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Flexible Endoscope Incident Report

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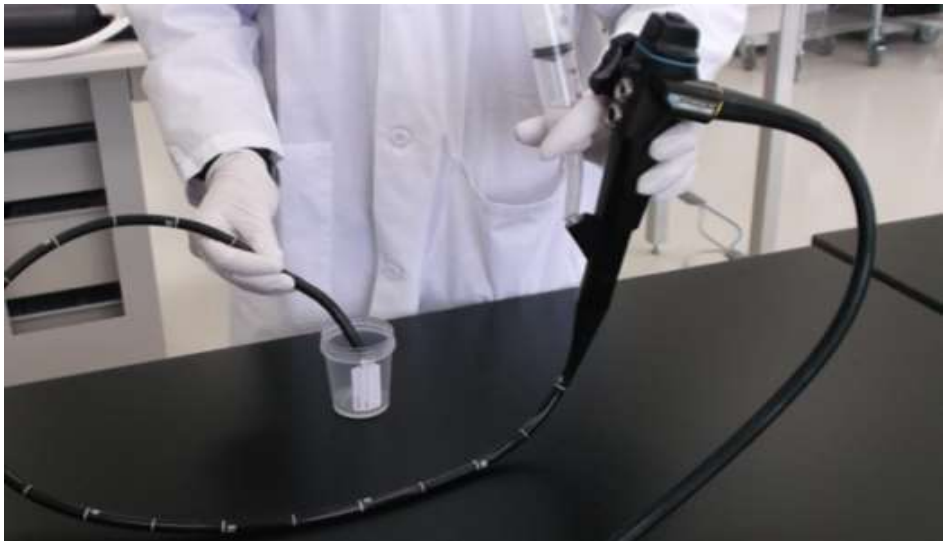

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The Flexible Endoscope Incident Report is created to be organized by topic, related by different failure modes, and is updated every quarter with new events and/or malfunctions that occur with endoscopes. The incidents in this document are found in the Manufacturer and User Facility Device Experience (MAUDE) data report. This database contains reports received by the U.S. Food and Drug Administration (FDA) of adverse events involving medical devices, which include manufacturers, importers, and user facilities. Reports in this document include endoscope associated death, injuries to patients, malfunctions with endoscopes, malfunctions with equipment, and use error.

1. Failure of Visual Inspection

1.1 Biopsy forceps were advanced through the biopsy channel of a colonoscope, and debris was expelled into the patient, April 2021

A report in the FDA's **MAUDE** database states during an unspecified procedure using an EVIS Exera LLL Colonovideoscope CF-HQ190L, the biopsy forceps were advanced through the biopsy channel. Staff noticed debris (that appeared to be an endo loop from a previous procedure) was expelled into the patient. The debris was removed from the patient, who experienced no adverse effects because of this occurrence. The scope has not been returned to Olympus for evaluation and the investigation is ongoing. The definitive cause cannot be determined at this time. An Endoscopic Support Specialist (ESS) was dispatched to the facility to offer education and observation of current reprocessing procedures. The customer expressed they are planning a skills day in early May and will be educating staff. The customer declined an onsite visit from the ESS to observe the staff reprocessing at this time. Information was emailed to the customer by the ESS to emphasize proper inspection techniques of the instrument channel. This report will be updated upon completion of the investigation or upon receipt of additional relevant information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11730886&pc=FDF

1.2 A competitor's stent used in a previous procedure remained in the duodenovideoscope after reprocessing, April 2021

A report in the FDA's **MAUDE** database states during an unspecified procedure, a piece of a competitor's stent, used in a previous procedure, remained in the EVIS Exera II

Duodenovideoscope TJF-Q180V after reprocessing. The scope was used on a second patient in an unknown procedure. The user reported a piece of broken stent was suctioned through the scope's channel where it remained. A similar scope was used to complete the procedure. An Endoscope Support Specialist (ESS) was dispatched to the user facility to assess their reprocessing practices and to provide reprocessing training if necessary. The ESS provided an in-service on leak testing and manual cleaning. The customer used the scope valet for automated flushing and Medivator DSD Edge for automated reprocessing. The ESS recommended the manufacturer of the stent also provide an in-service. . . . The scope was not returned to the service center for evaluation. The cause of the event could not be determined. The investigation is ongoing, and if additional information is received this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11633386&pc=FDT

1.3 A complaint from the OR reported a part of the insertion tube from the scope was torn and fell into the patient, March 2021

A report in the FDA's **MAUDE** database states Pentax Medical was made aware of a complaint about the Pentax Video Cysto Scope ECY-150S that occurred while in use in the operating room. ". . . the scope insertion part was torn and fell into the body, and the fallen debris was taken out with forceps." No serious injury or death of a patient or user was reported. During the inspection from the doctor, the scope insertion part was torn and fell into the body, and the fallen debris was taken out with forceps, "I think I've removed everything." On February 26, 2021, an investigation was completed under ivai-21-010016, the findings are as follows: ". . . it was confirmed that the black glue on both ends of the bending rubber had peeling or chipping. It is probable that the epoxy glue had deteriorated due to EtO sterilization. Since the user used the endoscope without pre-use inspection, it is presumed that the debris fell off due to contact with the patient's body." On January 5, 2021, a device history review (DHR) for the [cystoscope] was performed under ivai-20-120062, the DHR review confirmed the scope was manufactured on July 12, 2016, under normal conditions, passed all required inspections, and released accordingly. There were no reworks or concessions and the dates of approval for shipment and actual date shipped were confirmed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11515805&pc=FAJ

1.4 Tissue fell into a patient that remained in the gastroscope from a previous procedure, February 2021

A report in the FDA's **MAUDE** database states the service center was informed of tissue that remained in the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 from a previous patient and fell into another patient during an unspecified procedure. The facility verified there

was no issue with the scope. The gastroscope was returned for evaluation due to verifying no issue with the scope after a piece of tissue remained in the scope after cleaning and was dislodged. Visual inspection was performed on the received condition, inspected the biopsy, and suction channels for foreign material. An Olympus borescope was used to inspect both the biopsy and suction channels. The borescope was inserted through the distal end side of the channel and numerous scrape marks were found along the wall, which start from the distal end opening and proceed into the channel at approximately 80 mm. The borescope was then inserted through the channel from the control body side and a stain was found upon entering the channel. The suction channel was also checked using the Olympus borescope (no damages or foreign material were noted). The functionality of the air/water function was also tested and verified the water flows consistently, with no stoppage, until release of the valve as intended. The videoscope passed the leak test. Olympus dispatched an Endoscopy Support Specialist (ESS) to the user facility to assess their reprocessing practices as part of the ongoing investigation. The ESS will also provide reprocessing training if necessary.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11339123&pc=FDS

1.5 Black ink like substance was leaking from the distal tip of the scope after reprocessing, February 2021

A report in the FDA's **MAUDE** database states, after the EVIS EXERA III Colonovideoscope PCF-H190L was reprocessed and hung, a black-like substance was leaking from the scope's distal tip. The scope was returned to the service center/pending evaluation. No patient involvement occurred.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11285164&pc=FDF

1.6 A visual inspection was performed on the duodenovideoscope after it was sent back to the service center with findings of foreign residue and damage to the scope, February 2021

A report in the FDA's **MAUDE** database states the service center was informed the EVIS EXERA II Duodenovideoscope TJF-Q180V cultured positive twice for either non-pathogenic mold or bacteria. The scope was cultured twice in 2020. The facility reported all their scopes are cultured after every case. A visual inspection was performed on the scope and discovered foreign residue and stains inside the suction channel opening and biopsy channel opening. The biopsy channel was inspected with an Olympus Borescope and foreign residue was discovered at the distal end opening of the biopsy channel. Also, brownish stain was found on the backside of the forceps elevator, when fully manipulated in the up direction. The borescope was farther inserted into the biopsy channel to find kinks located with the bending section portion as well as scrape marks found halfway into the biopsy channel. On the biopsy channel wall, a black streak was found near the control body side approximately at the 10 cm marking. There were more findings

with inspection within the biopsy and suction channels, noted voids on the glue between the control body, and forceps elevator. The glue had discoloration (with pinholes and wear around the edges) on both sides of the bending section causing small gaps. The glue surrounding the objective lens was also worn with pinholes and discoloration noted. The light guide lens has reddish brown (dried) foreign material within. The videoscope passed the leak test. The investigation of this event is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11373732&pc=FDT

1.7 The bronchoscope was sent back to Olympus and found the bending section rubber was worn and peeled off with a deep cut on the surface of the insertion tube, February 2021

A report in the FDA's **MAUDE** database states the user facility forgot to reprocess the EVIS EXERA Bronchovideoscope Bronchofibervideoscope BF-3C160 after the procedure. The scope was not used on any patient. Microbiological testing by the user facility, no microbe was detected from the sample collected from the suction channel and the instrument channel of the device. It was requested by the user facility to have Olympus to check for biofilm. No report on infection associated with this report. The scope was returned to Olympus and sent to a third-party lab for microbiological testing. The results found the following microbes were detected from the sample collected from the scope. All channels contained Bacillus spp., mesophilic (1CFU/endoscope), and Coagulase-negative staphylococci (1CFU/endoscope). The testing cleared the French guidelines. The scope was checked and found the adhesive of the bending section rubber was worn out and peeled off and there was a deep cut on the surface of the insertion tube. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11330892&pc=EOQ

1.8 During a Ureteroscopy using a Uretero-Reno Videoscope the surgeon had some resistance putting the 2.2Fr basket down and fibers fell out of the scope, February 2021

A report in the FDA's **MAUDE** database states that during a Ureteroscopy and laser Lithotripsy using a Uretero-Reno Videoscope URF-V2R the surgeon had resistance putting the 2.2Fr basket down. The physician repositioned the scope and managed to pass the basket, but no fibers came out. The physician was able to retrieve one of the fibers, then took the rest out of the patient and irrigated the ureter/kidney. No patient injury or infection related to this event. The scope was received by Olympus for physical evaluation and the investigation is ongoing. Upon inspection of the returned scope, it was confirmed the scope is leaking from scrape marks found inside the instrument channel. The inspection also revealed cracks found in the bending section cover glue. The definitive cause of these issues is inconclusive. The report will be updated upon completion of the investigation, or upon receipt of additional relevant information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10944490&pc=FGB

1.9 Blood came out of the gastroscope the day after when it was used and reprocessed, January 2021

A report in the FDA's **MAUDE** database states the user informed Olympia Medical Systems Corp. (OMSC) that blood came out of the EVIS EXERA III Gastrointestinal Videoscope GIS-HQ190 the day after it had been used and reprocessed with the cleaning brush and a non-Olympus AER Soluscope, and was then put in the drying cabinet. The scope was not returned to OMSC for evaluation. The exact cause of the reported event could not be concluded at this time. There was no patient injury associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11176969&pc=FDS

1.10 A polyp tissue came out of the scope from a previous patient during a Colonoscopy, January 2021

A report in the FDA's **MAUDE** database states during a Colonoscopy the previous patient's polyp tissue came out of the EVIS EXERA LLL Colonovideoscope CF-HQ190L after cold biopsy forceps was placed down the channel. The scope was properly cleaned (according to facility protocol) and ran through the scope cleaner DSD machine. No patient harm or injury reported due to the event. The scope nozzle channel was inspected, and no foreign material was noted. However, the distal end plastic cover of the unit was observed with deep dents and scratches. Based on evaluation findings, the issue was not confirmed. Possible causes could be due to (mis)handling and/or maintenance issues. To date, no patient infection has been reported. Updates will be provided accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11140242&pc=FDF

1.11 During a Cystoscopy using a Visera Cysto-NephroVideoscope, the doctor felt more friction than normal resulting in the patient having some bleeding after the exam, January 2021

A report in the FDA's **MAUDE** database states the patient had some bleeding post-procedure after the Visera Cysto-Nephro VideoscopeCYF-V2 was removed. The doctor felt more friction than normal. The scope was examined by the customer after the procedure. It was noted on the tip of the flexible portion of the scope the outer covering is raised (formed a ring) and is not smooth. The procedure was completed as planned. No treatment was required because of this, and the patient's current condition is stable with no continued bleeding. The physical evaluation

of the scope was visual inspection of the condition of the scope was performed and found the bending section cover buckle/stretched. The inspector placed the bending section between two fingers and proceeded to moderately pull the bending section cover from the insertion tube side up to the distal end. After releasing the bending section cover it was noted that the cover became buckle/stretched, never returning to its original form. The inspector also tested the bending section, glue, and cover, as stated in the inspection standards. The ring gauge was passed over the distal end and obstruction was found at the section of the bending cover, which had become buckled. A review of the scope history record was conducted and confirmed there were no abnormalities in manufacturing. The scope was 13 years and nine months old. The a-rubber had deteriorated, and the buoyancy occurred when the rubber was moving during procedure. External force: there is evidence that some external force was applied to the a-rubber, damaging the a-rubber, and contributing to the movement.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11130270&pc=FAJ

1.12 After reprocessing, there was a black foreign material in the cleaning tank, December 2020

A report in the FDA's **MAUDE** database states after reprocessing, a black foreign material was found in the cleaning tank. No report of patient injury associated with this event. The user facility did not provide other detailed information. OMSC investigated the OER-5 100V Endoscope Reprocessor and the foreign material was a film-like green substance. As a result of the analysis, OMSC found that the main component of foreign material is alginic acid. Alginic acid is a type of dietary fiber and the main component of brown algae. In the medical field, it is used for surgical sutures, wound dressings, and hemostatic agents. OMSC surmised the following: (a) a kind of brown algae was grown in the device; (b) foreign material is derived from medical products. A device history record review indicates the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10932617&pc=FEB

1.13 After reprocessing green sticky substances remained on a tray and the outside of the gastroscope, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed from the user that the green sticky substances remained on a tray and on the outside of the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 after the scope was reprocessed. The following information was also shared by the user. Before the reprocessing, the gastroscope was used for the procedure in which there was an emergency case to retrieve two button batteries from a

patient. Once retrieved, the scope was cleaned as per the usual procedure with a bedside cleaning with no evidence to indicate an unusual solution on or in the gastroscope. A disinfect (Rapicide A and B, Matrix disinfectant) and alcohol (70%) cycle in the Non-Olympus AER Medivators Advantage was completed to clean the scope. After the reprocessing procedure was completed, the scope was hung over night. Olympus Australia checked the scope and found the reported phenomenon could not be duplicated. No reported infection associated with this report. The gastroscope has not been returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11064744&pc=FDS

1.14 It was observed after reprocessing that dirty water and black debris was coming from the gastroscope, December 2020

A report in the FDA's **MAUDE** database states the service center was informed that dirty water and black debris was observed coming from the auxiliary water supply after reprocessing. The EXIS Exera III Gastrointestinal Videoscope GIF-HQ190 was returned to the service center for evaluation. The customer's complaint of dirty water coming from the auxiliary water supply was not confirmed. The auxiliary water supply and water flow were found normal. A leak was observed at the scope's biopsy channel and tear marks noted in the gastroscopes forceps passage. The insertion tube was inspected, and its angulation appeared abnormal (snake-like) in shape when using the scope's control knob. The scope's ID chip displayed a total usage count of 685. The investigation is ongoing, and the root cause is currently unknown. If additional information becomes available this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11036083&pc=FDS

1.15 Six microbiological testing by the user, Olympia Multi Specialty Clinic (OMSC) found several malfunctions with the colonoscope, December 2020

A report in the FDA's **MAUDE** database states a user facility informed OMSC because of six microbiological testings upon the sample collected from the instrument/suction channel of the EVIS EXERA LLL Colonovideoscope CF-HQ190L, which tested positive for unspecified microbes. On August 6, 2020, they detected P. aeruginosa (10-100 CFU) microbes in the suction channel. Olympus checked the scope and found the suction cylinder cover port was leaking at the distal end, insulation test failed, the bending angle did not meet specification, the light guide lens was chipped/cracked, the rubber adhesive was detached, chipped, cracked, or had a burr. No report of infection associated with this report. The scope was not returned to OMSC for evaluation. The exact cause of the reported event is currently undetermined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11010250&pc=FDF

1.16 A clip came out of the instrument channel of the colonoscope during a procedure that did not require clips, December 2020

A report in the FDA's **MAUDE** database states the customer saw a clip coming out of the instrument channel of the EVIS EXERA LLL Colonovideoscope CF-HQ190I. The procedure did not require clips. The clip likely got stuck in the channel in the previous procedure using the same scope. The scope was not returned to OMSC for evaluation and no further details were provided. No report of patient injury associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11044276&pc=FDF

1.17 The manufacturer of the duodenovideoscope inspected the scope and found multiple areas of damage on the scope, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed because of microbiological testing by the facility, the sample collected from the suction channel of the EVIS EXERA II duodenovideoscope TJF-Q180V tested positive for Klebsiella (60 CFU/20mL), Serratia (30 cfu/20mL), and E. coli (23 cfu/20mL0. The scope has been reprocessed with Olympus AER ETD3 plus using peracetic acid. No report of infection associated with this report. The scope was not returned to OMSC but returned to Olympus OEKG for evaluation. OEKG sent the scope to third-party lab for microbiological testing and the results showed no detection of microbes from the sample collected from the scope. The testing result cleared the German guideline. OEKG checked the scope and the following: (a) signs of humidity under the light guide lens, (b) bending section rubber was porous, (c) insertion tube was kinked and buckled, (d) the control section was worn out, (e) the name plate on the control section was missing, (f) air/water cylinder was worn out and had corrosion, (g) suction cylinder was worn out, (h) electrical connector was corroded, (i) distal end corroded, and (j) corrosion under the forceps elevator. The exact cause could not be conclusively determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11042579&pc=FDT

2.Malfunctions of Single-Use Scopes and Endcaps

2.1 During an ERCP procedure an unspecified Boston Scientific device became stuck in the working channel of the duodenoscope, May 2021

A report in the FDA's **MAUDE** database states during an endoscope retrograde cholangiopancreatography (ERCP) using a EVIS Exera III Duodenovideoscope TJF-Q190V, an unspecified Boston Scientific device was sent down and lodged in the working channel of the duodenoscope. The physician removed the scope with the device still stuck and protruding out the distal end (presumably with the elevator not in the proper position since it was stuck). At the time the physician did not notice anything abnormal with the patient, but later discovered there was a tear at the distal end of the esophagus. The physician rectified to stop the bleeding and the patient stayed overnight in the ICU. The patient's condition, as of today, is "doing fine." The physician is not certain what caused the tear. The device has not been returned to Olympus for evaluation, and the investigation is ongoing. The definitive cause of the user's experience cannot be determined at this time. This report will be updated upon completion of the investigation or upon receipt of additional relevant information. This event has been reported by the importer on mdr#2951238-2021-00338.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11832287&pc=FDT

2.2 Tissue became entrapped within the one time use cap and duodenoscope during and ERCP procedure, May 2021

A report in the FDA's **MAUDE** database states during an endoscopic retrograde cholangiopancreatography (ERCP) using an EVIS Exera III Duodenovideoscope TJF-Q190V, tissue became entrapped within the one time use cap and duodenoscope. The physician stated he followed the Olympus recommendation to avoid suctioning when withdrawing the scope. An upper endoscopy was performed immediately after completing the ERCP as the tissue was noted immediately after the procedure. There was trauma to the stomach (fresh blood clot) in the proximal corpus along the lesser curvature. The patient does have pain after the procedure, which is likely from her recent incisions to her gallbladder surgery and drain. The patient was treated with a proton pump inhibitor to heal the erosions and scope trauma.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11898553&pc=FDT

2.3 Tissue material was found in the single use distal cover at the end of two ERCP procedures, April 2021

A report in the FDA's **MAUDE** database states Olympus Medical Systems Corp. (OMSC) was informed by the user that during an ERCP that there was tissue material in the single-use distal cover (MAJ-2315) at the end of the procedure when removing the MAJ-2315. This event occurred on two procedures. The user completed the procedure with the single-use distal cover MAJ-2315. Bleeding was observed along the lesser curvature of the stomach wall close to the pyloric sphincter, but medical intervention was not required. The procedure was not extended and there was no further issue with the patient. The MAJ-2315 caps were checked for cracks/splitting before and after each procedure but there was no problem. The user stated the tear line in the caps is hazardous because there isa slight V-shaped indent at the distal end of the tear line and could easily catch a fold in the mucosa wall and ultimately cause tissue to get trapped within the cap. The single-use distal cover was not returned to any Olympus locations, and therefore, they could not investigate the MAJ-2315. The exact cause of the event could not be concluded at this time. If additional information is received, this report will be supplemented. This event is one of two similar cases, and this report is regarding the MAJ-2315 of the first case.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11678261&pc=FDT

2.4 The distal end cover fell off from the duodenoscope and fell into the patient's stomach, April 2021

A report in the FDA's **MAUDE** database states during an endoscopic retrograde cholangiopancreatography (ERCP), the user found that the distal end cover fell off from the device and fell into the patient's stomach. The user did not retrieve the distal end cover and did not confirm whether the distal end cover was evacuated naturally from the patient's body. The facility commented that the patient died because of illness and did not provide other information including details of the patient's illness. The scope has not been returned to Olympus Medical Systems Corp. (OMSC) for evaluation. The exact cause of the event cannot be conclusively determined at this time. The OMSC concluded the scope did not cause or contribute to the death of the patient (at this time) and reported this event as a malfunction. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11618314&pc=FDT

2.5 A single use distal cover's tip detached and fell into a patient during a procedure, April 2021

A report in the FDA's **MAUDE** database states the single-use distal cover's tip detached during a procedure. According to the initial reporter, when they removed the cap from the patient, the

distal tip was not present. Requests were made to the user on whether the segment was still in the patient and the doctor stated that if it was still in the patient, it will pass. The nurse said she did follow up with the patient two days post-procedure, and the patient was not experiencing any complications. The scope has not been returned for evaluation. If additional information becomes prior to the conclusion of the investigation, a supplemental report will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11693196&pc=FDT

2.6 The single-use cover moved as the duodenovideoscope was removed from the patient during the end of the procedure, February 2021

A report in the FDA's **MAUDE** database states OMSC was informed by the user that when EVIS EXERA III Duodenovideoscope TJF-Q190V was removed from the patient during the end of the procedure of a biliary catheterism. The user noticed that the single-use distal cover, which was attached to the scope, moved. The user stated the single-use cover might have inappropriately positioned to the scope before the procedure. The single-use distal cover remained in the patient's larynx. The user removed the single-use distal cover from the patient, which resulted in oxygen desaturation of the patient. There was no patient consequence and no problem to date. Olympus will train the user by request from the user. The scope has not been returned to OMSC for evaluation. The manufacturing history of the scope confirmed no irregularity. The exact cause of the reported event could not be conclusively determined. However, based on the reported information, the event may have occurred because of inappropriate attachment to the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11325980&pc=FDT

2.7 The disposable distal end cap dislodged and fell into the patient during an Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedure, January 2021

A report in the FDA's **MAUDE** database states Pentax Medical was made aware of an event in 2020 that the user reported. During the ERCP, the disposable distal endcap was dislodged and fell into the patient. The Pentax Medical accessory model OE-A63 lot 0011020 uses a medical video Duodenoscope ED34-I10T2. The Endoscopist attempted to find the lost cap but was unable to locate it and eventually withdrew. The facility responded to a good faith effort request via email on December 18, 2020, which stated the site is at a loss to explain why the scope tip (distal endocap) could come off. It was checked by both nursing and the physician before the procedure, and they claim they did hear audible click. A site meeting between Pentax Medical and the PLC clinical team is scheduled to discuss the complaint currently under investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11166914&pc=FDT

2.8 A piece of meat came out of the scope during an ERCP clinical demonstration, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed from the user that during an ERCP clinical demonstration, using with the TJF-Q290V, which the device was attached, the patient had severe stenosis and the physician could not continue the procedure. The physician replaced the TJF-Q290V to the JF-260V and completed the procedure. During reprocessing, the TJF-Q290V, the device was detached from the TJF-Q290V, the unspecified tissue (a piece of meat) came out from the subject device. The facility stated that before the procedure, the facility brushed the TJF-Q290V and reprocessed the scope with OER-4. No other detailed information was provided by the user facility. The scope was returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11011384&pc=FDT

2.9 During an ERCP procedure the disposable distal end cover came off the endoscope as the customer was withdrawing the endoscope from the patient, December 2020

A report in the FDA's **MAUDE** database states the user performed an ERCP with the disposable distal end cover MAJ-2315 and an endoscope TJF-Q290V. The disposable distal end cover came off the endoscope during the procedure at the timing the customer was withdrawing the endoscope from the patient. The disposable distal end cover was removed from the patient's mouth and the procedure was completed. No report of patient injury associated with this event. The device was returned to OMSC for evaluation. This product is supposed to be destroyed when it is detached from the endoscope to prevent unintended reuse. However, the device was not broken and suggests the device was attached to the distal end of the endoscope firmly. The device probably came off when the distal end of the endoscope hit the patient's mouth. The instruction manual provided preventive measures against the reported failure mode.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10933945&pc=FDT

2.10 The subject device fell off into the patient during the withdrawal of the endoscope after an ERCP procedure, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed by the user that the subject device fell off into the patient during the withdrawal of the endoscope after the completion of the ERCP procedure. The physician inserted another endoscope into the patient to find the subject device but was unable to locate it. The physician stated the device did not fall off into the patient's lungs since the patient was intubated and general anesthetized. The physician did not retrieve the device from the patient, but they estimated the subject device would be excreted naturally. The device was not returned to OMSC for evaluation and the exact cause of the

reported event could not be conclusively determined at this time. No patient injury associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11027056&pc=FDT

3.Cleaning Verification Testing

3.1 A duodenovideoscope was sampled and cultured as part of post-market surveillance activity and tested positive for microbes, May 2021

A report in the FDA's **MAUDE** database states on April 13, 2021, Fujifilm corporation was informed that the Fujifilm Duodenovideoscope ED-580XT was cultured and tested positive for Enterococcus faecalis, Klebsiella pneumoniae, and Bacillus flexus (10 total CFU). As the scope was sampled and cultured as part of a post-market surveillance activity, no patients were involved or exposed to the endoscope. Per study protocol, the endoscope was immediately quarantined after initial sampling until culture data were available. Following the growth, the endoscope was not clinically reused. The scope was returned to and inspected by Fujifilm Medical Systems U.S.A, Inc. The inspection results found no issues with the scope. The scope was sent to Fujifilm Corporation for further investigation. No death or serious injury was associated with this event. The report is being submitted in abundance of caution. If any additional relevant information is provided, a supplemental report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11811789&pc=FDT

3.2 Microbes were detected after multiple microbiological testing by the user facility, May 2021

A report in the FDA's **MAUDE** database states Olympus medical systems corp. (OMSC) was informed that with multiple microbiological testing by the user facility, the following microbes were detected from the sample collected from the Cysto-Nephro Videoscope CYF-VH. First time in 2021: Staphylococcus aureus (3 CFU/endoscope). Second time in 2021: Lysinibacillus fusiformis (10-100 CFU/ml). Information on the reprocessing method was not provided. The scope was not returned to OMSC but was returned to Olympus. The scope was checked and found a dent on the insertion tube was found. The exact cause of the reported event could not be conclusively determined at this time. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11812712&pc=FAJ

3.3 During routine microbiological testing by the user facility, microbes were found on a uretero fiberscope, May 2021

A report in the FDA's **MAUDE** database states the Olympus was informed that the user facility performed routine microbiological testing on the Uretero-Reno Fiberscope URF-P7 with the following microbes detected from the sample collected: Bacillus cereus (2 CFU) and pseudomonas spp. (1 CFU). Other detailed information such as the reprocessing method was not provided. The scope was not returned to OMSC but was returned to Olympus France (OFR). OFR sent the scope to a third-party lab for microbiological testing and no microbe was detected from the sample collected from all the channels of the scope. The testing cleared the French guideline. The exact cause of the event could not be conclusively determined at this time. There was no report of infection associated with this report. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11825168&pc=FGB

3.4 With multiple microbiological testing, several microbes were detected from a sample collected from the duodenovideoscope, April 2021

A report in the FDA's **MAUDE** database states Olympus Medical Systems Corp. (OMSC) was informed that as the results of multiple microbiological testing by the user facility, the following microbes were detected from the sample collected for the EVIS Exera III Duodenovideoscope TJF-Q190V:

- First time (2021): unspecified channel; Klebsiella pneumoniae (150 CFU)
- Second time: unspecified channel; Klebsiella pneumoniae (quantity is unknown but was reported to be large)
- Third time: unspecified channel: P. aeruginosa (28 CFU)
- Fourth time: unspecified channel: P. aeruginosa (quantity is unknown but was reported to be large)
- Fifth time: unspecified channel: P. aeruginosa (300 CFU).

The scope had been reprocessed with a non-Olympus automated endoscope reprocessor, Medivators Rapid AER using peracetic acid. The customer said the AER would not be sufficient for reprocessing and reported that the customer used OneLIFE's enziQure® as a detergent for the process. Also, there was a slight scratch on the instrument channel. The scope was sent to Olympus and then sent to a third-party lab for microbiological testing. The results of the testing, no microbe was detected from the sample collected from all the channels and distal end of the scope. The testing result cleared the French guideline. The exact cause of the reported event has not yet been identified by legal manufacturer OMSC for this scope. There was not report of

infection associated with this report. If significant additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11669493&pc=FDT

3.5 A patient developed a respiratory tract infection with Mycobacerium llatzerense 19 days post a Bronchoscopy procedure, April 2021

A report in the FDA **MAUDE** database states a patient developed a respiratory tract infection with Mycobacterium llatzerense 19 days post Bronchoscopy procedure with an EVIS Evera II Bronchovideoscope BF-Q180—for the indication of hemoptysis for two months and cough. This was diagnosed with bronchial alveolar lavage (BAL). The endoscope was shipped back (and forwarded) for 3rd party culturing. The definitive cause of the user's experience cannot be determined at this time. It was discovered, at the end of each bronchoscopy procedure, tap ice water was being injected through the scope with a syringe intending to reduce post-procedure bleeding. Culture results of the water supply are: (a) heterotrophic place count (HTC) having a count of (214 CFU) and (b) a total coliform E. coli test. The water was not tested for the specific organism identified in the patient cultures. The water company came to culture the ice machine and could not because it was turned off. The water source was the same for the sink and ice machine. While they cultured the sink, they did not culture the ice machine (even after the machine was turned on). This investigation is ongoing, and the report will be updated upon completion of the investigator or upon receipt or additional relevant information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11665612&pc=EOQ

3.6 The user facility did multiple microbiological testing on a gastroscope, and microbes were detected, March 2021

A report in the FDA's MAUDE database states Olympus Medical Systems Corp. (OMSC) was informed because of multiple microbiological testing by the user facility that microbes were detected from a sample collected from the EVIS Exera Gastrointestinal Videoscope GIF-Q16Z.

- First time: Klebseilla pneumoniae (50 CFU), Acinetobacter baumannii (200 CFU).
- Second time: Acinetobacter baumannii (4 CFU).
- Third time: Acinetobacter baumannii (8 CFU), Klebseilla pneumoniae (5 CFU).

The scope had been reprocessed in a non-Olympus AER, Steelco ew2, using peracetic acid. The scope has not been returned to OMSC but was returned to Olympus Europa. The scope was sent to a third-party laboratory for microbiological testing and no microbes were detected from the

sample collected from the distal end and the forceps elevator and the suction, the instrument, the air/water channels of the scope. The testing result cleared the guideline. It was also confirmed in the evaluation of the scope- the adhesive of the light guide lens and the objective lens were worn; there were deposits on the distal end cover; the control section had damage; there were deposits on the air/water cylinder and suction cylinder; the adhesive part on the bending section rubber was worn out. There was no report of infection associated with this report. The exact cause of the reported event could not be conclusively determined at this time. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11410476&pc=FDS

3.7 Several microbes were detected in a colonoscope after the result of multiple microbiological testing by the user facility, March 2021

A report in the FDA's **MAUDE** database states OMSC was informed because of multiple microbiological testing by the user facility, the following microbes were detected from the sample collected from the EVIS Exera LLL Colonovideoscope CF-HQ190L.

- First time: Candida parapsilosis complex (< 10 CFU), Coagulase-negative staphylococcus (< 10 CFU), Corynebacterium sp. (< 10 CFU).
- Second time: Micrococcus luteus, Candida parapsilosis complex (<10 CFU).
- Third time: Kocuria sp. (8 CFU).

Other detailed information such as the reprocessing method was not provided. The scope was not returned to OMSC but returned to Olympus for evaluation. The scope was inspected and confirmed the following: (a) the universal cord was wrinkled, (b) endoscope connector unit was flooded, (c) object lens and light guide lens were cracked, and (d) the light guide lens was chipped, (e) there were dents and scratches on the distal end cap, (f) the resin part of the lens was worn, (g) angulation was slack and did not meet the specifications. Also, (h) the adhesive on the bending section rubber was peeling off, and (i) evidence of being repaired by a third-party and had third-party parts installed.
The insulation resistance value at the distal end did not meet the standard value due to the breakage of the bending section rubber. The control section was deformed, and the image guide protector was discolored. The endoscope connector was corroded, and the connector cover unit was deformed. The scope was repaired and an insertion tube, universal cord, control section, and endoscope connector were replaced. The exact cause of the reported event could not conclusively be determined at this time. There was not report of infection associated with this report. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11511093&pc=FDF

3.8 Four patients became symptomatic of a fungal infection after a surgical procedure with a Bronchoscope, March 2021

A report in the FDA's **MAUDE** database states that four patients became symptomatic of a fungal infection after having a surgical procedure with the Pentax Video Bronchoscope EB-1570K. Pentax medical was made aware of a complaint on February 25, 2021, by the user facility representative in the United States. The physician asked for the scope to be tested for fungus. February 26, the processing and infection control leader provided his recommendation on sampling and processing the returned endoscope and suggested a question to include in the good faith effort attempt to the customer. On March 1, the director took the action item to reach out to the user facility in regards communication of the sampling options, process, and associated fees. Good faith efforts were sent to the facility and sales rep requesting event and patient details on March 5 and March 16 as well as several questions about their cleaning and testing process. The user facility's point of contact responded with only the date and no additional information. According to the processing plan, the endoscope was sampled March 11 prior to reprocessing/cleaning, and again on March 15 after reprocessing/cleaning. Sampling of the endoscope before reprocessing: (1cfu), Staph. hominis. Low concern microorganism, skin flora, only (1cfu). After reprocessing, no growth was found. March 9, a device history record was performed, and the history record review confirmed the endoscope was manufactured on March 4, 2009, under normal conditions, passed all required inspections, and was released accordingly. The endoscope has been routinely serviced at a Pentax facility since the device was put into service on March 24, 2009. The endoscope is pending sampling results and further evaluation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11579157&pc=EOQ

3.9 Sample collected from the instrument channel of a gastroscope tested positive for Candida albicans after microbiological testing, December 2020

A report in the FDA's **MAUDE** database states OMCS was informed by the user facility a sample was collected from the instrument channel of an EXVIS Lucera Elite Gastrointestinal Videoscope GIF-H290 and tested positive for Candida Albicans (200 CFU/endoscope) after microbiological testing. The scope had been reprocessed with an Olympus AER OER-AW using peracetic acid. The gastroscope was not returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time. There was no report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11001085&pc=FDS

3.10 Sample collected from all channels on a colonoscope for microbiological testing resulted positive for microbes, December 2020

A report in the FDA's **MAUDE** database states microbiological testing by the user facility collected samples from all channels of the EVIS EXERA III Colonovideoscope CF-H190I tested positive for Enterococcus faecalis (>100 CFU) and Enterococcus faecium (>100 CFU). The scope had been reprocessed with an Olympus AER model ETD 3 Plus using peracetic acid. The scope was not returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time. There was no report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11071798&pc=FDF

3.11 Multiple microbiological testing for the duodenovideoscope microbes were detected from the sample collected, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed by the user facility of the result of multiple microbiological testing. The following microbes were detected from the sample collected from the EVIS EXERA II duodenovideoscope TJF-Q180V: a) First time- Stenotrophomonas maltophilia; b) Second time- P. aeruginosa and Stenotrophomonas maltophilia. The scope has been reprocessed with non-Olympus AER Wassenburg using peracetic acid. No infection was reported in association with this report. The scope was not returned to OMSC but returned to Olympus. OFR sent the scope to a third-party lab for microbiological testing. The sample collected from all channels of the scope tested positive for Micrococcaceae (1CFU/endoscope) and the sample collected form distal endo of the scope tested positive for gram positive bacteria (2 CFU/endoscope). The testing cleared the French guideline. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11052924&pc=FDT

4.Excessive Force with Equipment

4.1 The tip of an Ambu aScope single-use flexible bronchoscope broke off in the endotracheal airway tube of a patient, May 2021

A report in the FDA's **MAUDE** database states the tip of an Ambu® aScope™ single-use slim Flexible Video Bronchoscope 476001000 broke off inside the endotracheal airway tube of a patient. The physician retrieved the broken piece, and the patient was not affected. No sample was returned for investigation and Ambu® has not been able to verify the failure. The expected

cause of the failure is mishandling, where the bending section was not in straight (neutral) position during extraction of the bronchoscope from the Double Lumen Endotracheal Tube (DLT) and excessive force was applied to pull out the scope causing the distal end to break off. It is stated in the IFU, the distal tip must be set in a neutral or non-deflected position when being withdrawn and excessive force should be avoided. The reported problem is included in the product risk analysis.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11848431&pc=EOQ

4.2 During an unspecified procedure the Uretero-Reno Videoscope was found to have a broken tip, January 2021

A report in the FDA's **MAUDE** database states the Ureter-reno Videoscope URF-V2 was found with a broken tip during an unspecified procedure. The scope was evaluated by Olympus. The physical evaluation reveals: a) Leaks at the biopsy channel, b) Bending section was broken with protrusion of the skeleton, c) Dent in the insertion tube angulation was low. The manufacturers IFU provides the user information related to the reported event. The scope history record was reviewed and confirmed there were no abnormalities. The definitive cause of the reported event could not be established. Based on investigation results the probable cause may be the user inadvertently manipulated the scope with excessive force to bending section.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11215143&pc=FGB

5. Failures Due to Reprocessing Equipment (AERs)

5.1 The water filter has not been replaced in the OER since 2016, March 2021

A report in the FDA's MAUDE database states the user had not replaced the water filter of the OER-4 100V Endoscope Reprocessor since 2016. Other detailed information was not provided. The OER was not returned to Olympus Medical Systems Corp. (OMSC) for evaluation and could not be investigated. The device history record review (DHR) indicates the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. There was not report of patient injury associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11510848&pc=FEB

5.2 The level of disinfectant solution is only checked once a month, March 2021

A report in the FDA's MAUDE database states the local service engineer said the user only checks the level of disinfectant solution once a month. However, the concentration level needs to be checked every time. No other detailed information was provided. The OER was not returned to OMSC because the OER-4 100V Endoscope Reprocessor was not returned. The device history review indicates the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. When the user operates the OER, the disinfectant solution concentration level should be checked each time by the test strip. No report of patient injury associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11397640&pc=FEB

5.3 The user reported white crystalline material became adhered to the reprocessing basin of OER, March 2021

A report in the FDA's MAUDE database states the user informed Olympus Medical Systems Corp. (OMSC) that despite operating the Automated Endoscope Reprocessor (AER), as per normal, thick white crystalline material had become adhered to the reprocessing basin of the OER-4 100V Endoscope Reprocessor along the retaining rack. The issue was found during reprocessing; though, the AER had functioned without any problem. The OER was returned to OMSC for evaluation and reviewed the manufacturing DHR of the OER and confirmed no irregularity. OMSC performed analysis of component of the white crystalline material—oxygen, carbon, and silicone were mainly detected. It was considered the white crystalline material was a mixture of peracetic acid (disinfectant solution) and silicone-based material, which might be an antifoam agent or other medical agent. It was considered there was the possibility these might be mixed into the reprocessing basin, or these could not be rinsed completely, then remained in the reprocessing basin. The exact cause of the reported event could not be conclusively determined. There was no report of patient injury associated with the event. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11587597&pc=FEB

6. Endoscope Malfunctions

6.1 A colonoscope was cleaned after a procedure and the user found blood and metal exposed on the scope, April 2021

A report in the FDA's **MAUDE** database states that on December 4, 2020, the user reported they checked the Pentax Video Colonoscope EC-380FKP before the procedure and confirmed there was no abnormality. After the procedure, the user cleaned the scope with gauze, found something tough, and there was blood on the gauze. The user found some metal exposed at 22 cm of the scope, then stopped using the scope. During the APAC Region investigation, the distributor checked with the user and found the patient had scratches. The patient left the hospital after several days. Neither the user nor patient information was provided. After the inspection of the scope, the distal end-part/bending rubber had serious distortion/wrinkles. The wire of the mesh-part slightly popped out 20 cm. The angulation wire was tight, and the knob was worn. The rubber strain relief was loose. The engineer advised the user to do the pre-use check before and procedure including dent, wrinkle, bent, and over twisted. After checking to make sure all the functions are working well, then it can be used on the patient. If any abnormality was found, they should contact the engineer to evaluate. This is the first time the scope has been returned for service at a Pentax facility since the scope was put into service on March 8, 2016. On April 21, 2021, a device history record (DHR) review for the scope was performed confirming the scope was manufactured on September 5, 2015, under normal conditions, passed all required inspections, and was released accordingly. There were no reworks or concessions and the dates of approval for shipment and actual date shipped were confirmed for September 7, 2015. The engineer repaired the endoscope and returned it to the hospital. The type of investigation was testing of actual/suspected device. The findings of the investigation were maintenance problems identified. The conclusion of the investigation was unintended use error caused or contributed to event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11699945&pc=FDF

6.2 The surgeon made several attempts to remove the ureteroscope from the patient's ureter, March 2021

A report in the FDA's **MAUDE** database states a patient underwent a ureteroscopic laser lithotripsy. The surgeon was unable to remove the Uretero-Reno Videoscope Ureteroscope URF-V3R from the ureter, and after several attempts an exploratory laparotomy was performed. The surgeon noted the scope bunched and formed a ring that was caught on the ureteral mucosa. The left ureter was avulsed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11581007&pc=FGB

6.3 Two endoscopes became hot at the distal tip of the Gastroscopes during preparation in November, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed by the user that distal ends of two Olympus 1500 series endoscopes became hot. One hospital endoscopist experienced this issue during preparation on November 23 and at the beginning of procedures on November 24. The endoscopist touched the distal tip of the Gastrointestinal Videoscope GIF-Z1500 with gloves on to protect the patient from the scope's light and noticed the tip got hot. A nurse then touched the tip of the scope with gloves on for about 5 seconds and the scope made a mark on the gloves with its heat. There were no burns on the skin to the nurse's hands. The endoscopist continued to use the scope to complete the procedure. The gastroscope was being used in normal light mode at the timing of the event occurred. The gastroscope has been used a total of eight times but has not been used thereafter because the washing cycle failed. The scope has been reprocessed with a non-Olympus AER Getting Washer.

The scope was not returned to OMSC but was returned to Olympus service for evaluation. The scope was visually inspected and found no defects. Olympus services conducted scope surface temperature monitoring to reproduce the reported event. A significant increase in temperature was observed while activating the optical output of the video system center. The most significant increase in temperature was observed whilst activating the white light mode at maximum output. The highest temperature recorded was 72.5 °C and the ambient temperature was 23 °C. Olympus service did perform a surface contact test by pressing the distal end against the surface of nitrile inspection gloves and confirmed that direct contact with gloves burns them in white light imaging mode. Narrow band imaging mode and red dichromatic imaging mode did not burn the gloves but made marks on the gloves. The exact cause of the reported event could not be conclusively determined at this time. No report of patient injury associated with this event. There were no abnormalities that occurred on other endoscopes including the Olympus 290 series that the user facility owns. This is the second of two reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11070568&pc=FDS

7.Use Errors

7.1 After reprocessing yellow liquid came out of the distal end of the duodenovideoscope, May 2021

A report in the FDA's **MAUDE** database states Olympus Medical Systems Corp. (OMSC) was informed by the user that after reprocessing the EVIS Exera Lucera Duodenovideoscope TJF-260V, yellow liquid (possibly bile) came out of the distal end of the scope. The scope was reprocessed with an Olympus automated endoscope reprocessor (AER) model OER-3, OER05 (not available in the United States) using peracetic acid. No other detailed information was

provided. The Duodenoscope was not returned to Olympus Medial Systems Corp. (OMSC). The exact cause has been under investigation. There was no report of patient injury associated with the event. A supplemental report will be submitted if additional or significant information becomes available later. This is the first of the two reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11781197&pc=FDT

7.2 The uretero-reno fiberscope was observed to being reprocessed incorrectly at the user facility, May 2021

A report in the FDA's **MAUDE** database states an Olympus Endoscopy Support Specialist (ESS) reported that during a repair reduction observation at the user facility, the Uretero-Reno Fiberscope URF-P7 was being reprocessed incorrectly. The ESS observed that the customer did not perform any precleaning of the scope following the procedure. During the manual cleaning after the customer finished brushing, the channels were not flushed with detergent, water, or air using a 30 ml syringe. The ESS did inform the customer of the observation findings. The ESS sent the customer an email with all the findings and suggested setting up a reprocessing in-service to go over the correct way to clean the scope according to the IFU. The ESS recommends the customer create an action plan for the reprocessing technician to receive additional training and obtain the necessary cleaning/disinfection items to reprocess all scopes per Olympus reprocessing manual recommendations. The scope will not be returned for evaluation. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation. There was no patient harm to report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11827263&pc=FGB

7.3 The air-feeding function of the gastroscope was not working properly, April 2021

A report in the FDA's **MAUDE** database states Olympus Service Operation Repair Center (SORC) was informed by the user at an unspecified timing the air-feeding function of the EVIS Lucera Gastrointestinal Videoscope GIF-Q260 did not work properly. The scope was returned to SORC, where they found blood came out from the air/water cylinder. The scope was returned to Olympus Medical Systems Corp. (OMSC) for evaluation. There were no further details provided. If significant additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11618669&pc=FDS

7.4 Human body tissue came out of the instrument channel of the gastroscope while inserting an endotherapy accessory into it, April 2021

A report in the FDA's **MAUDE** database states the user informed Olympus Medical Systems (OMSC) that a human body tissue came out of the instrument channel of the EVIS Exera III Gastrointestinal Videoscope GIF-H190 while the user was inserting an endotherapy accessory into it. The scope was used with endotherapy accessories and a non-Olympus single-use biopsy valve. The user replaced the scope to the new gastroscope and completed the procedure. A blood test was done before the patient was discharged. The scope has not been returned to OMSC for evaluation. The sales representative provided additional information and confirmed the scope was used gastroscopy before the reported event occurred. The scope was then reprocessed with a non-Olympus AER, Soluscope. A non-Olympus channel cleaning brush was used to clean the endoscope. The user only brushed for patency while cleaning the scope. There was no report of patient injury associated with the event. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11669514&pc=FDS

7.5 A foreign substance was stuck to the distal end of a gastroscope during endoscopy procedures with a risk of cross-infection in a total of 84 patients, April 2021

A report in the FDA's **MAUDE** database states Fujifilm corporation was informed of an incident in Europe involving the Fujifilm EG-760R Gastroscope EG-760R. The endoscopy procedures were performed with the endoscope having a foreign substance stuck to the distal end, so there is a risk of cross-infection in a total of 84 patients who underwent the endoscopic procedure. The facility sent a letter to 84 patients about the possibility of cross-infection. It is unknown whether there were any health hazards associated with the event. Inspection of the scope by Fujifilm is pending. Per the facility's website: during an endoscopic procedure there was insufficient light output. An inspection of the scope determined there was a deviation from the precleaning instructions provided in the device labeling, which was fixed immediately. The facility is continuing to follow up with the affected patients and reported the incident to the NCA as well as started a detailed investigation still ongoing. If any additional relevant information is provided, a supplemental report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11651497&pc=FDS

7.6 After an unspecified procedure was completed, the scope was left overnight and then reprocessed the next morning, April 2021

A report in the FDA's **MAUDE** database states the user found a clip in the suction channel of the Evis Lucera Colonovideoscope CF-H260DL, which had been reprocessed at the preparation for

use. It was also reported the scope was used in the unspecified procedure, left overnight, and reprocessed the next morning. The hemostasis clip (Nova clip) came out from the scope during manual cleaning. The scope was used for one or possibly two patients. Then another clip came out from the scope. However, no clips were used during the procedures in the endoscopy. The scope was not returned to OMSC but returned to the service department of Olympus for evaluation. The service department checked the instrumental and suction channels of the scope, but nothing was found as the user reported; even inside the channel was checked using the thinnest industrial videoscope. No damage and blockages could be found with the channels and no clips were present. No report of patient injury associated with this event. The exact cause of the reported event could not be conclusively determined at this time. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11677487&pc=FDF

7.7 During reprocessing, a brown rust type liquid was coming from the tip of the cysto-nephro scope, April 2021

A report in the FDA's **MAUDE** database states the user facility reported to Olympus that a second leak test was performed on the Cysto-Nephro Videoscope CYF-VH the day before and the scope had passed the leak test; however, a brown-rust type liquid was coming from the tip of the scope even after a brush was run through it and it is unknown if it was a microorganism. The issue was found in reprocessing and was not EtO sterilized. The cysto-nephro scope was put through the OER-Pro after being hand washed. All reprocessing personnel were trained in how to properly reprocess an endoscope. The scope was returned to an Olympus center for evaluation and the reported issue was confirmed. There was a channel leak, the bending section rubber was worn and had scratches, and the Evis image was foggy/blurry. The body had corrosion and scratches, and the video cable had a minor dent. The scope connector had a loose end to open (EtO) valve and video connector had minor scratches. The endoscopy support specialist (ESS) was dispatched to observe the user facility's reprocessing practices from start to finish and provide a reprocessing in-service training (if necessary) to correct and address any reprocessing deviations. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation. No patient harm was reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11620257&pc=FAJ

7.8 A gastroscope was pulled out of the cabinet and blood was dripping from it, March 2021

A report in the FDA's **MAUDE** database states while preparing for a procedure, an EVIS Exera II Gastrointestinal Videoscope GIF-2TH180 was pulled from the cabinet and there was blood dripping from it. The scope was reprocessed the day before and was not used on any other

patients. It was stated at times, a scope would be reprocessed and when moved from the washer to the transfer case, debris would leak out of it, at which time the scope was reprocessed.

The Endoscopy Support Specialist (ESS) communicated to the customer the issue usually stems from not performing the bedside cleaning correctly. Therefore, debris is left behind. If the scope sets for any length of time, that debris hardens to the point the normal cleaning process cannot remove it all. The channels still have residual moisture in the channels after it comes out of the AER. As the residual moisture sits on the debris, it loosens it to the point that as the scope hangs to gravity dry, the loosened debris drips out of the distal tip. This can easily occur on a dual channel scope if the correct bedside cleaning is not performing correctly, which requires more than a general gastrointestinal scope. The ESS also performed an in-service visit to observe the user facility's reprocessing practices from start to finish and provided reprocessing in-service training to correct and address any reprocessing deviations. Also, the ESS sent delayed reprocessing instructions and the correct connection information when using and OER-Pro. The scope was not returned for evaluation, so the scope evaluation could not be completed at this time. The investigation is ongoing.

The legal manufacturer performed an investigation. The DHR review could not be performed as no lot number was reported and there was no scope return to inspect for a lot number. If the lot number becomes available later, the DHR shall be reviewed. The probable cause of the reported issue was due to the delay of the reprocessing after the procedure.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11422829&pc=FDS

7.9 A fragment fell out of the channel of the gastroscope into the patient during a diagnostic upper endoscopy procedure, March 2021

A report in the FDA's **MAUDE** database states the user informed Olympus Medical Systems Corp. (OMSC) during a diagnostic upper endoscopy with the EVIS Lucera Elite Gastrointestinal Videoscope GIF-XP290N, a fragment fell out of the channel of the device into the patient while flushing the patient's gastrointestinal tract. The physician retrieved the fragment from the patient. The fragment was a distal tip of a cleaning brush that was broken during the reprocessing in December 2020 and remained in the channel since then. The user completed the procedure by using the scope. The scope was returned to OMSC for evaluation. There was no report of patient injury associated with the event. No further details provided. If significant additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11522962&pc=FDS

7.10 Unknown black substance was exiting out of the colonoscope after being washed six times, March 2021

A report in the FDA's **MAUDE** database states during reprocessing of the EVIS Exera III Colonovideoscope CF-HQ190L, an unknow black substance was exiting out of the scope. According to the initial report, they washed the scope six times and were still seeing the black substance. There was no patient involvement during this event. The scope was returned, and initial evaluation was conducted by Olympus; however, investigation is ongoing. During the initial evaluation a scope leak check was performed on the forceps passage and a leak was noted from the bx channel. Additionally, a no image b30 error code was noted but cleared up after aeration. There were dents noted on the plastic cover of the device. If additional information becomes available following device evaluation, a supplemental report will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11597049&pc=FDF

7.11 Endoscopy Support Specialist observed during post procedure that no precleaning of the cystoscope was being performed, March 2021

A report in the FDA's **MAUDE** database states the service center was informed during a repair reduction visit at the user facility with an Endoscopy Support Specialist (ESS) it was observed during post procedure that no precleaning of the Cystonephrofiberscope CYF-5 was being performed. The ESS reported the employee sprayed the scope handle with Cavicide disinfectant spray and wiped the insertion tube of the scope down with a paper towel and water, then proceeded to place the cystoscope directly into a tube on the wall of disinfectant. While onsite, the ESS discussed improper precleaning with the staff and was informed due to time restriction the staff was not performing precleaning and other steps. The ESS inquired about the facility's manual cleaning steps and observed the staff wiped down the scope with detergent. When inquiring about brushing, the ESS was told the scope is brushed at the end of the day. The staff informed the ESS the facility did not have containers to submerge and flush scopes to complete the manual disinfection steps. The scopes are hung, and the insertion tube submerged in the disinfectant for 30 minutes, then removed. The ESS performed an in-service and demonstration of reprocessing the scope in accordance with the manufacturer's recommendations. The ESS briefly discussed the noted reprocessing deviations with the physician and scheduled a follow-up call. The physician inquired if there was a training video available and the ESS referred the physician to the Olympus university for further training opportunities. The scope will not be returned to the service center for evaluation. The investigation is ongoing and if additional information is received this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11477490&pc=FAJ

7.12 During a repair reduction teleconference with the user facility, it was determined that an incorrect or improperly reprocessed scope was used, March 2021

A report in the FDA's **MAUDE** database states the service center was informed during a repair reduction teleconference, with the user facility and endoscopy support specialist (ESS), it was confirmed that an incorrect or improperly reprocessed the Cystonephrofiberscope CYF-5 was used. The customer reported that leak testing has not been performed for twenty years due to the facility's time restrictions and staff issues. The scope is not rinsed 3x as this will delay the number of patients the facility can service. The facility does not have the appropriate set up for the proper reprocessing as stated in Olympus instructions for use. The ESS reeducated customer on the potential risks associated with improper reprocessing.

On February 23, 2021, an ESS was dispatched to the user facility to observe the facility's reprocessing practices and provide an in-service. During training a manager from the user facility timed the process starting from the precleaning until the high-level disinfectant (HLD). The ESS was informed by the manager the staff does not perform any precleaning or hanging of the scopes. The ESS observed the scopes are set in a distilled water basin (after the HLD and rinse) with the tip submerged in the distilled water for up to an hour before it is used again. It is unclear how often the water was changed. The ESS reported the reprocessing issues were discussed with the facility's manager. The manager informed the ESS that the problems with the cleaning and reprocessing of the scopes will be discussed with the doctor. The scope will not be returned to the service center for evaluation. The investigation is ongoing, and, therefore, the root cause of the reported event cannot be determined at this time. If additional information becomes available this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11453621&pc=FAJ

7.13 A Ureteroscope had black residue coming out of it after cleaning it several times, March 2021

A report in the FDA's **MAUDE** database states during reprocessing of an Uretero-Reno Videoscope URF-V3R using a Sterrad® reprocessor with a wire/nylon bristle brush for ureteroscopes, and after cleaning several times, black residue keeps coming out of it. The scope has been evaluated by Olympus with preliminary findings are reported. Physical evaluation of the scope reveals: a) A leak was found at the biopsy channel due to a cut/crack in the rubber glue, b) Forceps channel was found to be leaking with a scrape mark inside the borescope, and c) Angulation was low. The definitive cause of the user's experience cannot be determined at this time. The investigation is ongoing and will be updated upon completion or upon receipt of additional relevant information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11405795&pc=FGB

7.14 An Endoscopy Support Specialist from Olympus did an in-service observation of the facility's reprocessing staff and found several reprocessing steps were being missed, February 2021

A report in the FDA's **MAUDE** database states an Olympus ESS did an in-service observation of repair reductions and facility summary. The ESS observed the reprocessing staff at the facility needed improvements due to missing steps on their manual cleaning procedure. Improper leak testing, improper manual cleaning, and flushing syringe step was not performed. The sterile processing supervisor confirmed there were no patient injuries, infection, or harm associated with the urology and ENT flexible endoscopes. During the reprocessing steps, the ESS observed the following:

- Leak testing was conducted without operating the far end
- Detergent was used during the leak test
- During manual cleaning, compatible detergents were not prepared as recommended by the manufacturer and water was not filled to the fill line
- The diameter of the cleaning brush may not fit the channel because it did not use the sponge or the cloth without thread scraps
- Flushing by syringe was not done.

The ESS spoke with the nurse supervisor regarding the observation findings and sent an email with the observation summary including: forms, helpful literature, and the reprocessing manual for the Visera Cysto-Nephro Videoscope CYF-V2. The email included all the findings during repair reduction and the issues found during reprocessing. A follow-up in-service has not been finalized. The legal manufacturer performed the device history records for the scope and all records indicated that the product was manufactured according to all applicable procedures and met final product release criteria. No abnormalities were found. The legal manufacturer confirmed the most probable cause of the incorrect/insufficient reprocessing was due to user error.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11272180&pc=FAJ

7.15 Foreign matter was found adhering to the forceps/irrigation plug during a procedure, February 2021

A report in the FDA's **MAUDE** database states the user found foreign matter adhering to the Forceps/Irrigation Plug MAJ-891 during a procedure. After reprocessing, the user completed the procedure by using the device. Due to this problem the procedure did run longer than planned. No report of patient injury. The device was not returned to OMSC and could not be investigated. There was a possibility the incident reported was attributed to the insufficient reprocessing of the device by the user.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11357059&pc=FGB

7.16 A piece of the scope's sheathing came off and fell into the patient's lung, February 2021

A report in the FDA's **MAUDE** database states during a patient procedure with a Glidescope® BFlex 5.0 bronchoscope that a piece of the scope's sheathing came off and fell into the patient's lung. The customer said they believed they were able to suction the piece out. It was reported there was no delay in the procedure, use of a backup scope, or harm to the patient or user. The Glidescope® single-use bronchoscope was received by Verathon Inc. but was not yet analyzed. Verathon continues to investigate the reported event and a supplemental report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11304127&pc=EOQ

7.17 Patient coughed up piece of the light source from a bronchoscopy 12 days after procedure, January 2021

A report in the FDA's **MAUDE** database states 12 days after the bedside Bronchoscopy in the CVICUthe patient was coughing and coughed up a piece of the scope, which was the light source. The scope that was used for the procedure was a Glidescope® Bronchoscope BFlex. Post procedural X-ray did show device but was not resulted by the radiologist.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11228833&pc=EOQ

7.18 A user facility did not change the disinfectant in their endoscope reprocessor for 84 days, December 2020

A report in the FDA's **MAUDE** database states a local service engineer checked the endoscope reprocessor, 84 days had passed since the last disinfectant change. No other detailed information was provided. OMCS could not investigate the device, because the endoscope reprocessor was not returned to OMSC. The device history record review indicates that the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. Based on the report, OMSC surmised that the cause of this phenomenon was the following factor: Since the disinfectant solution concentration level is not checked each time, this event has occurred.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10963453&pc=FEB

7.19 The user facility utilized expired Acecide disinfectant in the endoscope reprocessor, December 2020

A report in the FDA's **MAUDE** database states the user facility reported to Olympus that they had utilized expired Acecide disinfectant in the endoscope reprocessor OER-PRO. The facility has a five-day limit on the usage of the disinfectant, but they utilized the reprocessor with the expired disinfectant on day six. Although the disinfectant was expired, the reprocessed scopes passed efficacy checks. One of the reprocessed scopes was used on a patient, which was reported on related MedWatch 8010047-2020-05979. The facility reported to Olympus that (to their knowledge) no patient injury or infection resulted from this event. The other scopes that were reprocessed with the expired disinfectant were reprocessed again with unexpired disinfectant. An Olympus Endoscopy Support Specialist (ESS) had a meeting with the endoscopy nurse manager to provide staff training on proper reprocessing and changing Acecide on or before day five of the validation. The device history record was reviewed, and it was verified the device was manufactured in accordance with documented specifications. A Corrective and Preventative Action(s) (CAPA) has been opened to manage the actions related to remediation of this issue and any required Medical Device Reporting (MDR). The device was not returned.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11030949&pc=FEB

7.20 The staff did not perform precleaning for the elevation channel of a duodenovideosocpe in some time, December 2020

A report in the FDA's **Maude** database states a customer reported the inside of a EVIS Lucera Duodenovideoscope JF-260V during precleaning has not been performed in a long time. The scope was reprocessed in a non-Olympus AER model Endoclens. The OMSC explained to the user facility the process method based on the instruction manual of the scope. The scope was not returned to OMSC for evaluation. The exact cause of the event could not be conclusively determined at this time. No report of injury or infection with associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11044381&pc=FDT

8.Gram Negative Bacteria Outbreak

8.1 Five Bronchoscopes were possibly infected with Klebsiella, and one patient was confirmed infected after a Bronchoscopy, March 2021

A report in the FDA's **MAUDE** database states the user facility commented that five Lucera Bronchovideoscope BF-F260 were possibly infected with Klebsiella. The physician at the

facility operated a procedure using these endoscopes for some of the patients. The user facility did confirm that a patient was infected with Klebsiella. The source of the infection and the number of infected patients is unknown. Information (i.e., the reprocessing method) was not provided. The endoscope has not been returned to Olympus Medical Systems Corp. (OMSC) for evaluation. The exact cause of the reported event could not be conclusively determined at this time. OMSC is submitting five medical device reports according to the number of infected endoscopes. This is one of five reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11491154&pc=EOQ

8.2 Seven patients were infected with Mycobacterium lentiflavum after Bronchoscopy procedure using the same bronchoscope, January 2021

A report in the FDA's **MAUDE** database states the user facility found that a total of seven patients were infected with Mycobacterium lentiflavum after a Bronchoscopy procedure, where the same bronchoscope EVIS EXERA III Bronchovideoscope BF-H190 was used. Microbiological testing for only bacteria (not including Mycobacterium of the bronchoscope performed in the last few months) was not detected. In November and December 2020, the facility took water samples of the washer, bronchoscope, taps, and drains for microbiological testing–the results have not come back yet. The user did not operate additional treatments for the seven patients. One of the patients did die; however, it was due to the patient's underlying pathology. The conditions of the six remaining patients have no problem. Endoscope reprocessing method was not provided and OMSC is submitting seven medical device reports due to the number of infected patients. The scope was not returned to OMSC for evaluation and the exact cause of the event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11168659&pc=EOQ

8.3 Nine patients were examined by the same cystoscope with urine samples cultured showing positive for Extended Spectrum Beta-Lactamase (ESBL) and E. coli after the procedures, December 2020

A report in the FDA's **MAUDE** database reports the attending physician reported nine patients were examined by the same Cysto-nephro Fiberscope CYF-5. The patients' urine samples were cultured and an ESBL and E. coli had been recovered and the patients were treated with antibiotics. The physician stated some of the patients have had a) urine retention, b) hematuria, c) septic issues, and d) UTI after the procedures, which triggered him to have the urine cultured. The cystoscope was returned to Olympus for evaluation to see if there had been any damage to the scope. It was reported the scope has been manually reprocessed and soaked in Cidex® OPA. The user facility did report there had been no cultures performed prior to returning the scope to

Olympus. The scope was sent to an off-site lab for microbiological testing. As part of the investigation, an ESS was sent out to visit the user facility to perform a scope reprocessing and infection control in-service for the staff. The ESS covered infection control information referenced in the manual and reprocessing manual. The ESS also requested the staff to show him each step in the use and reprocessing of the scope. The ESS observed the staff was not currently: a) using correct transport bins; b) precleaning; c) leak testing after each case; d) reprocessing stopcock; e) replacing saline bag or irrigation tubing between each case; f) reprocessing reusable brushes; g) soaking scope in detergent for recommended amount of time; h) properly rinsing the scope. The ESS communicated the findings to the facility staff and provided a list with recommended proper reprocessing techniques, proper handling, and storage of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10934571&pc=FAJ