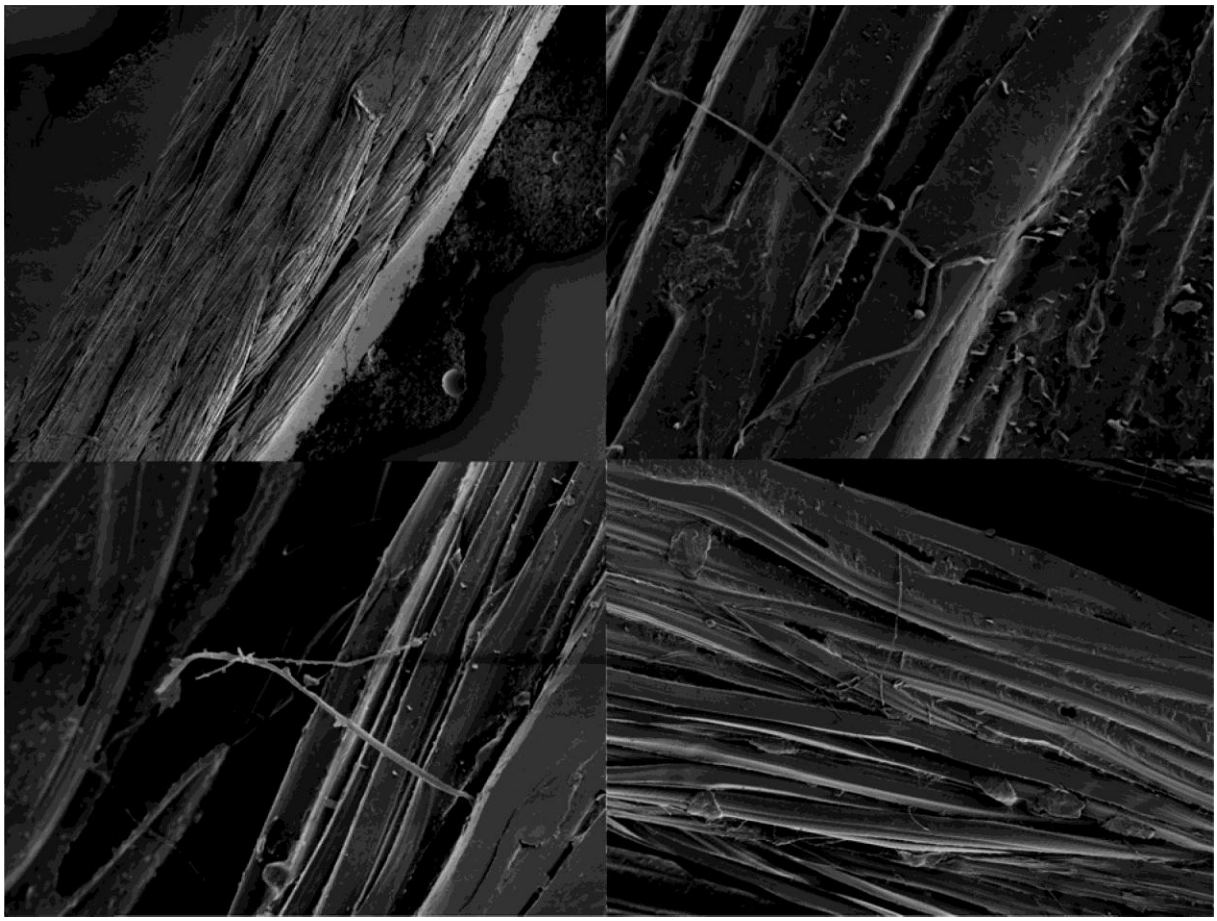
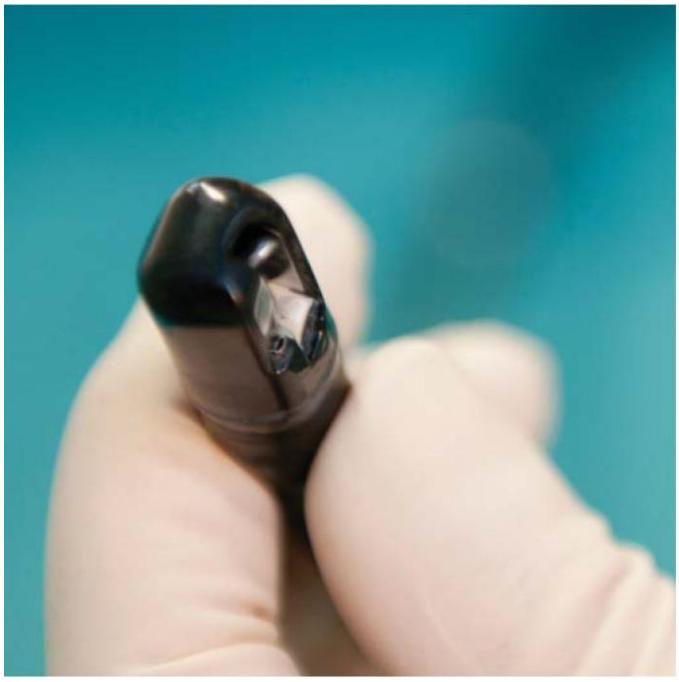


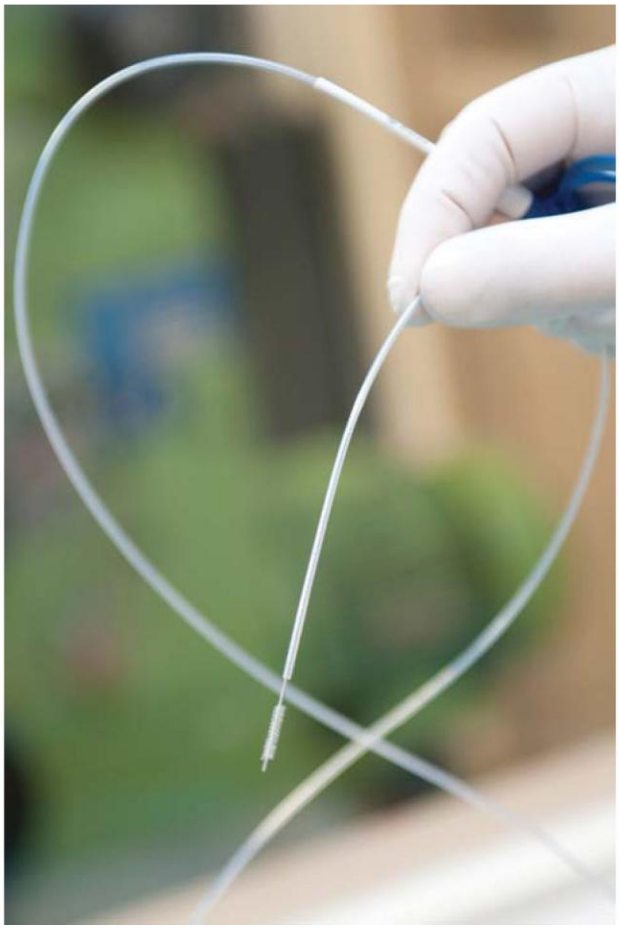
Figure B.3: Photos of the surface from the bottom of the sealing between the hard plastic cap of the tip and the cardan rubber of the scope.

Appendix C - Contact sheets all photos of the investigation



D300s-ACL0002-eKLsq.jpg

D300s-ACL0004-eKL.jpg



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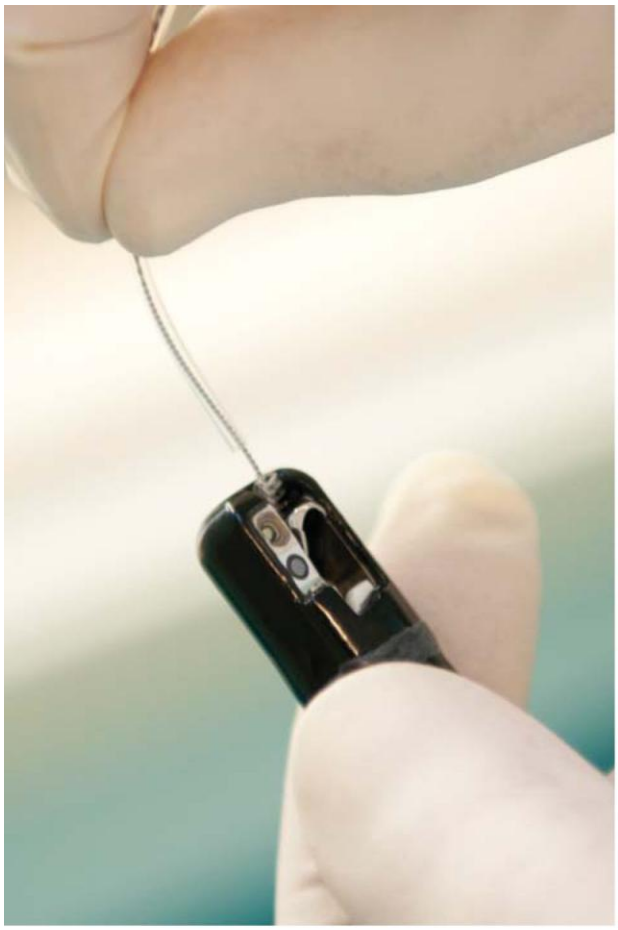
D300s-ACL0008-eKLsq.jpg



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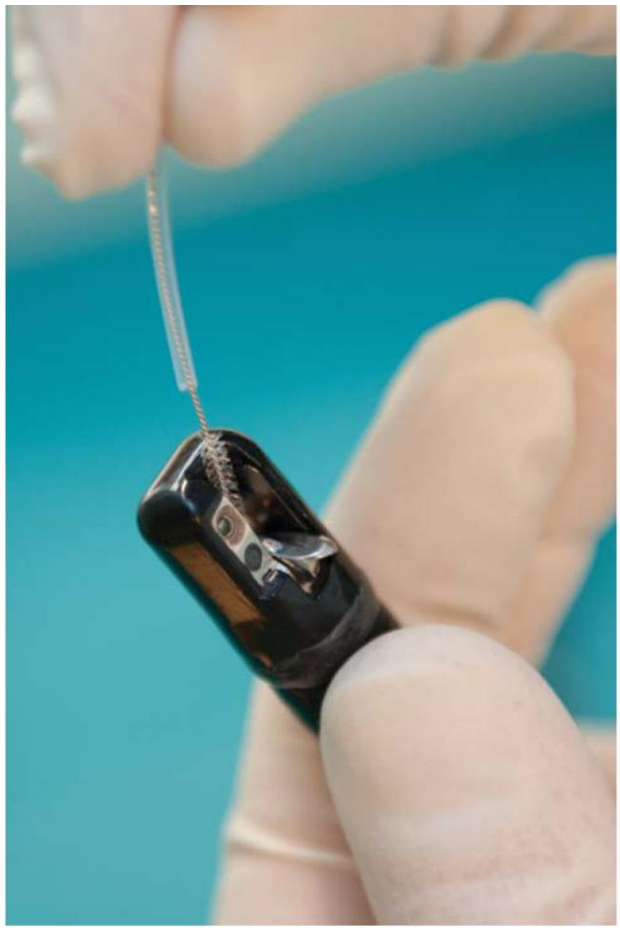

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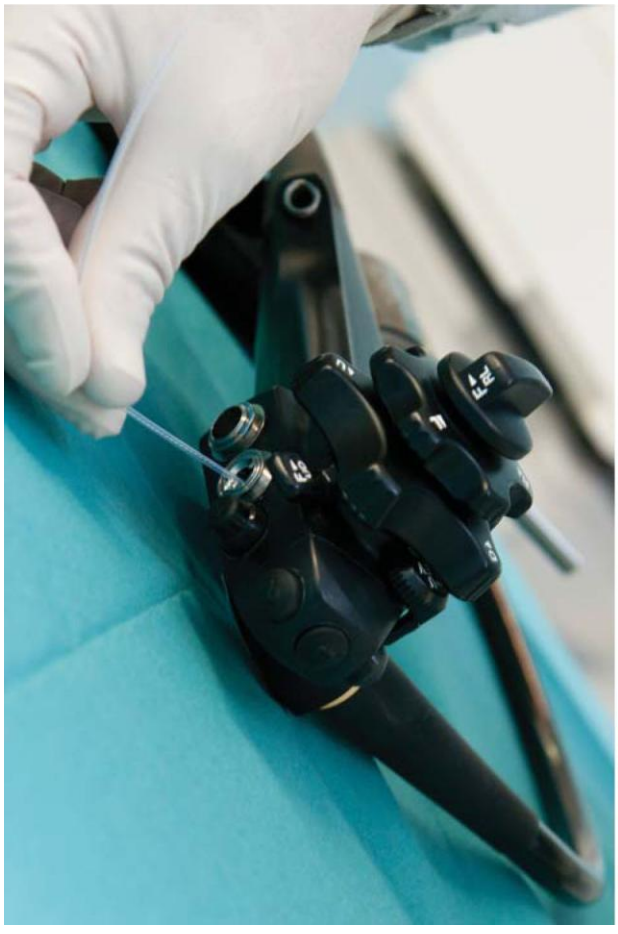

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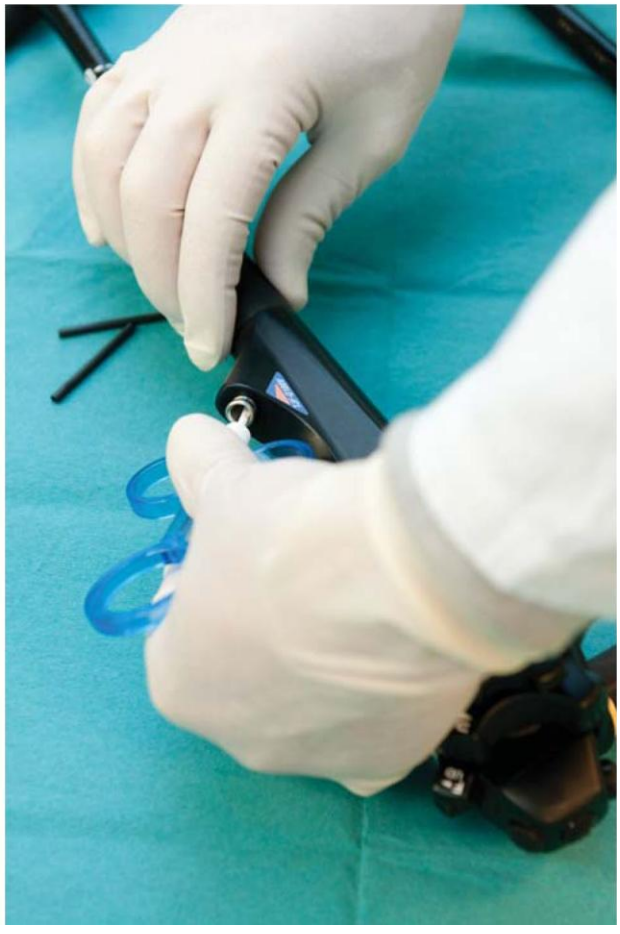
D300s-ACL0016-eKL.jpg

D300s-ACL0017-eKL.jpg



D300s-ACL18-eKL.jpg

D300s-ACL0019-eKLsq.jpg

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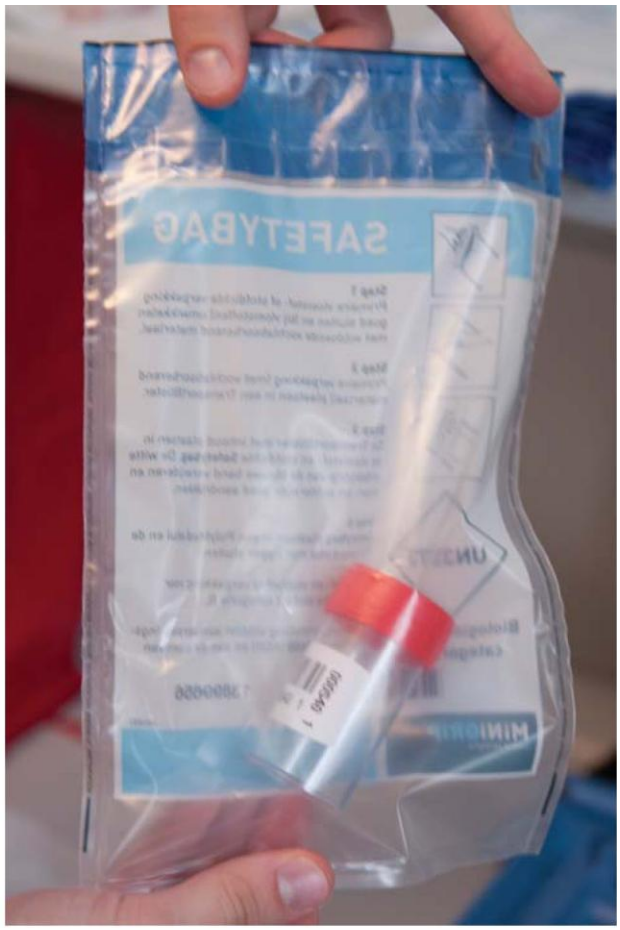
D300s-ACL22-eKL.jpg

D300s-ACL0023-eKL.jpg

D300s-ACL0024-eKL.jpg



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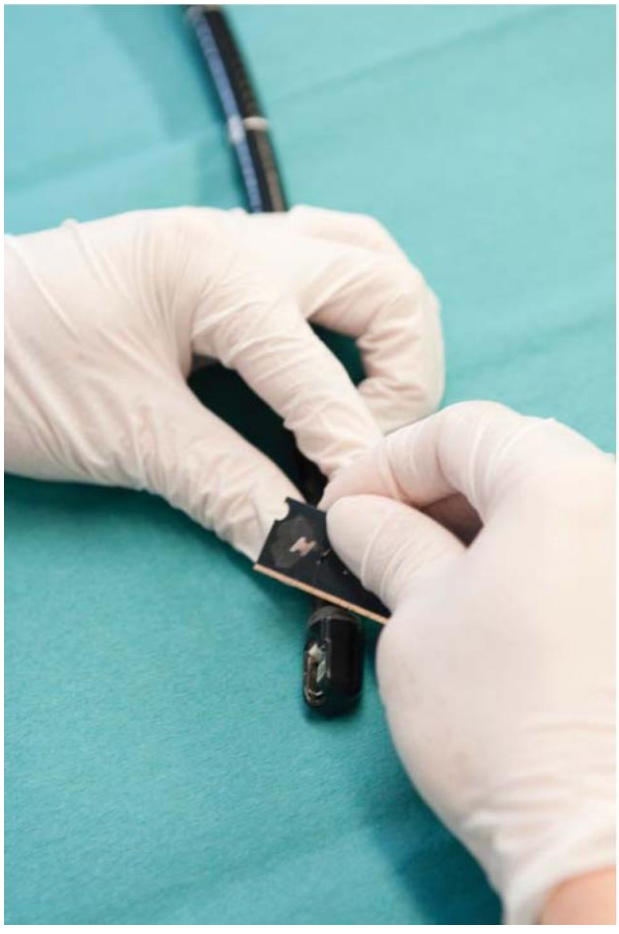

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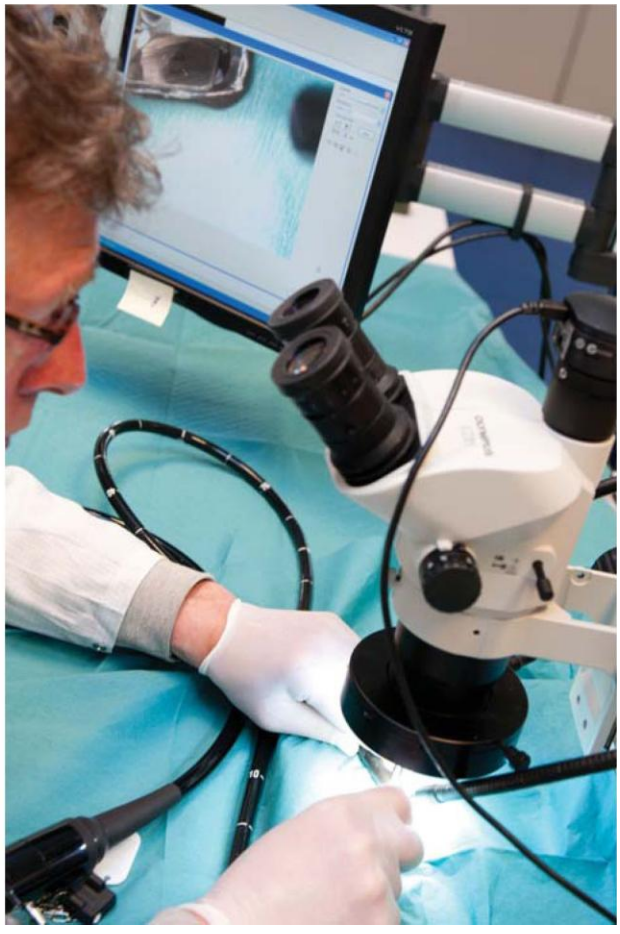

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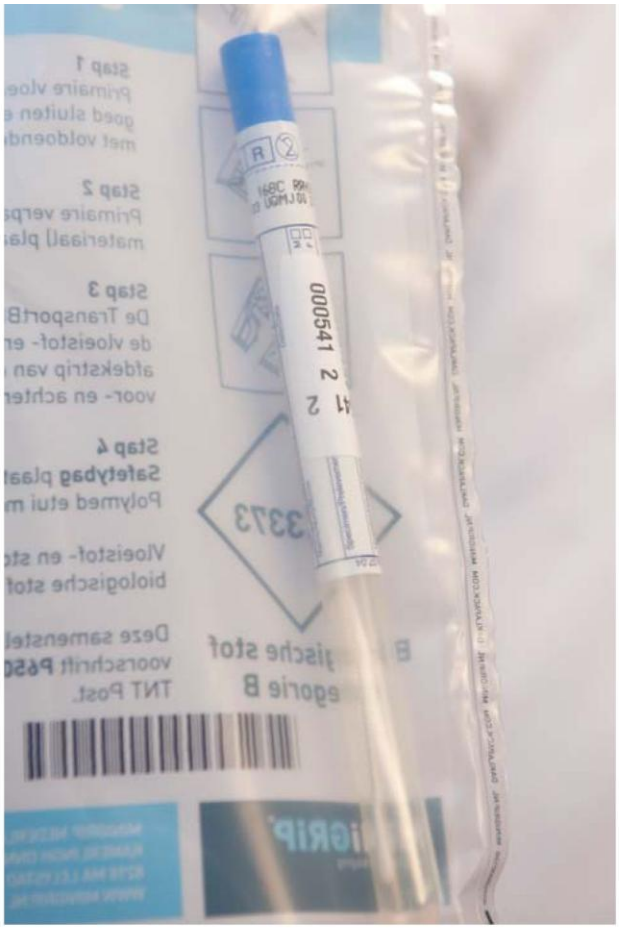

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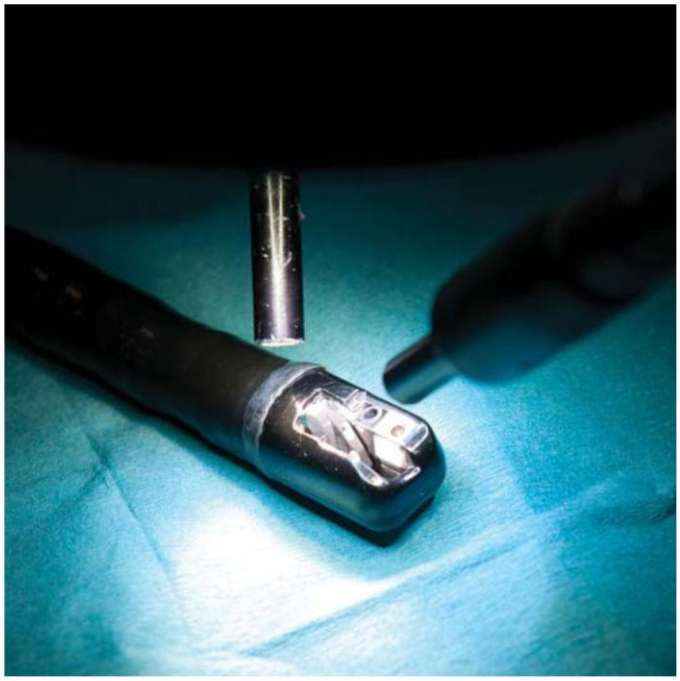

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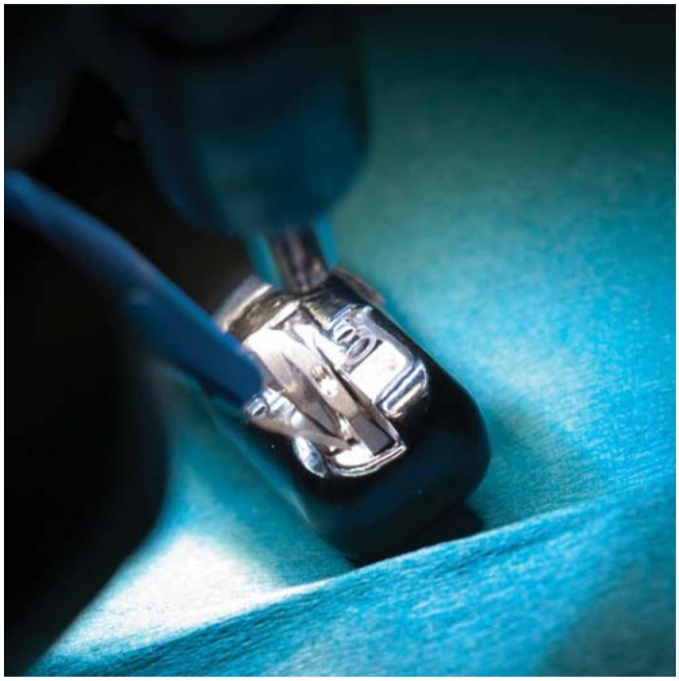

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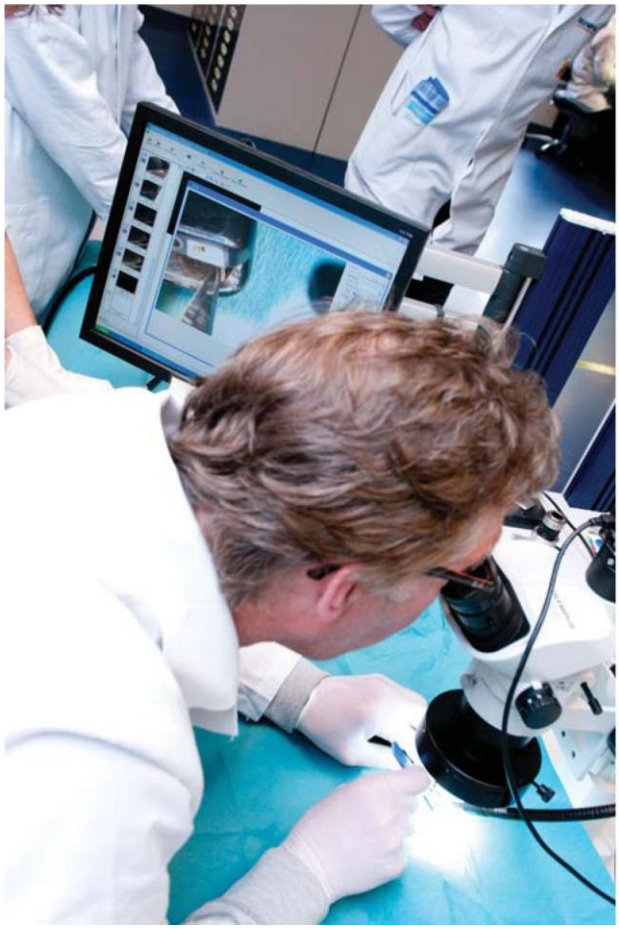

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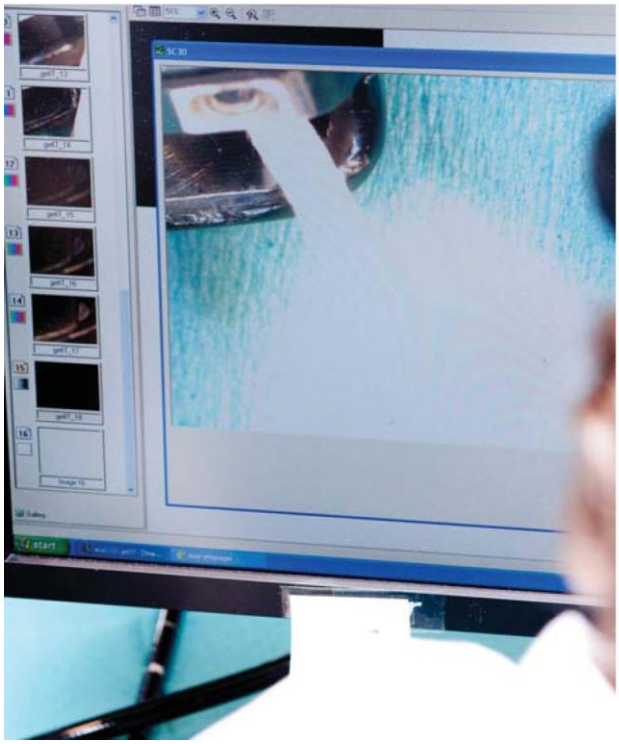

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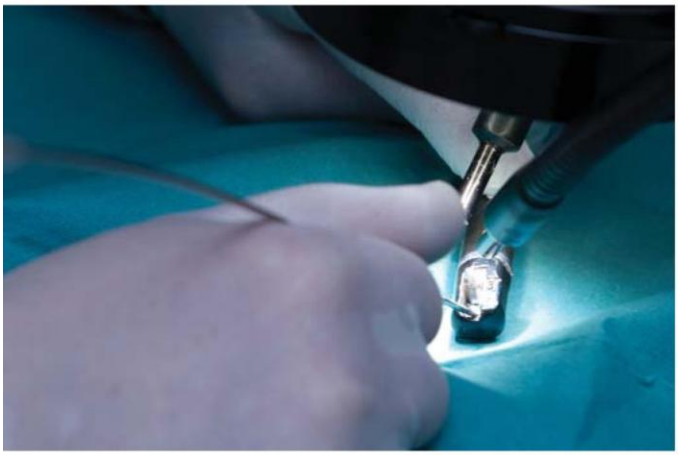

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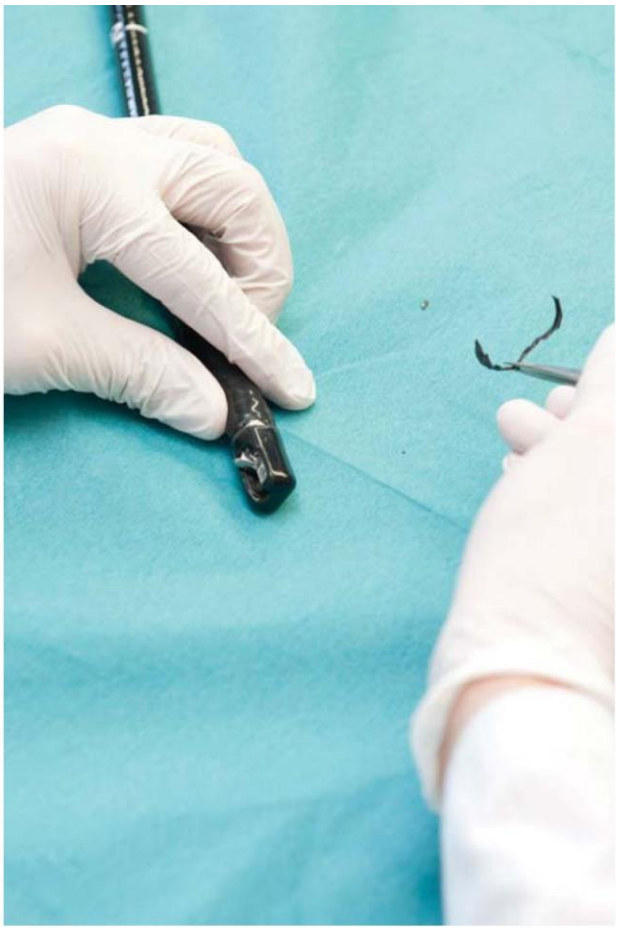

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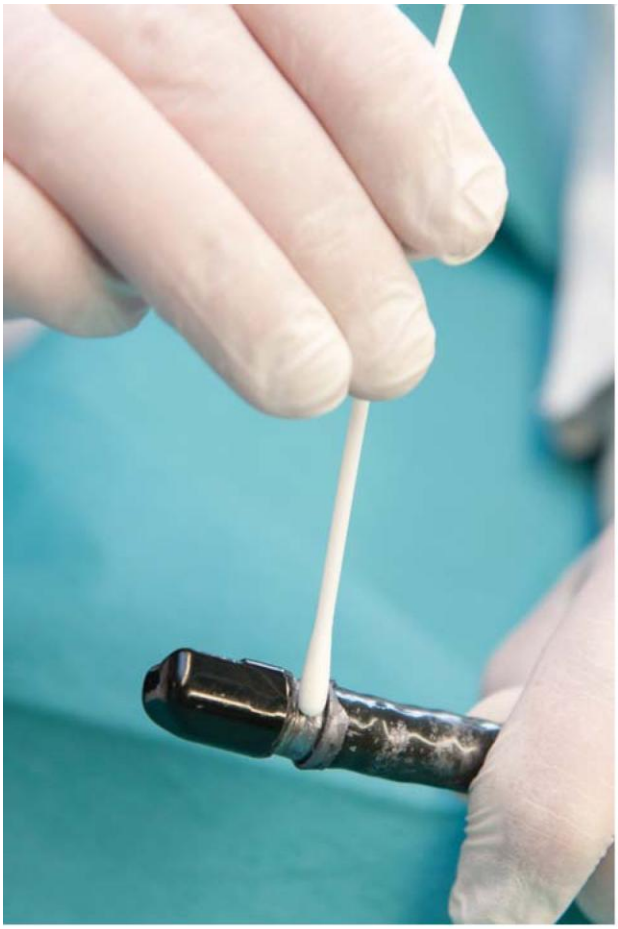

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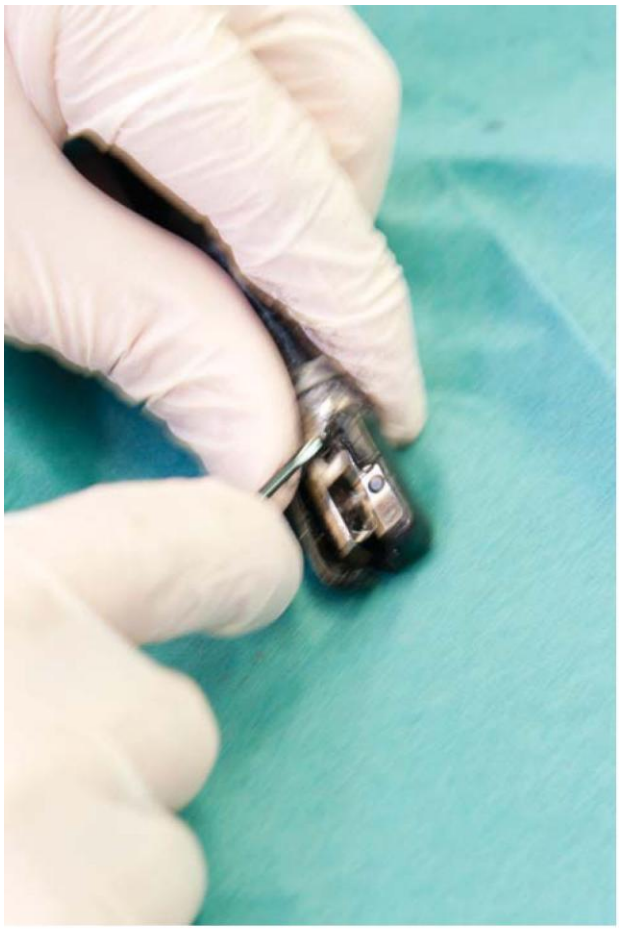

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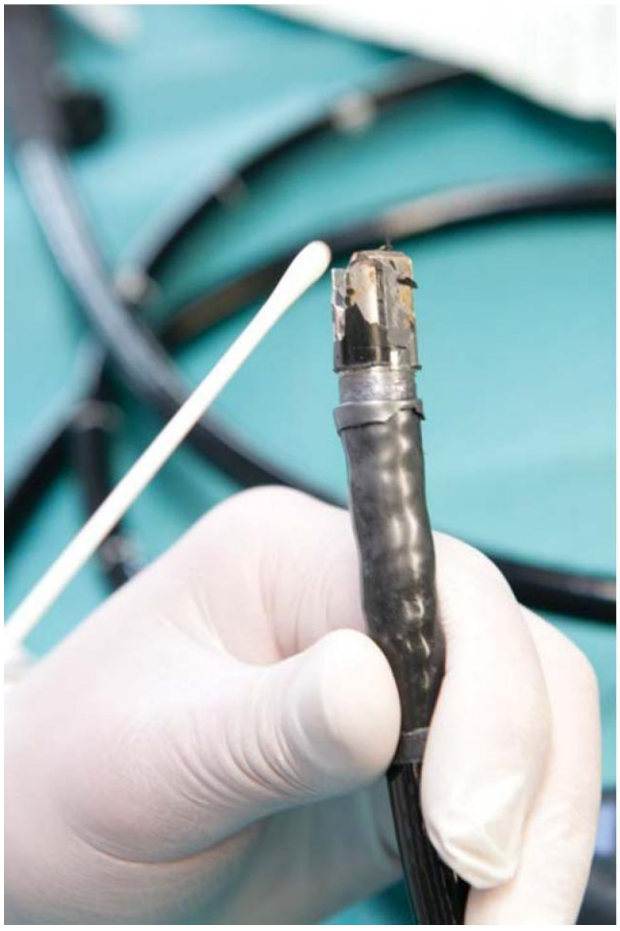

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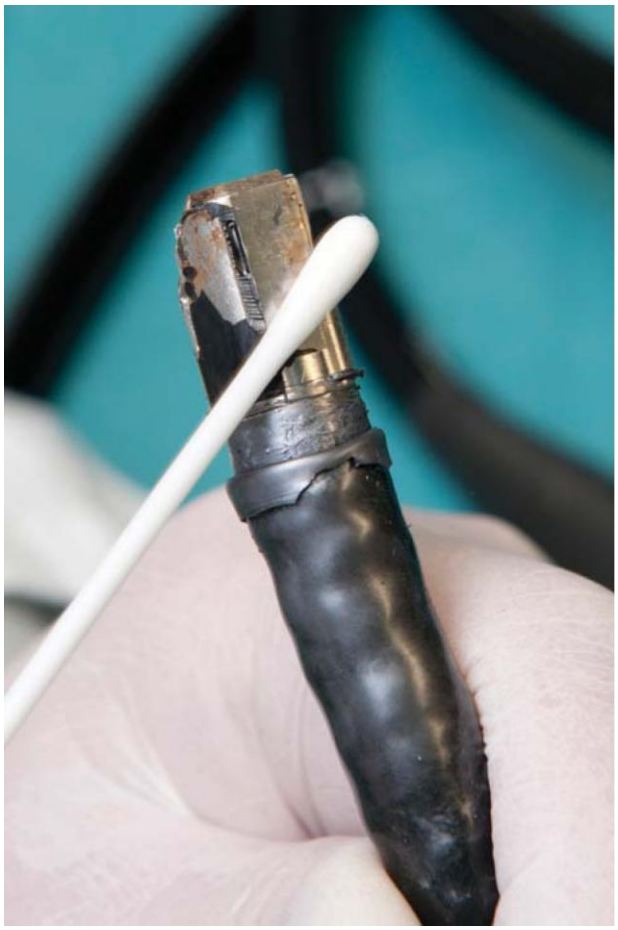

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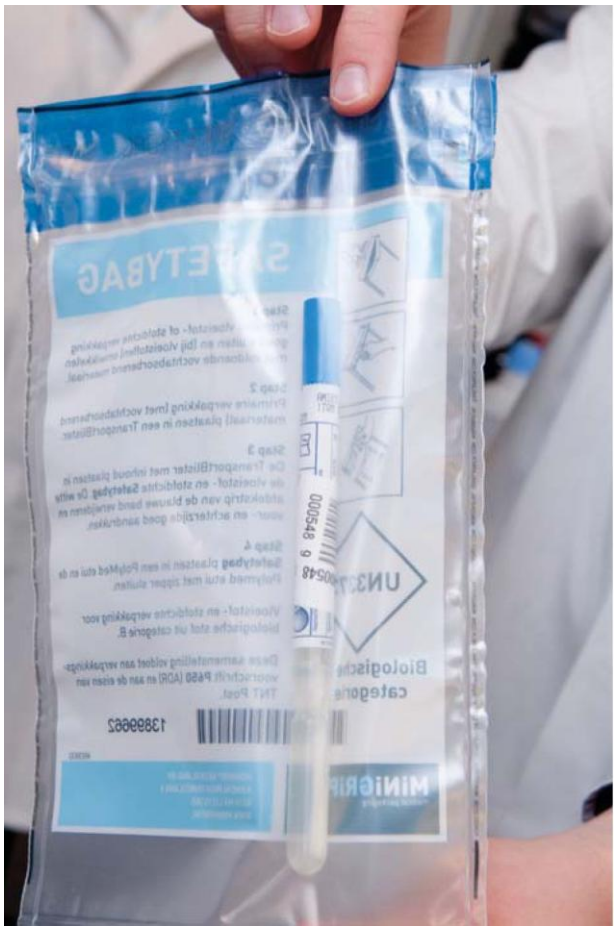

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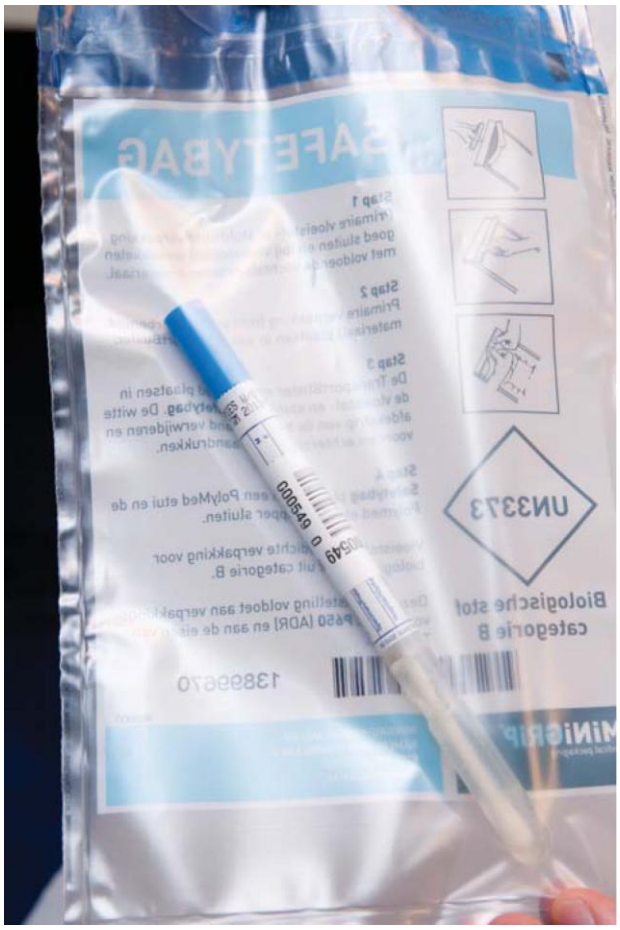

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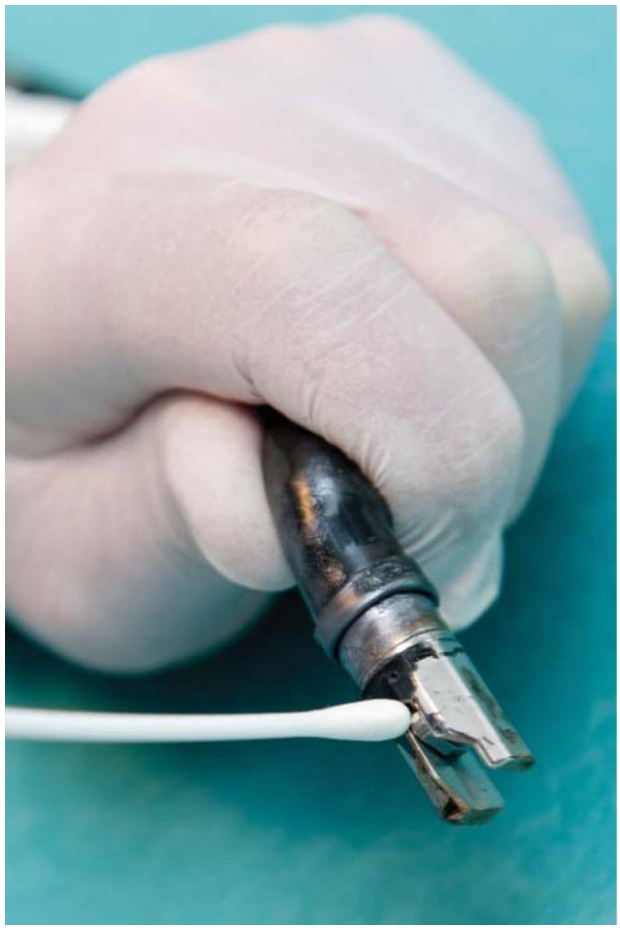

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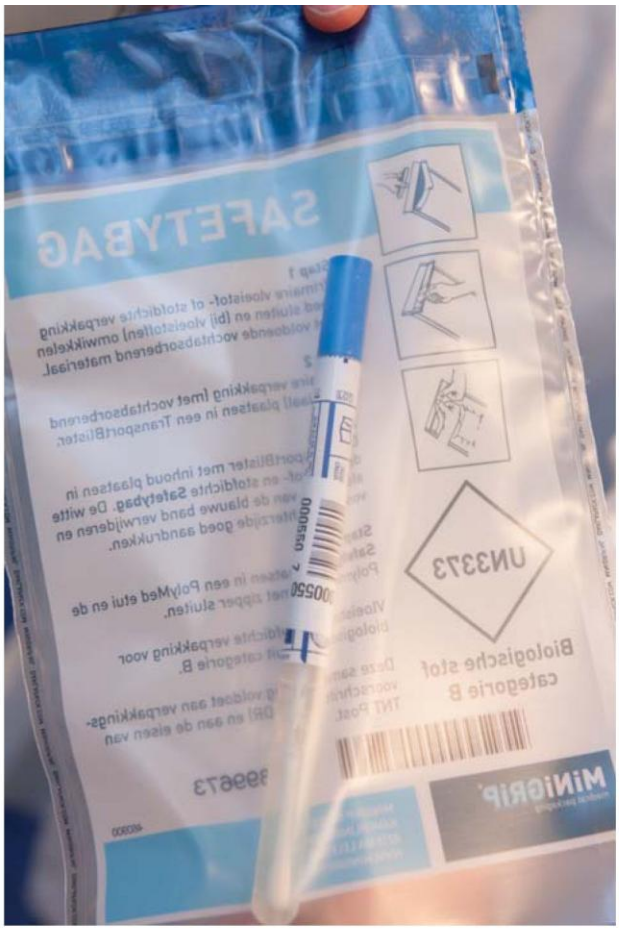

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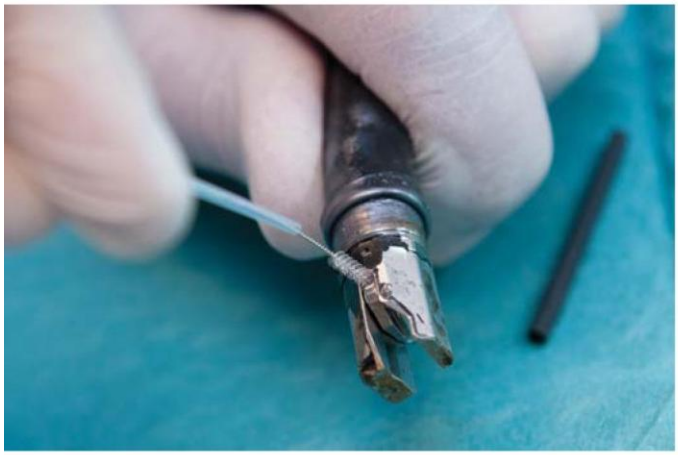

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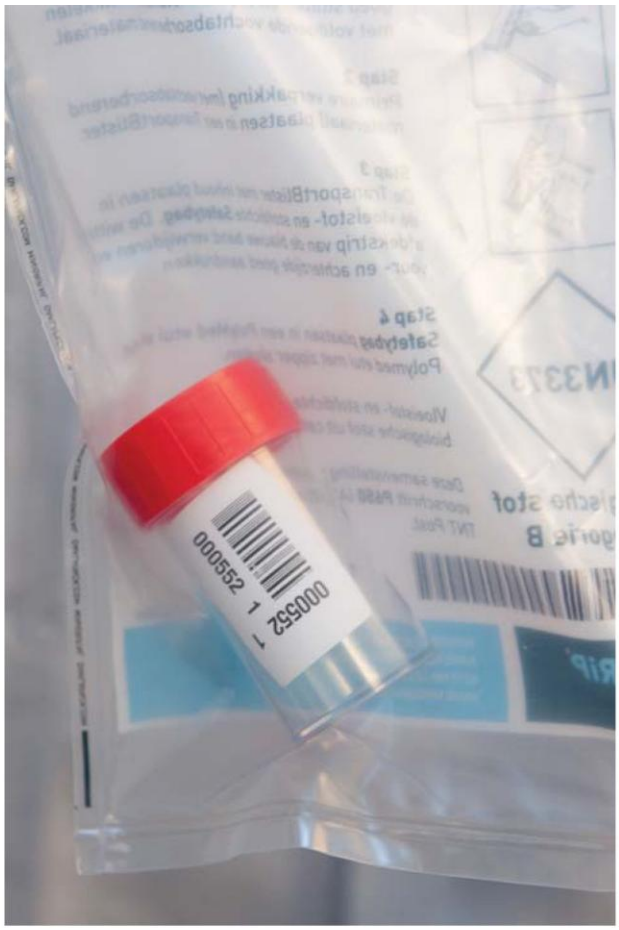

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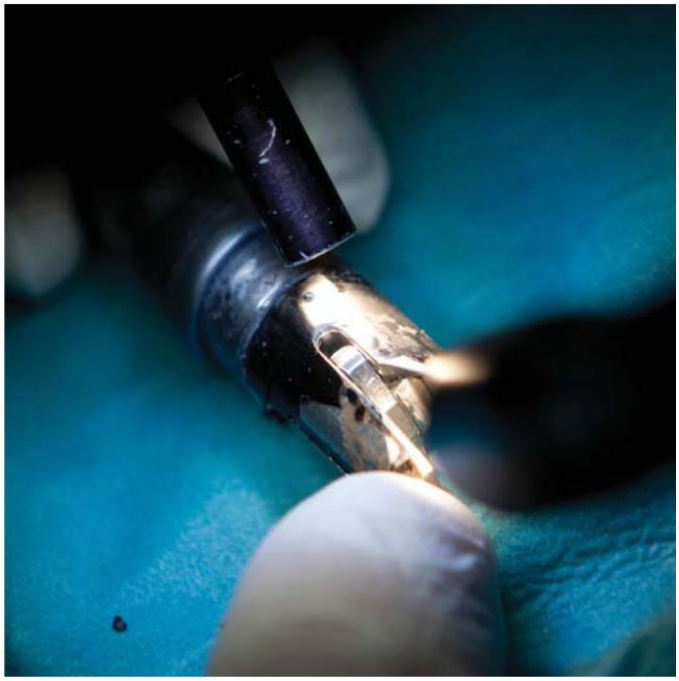

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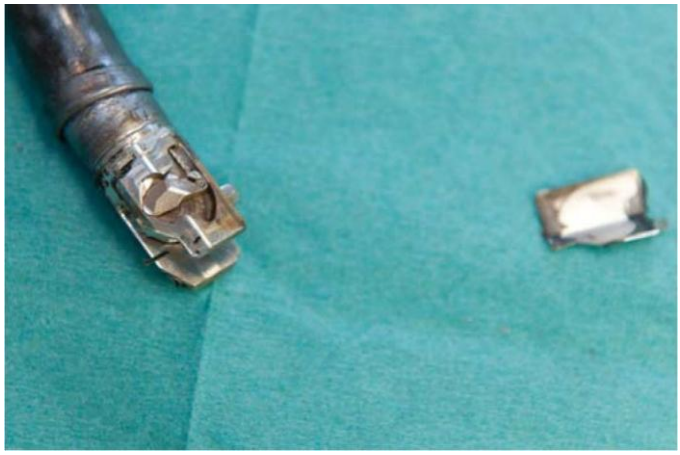

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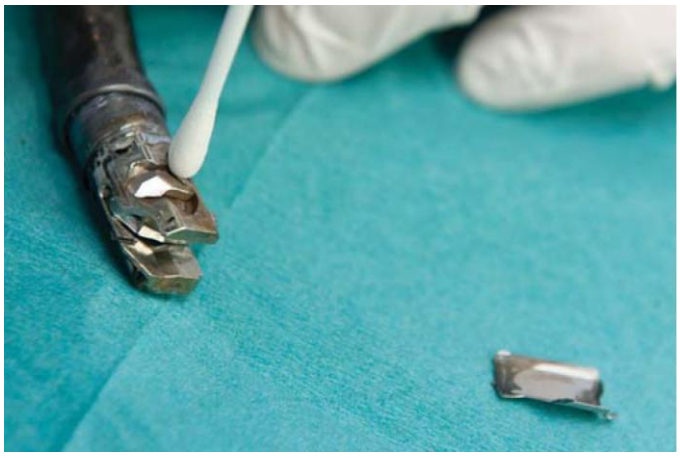

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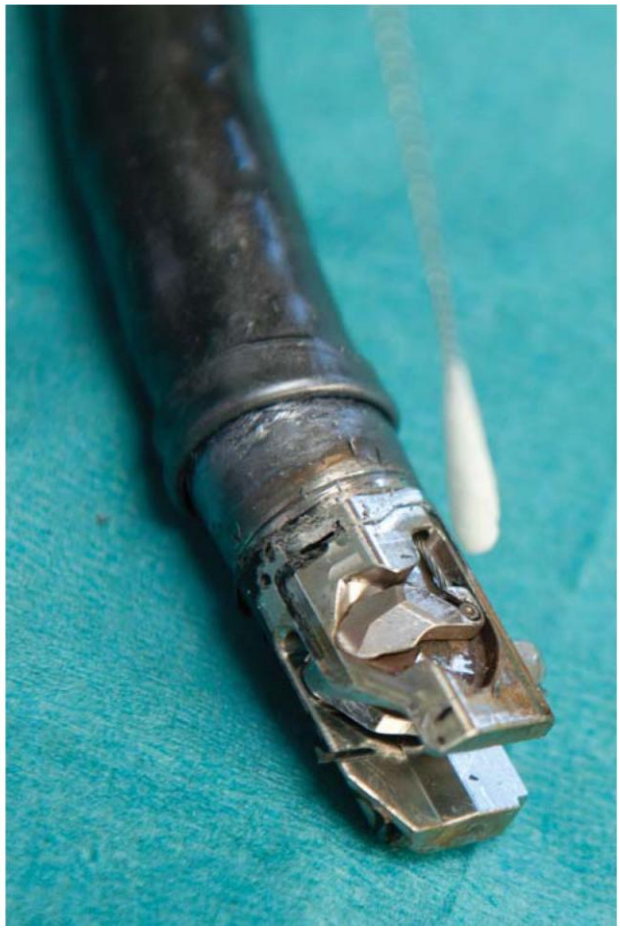

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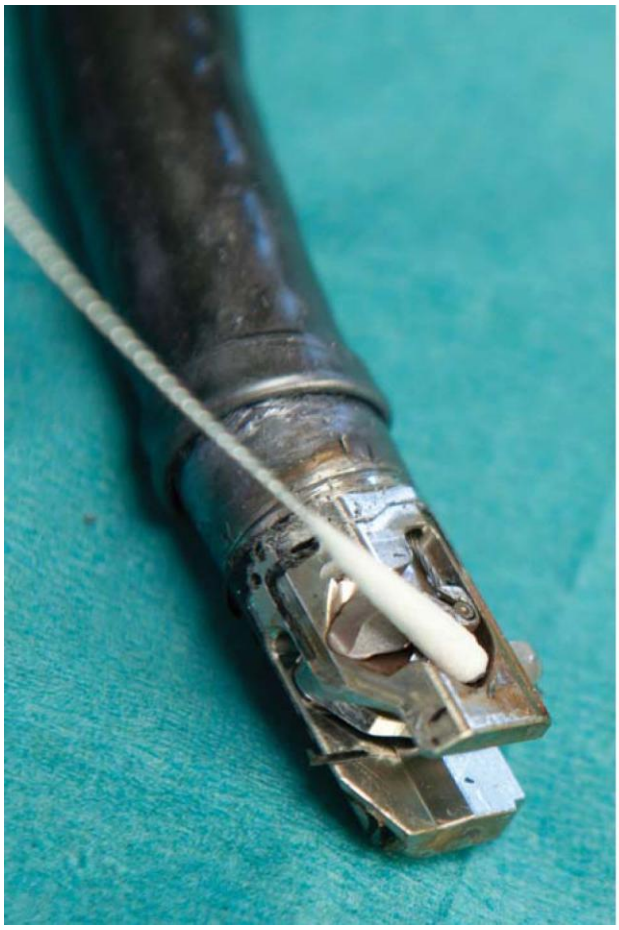

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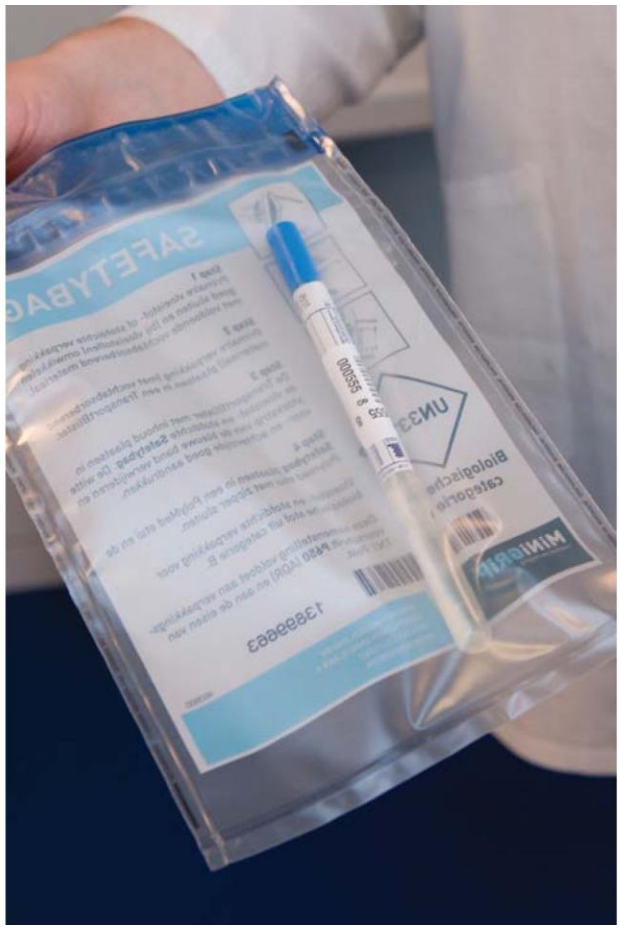

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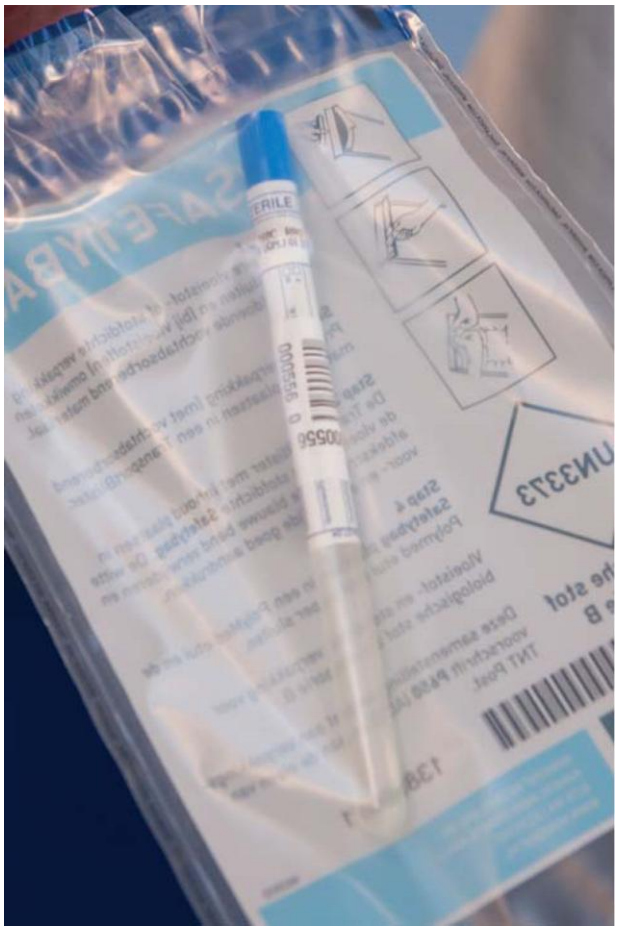

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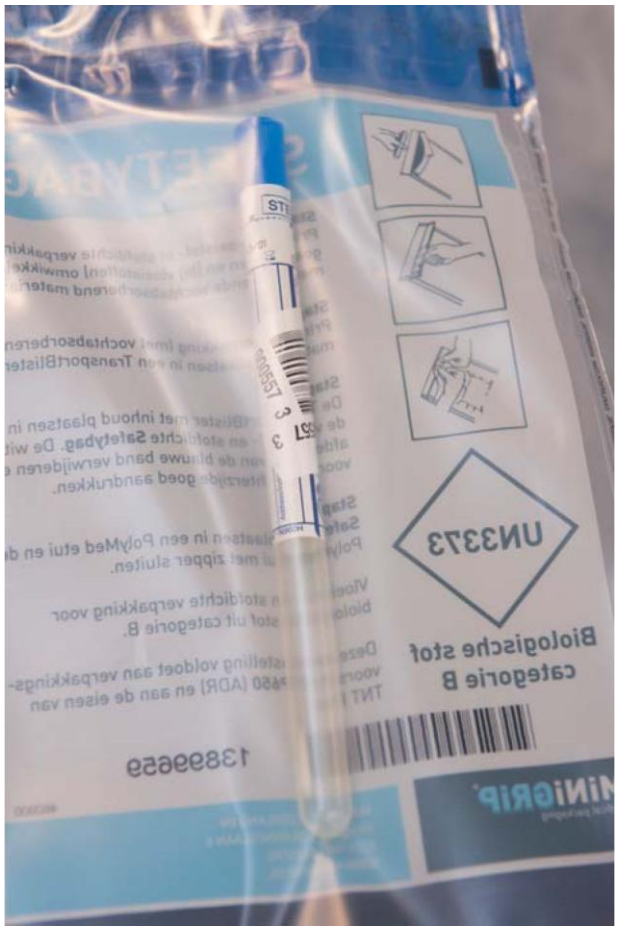

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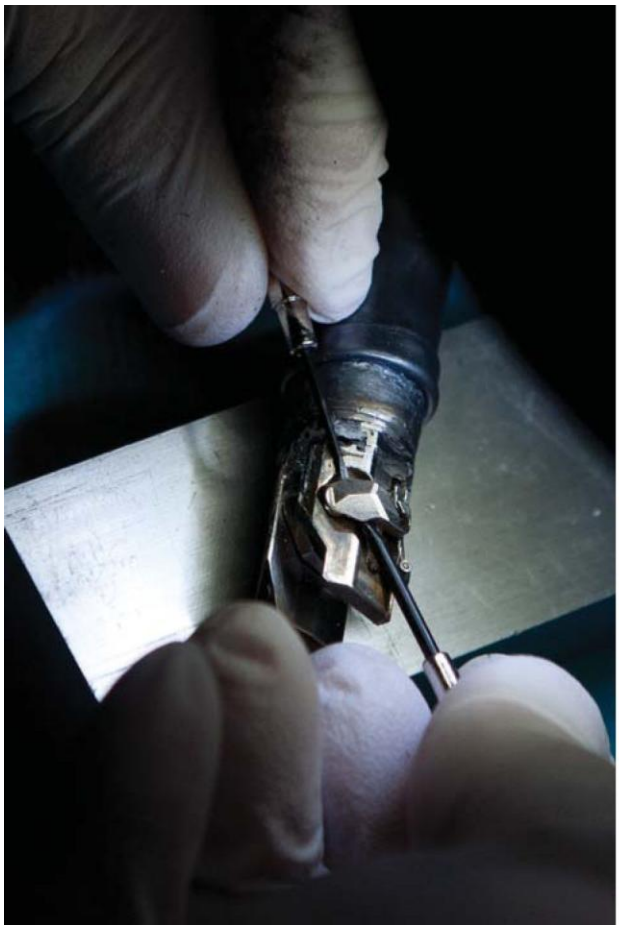

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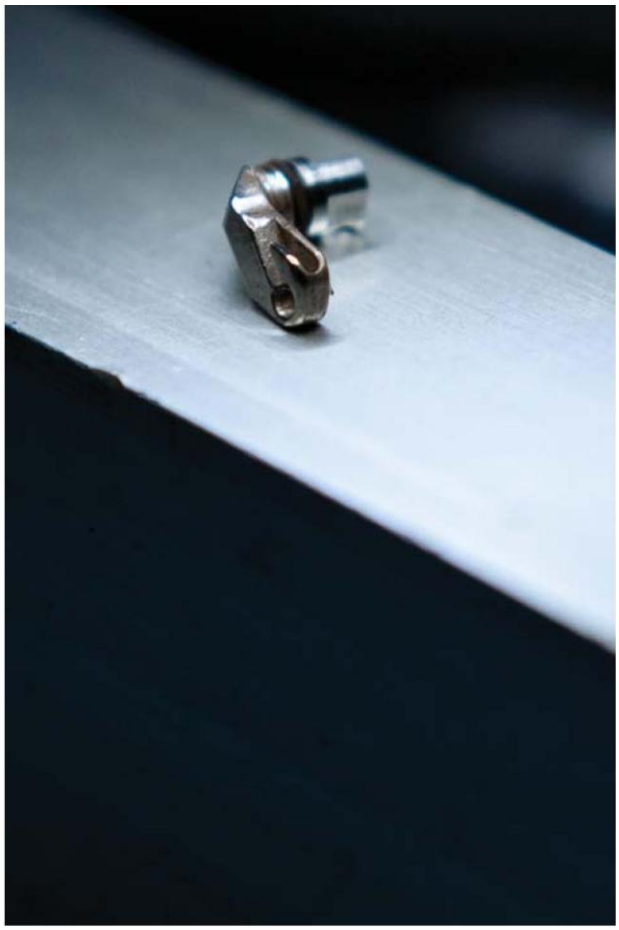

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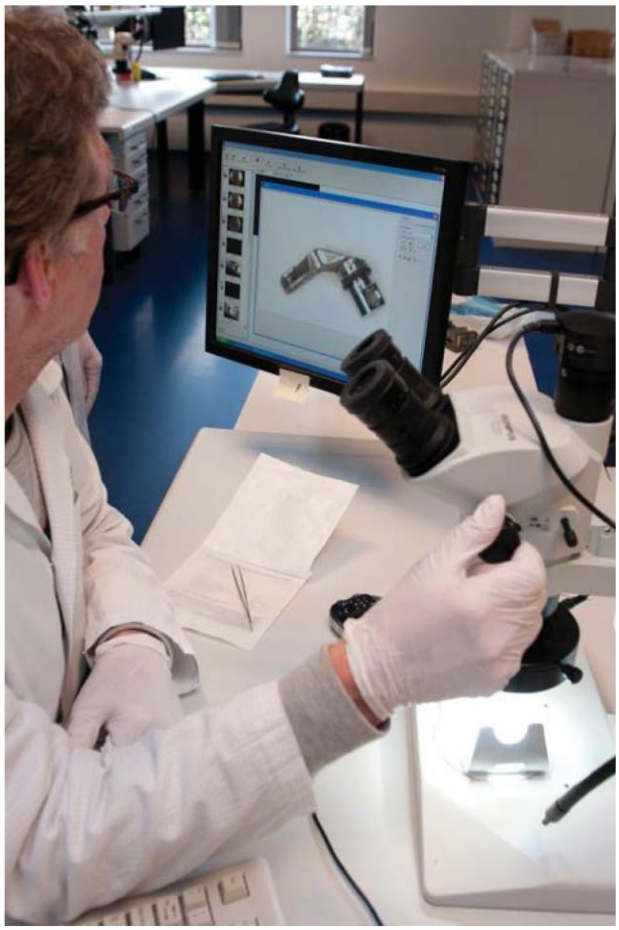

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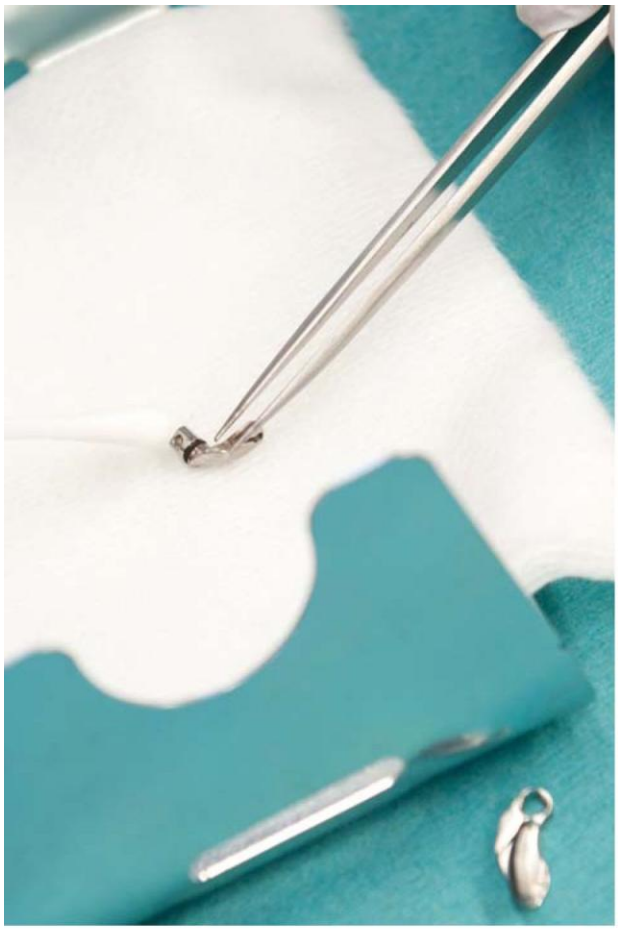

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D300s-ACL0130-eKL.jpg

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D300s-ACL0133-eKL.jpg

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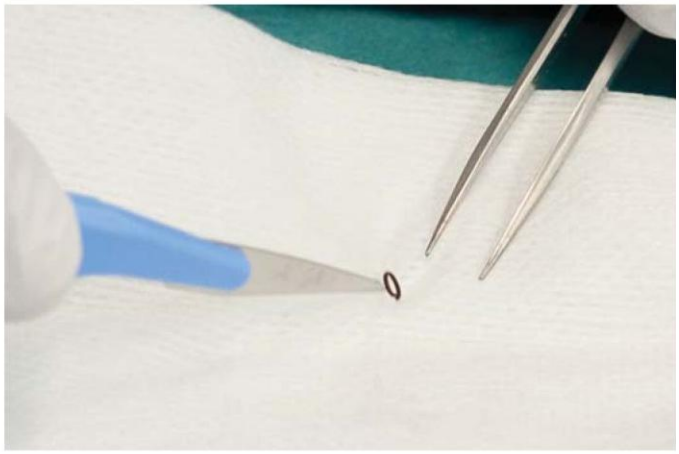

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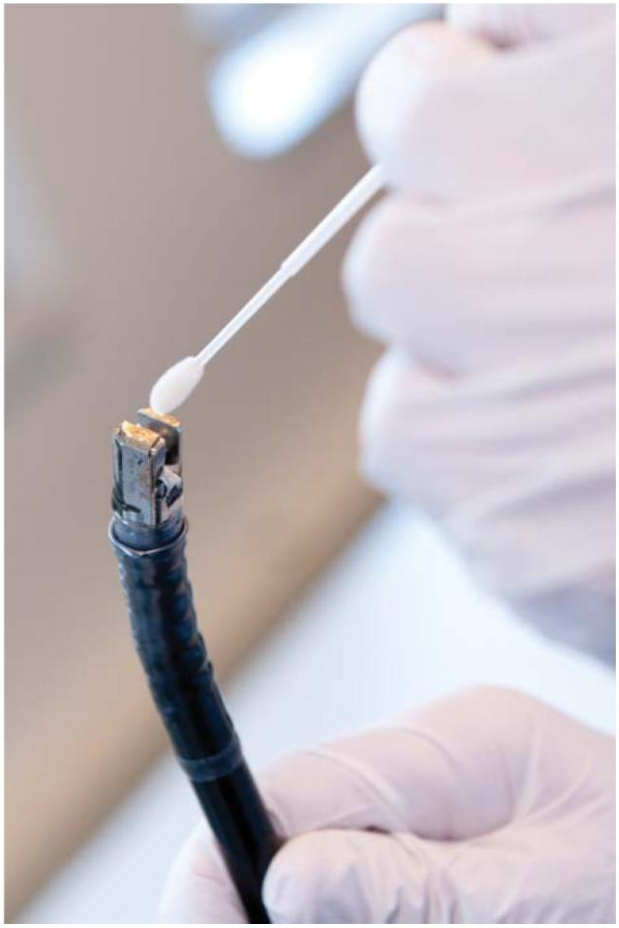

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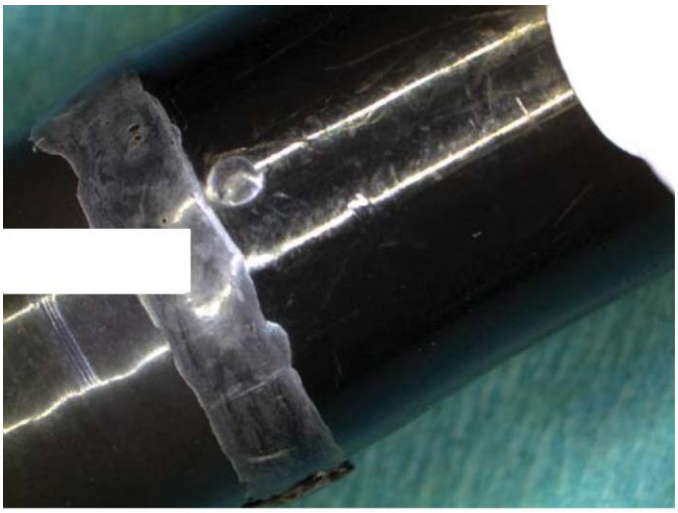
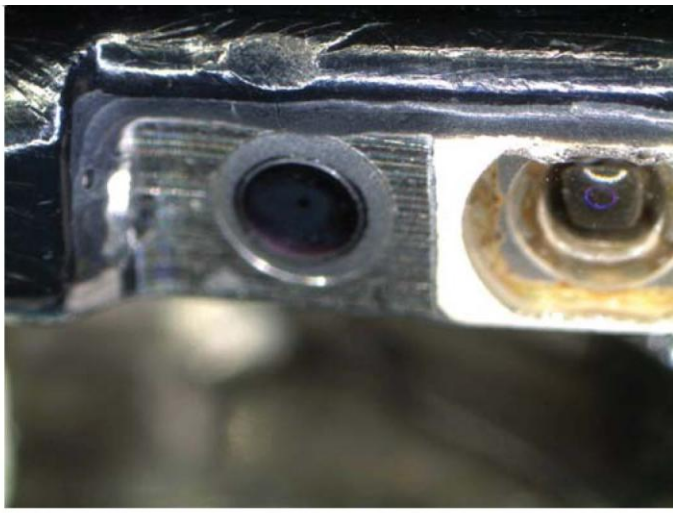


Microsc-001.jpg



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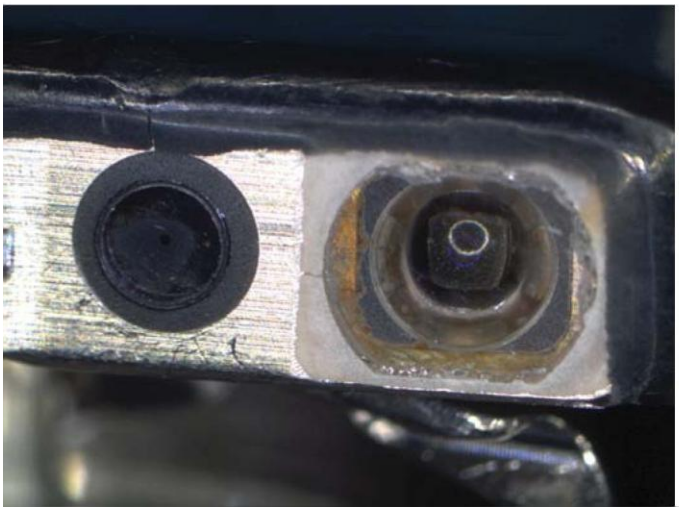

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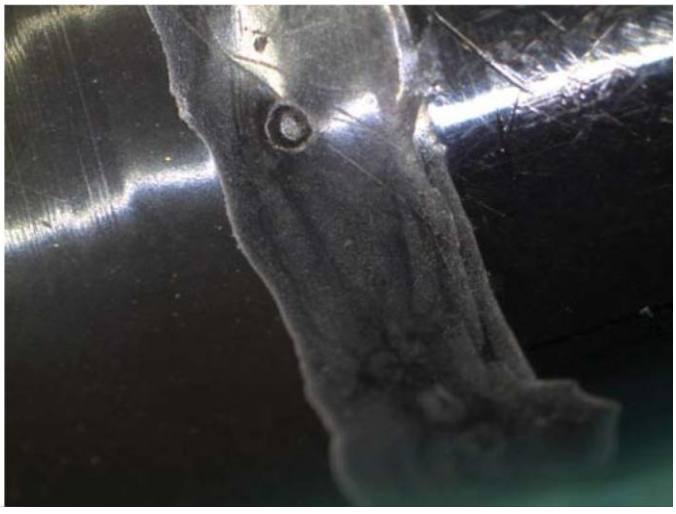

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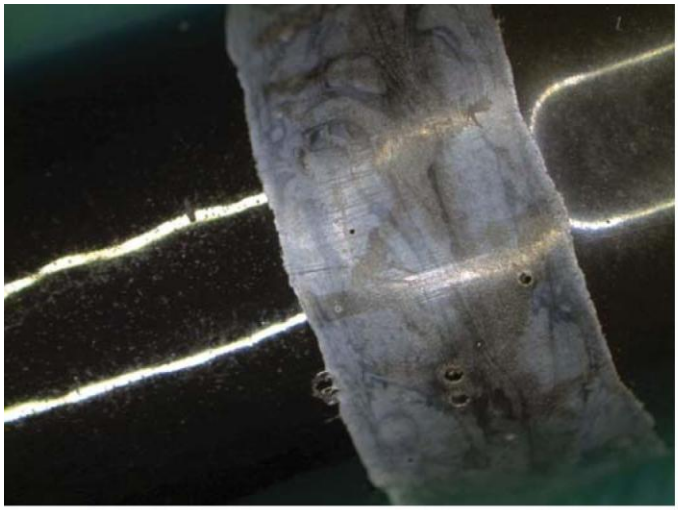

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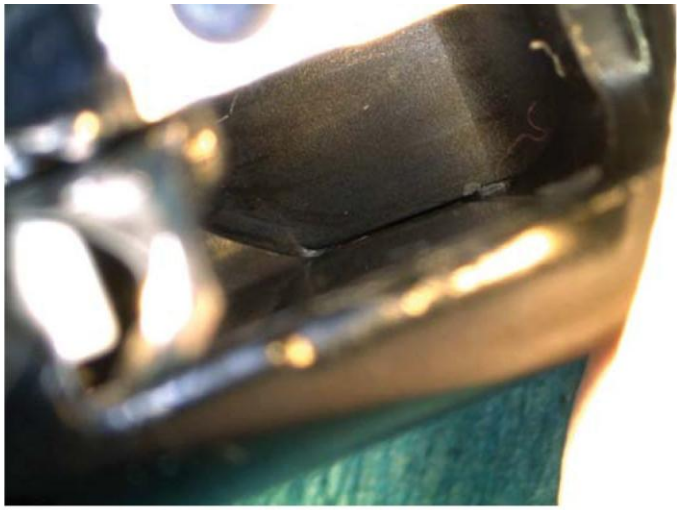

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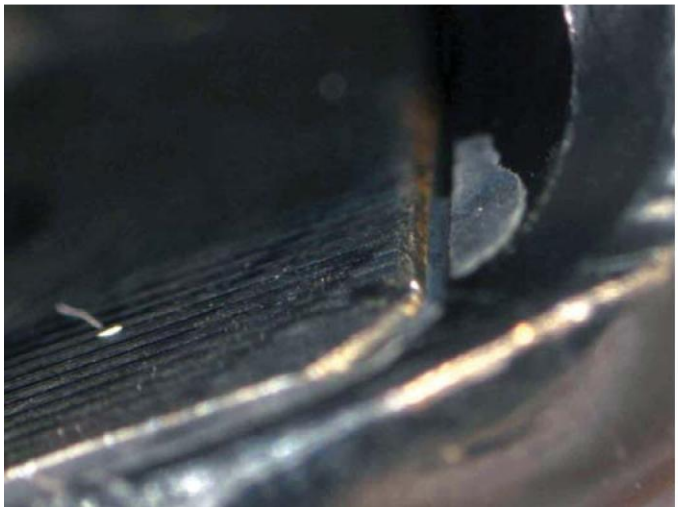

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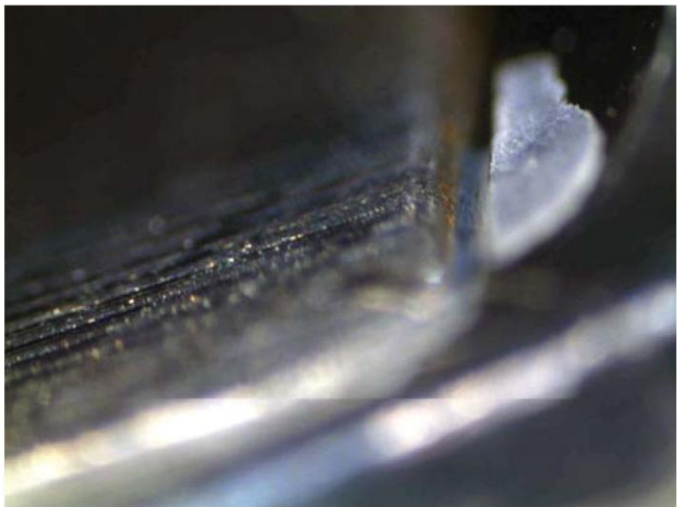

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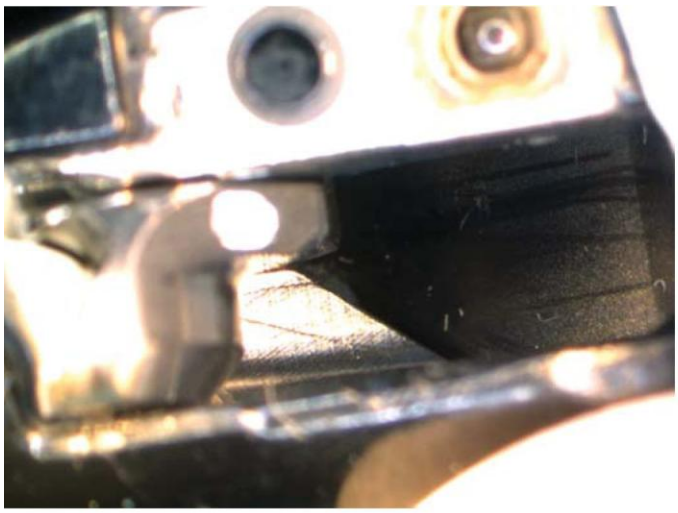

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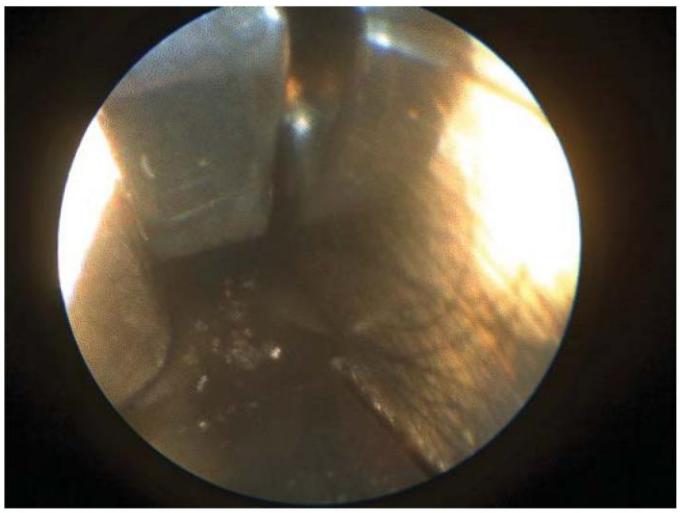

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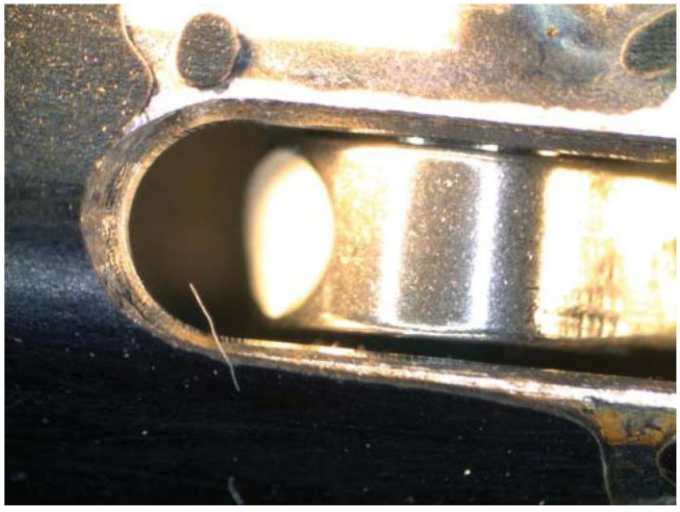

Microsc-020.jpg

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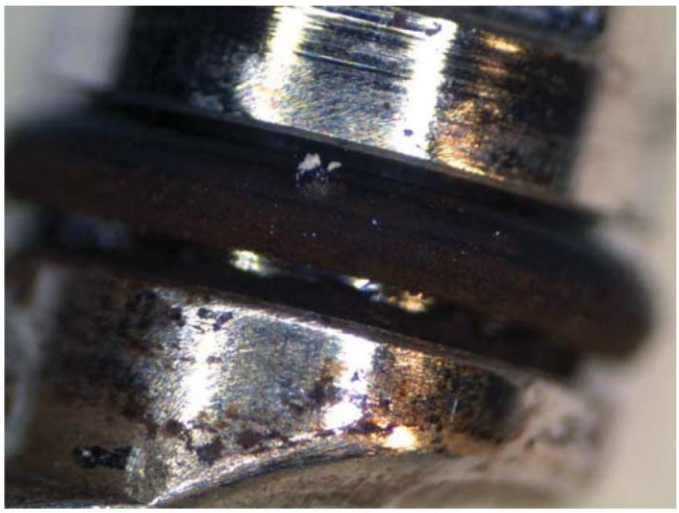

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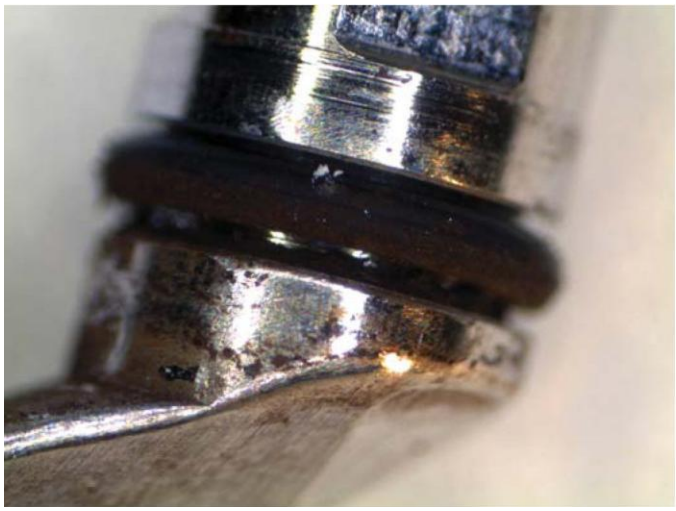
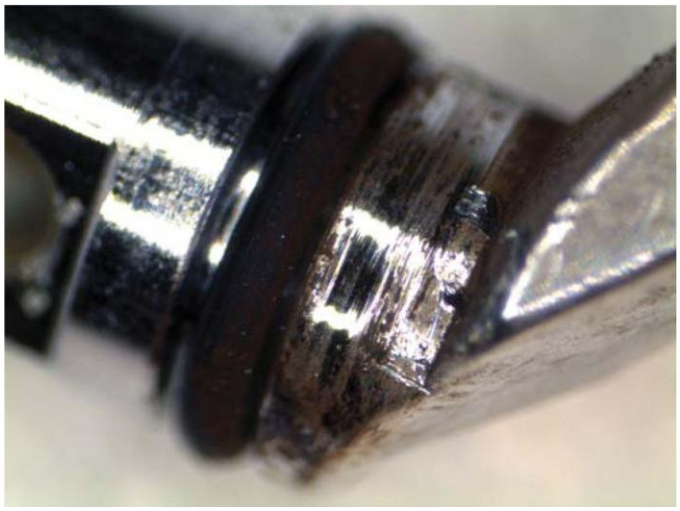
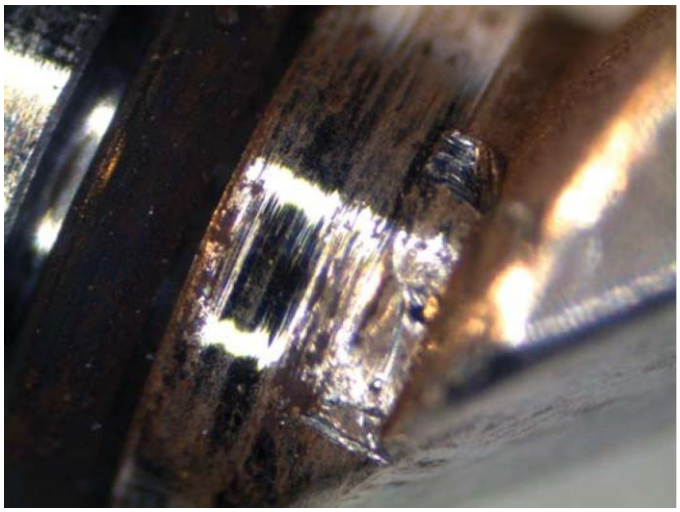


Microsc-024.jpg



Microsc-25.jpg



Microsc-026.jpg

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

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Disinfection of Olympus TFJ-Q180V ERCP endoscope

Advice requested by: [redacted]
Advice formulated by: [redacted]
Verified by: [redacted]
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 the 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 O-ring 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 O-ring 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 pre-cleaning 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 µl.
- 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 µl 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.

2. 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: [redacted]

Disinfection of Olympus TFJ-Q180V ERCP endoscope

Response from Erasmus MC

Advice requested by: [redacted]
Advice formulated by: [redacted]
Verified by: [redacted]
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.
Response from RIVM: 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**

Response from RIVM: 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.

- **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.

Response from RIVM: 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.

January 2013

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/Distributor
[Dept/Attn]
[Street No.]
[ZIP City]
Date Ref No. EXT-xxx
Important Safety Advice: Safe reprocessing of TJF-Q180V

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments.

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____

OLYMPUS

Your Vision, Our Future

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.

1 **At the light source:**

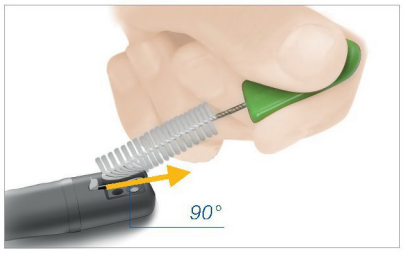
The distal cap of the TJF-Q180V is fixed and is therefore not removed prior to pre-cleaning

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

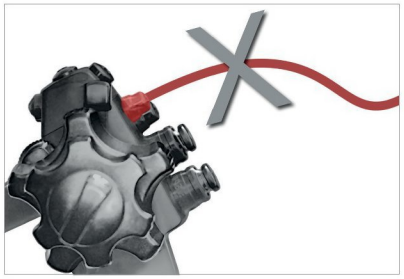
2 **During manual cleaning:**

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



3 **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.

OLYMPUS

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. The 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

[Dept/Attn] Olympus France S.A.S
[Street No.]
[ZIP City]
Date Ref No. EXT-xxx
Technical Advice: Additional Cleaning Procedure of TJF-Q180V

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments.

Name _____

Hospital _____

Department _____

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

Form Approved: OMB No. 0910-0291, Expires: 6/30/2016
See OMB statement on reverse.

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

Page 1 of 3

Mfr Report # 2431293-2014-00006

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
In confidence	or _____	☐ Female ☐ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: _____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
2014	XX

5. Describe Event or Problem

On 05/21/2014, FUJIFILM Medical Systems U.S.A., Inc. (FMSU) was contacted by Advocate Good Samaritan Hospital (AGSH) of Fujinon duodenoscopes and patients testing positive for CRE (carbapenem-resistant Enterobacteriaceae).

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Fujinon

2. Common Device Name: Duodenoscope

2b. Procode:

3. Manufacturer Name, City and State: FUJIFILM Optical Corporation, Mito Factory, 4112 Tono, Hitachiomiya City, Ibaraki, Japan, 319-2224

4. Model #	Lot #	5. Operator of Device
ED-530XT		☑ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other:
Serial #	Unique Identifier (UDI) #	
1D102A045		

6. 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

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: 07/18/2014 (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

[redacted]
Advocate Good Samaritan Hospital
3815 Highland Avenue, Downers Grove, IL 60515

Phone #	Email Address
[redacted]	[redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Administrator/Supervisor	☑ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: [redacted]

Address:
FUJIFILM Medical Systems USA, Inc.
Endoscopy Division
10 High Point Drive, Wayne, NJ 07470

FUJIFILM Optical Corporation, Mito

Email Address: [redacted]

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/14/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K042076

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 # 1

Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

8. Adverse Event Term(s):

9. Manufacturer Report Number: 2431293-2014-00001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☑ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☑ Yes ☑ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: 06/01/2007
5. Labeled for Single Use? ☐ Yes ☑ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*:

Patient Code	3190	2692		
Device Code	2895	1091		
Method	10			
Results	195	213		
Conclusions	71			

7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

The two subject endoscopes (second endoscope serial number ND102A125 reported under MDR number 2431293-2014-00007) were received at Fujifilm Medical Systems, Endoscopy Division (FMSU-ESD). The distal tips of the subject endoscopes were photographed and found to have foreign matter on the distal end area in the vicinity of the elevator and nozzle. However, according to the Equipment Service Request document received from the customer, both subject endoscopes were reprocessed in a Medivators AER prior to them shipping to FMSU-ESD. Therefore, it is not known if any foreign matter was removed from the endoscopes during that process. Some foreign matter was still visible even though the customer stated they reprocessed the endoscopes. Due to the nature of the incident involving CRE organism, both subject endoscopes were then reprocessed twice in the Medivators AER at FMSU-ESD as a precaution prior to further handling of the endoscopes. Both subject endoscopes were inspected following FMSU-ESD standard operating procedures, and were found to have minor repairs due to wear and tear. In addition to the necessary repairs, in an abundance of caution, the insertion section assemblies and all internal channels in the umbilicus sections were replaced.

(continued in attachment)

(Continued from section H 10)

A letter was e-mailed to [redacted] 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.

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

Form Approved: OMB No. 0910-0291. Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 2431293-2014-00002

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(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)*
2014	05/20/2014

5. Describe Event or Problem

On 05/20/2014, FUJIFILM Medical Systems U.S.A., Inc. (FMSU) was contacted by Advocate Good Samaritan Hospital (AGSH) and advised of Fujinon (note: FMSU's endoscopes bear the brand name of "Fujinon") duodenoscopes and patients testing positive for CRE (carbapenem-resistant Enterobacteriaceae).

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name Fujinon

2. Common Device Name Duodenoscope

3. Manufacturer Name, City and State
FUJIFILM Optical Corporation, Mito Factory, 4112 Tonc, Hitachiomiya City, Ibaraki,Japan, 319-2224

4. Model #	Lot #	5. Operator of Device
ED-530XT		☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Serial #	Other #	☐ Other:
ND102A125		

6. 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

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 treatment of event)*

E. INITIAL REPORTER

1. Name and Address

Phone # [redacted]

[redacted]
Advocate Good Samaritan Hospital
3815 Highland Avenue, Downers Grove, IL 60515

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Administrator/Supervisor	◉ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
[redacted]
U.S.A, Inc. Endoscopy Division
10 High Point Drive, Wayne, NJ 07470
[redacted]
FUJIFILM Optical Corporation, Mito Factory, 4112 Tono, Hitachiomiya City, Ibaraki, Japan, 319-2224

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/20/2014

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # K042076 Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes

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 # ____

8. Adverse Event Term(s):

9. Manufacturer Report Number: 2431293-2014-00002

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: CRE Positive Growth
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: 04/25/2012
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method 3263 - ____ - ____ - ____ Results 3233 - ____ - ____ - ____ Conclusions 11 - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

FUJIFILM Medical Systems U.S.A., Inc. (FMSU) immediately initiated an investigation, including a visit to AGSH, to identify the root cause for the incident. FMSU personnel were informed that, in response to CRE incidents at its sister hospital, Advocate Lutheran General, AGSH had conducted a review of prior medical records for its patients who were positive for CRE. At the time of this report, FMSU has been advised that two of three endoscopes (SN # 1D102A045 and SN # ND102A125) have allegedly been cultured positive for CRE. Three patients who had undergone ERCP procedures tested positive for CRE and two of three of these patients expressed symptoms consistent with positive CRE. The customer is unsure whether the patients transferred CRE to the endoscope or vice versa. Non-FUJIFILM equipment, including a channel cleaning device instead of cleaning brush, is used to manually clean the endoscopes and an AER is used for automated high-level disinfection. A review of FMSU service records for AGSH indicated no abnormalities other than general wear and tear repairs attributable to normal usage and handling of the device. FMSU has requested but has not received any information on any treatment or hospitalizations for these patients, at the time of this initial report. In addition, FMSU has requested that the duodenoscopes that tested positive for CRE be returned for a detailed examination. To date, the customer has not returned any duodenoscopes to FMSU. The investigation is still ongoing. FMSU will submit a supplemental MDR once the investigation is completed.

Advocate Lutheran General Hospital
Park Ridge, Illinois

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

MEDWATCH

FORM FDA 3500A (6/10)

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

Page 1 of 3

Form Approved: OMB No. 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
N/A In confidence	[redacted]		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☒ **Product Problem** *(e.g. defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
- ☐ Death: _____ *(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)* Patient Information	4. Date of This report *(mm/dd/yyyy)*
	08/29/2013

5. **Describe Event or Problem**

On August 29, 2013, PENTAX Medical received MedWatch Report (MW5031083) 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. 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:

[redacted]

6. **Relevant Tests/ Laboratory Data, Including Dates**
n/a

7. **Other Relevant History, Including Pre existing Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ dysfunctions, etc.)*
n/a

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

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/ labeler)*
#1
#2

2. Dose, Frequency,& Route Used	3. Therapy Dates *(If unknown, give duration) From/ to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID**

10. **Concomitant Medical Products and therapy Dates** *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. **Brand Name** PENTAX
2. **Common Device Name** VIDEO DUODENOSCOPE
3. **Manufacturer Name, City and State** **PENTAX Medical, Montvale, NJ**

4. Model #	Lot #	5. Operator of Device
ED-3490TK		☒ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/ Patient
Serial # A110084	**Other #**	☐ Other:

6. 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

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 treatment of event)*
see page 3 of 3, Concomitant Medical products

E. INITIAL REPORTER

1. Name and Address	Phone # Patient Information
Patient Information Advocate Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068	

2. Health Professional?	3. Occupation	4. Initial reporter Also Sent Report to FDA
☒ Yes ☐ No	[redacted]	☒ Yes ☐ No ☐ Unk.

MEDWATCH

FORM FDA 3500A (6/10)

FDA USE ONLY

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

1. **Check One** ☐ User Facility ☒ Importer
2. **UF/ Importer Report Number** 2518897-2013-00004

3. **User facility or Importer Name/ Address**
Pentax Medical
3 Paragon Drive
Montvale, NJ 07645

4. **Contact Person** [redacted]
5. **Phone Number** [redacted]

6. **Date User facility or Importer Became Aware of Event** *(mm/dd/yyyy)* 08/29/2013
7. **Type of Report** ☒ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)* 09/20/2013

9. **Approximate Age of Device** 4 yrs
10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code: 1735 - - -
Device Code: 1091 - 2303 - -

11. **Report Send to FDA?** ☒ Yes 09/20/2013 *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☒ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Center ☐ Outpatient Treatment Facility ☐ Other: *(Specify)*
13. **Report Sent to Manufacturer?** ☒ Yes 09/20/2013 *(mm/dd/yyyy)* ☐ No

14. **Manufacturers Name and Address**
Hoya Corporation PENTAX Miyagi Factory
30-2 Okada Aza-Shimomiyano
Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203

G. ALL MANUFACTURERS

1. **Contact Office – Name/ Address** *(and Manufacturing Site for devices)*
Contact Office = see F.3 above
Manufacturing Site = see F.14 above

2. **Phone Number** [redacted]

3. **Report Source** *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☒ Health Professional ☐ User facility ☐ Company Representative ☐ Distributor ☒ Other: MEDWATCH

4. **Date Received by Manufacturer** 08/29/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/ 510K # K092710
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

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 #

8. **Adverse Event Term(s)** n/a

9. **Manufacturer Report Number** 2518897-2013-00004

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☒ Serious Injury ☒ Malfunction ☐ Other
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☒ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not) or provide code:* See H.10 below
4. **Device Manufacture Date** *(mm/dd/yyyy)* 04/02/2009
5. **Labeled for Single Use?** ☐ Yes ☒ No
6. **Evaluation Codes** *(Refer to coding manual)*
Method: 10 - - - -
Results: 204 - 234 - -
Conclusions: 46 - 54 - -
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☒ Other see H.10 below ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment
8. **Usage of Device** ☐ Initial Use of Device ☒ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360 I(f), list correction/ removal reporting number:**
10. ☒ **Additional Manufacturer Narrative** and/ or 11. ☐ **Corrected Data**

During a conference call with Advocate Lutheran General Hospital on Sept. 6, 2013, PENTAX was informed that four patients developed carbapenem-resistant Enterobacteriaceae (CRE) infection after undergoing ERCP procedures using scope ED-3490TK, A110084. These patients were treated with antibiotics. Twenty-two additional patients screened positive for CRE but did not develop an infection, this occurred after this same scope was used on the patients for ERCP.

The scope was tested at the user facility and positive culture was found behind the elevator and through the hole of the scope. Customer confirmed that non-PENTAX brushes are used to manually reprocess their scopes. The cleaning brushes used at the facility are Medivators Pull-Thru ™ Pre-Cleaning Device. In addition, Surg-Enz® is the enzymatic detergent/cleaner used to reprocess the scope and Cidex OPA is used for High Level Disinfection.

According to the PENTAX Reprocessing/Maintenance Instruction For Use (IFU), it specifically states that user must "Be aware that all recessed areas around the elevator mechanism should be thoroughly cleaned with an appropriately sized cylinder cleaning brush (e.g. CS-C9S) and
in a cleaning detergent solution."

The use of non-PENTAX cleaning brushes and Surg-Enz® are considered off-label use. According to the PENTAX Reprocessing/Mainentance IFU, PENTAX highly recommends that ONLY PENTAX cleaning brushes specified in our instructions for use should be used to manually clean PENTAX endoscopes. In addition, Surg-Enz is not listed on the PENTAX Medical approved list of Compatible Reprocessing Systems/Agents.

The endoscope has since been taken out of commision and is currently being held by the Center of Disease Control (CDC). Therefore, PENTAX has not been able to evaluate the scope.

Investigation is ongoing.

MEDWATCH

FORM FDA 3500A (6/10)

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Test/ Laboratory 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 Medical Products and Therapy Dates *(exclude treatment of event) (For continuation of C.10 and/ or D.11; please distinguish)*

Other Remarks

F10 Patient Code 1735 = Infection, Bacterial

F10 Device Code 1091 =Device Cleaning Issue;
2303 = Bacterial contamination of device

H.6 Evaluation Codes
_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

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report #

UF/Importer Report # 2518897-2013-00004

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
In confidence	or _____	☐ Female ☐ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

☐ Death: _____ *(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)*
	07/03/2014

5. **Describe Event or Problem**

Per PENTAX Medical's investigation results, the CRE cases were limited to one hospital in Illinois and PENTAX Medical has not received any other reports potentially linking the ED-3490TK to CRE infection since the device received market clearance in 2009. Post market surveillance data for PENTAX Medical endoscopes demonstrated that the products have an excellent safety record. An extensive review of hospital procedures revealed that the hospital was not using validated detergent and high level disinfectant products, nor was it using cleaning equipment recommended by PENTAX Medical for reprocessing its duodenoscopes. This deviation from the validated reprocessing protocol potentially contributed to CRE contamination. For example, while PENTAX Medical recommends the use of a tri-bristle channel cleaning brush, investigation showed that ALGH personnel used a non-bristled (squeegee-type) channel cleaning device during the time leading up to the CRE incidents.

(Continue on page 3)

6. **Relevant Tests/Laboratory Data, Including Dates**

(Continue on page 3)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. Common Device Name	2b. Procode

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. 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

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 treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. **Name and Address**

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

FDA USE ONLY

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

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**: 2518897-2013-00004
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☑ Follow-up # 4
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___
11. **Report Sent to FDA?** ☑ Yes 07/03/2014 *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: *(Specify)*
13. **Report Sent to Manufacturer?** ☑ Yes 07/03/2014 *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
Name
Address
Email Address
2. **Phone Number**
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
5. (A)NDA # ___ IND # ___ BLA # ___ PMA/510(k) # ___ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 4
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction
2. **If Follow-up, What Type?** ☑ Correction ☑ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)*
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** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
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.

B.5. **Describe Event or Problem** *(continued)*

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: A110084, A110574 and A110299, A110086 and A110471. All of these endoscopes were tested for CRE and only one, A110084, 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.

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.6

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Back to Item B.7

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Back to Item C.10

Back to Item D.11

Other Remarks

MEDWATCH

FORM FDA 3500A (6/10) *(continued)*

FDA USE ONLY

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

1. Check One: ☐ User Facility ☑ Importer
2. UF/Importer Report Number: 2518897-2013-00005

3. User Facility or Importer Name/Address
PENTAX of America, Inc.
3 Paragon Drive
Montvale, NJ 07645

4. Contact Person: [redacted]
5. Phone Number: [redacted]

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*: 09/30/2013
7. Type of Report: ☑ Initial ☐ Follow-up #
8. Date of This Report *(mm/dd/yyyy)*: 10/28/2013

9. Approximate Age of Device: 3 months
10. Event Problem Codes *(Refer to coding manual)*
Patient Code: 1735
Device Code: 1091 ~ 2303

11. Report Sent to FDA? ☑ Yes 10/28/2013 *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☑ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: *(Specify)*
13. Report Sent to Manufacturer? ☑ Yes 10/28/2013 *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address
Hoya Corporation PENTAX Miyagi Factory
30-2 Okada Aza-Shimomiyano
Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
Contact office = see F3 above
Manufacturing Site = F14 above

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 09/30/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # K092710
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

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: 13-00307

8. Adverse Event Term(s)

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: 08/01/2013
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*
Method: 3263
Results: 3218
Conclusions: 18 ~ 24
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data:

B5 Additional information: During a conference call with Advocate Lutheran General Hospital on Sept. 30, 2013 PENTAX was informed that one patient developed carbapenem-resistant Enterobacteriaceae (CRE) infection after undergoing ERCP procedures using scope ED-3490TK, A110574. Additional twelve patients were screened for CRE; nine patients screened negative and 3 patients screened positive for CRE but did not develop an CRE infection.
The scope was tested at the user facility and positive culture was found behind the elevator and through the hole of the scope. Customer confirmed that non-PENTAX brushes are used to manually reprocess the PENTAX scopes. The cleaning brushes used at the facility are Medivators. In addition, Surg-Enz® is the enzymatic detergent/cleaner used to reprocess the scopes and is not on the PENTAX approved list of detergents. Cidex OPA is used for High Level Disinfection. According to the PENTAX Reprocessing/Maintenance Instruction For Use (IFU), it specifically states that user must "Be aware that all recessed areas around the elevator mechanism should be thoroughly cleaned with an appropriately sized cylinder cleaning brush (e.g. CSC9S) and in a cleaning detergent solution."
H6: Endoscope was evaluated by user and bacterial culture (CRE) was found behind elevator. The actual scope has not yet been evaluated by PENTAX.
Investigation is still ongoing.

[redacted]

Form Approved: OMB No. 0910-0291, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (6/10)

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

Mfr Report # 2518897-2013-00005

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: In confidence

2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: _____ (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): Patient Information

4. Date of This Report (mm/dd/yyyy): 09/30/2013

5. Describe Event or Problem

On September 30, 2013 user facility reported an event as follows: Patient underwent an Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure (date unknown) and developed an Carbapenem-resistant Enterobacteriaceae (CRE) infection. The patient received antibiotics. No further information is available at this point about the patient. CRE organism found behind elevator on scope.

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.)

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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: PENTAX

2. Common Device Name: VIDEO DUODENOSCOPE

3. Manufacturer Name, City and State:
PENTAX of America, Inc.
Montvale, NJ

4. Model #	Lot #	5. Operator of Device
ED-3490TK		☑ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other:
Serial #	Other #	
A110574		

6. 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

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 treatment of event)

E. INITIAL REPORTER

1. Name and Address: Phone #: Patient Information

Patient Information
Advocate Lutheran General Hospital
1775 Dempster Street
Park Ridge, IL 60068

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Other Healthcare Professional	◉ Yes ☐ No ☐ Unk.

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

MEDWATCH

FORM FDA 3500A (6/10)

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

Page 1 of 3

Form Approved: OMB No. 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr report #	2518897-2013-00006
UF/Importer Report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier
In confidence

2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g. defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)* Patient Information

4. Date of This report *(mm/dd/yyyy)*
10/18/2013

5. Describe Event or Problem

On October 18, 2013 user facility reported an event as follows: Patient underwent an Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure (date unknown) and developed an Carbapenem-resistant Enterobacterioaceae (CRE) infection. The patient received antibiotics and was released from the hospital on an unknown date. No further information is available at this point about the patient.

6. Relevant Tests/ Laboratory Data, Including Dates

Escherichia coli (E-coli) New Delhi Metallo-beta-lactamase (NDM) organism - Date unknown

7. Other Relevant History, Including Pre existing Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ dysfunctions, etc.)*

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

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/ labeler)*
#1
#2

2. Dose, Frequency,& Route Used
#1
#2

3. Therapy Dates *(If unknown, give duration) From/ to (or best estimate)*
#1
#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
PENTAX

2. Common Device Name
VIDEO DUODENOSCOPE

3. Manufacturer Name, City and State
PENTAX of America, Inc.
Montvale, NJ

4. Model # ED-3490TK	Lot #	5. Operator of Device ☒ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/ Patient
Serial # A110299	Other #	☐ Other:

6. 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

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 treatment of event)*

E. INITIAL REPORTER

1. Name and Address

Phone # [redacted] Patient Information

Patient Information
Advocate Lutheran General Hospital
1775 Dempster Street
Park Ridge, IL 60068

2. Health Professional? ☒ Yes ☐ No	3. Occupation Other Healthcare Professional	4. Initial reporter Also Sent Report to FDA ☒ Yes ☐ No ☐ Unk.

MEDWATCH

FORM FDA 3500A (6/10)

FDA USE ONLY

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

1. **Check One**: ☐ User Facility ☒ importer
2. **UF/ Importer Report Number**: 2518897-2013-00006
3. **User facility or Importer Name/ Address**:
Pentax Medical
3 Paragon Drive
Montvale, NJ 07645
4. **Contact Person**: [redacted]
5. **Phone Number**: [redacted]
6. **Date User facility or Importer Became Aware of Event** *(mm/dd/yyyy)*: 10/18/2013
7. **Type of Report**: ☒ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*: 11/12/2013
9. **Approximate Age of Device**: 2 yrs
10. **Event Problem Codes** *(Refer to coding manual)*: Patient Code 1735 - - ; Device Code 1091 - 2303 -
11. **Report Send to FDA?**: ☒ Yes 11/12/2013 *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred**: ☒ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Center ☐ Outpatient Treatment Facility ☐ Other: *(Specify)*
13. **Report Sent to Manufacturer?**: ☒ Yes 11/12/2013 *(mm/dd/yyyy)* ☐ No
14. **Manufacturers Name and Address**:
Hoya Corporation PENTAX Miyagi Factory
30-2 Okada Aza-Shimomiyano
Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203

G. ALL MANUFACTURERS

1. **Contact Office – Name/ Address** *(and Manufacturing Site for devices)*:
Contact Office = see F.3 above
Manufacturing Site = see F.14 above
2. **Phone Number**: 800-431-5880
3. **Report Source** *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☒ Health Professional ☒ User facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer**: 10/18/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/ 510K # K092710
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 #
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number**: 2518897-2013-00006

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**: ☐ Death ☒ Serious Injury ☐ Malfunction ☐ Other
2. **If Follow-up, What Type?**: ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?**: ☒ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not) or provide code:*
4. **Device Manufacture Date** *(mm/dd/yyyy)*: 08/03/2011
5. **Labeled for Single Use?**: ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)*: Method 3263 - - - ; Results 3218 - - - ; Conclusions 18 - 24 - - -
7. **If Remedial Action Initiated, Check Type**: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/ Adjustment ☐ Other
8. **Usage of Device**: ☐ Initial Use of Device ☒ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360 I(f), list correction/ removal reporting number:**
10. ☒ **Additional Manufacturer Narrative** and/ or 11. ☐ **Corrected Data**

H10 Additional Narrative:
[redacted]
B5: During a conference call with Advocate Lutheran General Hospital on October 18, 2013, PENTAX was informed that one patient developed carbapenem-resistant Enterobacteriaceae (CRE) infection after undergoing ERCP procedures using scope ED-3490TK, A110299. In addition, one patient was screened for CRE but did not develop an CRE infection.
The scope was tested at the user facility and positive culture was found behind the elevator and through the hole of the scope. Customer confirmed that non-PENTAX brushes are used to manually reprocess the PENTAX scopes. The cleaning brushes used at the facility are Medivators. In addition, Surg-Enz® is the enzymatic detergent/cleaner used to reprocess the scopes and is not on the PENTAX approved list of detergents. Metricide OPA is used for High Level Disinfection. According to the PENTAX Reprocessing/Maintenance Instruction For Use (IFU), it specifically states that user must "Be aware that all recessed areas around the elevator mechanism should be thoroughly cleaned with an appropriately sized cylinder cleaning brush (e.g. CSC9S) and in a cleaning detergent solution."

H6: Endoscope was evaluated by user and bacterial culture (CRE) was found behind elevator. The actual scope has not yet been evaluated by PENTAX. Investigation is still ongoing (Complaint #: 13-00309).

[redacted]

MEDWATCH

FORM FDA 3500A (6/10)

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Test/ Laboratory 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 Medical Products and Therapy Dates *(exclude treatment of event) (For continuation of C.10 and/ or D.11; please distinguish)*

Other Remarks

F10 Patient Code 1735 = Infection, Bacterial

F10 Device Code 1091 =Device Cleaning Issue;
2303 = Bacterial contamination of device

H.6 Evaluation Codes

_Method 3263 = ACTUAL DEVICE NOT EVALUATED

_Results 3218 = MICROBIAL CONTAMINATION

_Conclusion 18 = FAILURE TO FOLLOW INSTRUCTIONS ; 24 = OFF-LABEL, UNAPPROVED, OR CONTRAINDICATED USE

Form Approved: OMB No. 0910-0291, Expires: 9/30/2015
See OMB statement on reverse.

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

Mfr Report # 2518897-2013-00006

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier [redacted]

2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [✓] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- [ ] Death: _____ *(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)*: 02/25/2014

5. Describe Event or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Specimen from patient, and cultured for Carbapenem resistant enterobacteriaceae (CRE) on [Patient Information]. Test results: Patient positive test on [Patient Information]

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Sputum, E-Coli metallo-beta-lactamases (MBL), Pleural Effusion

(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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1
#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

5. Operator of Device
- [ ] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

Catalog #

Expiration Date *(mm/dd/yyyy)*

Serial #

Unique Identifier (UDI) #

6. 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

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 treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #

Email Address

2. Health Professional?
[ ] Yes [ ] No

3. Occupation

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

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices): Name; Address; Email Address
2. Phone Number
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☑ Other: CDC
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/28/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 2
8. Adverse Event Term(s)
9. Manufacturer Report Number: 2518897-2013-00006

H DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☑ Correction ☑ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code 1930 - ____ - ____; Device Code ____ - ____ - ____; Method ____ - ____ - ____ - ____; Results ____ - ____ - ____ - ____; Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☑ Corrected Data

```
H10 Additional Narrative:
A1, A2, B6, B7, G3, H6: Additional information.
B5: During conference call with representatives from CDC
and FDA on 01/28/2014, it was mentioned by the CDC
representative there were additional patients who were
considered as surveillance culture positives (i.e.,
positive test of CRE in patients), other than the one
patient [redacted] as reported in the initial
3500A (submitted on 11/12/2013). That patient was
considered as a clinical case as [redacted] had developed an
active CRE infection (MBL). Further, information was
provided to one additional patient [redacted]
[redacted] that is considered as a surveillance culture
positive. This was confirmed by information provided on
02/14/2014 and 02/18/2014 by the hospital (Advocate
General Hospital).
H11 Corrected Data:
A2: Patient age was reported in error, instead of 4[redacted]
[redacted]
```

Form Approved: OMB No. 0910-0291, Expires: 8/30/2016
See OMB statement on reverse.

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

Mfr Report # 2518897-2013-00006

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
[redacted]			

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(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)*
	02/25/2014

5. Describe Event or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Unique Identifier (UDI) #	☐ Lay User/Patient
		☐ Other:

6. 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

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 treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) — Name; Address; Email Address
2. Phone Number
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☑ Other: CDC
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 2
8. Adverse Event Term(s)
9. Manufacturer Report Number 2518897-2013-00006

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)* Patient Code 1930 - ____ - ____ Device Code ____ - ____ - ____ Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Form Approved: OMB No. 0910-0291, Expires: 8/30/2015
See OMB statement on reverse.

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

Mfr Report # 2518897-2014-00002

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier [redacted]

2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [ ] Hospitalization - initial or prolonged
- [x] 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): 03/06/2014

5. Describe Event or Problem

It was reported by facility on February 14, 2014; patient had underwent Endoscopic retrograde cholangiopancreatography (ERCP) procedure on Patient Information and was tested for CRE. Test results Patient Information revealed patient tested positive for Carbapenem-resistant Enterobacteriaceae (CRE), but had not developed an active CRE infection e.g., Klebsiella pneumoniae carbapenemase (KPC); metallo-ß-lactamases (MBL): New Delhi MBL (NDM); and Verona integron-encoded MBL (VIM). Additional information from the facility revealed one more patient [redacted] tested positive for CRE, but had not developed an active infection. These both cases are being reported as they are surveillance culture positive cases. There was no further information provided by the facility. This is 1 of 2 reports.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Specimen from patient, and cultured for Carbapenem resistant enterobacteriaceae (CRE) on Patient Information Test results: Patient positive test on Patient Information

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1

#2

2. Dose, Frequency & Route Used

#1

#2

3. Therapy Dates (if unknown, give duration) from/to (or best estimate)

#1

#2

4. Diagnosis for Use (Indication)

#1

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 [ ] Yes [ ] No [ ] Doesn't Apply

#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #

#1

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 [ ] Yes [ ] No [ ] Doesn't Apply

#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: PENTAX VIDEO DUODENOSCOPE

2. Common Device Name

2b. Procode: FDT

3. Manufacturer Name, City and State: PENTAX Medical, Montvale, NJ

4. Model #: ED-3490TK

Lot #

5. Operator of Device
- [x] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #: A110471

Unique Identifier (UDI) #

6. 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 [x] 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 [x] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Patient Information
Advocate Lutheran General Hospital
1775 Dempster Street
Park Ridge, IL 60068

Phone #: [redacted]atient Information

Email Address: Patient Information @advocatehealth.com

2. Health Professional? [x] Yes [ ] No

3. Occupation: Other Healthcare Profess

4. Initial Reporter Also Sent Report to FDA? [ ] Yes [ ] No [x] Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☑ Importer
2. UF/Importer Report Number: 2518897-2014-00002
3. User Facility or Importer Name/Address:
PENTAX Medical
3 Paragon Drive
Montvale, NJ 07645
4. Contact Person: [redacted]
5. Phone Number: [redacted]
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*: 02/14/2014
7. Type of Report: ☑ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*: 03/06/2014
9. Approximate Age of Device: 2yrs
10. Event Problem Codes *(Refer to coding manual)*
Patient Code: 1930
Device Code:
11. Report Sent to FDA? ☑ Yes 03/06/2014 *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☑ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:
Hoya Corporation PENTAX Miyagi Factory
30-2 Okada Aza-Shimomiyano
Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: [redacted]
Address:
3 Paragon Drive
Montvale, NJ 07645
Hoya Corporation PENTAX Miyagi Factory
30-2 Okada Aza-Shimomiyano
Email Address: [redacted]
2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 02/14/2014
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K092710 Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s)
9. Manufacturer Report Number: 2518897-2014-00002

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☑ No *(Attach page to explain why not)* or provide code: B1
4. Device Manufacture Date *(mm/yyyy)*: 06/13/2012
5. Labeled for Single Use? ☐ Yes ☑ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code: 1930
Device Code:
Method: 3263 - 3317
Results: 3221
Conclusions: 67
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

H10 Additional Narrative:
B5: PENTAX Medical was only recently (02/14/2014) made aware of patients with CRE organism after undergoing ERCP procedure with scope (serial number A110471). The scope was a loaner scope provided by PENTAX Medical and was shipped to the facility on 06/26/2013, and returned to PENTAX Medical on 08/16/2013. The facility did not test the scope for CRE.
H3, H6: A review of the Device History Records (DHR) showed there were no reports of any non-conformance issues during the manufacturing in-process and final inspection. The device was manufactured according to specifications. PENTAX did not evaluate the scope at the time of return from facility, as there were no reports coming from the facility of any adverse events or malfunctions associated with the scope. The scope has since then been in use at other user facilities and there have been no reports coming out from those facilities of any CRE cases associated with this scope.

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report # 2518897-2014-00002

User Facility/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier [redacted]

2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(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)*: 03/06/2014

5. Describe Event or Problem

It was reported by facility on February 14, 2014; patient had underwent Endoscopic retrograde cholangiopancreatography (ERCP) procedure on Patient Information and was tested for CRE. Test results Patient Information revealed patient tested positive for Carbapenem-resistant Enterobacteriaceae (CRE), but had not developed an active CRE infection e.g., Klebsiella pneumoniae carbapenemase (KPC); metallo-β-lactamases (MBL); New Delhi MBL (NDM); and Verona integron-encoded MBL (VIM). This is 2 of 2 reports.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Specimen from patient, and cultured for Carbapenem resistant enterobacteriaceae (CRE) on Patient Information. Test results: Patient positive test on Patient Information

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1

#2

2. Dose, Frequency & Route Used

#1

#2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*

#1

#2

4. Diagnosis for Use *(Indication)*

#1

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date *(mm/dd/yyyy)*

Serial #

Unique Identifier (UDI) #

5. Operator of Device

- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. 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

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 treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #

Email Address

2. Health Professional? ☐ Yes ☐ No

3. Occupation

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

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number: 2518897-2014-00002
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)*
   - Patient Code: 1930 - - -
   - Device Code: - - -
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name
   - Address
   - Email Address
2. Phone Number
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # _____ IND # _____ BLA # _____ PMA/510(k) # _____
   - Combination Product ☐ Yes
   - Pre-1938 ☐ Yes
   - OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s)
9. Manufacturer Report Number: 2518897-2014-00002

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
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: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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 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:

Department of Health and Human Services
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.

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 Approved: OMB No. 0910-0291; Expires: 8/30/2015
See OMB statement on reverse.

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

Mfr Report #

UF/Importer Report # 2518897-2015-00027

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☑ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (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): Patient Information

4. Date of This Report (mm/dd/yyyy): 07/18/2015

5. Describe Event or Problem

On 07/15/2015 PENTAX Medical received a Maude Event Report Patient Information from FDA involving a Video Duodenoscope Model ED-3490TK/Serial Number A110592. It stated a user facility had reported that "after appropriate cleaning and high level disinfection routine culturing on the device elevator produced a positive results for carbapenem-resistant enterobacteriaceae (CRE). This patient is at risk for potential exposure to the organism."

On 07/17/2015 Pentax sent an e-mail to the facility for additional information. On 07/21/2015 the facility informed PENTAX Medical that it became aware of the positive culture results on Patient Information Additionally, the facility advised that it immediately removed the scope from service, and 2 (two) patients who underwent procedures with the scope were identified. The event date for use of the scope on the patients was Patient Information The patients were tested for CRE and no patient tested positive. Therefore, the response from facility indicates there was no patient injury.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, including Dates

(Continue on page 3)

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates (if unknown, give duration) from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use (indication)
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D SUSPECT MEDICAL DEVICE

1. Brand Name: PENTAX

2. Common Device Name	2b. Procode
Video Duodenoscope	FDT

3. Manufacturer Name, City and State
HOYA Corporation
Tokyo, Japan

4. Model #	Lot #	5. Operator of Device
ED-3490TK		☑ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other:
Serial #	Unique Identifier (UDI) #	
A110592		

6. 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

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: 08/03/2015 (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E INITIAL REPORTER

1. Name and Address
Identifying Information
Lutheran General Hospital
1775 Dempster St.
Park Ridge, IL 60068

Phone #	Email Address
Identifying Information	Identifying Information

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Other Healthcare Profess	☑ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☑ Importer

2. UF/Importer Report Number: 2518897-2015-00027

3. User Facility or Importer Name/Address:
PENTAX MEDICAL
3 Paragon Drive
Montvale, NJ 07645

4. Contact Person: [redacted]

5. Phone Number: [redacted]

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*: 07/15/2015

7. Type of Report: ☐ Initial ☐ Follow-up #

8. Date of This Report *(mm/dd/yyyy)*: 08/07/2015

9. Approximate Age of Device: TBD

10. Event Problem Codes *(Refer to coding manual)*

Patient Code	3189	2645	
Device Code	1091		

11. Report Sent to FDA? ☑ Yes 08/07/2015 *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred: ☑ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: *(Specify)*

13. Report Sent to Manufacturer? ☑ Yes 08/07/2015 *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address:
HOYA Corporation
PENTAX Life Care Tokyo Office
2-7-5 Naka-Pajao, Shinjuku-ku
Tokyo, Japan 161-8525

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name:
Address:
Contact office - See F.3 above
Manufacturing site - See F.14 above
Email Address: [redacted]

2. Phone Number: See F.5

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/15/2015

5. (A)NDA #: IND #: BLA #: PMA/510(k) #: K092710
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

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 #

8. Adverse Event Term(s):

9. Manufacturer Report Number:

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☑ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☑ No *(Attach page to explain why not)* or provide code: 11

4. Device Manufacture Date *(mm/yyyy)*: TBD

5. Labeled for Single Use? ☐ Yes ☑ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code	3189	2645	
Device Code	1091		
Method	3263		
Results	3233		
Conclusions	11		

7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:

8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Delete Page

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

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

Back to Item B.5

B.5. Describe Event or Problem *(continued)*

Back to Item B.6

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Back to Item B.7

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

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)*

Back to Item D.11

Other Remarks

Patient Code 3189 - Not Applicable; Patient Code 2645 - No Patient Involvement
Device 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

MAUDE Adverse Event Report: PENTAX PENTAX PENTAX DUODENOSCOPE

PENTAX PENTAX PENTAX DUODENOSCOPE

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/Recalls[23]

New Search | Submit an Adverse Event Report[24]

Brand Name PENTAX
Type of Device PENTAX DUODENOSCOPE
Manufacturer *(Section D)* PENTAX
3 Paragon Drive
Montvale NJ 07645
MDR Report Key 3252445
Report Number MW5031083
Device Sequence Number 1
Product Code FDT[25]
Report Source Voluntary
Reporter Occupation RISK MANAGER
Type of Report Initial
Report Date 07/23/2013
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 07/23/2013
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator Health Professional
Device MODEL Number ED-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.

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

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report # 2951238-2015-00127

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier [redacted]

2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
02/23/2015	03/09/2015

5. Describe Event or Problem

Olympus received a Voluntary MedWatch that stated a patient's blood culture tested positive for CRE Klebsiella Pneumonia after undergoing an Endoscopic Retrograde Cholangio-Pancreatography(ERCP)procedure.The user facility noted that the patient had no history of the this organism.

Olympus has made multiple attempts to contact the user facility for additional information by phone and in writing with no results. No further information is available at this time.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

[redacted]

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus EVIS EXERA II Duodenvideoscope

2. Common Device Name	2b. Procode
Duodenvideoscope	FDT

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
TJF-Q180V	N/A	☐ Other:
Serial #	Unique Identifier (UDI) #	
UNK	N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
[redacted]
Allegheny General Hospital
320 East North Avenue
Pittsburgh, PA 15212

Phone #	Email Address
[redacted]	[redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Risk Manager	☐ Yes ☐ No ☑ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: [redacted]
Address:
OLYMPUS AMERICA, INC
2400 Ringwood Avenue
San Jose, CA 95131
Email Address: [redacted]

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 03/09/2015

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K080403 Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes

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 # ____

8. Adverse Event Term(s):

9. Manufacturer Report Number: 2951238-2015-00127

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*: Unk
5. Labeled for Single Use? ☐ Yes ☑ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*:
   - Patient Code: 1735 - ____ - ____
   - Device Code: 1091 - 2303 - ____
   - Method: ____ - ____ - ____ - ____
   - Results: ____ - ____ - ____ - ____
   - Conclusions: 67 - 92 - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

The device referenced in this report has not yet been returned to Olympus for evaluation. If any additional information becomes available this report will be supplemented accordingly.

As part of our investigation with this report, an Olympus Endoscopy Support Specialist (ESS) performed an In-Service and trained staff on TJF-180V reprocessing at the user facility on 05/24/2015. The ESS observed that the user facility was not following the IFU for reprocessing of duodenvideoscopes correctly. Freshwater was not being used for every scope, single-use items were being used to clean multiple scopes and reusable items were not autoclaved or high level disinfected per each use. Additionally, this account uses a third party for repairs and was unsure of the serial number of the scope.

Boca Raton Regional Hospital
Boca Raton, Florida

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

A. PATIENT INFORMATION

1. Patient Identifier *(In confidence)*	[redacted]	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)*

- [ ] Death
- [ ] Life-threatening
- [ ] Hospitalization - Initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [X] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/11/2014	04/14/2015

5. Describe Event or Problem

Olympus was informed that a total of nine patients tested positive for Carbenepenum Resistant Enterbacteriaceae (CRE) Klebsiella pneumoniae, after having undergone an endoscopic retrograde cholangiopancreatography (ERCP) procedure. However only six of those patients used an Olympus duodenovideoscope during their ERCP procedures. The other three patients underwent a procedure using either a Fuji or Pentax duodenovideoscope.

Olympus followed up with the user facility and was informed that they have implemented a double (2x's) with high level (HLD) disfectant in the AER disinfection process for all duodenovideoscopes. It was reported by the user facility that since mid 2014, they began to monitor and randomly cultured all their duodenovideoscopes after confirming five patient infections of CRE-KP ranging from August 08, 2014 to December 12, 2014 after each had undergone a ERCP procedure. The initial five patient infections with CRE-KP were confirmed utilizing test methods ranging from sputum, blood, urine, liver aspirate, and bile drainage. The patients were treated with antibiotics. It was reported that there were no further issues with the duodenovideoscopes testing positive until a sixth patient tested positive for Extended Spectrum Beta-Lactamase (ESBL) strain following the March 16, 2015 ERCP procedure using the same duodenovideoscope (s/n: 2102101). On March 21, 2015 the duodenovideoscope cultured positive, with the same ESBL strain. The duodenovideoscope was then sequestered, re-cleaned and underwent double (2x's)HLD in the AER disinfection cycle. The duodenovideoscope was re-cultured and showed no growth. The duodenovideoscope was placed back in service on March 24, 2015. The user facility said they will continue to monitor and complete random testing to control the issue in-house so no further issues occur.

This is the first of six reports.

6. Relevant Tests/Laboratory Data, Including Dates

Blood and urine test on 12/12/2014

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Pancreatic carcinoma

C. SUSPECT PRODUCT(S)

Section C is not applicable to devices.

D. SUSPECT MEDICAL DEVICE

1. Brand Name	2. Common Device Name	
Olympus EVIS EXERA II DUODENOVIDEOSCOPE	Duodenovideoscope, Product Code: FDT	
3. Manufacturer Name, City and State	**4. Model #**	**Catalog #**
OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA	TJF-Q180V	TJF-Q180V
	Serial # 2102101	**Lot #**
	Expiration Date *(mm/dd/yyyy)*	**Other #**
5. Operator of Device	**6. Implanted Date** *(mm/dd/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 Evaluation? *(Do not send to FDA)*
	( ) Yes (•) No ( ) No Information [ ] Returned to Manufacturer

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

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

[redacted]
Boca Raton Regional Hospital, Inc.
800 Meadows Road
Boca Raton, FL 33486-2368, US
[redacted]

2. Health Professional?
(•) Yes ( ) No ( ) No Information

3. Occupation
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
( ) User Facility ( ) Importer

2. User Facility/Importer Number

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)*
Patient Code(s): 1735
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

14. Manufacturer Name/Address
CA, US

G. ALL MANUFACTURERS

1, 2. Contact Office - Name/Address/Phone Number

[redacted]
Olympus America
2400 Ringwood Ave
San Jose, CA 95131, US
[redacted]

1, 2. (Continued) Manufacturing Site Address/Phone for Devices

3. Report Source *(Check all that apply)*

[ ] Foreign
[ ] Study
[ ] Literature
[ ] Consumer
[ ] Other
[X] Health Professional
[X] User Facility
[X] Company Representative
[ ] Distributor

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

5. PMA/510(k)
K080403

6. If IND, Give Protocol #

7. Type of Report
[ ] 5-day [X] Initial [ ] Follow-up

8. Adverse Event Term(s)

9. Manufacturer Report Number
2951238-2015-00184

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
( ) Death
(•) Serious Injury
( ) Malfunction
( ) No Information

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation
[ ] No Information

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
( ) Yes [ ] Evaluation Summary Attached
(•) No

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

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
( ) Yes ( ) No ( ) No Information

6. Evaluation Codes *(Refer to coding manual)*
Method Code(s): 3320
Result Code(s):
Conclusion Code(s): 20 - 67

7. If Remedial Action Initiated, Check Type
[ ] Recall
[ ] Repair
[ ] Replace
[ ] Relabeling
[ ] Other
[ ] Notification
[ ] Inspection
[ ] Patient Monitoring
[ ] Modification/Adjustment

8. Usage of Device
( ) Initial Use of Device
( ) Reuse
( ) Unknown
( ) No Information

9. If action reported to FDA under 21 USC 360l(f), list correction/removal reporting number

10. [X] Additional Manufacturer Narrative **and/or 11.** [ ] Corrected Data

The device referenced in this report has been returned to Olympus for evaluation. However, the device was sent to an off-site independent laboratory for further testing. Once returned a physical evaluation will be performed on the referenced device. 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.

As part of our investigation with this report, an Endoscopy Support Specialist (ESS) visited the user facility to observe the user facility's reprocessing practices. During the on-site visit, several reprocessing practices were discussed such as manual cleaning, pre-cleaning, manual cleaning w/HLD, Rinsing, Alcohol flush but were not demonstrated as the customer stated that they are using a Medivator DSD-Edge AER. It was also reported that the customer sometimes lay down their scopes coiled up after removing from the AER. The customer was informed that the scopes need to be hung immediately after the HLD process. It was noted that the user facility was not using a MH-856 (suction cleaner adapter), as recommended in the instruction manual.

Please cross-reference the associated complaints:
2951238-2015-00185, 2951238-2015-00186, 2951238-2015-00187, 2951238-2015-00188, 2951238-2015-00197

File Attachments

No files attached.

Carolinas Medical Center,
Charlotte North Carolina

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

A. PATIENT INFORMATION

1. Patient Identifier *(In confidence)*		4. Weight
	[redacted]	

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
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	05/14/2015

5. Describe Event or Problem

In an article published on May 15, 2015, it was reported that a patient at a medical center died in 2013 as a result of carbapenem-resistant Enterobacteriacaea (CRE) infection following an ERCP procedure using an Olympus duodenoscope.

Olympus followed up with the user facility in an effort to obtain additional information regarding the reported event, but with no results after multiple inquiries.

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.)*

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, Product Code: FDT	
3. Manufacturer Name, City and State	**4. Model #**	**Catalog #**
Olympus Medical System Corporation 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, JA	TJF-Q180V	TJF-Q180V
	Serial #	**Lot #**
	Unk	N/A
	Expiration Date *(mm/dd/yyyy)*	**Other #**
5. Operator of Device	**6. Implanted Date** *(mm/dd/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 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?
[redacted] Carolinas Medical Center 1000 Blythe Blvd. Charlotte, NC 28203-5871, US [redacted] Email:Unk	(•) Yes ( ) No ( ) No Information
	3. Occupation Risk Manager
	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

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

( ) 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)*
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

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1, 2. Contact Office - Name/Address/Phone Number

[redacted]
Olympus America, Inc.
2400 Ringwood Avenue
San Jose, CA 95131, US
[redacted]

1, 2. (Continued) Manufacturing Site Address/Phone for Devices

3. Report Source *(Check all that apply)*
[ ] Foreign
[ ] Study
[X] Literature
[X] Consumer
[ ] Other
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/14/2015

5. PMA/510(k)
K080403

6. If IND, Give Protocol #

7. Type of Report
[ ] 5-day [X] Initial [ ] Follow-up

8. Adverse Event Term(s)

9. Manufacturer Report Number
2951238-2015-00254

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
(•) Death
( ) Serious Injury
( ) Malfunction
( ) No Information

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation
[ ] No Information

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
( ) Yes [ ] Evaluation Summary Attached
(•) No

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
( ) Yes (•) No ( ) No Information

6. Evaluation Codes *(Refer to coding manual)*
Method Code(s):
Result Code(s):
Conclusion Code(s): 67 - 92

7. If Remedial Action Initiated, Check Type
[ ] Recall
[ ] Repair
[ ] Replace
[ ] Relabeling
[ ] Other
[ ] Notification
[ ] Inspection
[ ] Patient Monitoring
[ ] Modification/Adjustment

8. Usage of Device
( ) Initial Use of Device
(•) Reuse
( ) Unknown
( ) No Information

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number

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.

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 #:	2951238-2015-00254
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.

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

A. PATIENT INFORMATION

1. Patient Identifier *(In confidence)*	2. Age at Time of Event, Date of Birth	3. Sex	4. Weight
		No Information	

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
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	05/14/2015

5. Describe Event or Problem

Olympus became aware of a news article in February 2015 which reported that 18 people at one medical center had carbapenem-resistant Enterobacteriacaea (CRE) in the first months of 2015. Of those, 15 had CRE upon admission to the hospital; three acquired it in the hospital, and one died. The cause of death was not reported. No details were reported about how the three became infected in the hospital. Olympus followed up with the user facility in an effort to obtain additional information regarding the reported event, but with no results after multiple inquiries.

In an article published on May 15, 2015, it was reported that a patient at the same medical center had allegedly died in 2013 as a result of CRE infection following an ERCP procedure using an Olympus duodenoscope. Because the May 15 article reports that an Olympus product was allegedly associated with CRE infection at the medical center in 2013, Olympus has determined to submit a report for the three CRE cases discussed in the February 2015 article based on the possibility that an Olympus duodenoscope may have been associated with the three CRE events reported to have been acquired at this medical center earlier this year.

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.)*

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, Product Code: FDT	
3. Manufacturer Name, City and State	**4. Model #**	**Catalog #**
Olympus Medical System Corporation 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, JA	Unk	Unk
	Serial #	**Lot #**
	Unk	N/A
	Expiration Date *(mm/dd/yyyy)*	**Other #**

5. Operator of Device	6. Implanted Date *(mm/dd/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 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?
[redacted] Carolinas Medical Center 1000 Blythe Blvd.	(•) Yes ( ) No ( ) No Information
	3. Occupation

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

Charlotte, NC 28203-5871, US
[redacted]
Email:Unk

Risk Manager

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
( ) User Facility ( ) Importer

2. User Facility/Importer Number

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)*
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

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1, 2. Contact Office - Name/Address/Phone Number
[redacted]
Olympus America, Inc.
2400 Ringwood Avenue
San Jose, CA 95131, US
[redacted]

1, 2. (Continued) Manufacturing Site Address/Phone for Devices

3. Report Source *(Check all that apply)*
[ ] Foreign
[ ] Study
[X] Literature
[X] Consumer
[ ] Other
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/14/2015

5. PMA/510(k)
Unk

6. If IND, Give Protocol #

7. Type of Report
[ ] 5-day [X] Initial [ ] Follow-up

8. Adverse Event Term(s)

9. Manufacturer Report Number
2951238-2015-00281

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
(•) Death
( ) Serious Injury
( ) Malfunction
( ) No Information

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation
[ ] No Information

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
( ) Yes [ ] Evaluation Summary Attached
(•) No

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
( ) Yes (•) No ( ) No Information

6. Evaluation Codes *(Refer to coding manual)*
Method Code(s):
Result Code(s):
Conclusion Code(s): 67 - 92

7. If Remedial Action Initiated, Check Type
[ ] Recall
[ ] Repair
[ ] Notification
[ ] Inspection

8. Usage of Device
( ) Initial Use of Device
(•) Reuse

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number

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

[ ] Replace [ ] Relabeling [ ] Other	[ ] Patient Monitoring [ ] Modification/Adjustment	( ) Unknown ( ) No Information	

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.

Please cross reference Mfr. Report Number: 2951238-2015-00254, 2951238-2015-00258, and 2951238-2015-000259.

File Attachments

No files attached.

Cedars-Sinai Medical Center
Torrance, California

OLYMPUS

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report # 2951238-2015-00094
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: unk *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - Initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/01/2014-02/28/2015	03/04/2015

5. Describe Event or Problem

Olympus was informed that four patient's may have been infected by a "drug resistant organism" of Carbapenem-resistant 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.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name Olympus Duodenovideoscope

2. Common Device Name	2b. Procode
Duodenovideoscope	KOG

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
Unk	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Unk	N/A	☐ Other:
Serial #	Unique Identifier (UDI) #	
Unk		

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
[redacted]
Cedars-Sinai Medical Center
4100 W. 190th Street
Torrance, CA 90504-5513

Phone #	Email Address
[redacted]	[redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Risk Manager	☐ Yes ☐ No ☑ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   Name: [redacted]
   Address: OLYMPUS AMERICA, INC
   2400 Ringwood Avenue
   San Jose, CA 95131
   Email Address: [redacted]
2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☑ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 03/04/2015
5. (A)NDA# ____ IND# ____ BLA# ____ PMA/510(k)# ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 2951238-2015-00094

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☑ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*: Unk
5. Labeled for Single Use? ☐ Yes ☑ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*:

Patient Code	1802	1735		
Device Code	1120	2303		
Method				
Results				
Conclusions	20	92		

7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

The device referenced in this report has not been returned to Olympus for evaluation. The exact cause of the reported event could not be conclusively determined at this time. However, an Olympus Endoscopy Support Specialist (ESS) has been scheduled to visit the site to perform a demonstration of Olympus recommended reprocessing practice.

If additional information becomes available at a later time, this report will be supplemented.

Please cross reference mfr. report numbers: 2951238-2015-00095, 2951238-2015-00140, and 2951238-2015-00141.

Charite-Universitatsmedizin
Berlin, Germany

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2013-00092
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
Unk In confidence	Unk or Unk	☐ Female ☐ Male	Unk lbs or Unk kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
Unk	3/27/2013

5. Describe Event or Problem
he subject device was returned to OLYMPUS Deutschland GmbH (ODE) for repair purpose. ODE sterilized and repaired the subject device as routine work. After that, ODE received the information that some patients which were treated with the subject device got a Klebsiella infection. According to information from the facility, the same bacteria was not detected from the subject device. There was no additional information.

6. Relevant Tests/Laboratory Data, Including Dates
Unk

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
Unk

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 N/A
#2 N/A

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 N/A #2 N/A	#1 #2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 N/A #2 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 N/A #2 N/A	#1 N/A #2 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
N/A

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE
2. Common Device Name: DUODENOENDOSCOPE
3. Manufacturer Name, City and State:
OLYMPUS MEDICAL SYSTEMS CORPORATION.
2951 Ishikawa-cho Hachiouji-shi, Tokyo, 192-8507 Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
N/A		☐ Other:
Serial #	Other #	
2000700	N/A	

6. 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

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 treatment of event)*
N/A

E. INITIAL REPORTER

1. Name and Address | Phone #

[redacted]
Charite-Universitatsmedizin Berlin
Campus Virchow-Klinikum Humboldt
Universitat zu Berlin
Augustenburger Platz 1
13353 Berlin Germany

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No		☐ Yes ◉ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 1735 - - ; Device Code 3190 - -
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
[redacted]
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan
2. Phone Number:
3. Report Source *(Check all that apply)*: ☑ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 3/28/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 8010047-2013-00092

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: Potential Infection
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: August/2010
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method - - - - ; Results - - - - ; Conclusions 67 - 92 - - -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Since the subject device had already sterilized and repaired, OLYMPUS MEDICAL SYSTEMS CORP. (OMSC) could not evaluate it. Thus, OMSC cannot conclusively determine the cause of this event. However, it can be considered as a possible cause of this phenomenon that patients infected from other than the endoscope and procedure such as environmental factor in the facility, because the same bacteria was not detected from the subject device.

This report is being submitted as a medical device report in an abundance of caution.

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2013-00092
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*

5. Describe Event or Problem

his is a supplemental report for Mfr Report # 8010047-2013-00092 to provide additional information based on the report from the user facility through BfArM, Competent Authority in Germany.
A patient who had been diagnosed with Klebsiella pneumoniae was examined on February 8th 2013. In total, the subject device was used to carry out another twenty-eight examination on twenty-six patients between February 8th and March 11th before it was sent to Olympus for repair. Subsequently, K. pneumoniae were found 5 of these patients. Two of the five patients have since died. OLYMPUS MEDICAL SYSTEMS CORP. has not been informed the cause of the patient death.

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 N/A
#2 N/A

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 N/A	#1
#2 N/A	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 N/A	#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
N/A

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. 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

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 treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		◉ Yes ☐ No ☐ Unk.

FDA USE ONLY

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

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
2. Phone Number
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 1
8. Adverse Event Term(s)
9. Manufacturer Report Number
8010047-2013-00092

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

According to the request from the user facility, OLYMPUS EUROPA disassembled the subject device in conjunction with personnels from the user facility. They took eight samples from each part dismantled from the subject device for culture test. The personnels from the user facility brought them back and performed the culture test. Subsequently, all samples collected from the parts were tested negative.
Based on the result of the culture test, OLYMPUS MEDICAL SYSTEMS CORP. thinks that this event was most likely caused due to the other cause than the subject device.

Clinique De Bercy
Charenton-le-Pont, France

8-12-0045

FR

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 0910-0291, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2012-00452

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
in confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: _____ *(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)*
10/08/2012	11/21/2012

5. Describe Event or Problem

The user facility reported to identified biliary infections of 3 patients that underwent ERCP at the facility and tested positive for Escherichia coli. There was no report of infections or other patient harm.

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
N/A

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name: DUODENOENDOSCOPE

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEMS CORPORATION.
2951 Ishikawa-cho Hachiouji-shi,Tokyo, 192-8507 Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V		☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Serial #	Other #	☐ Other:
2101357		

6. 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

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 treatment of event)*

E. INITIAL REPORTER

1. Name and Address: [redacted]
Clinique De Bercy
Charention Le Point, 94, France

Phone #: [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Other Healthcare Professional	☐ Yes ◉ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 2199 - - ; Device Code 1091 - -
11. ort Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:

[redacted]

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☑ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/21/2012

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes

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 # ____

8. Adverse Event Term(s):

9. Manufacturer Report Number: 8010047-2012-00452

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: Potential Infection
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: 01/2011
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method ; Results ; Conclusions 67 - 92 - -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Olympus followed up with the user facility to obtain additional information regarding this report, and was informed that the device had been cultured, but was negative for growth at the facility.
The subject device was not returned to Olympus for evaluation, and will be sent to an independent microbiology laboratory for microbiological testing. At the present time, the exact cause of the reported phenomenon cannot be determined, however insufficient reprocessing and user handling cannot be ruled out as contributory factors.
If significant additional information is received, a supplemental report will follow.

This report is being submitted as a Medical Device Report in an abundance of caution.

Cross-reference Mfr. Report# 8010047-2012-00453, and 8010047-2012-00454 for other related reports.

Form Approved: OMB No. 09 10-029 1, Expires12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2013-00595

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
Unk In confidence	Unk or Unk	☐ Female ☐ Male	Unk lbs or Unk kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
11/08/2013	11/21/2013

5. Describe Event or Problem

Olympus Medical Systems CORP. (OMSC) was informed that after endoscopic retrograde cholangiopancreatography (ERCP) using the subject device, Enterobacteries and Pseudomonas were detected from two patients. The user facility said the same bacteria were detected from the instrument channel and the suction channel of the subject device, too. The outcome of the patients is unknown.

6. Relevant Tests/Laboratory Data, Including Dates

Unk

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Unk

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 N/A

#2 N/A

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 N/A	#1
#2 N/A	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 N/A	#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

N/A

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name: DUODENOENDOSCOPE

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEMS CORPORATION.
2951 Ishikawa-cho Hachiouji-shi, Tokyo, 192-8507 Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
N/A		☐ Other:
Serial #	Other #	
2101336	N/A	

6. 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

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 treatment of event)*

N/A

E. INITIAL REPORTER

1. Name and Address

Clinique de Bercy
9 Quai de Bercy, 94220 Charenton-le-Pont, France

Phone # [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No		☐ Yes ◉ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 1735 – – ; Device Code 3190 – –
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
[redacted]
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan
2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☑ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/25/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 8010047-2013-00595

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: Potential Infection
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: 01/2011
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method – – – ; Results – – – ; Conclusions 67 – 92 – –
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Olympus France investigated the reprocessing practice in the facility. The facility brushed the distal end, the instrument channel, the suction channel, and the instrument channel opening with the same cleaning brush, which Olympus does not recommend. In addition, the instruction manual of the subject device directs to use the specific cleaning brush for the distal end and the instrument channel opening, which is different from the cleaning brush used for the instrument channel and the suction channel. Olympus Medical Systems CORP (OMSC) could not determine the root cause of this event. However, improper reprocessing could not be ruled out as a contributory factor to the reported event.

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/20
See OMB statement on rever

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

Mfr Report # 8010047-2015-00210

UF/Importer Report #

FDA Use On

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(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)*
11/08/2013	11/21/2013

5. Describe Event or Problem

Olympus Medical Systems CORP. (OMSC) was informed that after endoscopic retrograde cholangiopancreatography (ERCP) using the subject device, Enterobacteries and Pseudomonas were detected from two patients. The user facility said the same bacteria were detected from the instrument channel and the suction channel of the subject device, too. The outcome of the patients is unknown.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name	2b. Procode
DUODENOENDOSCOPE	

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEMS CORPORATION.
2951 Ishikawa-cho Hachiouji-shi, Tokyo, 192-8507 Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	**Expiration Date *(mm/dd/yyyy)***	☐ Lay User/Patient
TJF-Q180V	N/A	☐ Other:
Serial #	**Unique Identifier (UDI) #**	
2101336	N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
Clinique de Bercy
9 Quai de Bercy, 94220 Charenton-le-Pont, France

Phone #	Email Address
[redacted]	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No		☐ Yes ☑ No ☐ Unk

PLEASE TYPE OR USE BLACK INK

MEDWATCH

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

FDA USE ONLY

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

1. Check One: [x] User Facility [ ] Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*
   Patient Code: ____ - ____ - ____
   Device Code: ____ - ____ - ____
11. Report Sent to FDA? [ ] Yes ____ *(mm/dd/yyyy)* [ ] No
12. Location Where Event Occurred: [ ] Hospital [ ] Outpatient Diagnostic Facility [ ] Home [ ] Ambulatory Surgical Facility [ ] Nursing Home [ ] Outpatient Treatment Facility [ ] Other: ____ *(Specify)*
13. Report Sent to Manufacturer? [ ] Yes ____ *(mm/dd/yyyy)* [ ] No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   Name: [redacted]
   Address: OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
   Email Address:
2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: [x] Foreign [ ] Study [ ] Literature [ ] Consumer [x] Health Professional [x] User Facility [ ] Company Representative [ ] Distributor [ ] Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/25/2013
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product [ ] Yes Pre-1938 [ ] Yes OTC Product [ ] Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: [ ] 5-day [x] 30-day [ ] 7-day [ ] Periodic [ ] 10-day [x] Initial [ ] 15-day [ ] Follow-up # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 8010047-2015-00210

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: [x] Death [x] Serious Injury [ ] Malfunction
2. If Follow-up, What Type? [ ] Correction [ ] Additional Information [ ] Response to FDA Request [ ] Device Evaluation
3. Device Evaluated by Manufacturer? [ ] Not Returned to Manufacturer [ ] Yes [ ] Evaluation Summary Attached [ ] No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? [ ] Yes [ ] No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
   Patient Code: 1735 - ____ - ____
   Device Code: 3190 - ____ - ____
   Method: ____ - ____ - ____ - ____
   Results: ____ - ____ - ____ - ____
   Conclusions: 67 - 92 - ____ - ____
7. If Remedial Action Initiated, Check Type: [ ] Recall [ ] Notification [ ] Repair [ ] Inspection [ ] Replace [ ] Patient Monitoring [ ] Relabeling [ ] Modification/Adjustment [ ] Other: ____
8. Usage of Device: [ ] Initial Use of Device [ ] Reuse [ ] Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. [x] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

This report is being submitted upon further review of the MDR complaint filed on December 17, 2013 (Mfr# 8010047-2013-00595). It has been determined that one additional MDR is needed to account for the reported number of patients allegedly infected by the scope.

Please cross reference these associated complaints: 8010047-2013-00595

Olympus France investigated the reprocessing practice in the facility. The facility brushed the distal end, the instrument channel, the suction channel, and the instrument channel opening with the same cleaning brush, which Olympus does not recommend. In addition, the instruction manual of the subject device directs to use the specific cleaning brush for the distal end and the instrument channel opening, which is different from the cleaning brush used for the instrument channel and the suction channel. Olympus Medical Systems CORP (OMSC) could not determine the root cause of this event. However, improper reprocessing could not be ruled out as a contributory factor to the reported event.

Erasmus Medical Center
Rotterdam, Netherlands

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/1
See OMB statement on reverse

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2012-00157

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
Unk In confidence	Unk or ____ Unk	☐ Female ☐ Male	Unk lbs or Unk kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☑ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(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)*
January/2012	4/26/2012

5. Describe Event or Problem

In April 2012, the user facility reported that Pseudomonas aeruginosa were identified from 16 patients. The facility also reported that the device was tested because the patients received endoscopic diagnosis using the device before and same bacteria was detected in the sample which collected from distal end the device. The microbiology test for patients had been reportedly conducted since January 2012. There is no additional information on the patients.

evant Tests/Laboratory Data, Including Dates

Unk

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Unk

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 N/A

#2 N/A

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 N/A	#1
#2 N/A	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 N/A	#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 N/A	#2 N/A	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

N/A

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name: DUODENOENDOSCOPE

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEMS CORPORATION.
2951 Ishikawa-cho Hachiouji-shi,Tokyo, 192-8507 Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
N/A		☐ Other:
Serial #	Other #	
2101363	N/A	

6. 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

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 treatment of event)*

N/A

E. INITIAL REPORTER

1. Name and Address

[redacted]
Erasmus Medical Center,
Rotterdam Netherland

Phone # [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☐ Yes ◉ No ☐ Unk

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 1735 - - ; Device Code 3190 - -
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
[redacted]
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan
2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☑ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 4/26/2011
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 8010047-2012-00157

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: Potential Infection
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: January /2011
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method ; Results ; Conclusions 67 - 92 -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
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, 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.

This report is being submitted as a medical device report in an abundance of caution.

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report # 8010047-2012-00157
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
1/4/2012	

5. Describe Event or Problem

This supplemental report is being submitted to provide additional information based on the medical journal article that Olympus found on April 27, 2015.

From January to April 2012, 30 patients with a VIM-2-producing Pseudomonas aeruginosa were identified. 22 out of 30 patients had undergone an endoscopic retrograde cholangiopancreatography (ERCP) using the subject device. 8 out of 30 patients had not undergone an ERCP. 7 out of 8 patients without a history of ERCP had a history of ICU stay. The device was introduced to the user facility in February 2011. No infection in which the device was involved occurred until January 2012. The device was withdrawn from clinical use on March 14, 2012.

The first patient underwent an ERCP on January 3, 2012 with the device, and subsequently the VIM-2 (Type-B) was isolated from patient's blood culture on January 4, 2012.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. 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

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 treatment of event)*
Enzymatic cleaner for manual cleaning
ETD-3 in combination with peracetic acid as a disinfectant

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)*: Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
Address
Email Address
2. Phone Number
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☑ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # _____ IND # _____ BLA # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 2
8. Adverse Event Term(s)
9. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
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: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

According to the journal, the user facility cultured the subject device, and clonal relatedness of the VIM-2 P. aeruginosa was confirmed for 22 cases and for the VIM-2 strain isolated under the forceps elevator of the device. Enterococcus faecium was also isolated from this site. Environmental sampling was performed, and revealed the VIM-2 P. aeruginosa in four sinks at the Gastroenterology and Hepatology (GEH) department and in a water recipient in the endoscopy suite. In addition, the VIM-2 is known to be present at the ICU at a low endemic level.

Repair history of the device was reviewed by an Olympus subsidiary in Europe. The record showed that the device was repaired one time in November 2011. The device passed all inspection items of final inspection after the repair.

It could not be identified that the device or environment such as the GEH department and the ICU related to the patient infection. The cause of the infection could not be conclusively determined.

Evangelisches Waldkrankenhaus Spandu
Berlin, Germany

OLYMPUS

Your Vision, Our Future

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,

[redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2014-00393

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: R. R. (in confidence)
2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- [ ] Death: _____ *(mm/dd/yyyy)*
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [ ] Hospitalization - initial or prolonged
- [x] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*: 05/26/2014

4. Date of This Report *(mm/dd/yyyy)*: 06/12/2014

5. Describe Event or Problem

Olympus was informed that four patients tested positive for carbapenem resistant Klebsiella pneumonia after having undergone an endoscopic retrograde cholangiopancreatography (ERCP) procedure. The patients were examined with the same duodenovideoscope.

The user facility conducted a control test on the endoscope on Jun 3, 2014, and Klebsiella pneumonia was found. The last routine sampling of the endoscope on April 29, 2014 did not indicate anything abnormal.

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1
#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name: DUODENOENDOSCOPE

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	[x] Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	[ ] Lay User/Patient
TJF-Q180V	N/A	[ ] Other:
Serial #	**Other #**	
2202615	N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*: N/A

7. If Explanted, Give Date *(mm/dd/yyyy)*: N/A

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [x] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
N/A

10. Device Available for Evaluation? *(Do not send to FDA)*
[x] Yes [ ] No [x] Returned to Manufacturer on: 06/12/2014 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
[redacted]

Evangelisches Waldkrankenhaus Spandau
Stadtrandstraße 555, 13589 Berlin, Germany

Phone # [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
[x] Yes [ ] No	Physician	[ ] Yes [•] No [ ] Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 1735 – – ; Device Code 2303 – –
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☑ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:

[redacted]

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☑ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☑ Company Representative ☑ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/01/2014
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 8010047-2014-00393

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: 03/2012
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method 10 – 38 – – ; Results 142 – – – ; Conclusions 51 – – –
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

The referenced TJF-Q180V was returned to OLYMPUS EUROPA SE & CO. KG (OEKG) for evaluation. The evaluation confirmed brown stain and black foreign material on the instrument channel. In addition, there was black stain on the suction channel.

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 three patients: 8010047-2014-00407, 8010047-2014-00408, and 8010047-2014-00409.

Fox Chase Cancer Center,
Philadelphia, Pennsylvania

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report # 2431293-2015-00007

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☑ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
	06/05/2015

5. Describe Event or Problem

As reported by the customer:
Sometime between 04/21/2015 and 05/06/2015, the subject endoscope was cultured and tested positive for Klebsiella Pneumoniae.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Fujinon

2. Common Device Name	2b. Procode
Endoscope	78FDT

3. Manufacturer Name, City and State
Fujifilm Optics Co., Ltd. Mito Factory
4112 Tono, Hitachiomiya City, Japan 319-2224

4. Model #	Lot #	5. Operator of Device
ED-530XT		☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Serial #	Unique Identifier (UDI) #	☐ Other:
ND102A064		

6. 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

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: 05/22/2015 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
[redacted]
Fox Chase Cancer Center
333 Cottman Ave.
Philadelphia, PA 19111

Phone #	Email Address
[redacted]	

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☐ Yes ☐ No ☑ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____; Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name: [redacted]

Address:
Fujifilm Medical Systems USA Inc.
10 High Point Drive, Wayne, NJ 07470

Fujifilm Optics Co., Ltd, Mito Factory
4112 Tono,Hitachiomiya City, Japan

Email Address: [redacted]

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/06/2015

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K042076 Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes

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 # ____

8. Adverse Event Term(s):

9. Manufacturer Report Number: 2431293-2015-00007

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☑ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*: 12/21/2011
5. Labeled for Single Use? ☐ Yes ☑ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*:

Patient Code	3190		
Device Code	2895	2303	1091
Method	10		
Results	142		
Conclusions	18	61	

7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☑ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

On 05/07/2015, representatives from Fujifilm Medical Systems Endoscopy Division visited the facility as a follow up. At this time patient status is unknown and Risk Management is still investigating. It is believed three patients, which had multidrug resistant Klebsiella, had previously been exposed to the endoscope in question. It is unknown if the patients were infected by the endoscope.

Three subsequent contact attempts on 05/19/2015, 05/22/2015 and 05/26/2015 were made to the facility's Director of Patient Safety regarding condition of patients examined with the subject endoscope. As of 06/05/2015, no information has been provided by the facility.

On 05/22/2015, the subject endoscope was received at Fujifilm Medical Systems Endoscopy Division and placed in quarantine. The customer states that prior to shipment to Fujifilm, the subject endoscope was high level disinfected and subsequently tested negative on two occasions. It was then EO gas sterilized prior to shipment to Fujifilm.

Froedtert Hospital
Milwaukee, Wisconsin

OLYMPUS

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 2951238-2014-00023
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*

5. Describe Event or Problem

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. 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

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 treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ◉ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
2. Phone Number:
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 08/11/2014
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 2
8. Adverse Event Term(s):
9. Manufacturer Report Number: 2951238-2014-00023

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type?: ☒ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method 10 - 23 - 37 - 3264; Results 3251 - - - ; Conclusions 75 - - -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360l(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☑ Corrected Data

This supplemental report is being submitted to correct the incorrect MFR Report number of 2951238-2014-00041. The correct MFR Report number should be 2951238-2014-00023. See section G9.

As part of our investigation into this report the device was sent to an independent off-site laboratory for microbiological testing and Escherichia coli was recovered from the device. The device was then forwarded to Olympus for physical evaluation.

The device was returned to Olympus for evaluation. The device passed the leak test. The evaluation found no issues that could contribute or confirm the reported phenomenon. There was no sign of bio-materials in the device. The device was refurbished and returned to the user facility.

OLYMPUS

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.

Sincerely,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 2951238-2014-00023
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: In confidence
2. [redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: _____ (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): 05/19/2013
4. Date of This Report (mm/dd/yyyy): 01/06/2014

5. Describe Event or Problem

Olympus was informed that five patients tested positive for Carbenepenum Resistant Enterbacteriaceae containing New Delhi Metallo-beta-lactamase (CRE-NDM) after having undergone an endoscopic retrograde cholangiopancreatography (ERCP) procedure. The patients were examined with the same duodenovideoscope.

On April 25, 2013, resistant E.coli was found in the first patient's blood. On May 19, 2013 that patient underwent an ERCP with stone extraction subsequently developing cholangitis. On May 20, 2013 resistant E. coli was found in the patient's bile duct fluid. The patient was hospitalized for an unspecified amount of time. The patient was discharged went back to India.

An Endoscopy Support Specialist was dispatched to the user facility. A reprocessing in-service has not been scheduled to date.

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.)

Non-Hodgkin's Lymphoma, chemo, S/P autologous peripheral stem cell transplant (4/18/13), prior cholecystectomy, CBD dialation, MRCP shows some biliary stone

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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus EVIS EXERA II Duodenovideoscope
2. Common Device Name: Duodenovideoscope
3. Manufacturer Name, City and State:
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

4. Model #: TJF-Q180V
Lot #: N/A
Catalog #: TJF-Q180V
Expiration Date (mm/dd/yyyy): Unk
Serial #: 2101529
Other #: N/A

5. Operator of Device
☑ Health Professional
☐ Lay User/Patient
☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy): N/A
7. If Explanted, Give Date (mm/dd/yyyy): N/A

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
N/A

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 treatment of event)
Scope Buddy Model sn# unk
Medivators scope washer model/sn# unk

E. INITIAL REPORTER

1. Name and Address
[redacted]
Froedert Hospital
2900 W. Wisconsin Avenue
Milwaukee, WI 53226

Phone #: [redacted]

2. Health Professional? ☑ Yes ☐ No
3. Occupation: Risk Manager
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ◉ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code: 1735 - - ; Device Code: 2993 - -
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
[redacted]
OLYMPUS AMERICA, INC
2400 Ringwood Avenue
San Jose, CA 95131

OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☑ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/06/2014
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 2951238-2014-00023

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: unk
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method - - - ; Results - - - ; Conclusions 20 - - -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
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.

Please cross-reference the following reports for the other four patients: 2951238-2014-00024, 2951238-2014-00025, 2951238-2014-00026, and 2951238-2014-00027.

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Page 1 of 2

Mfr Report # 2951238-2014-00174

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
In confidence	or	☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
01/27/2014	05/02/2014

5. Describe Event or Problem

Olympus was informed that twelve patients tested positive for Escherichia coli (E. coli) containing Extended-Spectrum Beta Lactamase (ESBL) after having undergone an endoscopic retrograde cholangiopancreatography (ERCP) procedure. The positive cultures were isolated from the patient's blood, pseudocyst, and bile. The patients were examined with four different duodenovideoscopes. These duodenovideoscopes were cultured twice by the user facility. No organisms were isolated.

On January 27, 2014, the first patient underwent an ERCP. After the procedure, the patient reportedly tested positive for resistant E. coli. No additional information was available.

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.)*

Bile duct obstruction 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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus EVIS EXERA II Duodenovideoscope

2. Common Device Name: Duodenovideoscope

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	**Expiration Date *(mm/dd/yyyy)***	☐ Lay User/Patient
TJF-Q180V	Unk	☐ Other:
Serial #	**Other #**	
2304031	N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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
N/A

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 treatment of event)*
Custom Ultrasonics reprocessor

E. INITIAL REPORTER

1. Name and Address

[redacted]
Hartford Hospital
80 Seymour Street
Hartford, CT 06102

Phone # [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Administrator/Supervisor	☐ Yes ☐ No ◉ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*
   - Patient Code: 1735
   - Device Code: 2993
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

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

[redacted]

OLYMPUS AMERICA, INC
2400 Ringwood Avenue
San Jose, CA 95131

OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☑ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 05/02/2014
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 2951238-2014-00174

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: unk
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*
   - Method: ____ - ____ - ____ - ____
   - Results: ____ - ____ - ____ - ____
   - Conclusions: 20 - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

The device referenced in this report has not yet been returned to Olympus for evaluation.

As part of our investigation with this report, Olympus representatives visited the user facility to observe the user facility's reprocessing practices. There were minor deviations noted during the reprocessing of the device. It was noted that the user facility had no suction in the reprocessing room and the staff were not using a syringe to flush around the forceps elevator riser area.

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.

Please cross-reference the following reports for the other eleven cases: 2951238-2014-00211, 2951238-2014-00212, 2951238-2014-00213, 2951238-2014-00219, 2951238-2014-00220, 2951238-2014-00221, 2951238-2014-00222, 2951238-2014-00223, 2951238-2014-00224, 2951238-2014-00225 and 2951238-2014-00226.

OLYMPUS

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.

Sincerely,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report # 2951238-2015-00001

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
In confidence	or _____	☐ Female ☐ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*

5. Describe Event or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. 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

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: 01/29/2015 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)*
   Patient Code ____ - ____ - ____
   Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred
   ☐ Hospital ☐ Outpatient Diagnostic Facility
   ☐ Home ☐ Ambulatory Surgical Facility
   ☐ Nursing Home
   ☐ Outpatient Treatment Facility
   ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   Name
   Address
   Email Address
2. Phone Number
3. Report Source *(Check all that apply)*
   ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/23/2015
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*
   ☐ 5-day ☑ 30-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 2
8. Adverse Event Term(s)
9. Manufacturer Report Number: 2951238-2015-00001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type?
   ☐ Correction ☑ Additional Information ☐ Response to FDA Request ☑ Device Evaluation
3. Device Evaluated by Manufacturer?
   ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
   Patient Code ____ - ____ - ____
   Device Code ____ - ____ - ____
   Method 10 - 26 - 37 - 38
   Results 3218 - 180 - ____ - ____
   Conclusions 63 - 19 - ____ - ____
7. If Remedial Action Initiated, Check Type
   ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device
   ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

This supplemental report is to provide the laboratory results, and device evaluation results.

Based on the microbiological testing conducted by an off-site laboratory, the scope tested positive for Microbacterium lacticum. Microbacterium is not considered clinically significant and is often an environmental organism. The organism was recovered from the forceps elevator recess.

The device was ETO sterilized by the off-site laboratory before returning to Olympus. A boroscope was used to examine the internal instrument channels and found no foreign material. A visual inspection was performed on the forceps elevator and found no foreign material inside. The device passed leak test. There were minor damages noted on the device, however, this would not likely cause the reported phenomenon. The device was serviced and returned to the user facility.

Massachusetts General Hospital,
Boston, Massachusetts

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report #

UF/Importer Report # 2518897-2014-00012

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
UNK In confidence	UNK UNK	☐ Female ☐ Male	UNK lbs or UNK kgs

B ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: (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)
2014	11/17/2014

5. Describe Event or Problem

On 11/17/2014, PENTAX Medical received a report from Patient Information of Massachusetts General Hospital stating that Duodenoscope Model ED-3490TK/SN A110428 showed an increased incidence in post-procedure drug-resistant E. coli bacteremia. The Duodenoscope was also associated with a significantly higher proportion of infections.

The Duodenoscope was returned to PENTAX Medical on 12/01/2014 and is currently under evaluation.

In order to receive additional information regarding the event, PENTAX Medical contacted the initial reporter via email on 12/15/2014.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

N/A

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

N/A

(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.

C SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)

#1

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (if unknown, give duration) from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D SUSPECT MEDICAL DEVICE

1. Brand Name: PENTAX

2. Common Device Name: Video Duodenoscope

2b. Procode: FDT

3. Manufacturer Name, City and State: HOYA Corporation Tokyo, Japan

4. Model #	Lot #	5. Operator of Device
ED-3490TK	N/A	☑ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
N/A	N/A	☐ Other:
Serial #	Unique Identifier (UDI) #	
A110428	N/A	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
N/A	N/A

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

N/A

10. Device Available for Evaluation? (Do not send to FDA)

☑ Yes ☐ No ☑ Returned to Manufacturer on: 12-01-2014 (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

N/A

(Continue on page 3)

E INITIAL REPORTER

1. Name and Address

Patient Information
Massachusetts General Hospital
55 Fruit Street, Bulfinch 3-331
Boston, MA 02114

Phone #	Email Address
UNK	Patient Information

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Nurse	☐ Yes ☐ No ☑ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☑ Importer

2. UF/Importer Report Number: 2518897-2014-00012

3. User Facility or Importer Name/Address:
PENTAX Medical
3 Paragon Drive
Montvale, NJ 07645

4. Contact Person: [redacted]

5. Phone Number: [redacted]

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*: 11/17/2014

7. Type of Report: ☑ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*: 12/15/2014

9. Approximate Age of Device: 3 years

10. Event Problem Codes *(Refer to coding manual)*
Patient Code: 1735
Device Code: 3190

11. Report Sent to FDA? ☑ Yes 12/15/2014 *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred: ☑ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☑ Yes 12/15/2014 *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address:
Hoya Corporation
PENTAX Life Care Tokyo Office
2-7-5 Naka-Pajao, Shinjuku-ku
Tokyo, Japan 161-8525

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: [redacted]
Address:
Contact office - See F.3 above
Manufacturing site - See F.14 above
Email Address: [redacted]

2. Phone Number: see F.5

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: ____

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/17/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K092710
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give Protocol #: N/A

7. Type of Report *(Check all that apply)*: ☐ 5-day ☑ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☐ 15-day ☐ Follow-up # ____

8. Manufacturer Report Number: N/A

8. Adverse Event Term(s): N/A

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not) or provide code:* ____

4. Device Manufacture Date *(mm/yyyy)*: 04/2012

5. Labeled for Single Use? ☐ Yes ☑ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code: 1735
Device Code: 3190
Method: TBD
Results: 3233
Conclusions: 11

7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number: N/A

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data
N/A

Delete Page

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

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

Back to Item B.5 | Back to Item B.6 | Back to Item B.7 | Back to Item C.10 | Back to Item D.11

B.5. Describe Event or Problem *(continued)*
N/A

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*
N/A

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*
N/A

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(For continuation of C.10 and/or D.11, please distinguish)*
N/A

Other Remarks
Patient Code 1735 - Bacterial infection. Device Code 3190 - No Information. Method Code - To be Determined. Results Code 3233 - Results Pending Completion of Evaluation. Conclusions Code 11 - Conclusion not yet available, Evaluation in Progress.

Form Approved: OMB No. 0910-0291 Expires: 8/30/2015
See OMB statement on reverse.

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

Mfr Report #

UF/Importer Report # 2518897-2015-00009

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
[redacted] In confidence	UNK UNK / UNK	☐ Female ☐ Male	UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☑ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: (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)
2014	

5. Describe Event or Problem

PENTAX Medical contacted the Initial Reporter via email on 01/05/2015 and 01/20/2015. Responses were received from the facility on 01/23/2015 indicating 3 patients tested positive for a single strain type of ceftriaxone-resistant E.coli post-ERCP procedure performed with Video Duodenoscope Model ED-3490TK/Serial A11428. Strain types 5A-H are related to each other. Patient [redacted] met the case of "Immediate bacteremia post-ERCP" meaning patient had (+) blood culture post-ERCP within 72 hours. The facility protocol for infections that are part of the hospital surveillance plan, which includes bacteremias, is that the department leadership and the provider are notified of the infection; any trends identified and a review of the infection (root cause analysis) is completed. The group of patients undergoing ERCP was being treated for a range of pancreatic and biliary diseases; it would be difficult to determine specific signs and symptoms other than fever/chills and malaise that would be related to the post-procedure bacteremias. Patient was treated for bacteremias with appropriate antibiotics. Patient was not recalled for further screening as the marker for this outbreak investigation was a (+) blood culture for

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Strain type as determined by pulsed-field electrophoresis) - 5A

Time of 1st(+)culture - +(within 72 hours of procedure)

Date of Scope Use - Patient Information

Site of(+)culture - Blood

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)

#1

#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. 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

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 treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number: 3518857-2015-00009
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☑ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*: 06/23/2015
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
   - Patient Code: 1735
   - Device Code:
11. Report Sent to FDA? ☑ Yes 06/23/2015 *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: *(Specify)*
13. Report Sent to Manufacturer? ☑ Yes 06/23/2015 *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name
   - Address
   - Email Address
2. Phone Number
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/23/2015
5. (A)NDA # / IND # / BLA # / PMA/510(k) # / Combination Product ☐ Yes / Pre-1938 ☐ Yes / OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s)
9. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
   - Patient Code: 1735
   - Device Code:
   - Method:
   - Results:
   - Conclusions:
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Back to Item B.5

B.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 from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID [redacted]

Initial MDR 2518897-2015-00009 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID [redacted]
Initial MDR 2518897-2015-00010 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID [redacted]
Initial MDR 2518897-2015-00011 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID [redacted]
Initial MDR 2518897-2015-00012 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID [redacted]
Initial MDR 2518897-2015-00013 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID [redacted]
Initial MDR 2518897-2015-00014 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID [redacted]

Back to Item B.6

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Back to Item B.7

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Back to Item C.10 Back to Item D.11

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.

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report #

UF/Importer Report # 2518897-2015-00018

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
[redacted] In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death ____ *(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)*
Patient Information	01/23/2015

5. Describe Event or Problem

PENTAX Medical received a report on 01/23/2015 indicating 1 patient tested positive for a single strain type of ceftriaxone-resistant E. coli post-ERCP procedure. No information on the Medical Device used during the ERCP procedure was received at the time of this report. Patient [redacted] met the case definition of "Delayed bacteremia post-ERCP" meaning patient had (+) blood culture post-ERCP after 72 hours but within 30 days post-procedure. The facility protocol for infections that are part of the hospital surveillance plan, which includes bacteremias, is that the department leadership and the provider are notified of the infection; any trends identified and a review of the infection (root cause analysis) is completed. The facility also indicated that patients undergoing ERCP are being treated for a range of pancreatic and biliary diseases; it would be difficult to determine specific signs and symptoms other than fever/chills and malaise that would be related to the post-procedure bacteremias. Patient was treated for bacteremias with appropriate antibiotics. Patient was not recalled for further screening as the marker for this outbreak investigation was a (+) blood culture for ceftriaxone-resistant

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

Strain type as determined by pulsed-field electrophoresis - B

Time of 1st(+)culture - Delayed(>72 hours but <30 days)

Date of Scope Use - Patient Information

Site of(+)culture - Blood

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☑ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. 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

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 treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Patient Information

MGH Gastroenterology Associates
55 Fruit Street, Blake 4
Boston, MA 02114-2696

Phone #	Email Address
Patient Information	Patient Information

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☐ Yes ☑ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☑ Importer
2. UF/Importer Report Number: 2518897-2015-00018
3. User Facility or Importer Name/Address:
PENTAX Medical
3 Paragon Drive
Montvale, NJ 07645
4. Contact Person: Anastasia Vlamis
5. Phone Number: 201-571-2300- x2066
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☑ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*: 07/02/2015
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code 1735 - - ; Device Code 3190 - -
11. Report Sent to FDA? ☑ Yes 07/02/2015 *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☑ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☑ Yes 07/02/2015 *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:
Hoya Corporation
PENTAX Life Care Tokyo Office
2-7-5 Naka-Psjao, Shinjuku-ku
Tokyo, Japan 161-8525

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: [redacted]
Address:
Contact office - See F.3 above
Manufacturing site - See F.14 above
Email Address:
2. Phone Number: see F.5
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/23/2015
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number:

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code 1735 - - ; Device Code 3190 - - ; Method - - - - ; Results - - - - ; Conclusions - - - -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Delete Page

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

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

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.

Back to Item B.6

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Back to Item B.7

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

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)*

Back to Item D.11

Other Remarks

Patient Code 1735 - Bacterial infection. Device Code 3190 - No Information.

Form Approved: OMB No. 0910-0291. Expires: 6/30/2015
See OMB statement on reverse.

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

Page 1 of 3

Mfr Report #

UF/Importer Report # 2518897-2015-00031

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
UNK In confidence	UNK or UNK	☐ Female ☐ Male	UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☑ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: _____ (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): Patient Information

4. Date of This Report (mm/dd/yyyy): 07/20/2015

5. Describe Event or Problem — Patient Information

PENTAX Medical was made aware of an event on stating "Post ERCP Bacteremias with CTX RE Coli which has been associated with 3 patients since January." The Duodenoscope involved was received at PENTAX Medical on 07/09/2015 to repair a reported leak and is currently on hold pending further evaluation.

Good Faith Effort attempts were made via e-mail on 07/23/2015 and 07/30/2015 to the facility to confirm details of the event, and to obtain a facility contact to receive information on the 3 patients.

No information has been received from the facility to date.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: PENTAX

2. Common Device Name: Video Duodenoscope

2b. Procode: FDT

3. Manufacturer Name, City and State
HOYA Corporation
Tokyo, Japan

4. Model #	Lot #	5. Operator of Device
ED-3490TK		☑ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Lay User/Patient
		☐ Other
Serial #	Unique Identifier (UDI) #	
8110743		

6. 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

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: 07/09/2015 (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
Identifying Information

Massachusetts General Hospital
55 Fruit Street, Bulfinch 3-331
Boston, MA 02114

Phone #: Identifying Information

Email Address: Identifying Information

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ☑ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☑ Importer

2. UF/Importer Report Number: 2518897-2015-00031

3. User Facility or Importer Name/Address
PENTAX MEDICAL
3 Paragon Drive
Montvale, NJ 07645

4. Contact Person: [redacted]

5. Phone Number: [redacted]

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*: 07/20/2015

7. Type of Report: ☑ Initial ☐ Follow-up #

(mm/dd/yyyy): 08/11/2015

8. Approximate Age of Device:

9. Event Problem Codes *(Refer to coding manual)*
Patient Code: 1735
Device Code: 2379

10. Report Sent to FDA? ☑ Yes 08/11/2015 *(mm/dd/yyyy)* ☐ No

11. Location Where Event Occurred: ☑ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: *(Specify)*

12. Report Sent to Manufacturer? ☑ Yes 08/11/2015 *(mm/dd/yyyy)* ☐ No

13. Manufacturer Name/Address
HOYA Corporation
PENTAX Life Care Tokyo Office
2-7-5 Naka-Ochiai, Shinjuku-ku
Tokyo, Japan 161-8525

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: [redacted]
Contact office - See F.3 above
Manufacturing site - See F.14 above
Email Address:

2. Phone Number: See F.5

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/20/2015

5. (A)NDA #: IND #: BLA #: PMA/510(k) #: K092710
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

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 #

8. Adverse Event Term(s):

9. Manufacturer Report Number:

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*:

5. Labeled for Single Use? ☐ Yes ☑ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code: 1735
Device Code: 2379
Method: 10
Results: 3233
Conclusions: 11

7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:

8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Delete Page

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

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

Back to Item B.5

B.5. Describe Event or Problem *(continued)*

Back to Item B.6

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

Back to Item B.7

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

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)*

Back to Item D.11

Other Remarks

Patient Code 1735 - Bacterial Infection
Device Code 2379 - Device Issue
Method code 10 - Actual Device Evaluated
Results code 3333 - Results Pending Completion of Evaluation
Conclusions Code 11 - Conclusion Not Yet Available - Evaluation in Progress

New York-Presbyterian/Weill Cornell Medical Center
New York City, New York

OLYMPUS

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,

[redacted]

[redacted]

Form Approved: OMB No. 0910-0291. Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2013-00176

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☑ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
Unk	05/09/2013

5. Describe Event or Problem

Olympus was informed that the customer had cultured four of their duodenovideoscopes and they are follows: models TJF-Q180V, with the following serial numbers: 2101850, 2101853, 2101894, and 2000446 after high-level disinfection and the duodenoscopes tested positive for the following bacteria: Klebsiella pneumoniae, Pseudomonas aeroginosa, and enterococcus. However, the user facility reported that not all three duodenovideoscopes grew all three organisms, but rather it was a mix. The user facility further reported that one of the 160 duodenovideoscope also cultured and grew Klebsiella pneumoniae. The user facility further reported that there were 15 cases of patient infection and they believed that it is related to the duodenovideoscopes.

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus EVIS EXERA Duodenovideoscope

2. Common Device Name: Duodenovideoscope

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-160VF	N/A	☑ Health Professional
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	☐ Lay User/Patient
TJF-160VF	Unk	☐ Other:
Serial #	**Other #**	
2802210	N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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
N/A

10. Device Available for Evaluation? *(Do not send to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: 06/04/2013 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: [redacted]

Phone #: [redacted]

Infection Control Nurse
NYP Weill Cornell Medical Center
512 E. 71th Street
New York, NY 10021

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Administrator/Supervisor	☐ Yes ☐ No ◉ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or 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)*
    - Patient Code: 1735 - - -
    - Device Code: 1091 - 2303 - -
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

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

[redacted]
OLYMPUS AMERICA, INC
2400 Ringwood Avenue
San Jose, CA 95131

OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. **Phone Number** 484-896-5688
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 05/09/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number** 8010047-2013-00176

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: patient infection
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☑ Yes ☑ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)* unk
5. **Labeled for Single Use?** ☐ Yes ☑ No
6. **Evaluation Codes** *(Refer to coding manual)*
    - Method: 10 - 37 - 38 -
    - Results: 100 - - -
    - Conclusions: 51 - - -
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☑ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

Evaluation Summary Attached

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.

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.

MAUDE Adverse Event Report: OLYMPUS OLYMPUS ERCP ENDOSCOPE

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/Recalls[23]

New Search | Submit an Adverse Event Report[24]

Brand Name OLYMPUS
Type of Device ERCP ENDOSCOPE
Manufacturer *(Section D)* OLYMPUS
Center Valley PA 18034
MDR Report Key 3413223
Report Number MW5032234
Device Sequence Number 1
Product Code KOG[25]
Report Source Voluntary
Reporter Occupation ATTORNEY
Type of Report Initial
Report Date 10/09/2013
***2* DeviceS WERE Involved in the Event:** 1 2
***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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7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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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=KOG

Page Last Updated: 09/30/2015

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7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
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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=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 [redacted]	**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)*

- [ ] Death
- [ ] Life-threatening
- [X] Hospitalization - initial or prolonged
- [X] Required Intervention to Prevent Permanent impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

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 carbapenem-resistant enterobacteriaceae (CRE) infection after undergoing three different ERCP procedures. It was reported that two TJF -Q180V and one TJF-160V Duodenvideoscopes were used to perform the patient's procedures on February 28, 2013, April 18, 2013 and May 21, 2013 at different user facilities. After, the procedure on May 21, 2013, the patient began to experience symptoms of infection with epigastric pain and was admitted to the hospital for observation. The patient was later discharged on May 25, 2013.

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 regarding the reported event by telephone and in writing but with no results. The exact serial numbers of the duodenvideoscopes used in the procedure are unknown at this time.

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.)*

Pancreatitis

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	Duodenovideoscope, Product Code: FDT	
3. Manufacturer Name, City and State	**4. Model #**	**Catalog #**
OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA	Unknown	Unknown
	Serial #	**Lot #**
	Unknown	N/A
	Expiration Date *(mm/dd/yyyy)*	**Other #**
5. Operator of Device	**6. Implanted Date** *(mm/dd/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 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?**
[redacted]	( ) Yes (•) No ( ) No Information

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:	

123 Sount Broad Street
Suite 2250
Philadelphia, PA 19109, US
[redacted]

3. Occupation
Attorney

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
( ) User Facility ( ) Importer

2. User Facility/Importer Number

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)*
Patient Code(s): 1735 - 1994
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

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1, 2. Contact Office - Name/Address/Phone Number
[redacted]
Olympus America
2400 Ringwood Ave
San Jose, CA 95131, US
[redacted]

1, 2. (Continued) Manufacturing Site Address/Phone for Devices

3. Report Source *(Check all that apply)*
[ ] Foreign
[ ] Study
[ ] Literature
[ ] Consumer
[x] Other: Attorney
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/17/2015

5. PMA/510(k)
K080403

6. If IND, Give Protocol #

7. Type of Report
[ ] 5-day [x] Initial [ ] Follow-up

8. Adverse Event Term(s)

9. Manufacturer Report Number
2951238-2015-00249

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
( ) Death
(•) Serious Injury
( ) Malfunction
( ) No Information

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation
[ ] No Information

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
( ) Yes [ ] Evaluation Summary Attached
(•) No

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
( ) Yes (•) No ( ) No Information

6. Evaluation Codes *(Refer to coding manual)*
Method Code(s):
Result Code(s):
Conclusion Code(s): 67 - 92

7. If Remedial Action Initiated, Check Type
[ ] Recall [ ] Notification

8. Usage of Device
( ) Initial Use of Device

9. If action reported to FDA under 21 USC 360I(f), list correction/removal reporting number

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:	

[ ] Repair	[ ] Inspection	(•) Reuse	
[ ] Replace	[ ] Patient Monitoring	( ) Unknown	
[ ] Relabeling	[ ] Modification/Adjustment	( ) No Information	
[ ] Other			

10. [X] Additional Manufacturer Narrative **and/or 11.** [ ] Corrected Data

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.
The user facility uses a custom Ultrasonic machine to reprocess their endoscopes. The ESS demonstrated all steps as per the new protocol for the TJF-Q180V.

Please see associated medical device reports: 2951238-2015-00248 and 2951238-2015-00253.

File Attachments

No files attached.

MAUDE Adverse Event Report: OLYMPUS MEDICAL SYSTEM CORPORATION DUODENOVIDEOSCOPE

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/Recalls[2323]

New Search[24] | Submit an Adverse Event Report[2524]

Brand Name DUODENOVIDEOSCOPE
Type of Device DUODENOVIDEOSCOPE
Manufacturer *(Section D)* OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-Cho,
Hachioji-Shi
Tokyo 192-8 507
JAPAN 192-8507
Manufacturer Contact Noemi Schambach
2400 Ringwood Avenue
San Jose , CA 95131
(408) 408 -4089
40893550 4089355002
MDR Report Key 5030603

Report Number 2951238-2015-00387
Device Sequence Number 1
Product Code FDT[2625]
Report Source Manufacturer
Source Type LITERATURE,OTHER,USER FACILIT
Reporter Occupation Other
Type of Report Initial
Report Date 08/05/2015
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 08/25/2015
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? No
Device Operator Health Professional
Device LOT Number N/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? No
Type of Device Usage Reuse

Patient TREATMENT DATA
Date Received: 08/25/2015 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
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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
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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
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

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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
11. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
12. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
16. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
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24. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Search.cfm
25. https://www.accessdata.fda.gov/scripts/medwatch/
26. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=&ProductCode=FDT

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

USA.gov

For GovernmentFor Press

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U.S. Department of Health & Human Services

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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
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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
22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
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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
11. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
12. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
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17. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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UCLA Medical Center
Los Angeles, California

OLYMPUS

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Mfr Report #	2951238-2015-00064
UF/Importer Report #	
	FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☑ Death: 01/XX/2015 *(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)*
10/03/2014- 01/24/2015	01/28/2015

5. Describe Event or Problem

Olympus was informed that a patient with an infection with a "drug resistant organism" had undergone an Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure on October 3,2014. It was reported that the patient who had the ERCP on October 3, 2014 was not doing well. The user facility decommisioned all their duodenovideoscopes as a precaution when six other patients were confirmed to be infected. The user facility isolated all their duodenovideoscopes for laboratory testing, as part of their internal investigation.

Olympus was later informed that one of the seven patients expired. The cause of death is unknown.

Olympus has been in ongoing communication with the user facility via telephone and in writing to obtain more detailed information regarding the reported events.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name	2b. Procode
Doudenovideoscope	KOG

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
TJF-Q180V	N/A	☐ Other:
Serial #	Unique Identifier (UDI) #	
2405047		

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
[redacted]
The Regents University of California
200 UCLA Medical Plaza
Los Angeles, CA 90095

Phone #	Email Address
[redacted]	[redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Nurse	☐ Yes ☐ No ☑ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or 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)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

Name [redacted]

Address

OLYMPUS AMERICA INC
2400 Ringwood Avenue
San Jose, CA 95131

Email Address [redacted]

2. Phone Number [redacted]

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☑ User Facility
☐ Company Representative
☐ Distributor
☐ Other: ____

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

01/28/2015

5.

(A)NDA # ____

IND # ____

BLA # ____

PMA/510(k) # K024033

Combination Product ☐ Yes

Pre-1938 ☐ Yes

OTC Product ☐ Yes

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 # ____

8. Adverse Event Term(s)

9. Manufacturer Report Number

2951238-2015-00064

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☑ Death ☐ Serious Injury ☐ Malfunction

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

Unk

5. Labeled for Single Use? ☐ Yes ☑ No

6. Event Problem and Evaluation Codes *(Refer to coding manual)*

Patient Code	1735	1802		
Device Code	1120	2303		
Method				
Results				
Conclusions	20	92		

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☑ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☑ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

The device has not been returned to Olympus for evaluation. An Olympus Endoscopy Support Specialist (ESS) visited the site to assess the reprocessing practices at the user facility and provided training and education to the user facility staff. The ESS noted reprocessing inconsistencies during the site visit.

The cause of the patient death is unknown at this time. If additional information becomes available at a later time this report will be supplemented.

Cross reference mfr. report numbers: 2951238-2015-00065,2951238-2015-00066,2951238-2015-00067,2951238-2015-00068, 2951238-2015-00069, and 2951238-2015-00070.

The filing of this report is not an admission that the device has caused or contributed to the reported event.

UMass Memorial Medical Center, Worchester, Massachusetts

OLYMPUS

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 2951238-2013-00017
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
UNK In confidence	UNK UNK or UNK	☐ Female ☐ Male	UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
Unk	8/28/2013

5. Describe Event or Problem

Olympus was informed that there were multiple patients infected with an unspecified bacteria that was traced back to using the duodenovideoscope. The duodenovideoscope was reprocessed using Cidex OPA with an automated endoscope reprocessor. There was no reported issue with reprocessing of the duodenovideoscope and no reports of obstructions or difficulty passing the cleaning brush through the duodenovideoscope. Prior to this event, the duodenovideoscope had not been used since January 2013.

Olympus contacted the user facility to obtain more detailed information regarding the report and was informed that there were 20 plus patients infected with the unspecified bacteria. The same bacteria was said to have been isolated from the duodenovideoscope. However, there was no further information provided.

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus EVIS EXERA II Duodenovideoscope
2. Common Device Name: Duodenovideoscope
3. Manufacturer Name, City and State:
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
TJF-Q180V		☐ Other:
Serial #	Other #	
2102040		

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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
N/A

10. Device Available for Evaluation? *(Do not send to FDA)*
☑ Yes ☐ No ☑ Returned to Manufacturer on: 8/28/2013 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
Cidex OPA
Custom Ultrasonic Machine

E. INITIAL REPORTER

1. Name and Address: [redacted]
Phone #: [redacted]

UMASS Memorial Medical Center
55 Lake Avenue North
Worcester, MA 001655

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Nurse	☐ Yes ☐ No ◉ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or 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)*
   - Patient Code: 1735 - - -
   - Device Code: 2303 - - -
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

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

[redacted]
OLYMPUS AMERICA, INC.
2400 Ringwood Avenue
San Jose, CA 95131

OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. **Phone Number** [redacted]
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 08/28/2013
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number** 2951238-2013-00017

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☑ Serious Injury ☐ Malfunction ☐ Other:
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)* XX/2011
5. **Labeled for Single Use?** ☐ Yes ☑ No
6. **Evaluation Codes** *(Refer to coding manual)*
   - Method: 10 - 23 - 37 - 38
   - Results: 115 - - -
   - Conclusions: 51 - - -
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☑ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

The device referenced in this report has been sterilized and was returned to Olympus for evaluation. The instrument channel was examined using a borescope and rigid telescope and slight white substances and debris was found in the instrument channels, channel mount, and cylinder unit. The distal end plastic cover was cracked with nicks and dents. The device failed the leak test, as leak was detected from the seam of the control body unit and at the distal end. The bending section glue was cracked.

As part of our investigation into this report, an Olympus Endoscopy Support Specialist has been dispatched to the user facility to reassess the reprocessing practices.

The exact cause of user's report could not be conclusively determined at this time; however, insufficient reprocessing of the device could not be ruled out as a contributory factor to the reported event. This report will be supplemented if additional information becomes available at a later time.

Universitair Medisch Centrum
Utrecht, Netherlands

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 #:	8010047-2015-00816
UF/Importer Report #:	
Form Code:	

A. PATIENT INFORMATION

1. Patient Identifier *(In confidence)*	2. Age at Time of Event, Date of Birth	3. Sex	4. Weight
		No Information	

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)*

- [ ] Death
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [X] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	08/19/2015

5. Describe Event or Problem

Olympus was informed that eight patients were infected with unidentified bacteria after undergoing an endoscopic retrograde cholangiopancreatography (ERCP) procedure using a TJF-Q180V between 1st Jan 2015 and 15th Aug 2015.
The facility is recalling patients.
The hospital informed olympus that all TJF-Q180V scopes were contaminated.
No detailed information is available at this moment.

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.)*

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	DUODENOVIDEOSCOPE, Product Code: FDT	
3. Manufacturer Name, City and State	**4. Model #**	**Catalog #**
OLYMPUS MEDICAL SYSTEMS CORPORATION 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA	TJF-Q180V	
	Serial # unk	**Lot #**
	Expiration Date *(mm/dd/yyyy)*	
	Unique Identifier (UDI) #	

5. Operator of Device	6. Implanted Date *(mm/dd/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 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?
[redacted] Universitair Medisch Centrum Heidelberglaan 100 3584 CX UTRECHT NL [redacted]	(•) Yes ( ) No ( ) No Information
	3. Occupation Physician
	4. Initial Reporter Also Sent Report to FDA? ( ) Yes (•) No ( ) Unknown ( ) No Information

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 #:	8010047-2015-00816
UF/Importer Report #:	
Form Code:	

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

1. User Facility or Importer
( ) User Facility ( ) Importer

2. User Facility/Importer Number

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)*
Patient Code(s):
Device Code(s):

11. Report Sent to FDA?
( ) Yes ( ) No ( ) No Information

12. Location Where Event Occurred

13. Report Sent to Manufacturer?
( ) Yes ( ) No ( ) No Information

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1, 2. Contact Office - Name/Address/Phone Number
[redacted]
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507, JA
[redacted]

1, 2. (Continued) Manufacturing Site Address/Phone for Devices

3. Report Source *(Check all that apply)*
[X] Foreign
[ ] Study
[ ] Literature
[ ] Consumer
[ ] Other
[ ] Health Professional
[X] User Facility
[ ] Company Representative
[X] Distributor

4. Date Received by Manufacturer *(mm/dd/yyyy)*
08/19/2015

5. PMA/510(k)
K080403

6. If IND, Give Protocol #

7. Type of Report
[ ] 5-day [X] Initial [ ] Follow-up

8. Adverse Event Term(s)

9. Manufacturer Report Number
8010047-2015-00816

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
( ) Death
(•) Serious Injury
( ) Malfunction
( ) No Information

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation
[ ] No Information

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
( ) Yes [ ] Evaluation Summary Attached
(•) No

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
( ) Yes (•) No ( ) No Information

6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code(s): 1930 - 1735
Device Code(s): 1120
Method Code(s): 3263
Result Code(s): 3221
Conclusion Code(s): 92

7. If Remedial Action initiated, Check Type
[ ] Recall
[ ] Repair
[ ] Replace
[ ] Relabeling
[ ] Other
[ ] Notification
[ ] Inspection
[ ] Patient Monitoring
[ ] Modification/Adjustment

8. Usage of Device
( ) Initial Use of Device
(•) Reuse
( ) Unknown
( ) No Information

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number

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 #:	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

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Page 1 of 2

Mfr Report # 8010047-2012-00481

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☑ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*
Unknown	11/19/2012

5. Describe Event or Problem

The user facility reported that 10-13 patients that had been examined with the subject device were potentially infected with Klebsiella pneumonia. There was no information provided regarding what, if any treatment had been provided to the patients.

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus EVIS EXERA II DUODENOVIDEOSCOPE

2. Common Device Name: Duodenoscope

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-Q180V	N/A	☑ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
TJF-Q180V	N/A	☐ Other:
Serial #	Other #	
2001160	N/A	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
N/A	N/A

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: 12/11/2012 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
[redacted]
UPMC Presbyterian
200 LOTHROP STREET
Pittsburgh, PA 15213

Phone # [redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Other Healthcare Professional	☐ Yes ☐ No ◉ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 1735 - - ; Device Code 2993 - -
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:

[redacted]
OLYMPUS AMERICA, INC.
2400 Ringwood Avenue
San Jose, CA 95131

OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo
192-8507, Japan

2. Phone Number: [redacted]
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☑ User Facility ☑ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 11/19/2012
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # ____
8. Adverse Event Term(s):
9. Manufacturer Report Number: 8010047-2012-00481

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☑ Other: Klebsiella pneumonia
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☑ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☑ No
6. Evaluation Codes *(Refer to coding manual)*: Method 10 - 38 - - ; Results 3233 - - - - ; Conclusions 11 - - - -
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Olympus followed-up with the user facility to obtain additional information regarding this report. The user facility reported that all potentially affected patients had undergone ERCP procedures and were transplant patients. The user facility reported that 6 ERCP endoscopes were cultured and 1 of the endoscopes which is the subject device referenced in this report was found to have Klebsiella pneumonia on two separate occasions after numerous cultures. Nevertheless, the user facility reported that there was no direct evidence of the infection being tied to any particular endoscope.

As part of our investigation into this report, two Olympus representatives had been dispatched to the user facility to assess the facility's reprocessing practices and to perform a device evaluation. Additionally, the ECRI Institute was also involved in the investigation. Olympus performed a visual inspection of the device referenced in this report with no major observation noted. The user facility's reprocessing practices was assessed with no major risk factor for K. pneumonia transmission observed.

The device was sent to an independent testing laboratory for microbiological testing. The results of the testing are pending, and the device has not yet been returned to Olympus for a complete evaluation. This report will be supplemented when the evaluation is complete.

This report is being submitted as a Medical Device Report in an abundance of caution.

OLYMPUS

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

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

MEDWATCH

FORM FDA 3500A (1/09)

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

Mfr Report # 8010047-2012-00481

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(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)*

5. Describe Event or Problem

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.)*

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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(if unknown, give duration) from/to (or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. 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

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 treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or 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)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
2. Phone Number
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
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 # 1
8. Adverse Event Term(s)
9. Manufacturer Report Number 8010047-2012-00481

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☒ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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 supplemented as the final results become available.

MAUDE Adverse Event Report: OLYMPUS OLYMPUS 160/180 SERIES ENDOSCOPE ERCP SCOPE 1160

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/Recalls[23]

New Search | Submit an Adverse Event Report[24]

Brand Name OLYMPUS 160/180 SERIES ENDOSCOPE
Type of Device ERCP SCOPE 1160
Manufacturer *(Section D)* OLYMPUS
2400 Ringwood Ave.
San Jose CA 95131
MDR Report Key 2999629
Report Number MW5029305
Device Sequence Number 1
Product Code FDS[25]
Report Source Voluntary
Reporter Occupation Nurse
Type of Report Initial
Report Date 03/04/2013
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 03/04/2013
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 Number TJF-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:

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=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.

Virginia Mason Hospital and Medical Center
Seattle, Washington

OLYMPUS

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,

[redacted]

Copies: [redacted]

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

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

Page 1 of 2

Mfr Report # 2951238-2014-00364

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(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)*
xx/xx/2013	07/25/2014

5. Describe Event or Problem

Olympus was informed of 37 alleged infections at the user facility involving multiple duodenoscopes (160 series/180series).

In early 2013 the Washington State Department of Health identified seven cases of carbapanem resistant enterobacteriaceae (CRE) cultures from samples sent by the user facility. There were no specific endoscope models or serial numbers provided by the user facility. Four deaths were identified by the user facility. The cause of patient deaths is unknown.

Additionally, Olympus was notified of 30 patient infections based on culture of variant E.coli from patient's blood, bile, urine, or the respiratory tract. Olympus contacted the user facility via telephone and in writing to obtain more detailed information regarding the reported events but no further information was provided.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/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.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Olympus Duodenovideoscope

2. Common Device Name	2b. Procode
Duodenovideoscope	KOG

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan

4. Model #	Lot #	5. Operator of Device
TJF-160VF	N/A	☑ Health Professional
Catalog # TJF-160VF	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Serial # UNK	Unique Identifier (UDI) #	☐ Other:

6. 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

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 treatment of event)*
TJF-Q180V Serial Number (Unknown)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
[redacted]
Virginia Mason Medical Center
1100 9th Avenue
Seattle, WA 98101

Phone #	Email Address
[redacted]	[redacted]

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☑ Yes ☐ No ☐ Unk.

MEDWATCH

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

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or 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)*: Patient Code 1735 – 1930 – ; Device Code 2993 – – –
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name: [redacted]
Address:
OLYMPUS AMERICA, INC
2400 Ringwood Avenue
San Jose, CA 95131

OLYMPUS MEDICAL SYSTEM CORPORATION
Email Address: [redacted]

2. Phone Number: [redacted]

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☑ Health Professional ☑ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/25/2014

5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # K024033
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

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 # ____

8. Adverse Event Term(s):

9. Manufacturer Report Number: 2951238-2014-00364

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☑ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☑ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*: UNK
5. Labeled for Single Use? ☐ Yes ☑ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*: Patient Code 1735 – 1930 – ; Device Code 2993 – – –; Method – – – –; Results – – – –; Conclusions 67 – – – –
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☑ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☑ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

No devices were returned to Olympus for evaluation. Olympus offered an on-site visit to the user facility to assess their reprocessing practices, but the user facility declined. The exact cause of the patient outcome could not be conclusively determined. If additional and significant information becomes available at a later time, this report will be supplemented.

Cross Reference mfr. Report numbers:
2951238-2014-00348, 2951238-2014-00349,
2951238-2014-00350, 2951238-2014-00350,
2951238-2014-00351, 2951238-2014-00352,
2951238-2014-00353, 2951238-2014-00354,
2951238-2014-00355, 2951238-2014-00356,
2951238-2014-00357, 2951238-2014-00358,
2951238-2014-00359, 2951238-2014-00360,
2951238-2014-00361, 2951238-2014-00362,
2951238-2014-00363, 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, and 2951238-2014-00383

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 #:	2951238-2015-00230
UF/Importer Report #:	
Form Code:	

A. PATIENT INFORMATION

[redacted]

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)*
- [ ] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

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
Duodenovideoscope

2. Common Device Name
Duodenovideoscope, Product Code: FDT

3. Manufacturer Name, City and State
OLYMPUS MEDICAL SYSTEM CORPORATION
2951 Ishikawa-cho,
Hachioji-shi
Tokyo 192-8507, JA

4. Model #
Unk

Catalog #
Unk

Serial #
Unk

Lot #
N/A

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
[redacted]
Virginia Mason Medical Center
1100 9th Avenue

2. Health Professional?
(•) Yes ( ) No ( ) No Information

3. Occupation

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 #:	2951238-2015-00230
UF/Importer Report #:	
Form Code:	

Seattle, WA 98101-2756, US
Telephone: [redacted]
Email: [redacted]

Other Health Care Professional

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
( ) User Facility ( ) Importer

2. User Facility/Importer Number

3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number
CA, US

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)*
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

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1, 2. Contact Office - Name/Address/Phone Number
[redacted]
OLYMPUS AMERICA INC
2400 Ringwood Avenue
San Jose, CA 95131, US
[redacted]

1, 2. (Continued) Manufacturing Site Address/Phone for Devices

3. Report Source *(Check all that apply)*
[ ] Foreign
[ ] Study
[X] Literature
[X] Consumer
[ ] Other
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/13/2015

5. PMA/510(k)

6. If IND, Give Protocol #

7. Type of Report
[ ] 5-day [X] Initial [ ] Follow-up

8. Adverse Event Term(s)

9. Manufacturer Report Number
2951238-2015-00230

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
(•) Death
( ) Serious Injury
( ) Malfunction
( ) No Information

2. If Follow-up, What Type?
[ ] Correction
[ ] Additional Information
[ ] Response to FDA Request
[ ] Device Evaluation
[ ] No Information

3. Device Evaluated by Manufacturer?
[ ] Not Returned to Manufacturer
( ) Yes [ ] Evaluation Summary Attached
(•) No

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
( ) Yes (•) No ( ) No Information

6. Evaluation Codes *(Refer to coding manual)*
Method Code(s):
Result Code(s):
Conclusion Code(s): 67 - 92

7. If Remedial Action Initiated, Check Type
[ ] Recall
[ ] Repair
[ ] Notification
[ ] Inspection

8. Usage of Device
( ) Initial Use of Device
(•) Reuse

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number

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 #:	2951238-2015-00230
UF/Importer Report #:	
Form Code:	

[ ] Replace [ ] Relabeling [ ] Other	[ ] Patient Monitoring [ ] Modification/Adjustment	( ) Unknown ( ) No Information	

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 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.