

Flexible Endoscope Incident Report

July 2019

Volume II





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The Flexible Endoscope Incident Report is created to be organized by topic that is 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 MAUDE (Manufacturer and User Facility Device Experience) data report. This database contains reports received by the FDA of adverse events involving medical devices which include manufacturers, importers and user facilities. Reports in this document includes endoscope associated death, injuries to patients, malfunctions with endoscopes, malfunctions with equipment and use error.

1. Failure of Visual Inspection

1.1. A Duodenoscope failed ATP monitoring during reprocessing, May 2019

A report in the FDA's **MAUDE** database states that Pentax medical became aware of a report on April 5, 2019 a Video Duodenoscope ED-349TK failed ATP monitoring during reprocessing. The scope was received at Pentax medical on April 11, 2019 for evaluation and inspected on April 23, 2019. The findings of the inspection include: distal cap-fixed type failed seal integrity inspection; primary operation channel resistance; bending rubber severe discoloration; up/down angulation knob play; right/left angulation knob play; insertion tube lump at stage 1; lightguide prong bent; middle ICB distal cover glass glue is missing; image shadows; down angulation decreased; insertion tube mild crush at stage 2; operation channel-primary sever scratch inside; right/left brake knob auto lock when right/left angulation is manipulated; light carrying bundle distal cover glass middle scratched; prism scratched. The Duodenoscope has not yet been updated pursuant to February 2018 field correction to replace forceps elevator, o-rings, and distal end covering. The scope is undergoing repairs and organic sampling.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8579952&pc=FDT

1.2. A therapeutic procedure was aborted due to the insertion tube is bent and could not withdraw the Cysto-Nephro Videoscope in the patient's urethra, May 2019

A report in the FDA's **MAUDE** database states the user facility aborted a therapeutic procedure since the insertion tube was bent and they could not withdraw the Cysto-Nephro Videoscope

CYF-VA2 from the stenosis in the patient's urethra. The scope was removed from the patient by cutting the insertion tube of the scope and inserting a metal rod into the urethra to straighten the bent insertion tube.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8614784&pc=FAJ

1.3. Bal samples tested positive for P. aeruginosa from three pediatric patients with a contaminated Video Bronchoscope, April 2019

A report in the FDA's **MAUDE** database states on March 29, 2019 Pentax medical received a copy of a report which was submitted by the user facility. The reported stated the "discovery of three samples of broncho-pulmonary positive to P. aeruginosa on three children hospitalized in pneumo-peds department that microbiological testing was performed on the Video Bronchoscope EB-1170K used during the examinations". The sample collected from the contaminated device found 200 CFU: P. aeruginosa and Escherichia coli (E. coli). On August 6, 2019 was the last annual microbiological check and came back satisfactory. The bronchoscope was used on 38 children since that date. With additional information submitted by the user facility on that day was precautionary measures and actions taken by the user facility: the endoscope was quarantined by the user biomedical engineering service before maintenance. The maintenance and disinfection procedures were reviewed by the facility and they did not reveal any anomalies, including two similar type devices at the facility. Other cases of contamination are undergoing a review by the facility and associated clinical consequences by their hospital hygiene service. On March 29, 2019 the Video Bronchoscope was evaluated and in addition to noting the bronchoscope was contaminated the Pentax media service technician documented in their test report the insertion tube was pleated and crushed. The user facility provided responses to the endoscope reprocessing questionnaire and a copy of their reprocessing procedure. The investigation is currently in process.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8556304&pc=EOQ

1.4. A damaged scope was used on a patient that was missing a bending section glue and showing separation from the insertion tube, April 2019

A report in the FDA's **MAUDE** database states that an Olympus Endoscopy Support Specialist conducted observations with bronchoscopes being used in procedures and found a damaged scope was not removed from rotation and was used on a patient in an unspecified diagnostic procedure. The scope was damaged with a missing bending section glue (showing separation from the insertion tube). The ESS provided instructions to the user facility to perform an inspection of their scopes and on what to look for prior to using in procedures. No information was obtained when Olympus followed up with the user facility for detailed information regarding the reported event and reprocessing of the scope. The scope was returned to Olympus for evaluation and was confirmed that the entire bending section cover glue at the insertion tube side was missing on the scope. The scope failed a leak test with a heavy dent on the bending section. Due to the leak it also caused the electrical continuity test failure. The scope was purchased on August 23, 2014 and last repaired on October 22, 2018. The missing bending section cover glue cannot be confirmed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8557979&pc=EOQ

1.5. A field correction was initiated by Pentax of America for the inspection of the suction arm on affected Bronchoscope models, April 2019

A report in the FDA's **Maude** database states that Pentax of American initiated a field correction which included inspection of the suction arm on affected models pursuant to predefined inspection criteria. This was to locate part C255-AB171 (suction arm) and verify it is not loose. If it is found to be loose, the device was considered to fail the inspection criteria. On March 14, 2019 the device was returned to Pentax from a customer and inspection was performed on March 18, 2019 where the quality control inspector found the following: suction arm loose, insertion tube non-Pentax material, leak at pve connector, failed wet leak test, umbilical cable non-Pentax material, up/down brake lever cracked, distal body chipped, up/down control knob/lever cracked, lightguide prong scratched/pitted, failed dry leak test, lightguide prong cover glass set scratched, light carrying bundle broken, lightguide prong cover glass set dented, chemical residue buildup on control body, primary operation channel resistance, ccd circuit board poor solder technique, hole in #2 remote control button cover, image blackout. The inspection of the suction arm was performed, and the device failed the inspection criteria. The part that were replaced: o-rings and seals, distal end with cc-m pb-free/ntcs, insertion flex tube with seg pb-free, bending rubber, distal attaching pin, segment steel braid, light guide cable, electrical connector assy, light guide prong imp-1, large prong insulation ring, large prong attaching nut, light guide prong washer imp-1, large cover glass set

(lens type), friction lever assy, angle lever assy, insertion/s-nipple attaching screw, suction connection tube.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8497605&pc=EOQ

1.6. Samples collected from five patients were tested positive for Klebsiella spp. CPE, new Delhi metallo-beta-lactamase or Klebsiella pneumoniae, April 2019

A report in the FDA's **MAUDE** database states the Olympus was informed that the samples collected from five patients were tested positive for Klebsiella spp., CPE, New Delhi metallo-beta-lactamase or Klebsiella pneumoniae after a procedure using an Olympus Evis Exera Duodenovideoscope TJF-160VR in 2019. First patient underwent a procedure for replacement of prosthesis after a migration using the device in 2019. Klebsiella spp., and NDM were detected from the bile sample collected from the patient. The second patient underwent an ERCP using the device in 2019 and was reported that CPE NDM and klebsiella pneumoniae were detected from the bile and rectal samples collected from the patient. Third patient underwent a procedure for replacement of prosthesis using the subject device in 2019. Klebsiella pneumoniae, CPE and NDM were detected from the rectal sample collected from the patient. The fourth patient underwent and ERCP using the device in 2019 and Klebsiella pneumoniae, CPE and NDM were detected from the bile sample collected from the patient. The fifth patient underwent a procedure for replacement of Biliary pneumoniae using the device in 2019, Klebsiella pneumoniae, CPE and NDM were detected from the rectal sample collected from the patient. The Duodenoscope was reprocessed with a Non-Olympus AER, Soluscope Serie 3, using peracetic acid. Olympus subsidiary had received the device for repair from the user facility in March 2019 before aware of the reported event. The results of the evaluation of the device were as follows: air leakage from the distal end, instrument channel had wear and scratches, the adhesive of the rubber of the bending section has wear and a tear, scratches on the distal end, and scratches on the light guide lens. OMSC reviewed the manufacturing history of the device and confirmed no irregularity. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8547675&pc=FDT

1.7. Enterococcus casseliflavus were detected from bile samples collected from five or six patients during ERCP procedures using the Duodenoscope, April 2019

A report in the FDA's **MAUDE** database states that Olympus Medical Systems Corp. was informed that Enterococcus casseliflavus were detected from five or six patients during ERCP procedures using the EVIS Lucera Duodenovideoscope TJF-260V. All patients have not developed any symptoms of infection. No microbial growth for the sample collected from the channel, distal end around the forceps elevator of the device that was collected by the user facility. The facility reused a non-disposable biopsy valve several times. No microbial growth was detected for the sample collected from the disposable biopsy valve. The Duodenoscope was reprocessed using an Olympus AER model OER4- or OER 5. The user facility concluded that the cause of the reported event was not the scope. Olympus is submitting MDR according to the number of the patients who were infected potentially associated with the endoscope. The device was not returned to OMSC for evaluation and the manufacturing history was reviewed and confirmed no irregularity. 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=8538524&pc=FDT

1.8. A Duodenoscope tested positive two times for microbial growth with a high concern bacterium and Cocci-Staphylococcus warneri in March 2019, April 2019

A report in the FDA's **MAUDE** database states Pentax medical became aware of a report on March 13, 2019 stating Pentax Video Duodenoscope ED-3490TK yielded high concern bacterium after sampling and another sampling performed identified a raw count to numerous to count as comprising of the following 1 isolates: positive Staphylococcus warneri. Pentax received the Duodenoscope on March 15, 2019 and inspected on March 16th and confirmed discontinuities and gaps in zone F, twisted operational channel in the bending section, and mild resistance in the primary operational channel and the distal cap.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8488618&pc=FDT

1.9. A foreign polyp came out of a Colonoscope when the physician went to insert a Non-Olympus snare into a biopsy channel, April 2019

A report in the FDA's **MAUDE** database states the physician went to insert a Non-Olympus snare into the biopsy channel of the scope and a foreign polyp, came out during a Colonoscopy procedure on March 11, 2019. It was believed the polyp did not come out of the EVIS Exera LLL Colonovideoscope CF-HQ190L after cleaning and disinfection as no polyp had been removed from the patient yet. There was no resistance when introducing the snare and the foreign polyp did not fall in the patient but did notice it on the monitor and was stuck in the sheath of the scope as reported by the Registered Nurse. The poly was retrieved when the scope was removed, and the same scope was used to complete the procedure. Olympus received the scope for evaluation and the service group could not confirm the cause of the reported event as a visual inspection was performed using a borescope and there was no note of foreign objects inside the biopsy channel, however there was a red stain inside the channel and the bending section cover glue at the distal end of the insertion tube was found peeling. The scope was purchased on November 11, 2014 and last repaired on February 15, 2019. The foreign polyp was tested and sent to the lab. The patient was injected with hepatitis B immune globulin and blood tests were performed. The user facility reported there was no endotherapy accessory inserted into the biopsy channel to inspect the channel prior to procedure as it is not a standard procedure to check the biopsy channel in the procedure rooms. The user facility utilizes an AER Olympus OER-Pro and the last preventive maintenance was on January 23, 2019.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8493183&pc=FDf

1.10. A ureteroscope's bending section broke and became stuck in the patient's kidney, April 2019

A report in the FDA's MAUDE database states Olympus was informed that during a ureteroscopy procedure, the Uretero-Reno Videoscope URF-V2R bending section broke and became stuck in the patient's kidney. The scope was returned to Olympus for evaluation and the bending section cover was removed and found the scope's skeleton broken and lifting. Due to the skeleton breakage the scope's angulation was found to be abnormal. The large bundle fibers were found to be broken and failed a leak test. Based on similar reported events the cause of the scope's broken skeleton could be attributed to the operator's technique. The OEM has conducted a field corrective action including a distribution of instructions for safe use.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8525485&pc=FGB

1.11. During a kidney stone removal procedure, the distal end of the scope froze in a curled position, April 2019

A report in the FDA's MAUDE database states that during a kidney stone removal procedure, the user facility reported that an unspecified stent was used and the distal end of the Uretero-Reno Fiberscope URF-P6R reportedly froze in a curled position and the doctor experienced difficulty removing the scope. The scope was withdrawn from patient with the use of an unspecified Non-Olympus guidewire to straighten the distal end. The procedure was aborted, and no patient injury reported. The scope was returned to Olympus for evaluation and was visually inspected and noted the distal end was in a relaxed and not curled position when received. During testing, the distal end never became stuck despite multiple attempts at manipulation of the bending section using the control knobs. A leak was discovered from the biopsy channel during the water dunk leak check. Large tears/holes and multiple scrape marks were found at the distal end side of the channel. Damages to the biopsy channels start at the distal end opening and continue up until about 70mm. The control body was opened, and signs of rust located on the drum unit that houses the angle wires. Drops of water were found inside the control body and corrosion on the coil holder. The image has excessive broken fibers scattered throughout, the bending section cover glue at the distal end is chipped and missing a small portion. The scope was purchased on August 28, 2013 and last repair was on May 18, 2016. Based on evaluation findings, fluid invasion or operational error cannot be ruled out as contributory factor. The exact cause of reported event could not be confirmed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8542526&pc=FGB

1.12. A stent came out of a Duodenovideoscope and fell into a patient, March 2019

A report in the FDA's MAUDE database states that a stent remained in the EVIS Exera II Duodenovideoscope TJF-Q180V following procedure. The scope was reprocessed but was never retrieved. During a second procedure the stent fell out of the device into a patient. An ESS visited the user facility of February 19, 2019 to provide a scope reprocessing in-service. The staff do not perform suction during manual cleaning, as they have no suction in the reprocessing room. The ESS trained the main technician about the correct order of brushing of channels based on the recommended steps in the instruction for use. The ESS also provided the part number of the Olympus cleaning and compatible endotherapy devices. The cause of

the user's experience cannot be conclusively determined but the use of a non-Olympus cleaning brushes cannot be ruled out as contributory factor.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8380730&pc=FDT

1.13. A field correction initiated by Pentax that included the inspection of the seal around the distal body and distal cap of the Duodenoscope, March 2019

A report in the FDA's **MAUDE** database states that Pentax of America initiated a field correction that included inspection of the seal around the distal body and distal cap of the Duodenoscope ED-3490TK pursuant to predefined inspection criteria. The objective was to verify there were no defects/discontinuities in the seal between the distal body and distal cap. The customer device was previously returned to Pentax medical from a customer on February 6, 2019 and inspection of the unit was performed on February 11, 2019 where the quality control inspector found the following: distal tip-fixed types failed seal integrity inspection, operation channel twisted in bending section, failed dry/wet leak test, lightguide prong cover glass set loose, bending rubber pinhole, umbilical cable single buckled under pve root brace, operation channel-primary slice by accessory.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8414557&pc=FDT

1.14. A patient's mucosa was lacerated in three areas during a diagnostic Colonoscopy, March 2019

A report in the FDA's **MAUDE** database states during a diagnostic Colonoscopy the doctor noticed minor bleeding near the proximal sigmoid. The EVIS Exera LLL Colonovideoscope CF-HQ190L was partially withdrawn several centimeters and the doctor observed that the patient's mucosa was lacerated in three areas. The doctor stopped the procedure and upon completely withdrawing the scope, the doctor observed its bending section was torn open with exposed metal coils. There were no sharp instruments inserted into the scope at any point of the procedure. No additional treatment or hospitalization was required for the patient, the intended procedure was completed with a similar device. It is unknown if the scope was

inspection prior to use. The scope was sent back to Olympus for evaluation and a visual inspection was performed and found 1 cm of the scope's bending section cover is torn off and missing but the missing bending section was not returned. The bending section is detached from the insertion tube side causing the elements inside to be exposed. The screw that holds the bending section together is missing which attributed to the detachment of the bending section and was noted to be stripped. There were non-Olympus repairs identified with the distal end, bending section cover, bending section cover glue, the objective lens glue and light guide lens glue. This is most likely what caused the torn bending section cover and detached bending section.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8438810&pc=FDf

1.15. During a Colonoscopy procedure with biopsy, foreign tissue was pushed out o the biopsy channel at the distal end, March 2019

A report in the FDA's **MAUDE** database states during a Colonoscopy procedure with biopsy, the user facility reported that a foreign tissue was pushed out of the biopsy channel at the distal end of the scope before patient's tissue was biopsied. The nurse did not see the foreign tissue fall into the patient but was uncertain if the foreign tissue was suctioned or where it went. A visual inspection was performed by Olympus and found kinks noted on the suction channel and at the instrument channel wall from the distal end area. There were no signs of foreign objects/materials inside the instrument/suction channel. The cause of the kinks is potentially due to handling from excessive force applied to the scope. A review of the EXIS Exera III Colonovideoscope PCF-H190DL history indicates the scope was purchased on August 9, 2015 and last repaired on February 15, 2019. There was no patient injury reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8463180&pc=FDf

1.16. A user facility found a brush head came out from the Gastrointestinal Videoscope and fell off within the patient, March 2019

A report in the FDA's **MAUDE** database states that during an unspecified endoscopy procedure using the EVIS Exera III Gastrointestinal Videoscope GIF-H185, the user facility found a brush head came out from the scope and fell off within the patient. The brush head was safely removed from the patient and no injury associated with this report. The scope was reprocessed with a Non-Olympus AER, Wassenburg. The facility reported that the scope was

used the day before the procedure without any problem and the brush head was not from the brushes used by the user facility. The scope was not returned to OMSC for evaluation but review the manufacture history of the device and confirmed no irregularity. 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=8415543&pc=FDS

1.17. A Uretero-Reno Fiberscope was tested by the OR nurse manager prior to use and observed the scope to be broken, March 2019

A report in the FDA's **MAUDE** database states that the user facility's OR nurse manager tested the Uretero-Reno-Fiberscope URF-P6R tested prior to use and observed the scope was broken. There was no patient involvement reported with the subject scope. Olympus followed up with the facility via telephone and in writing in an attempt to obtain additional regarding the reported event, but no information was obtained. The scope was returned to Olympus for evaluation and found the bending section was broken with sharp metal exposed from the bending section skeleton. The scope failed the leak test from a hole on the bending section cover. The image has excessive broke image guide bundle breakage (black dots), the angulation low is below specification. The insertion tube and bending section cover/glues are Non-Olympus parts/repairs. The most probable cause of the reported event could be attributed to improper maintenance and or handling. The user facility declined repairs and the scope was returned to the user facility unrepaired. The scope was purchased on March 28, 2018 with no repair history.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8434886&pc=FGB

1.18. During an unspecified procedure, black plastic fragment fell from the distal tip of the scope into the patient's bladder, March 2019

A report in the FDA's **MAUDE** database states Olympus medical systems corp. was informed that a black plastic fragment fell from the distal tip of the EVIS Cystovideoscope CYF-240 into the patient's bladder during an unspecified diagnostic procedure. The scope was sent back to Olympus and confirmed the followings during inspection. The adhesive of one of the two light guide lenses was completely missing. The adhesive of the other light guide lenses was deteriorated and partially missing. Cracks and chipping in the light guide lenses. Olympus

surmised that the fragment found within the patient's bladder was missing adhesive from the light guide lenses.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8389204&pc=FAJ

1.19. A piece of mucosa fell out of the Gastrointestinal Videoscope into the patient during an unspecified procedure, February 2019

A report in the FDA's **MAUDE** database states during an unspecified procedure, a piece of mucosa fell out of the EVIS Exera III Gastrointestinal Videoscope GIF-H190 into the patient while in the small bowel. The biopsy forceps were passed down the scope when the event occurred. The physician thinks the mucosa was fresh and unsure if it was suctioned up during the procedure. The biopsy on this patient had not been performed, it was unclear as to where the foreign material came from. It is unknown if the procedure was completed. The scope was sent back to Olympus for evaluation and a visual inspection was performed with an Olympus borescope on the returned scope. Scratch marks on the outer walls of the channel from the bending section side. The instrument channel from the control body section was inspected and there were stains, marks, or kinks noted. There were external damages to the insertion tube and the light guide tube, the scope also passed leak testing. The scope was purchased in 2016 and no service/repair records found since the date of purchase.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8365045&pc=DFD

1.20. Pieces of a reprocessing brush fell out of the Gastrointestinal Videoscope into the patient, February 2019

A report in the FDA's **MAUDE** database states that during an Esophagogastroduodenoscopy (EGD) procedure, pieces of a reprocessing brush fell out of the scope into the patient. The fragments were retrieved using a basket and forceps. No additional bleeding observed, and the procedure was completed with the same device with no patient injury reported. The EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 was returned to Olympus for evaluation and a borescope was used to inspect the biopsy channel for any objects or foreign material within, the evaluation did not locate any foreign material inside the biopsy channel. However, Multiple kinks inside the channel starting at 20cm up until the 40cm mark from the bending section. The scope could not be leak tested since it had already been opened by estimation. The quality inspection results noted the scope passed the water dunk test.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8380633&pc=FDS

2. Excessive Force with Equipment

2.1. The button on the suction valve became stuck during an unspecified procedure causing the patient's bronchus to bleed, April 2019

A report in the FDA's **MAUDE** database states that during an unspecified procedure, the button on the suction valve stuck causing continuous suction and the patient's bronchus to bleed. It was reported that due to the bleed extubating the patient was difficult. The single use suction valve MAJ-209 was not returned to Olympus for evaluation. The evaluation did not confirm the customer's complaint of the reported event. Based on the OEM's investigation, an increase of reported complaints was observed since the manufacturing process and molding supplier for the suction valve were changed or replaced in August 2018. The OEM reported that the suction valves that were manufactured prior to and post the changes meet the product's standard for stiffness. When an unexpected large load or excessive force is applied to the suction connector, the OEM confirmed that the product before changes did not break, but the products that were manufactured after the changes were breaking or may break.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8562580&pc=EOQ

2.2. Customer keeps plyers in the room so they can remove the valves at the end of their cases, April 2019

A report in the FDA's **MAUDE** database states that Olympus was informed that these valves snap off in the same place every time. This event delays cases by 10 minutes to which the customer keeps plyers in the room so they can remove these valves at the end of their cases. The intended procedures were still completed and had to open another valve of the same model. The breakage is on the elbow of the device. The suction valve was not returned to Olympus for evaluation and did not confirm the customer's complaint of the suction valve snap off. The most likely cause of the reported phenomenon was attributed to excessive force applied to the suction connector. The OEM investigation the reported increase of complaints

was observed since the manufacturing process and molding supplier for the suction valve were changed or replaced in August 2018. The OEM reported that the suction valves that were manufactured prior to and post the changes meet the product's standard for stiffness. When the unexpected large load or excessive force is applied to the suction connector, the OEM confirmed that the product before the changes did not break, but the products that were manufactured after the changes were breaking or may break.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8485519&pc=EOQ

3. Failures Due to Reprocessing Equipment (AERs)

3.1. A Medivators sales representative observed a technician incorrectly reprocessing endoscopes in their CER-2 Optima AER, May 2019

A report in the FDA's **MAUDE** database states a Medivators sales representative reported observing the facility's technician incorrectly reprocessing endoscopes in their CER-2 Optima AER. The required AER hookup connectors were not being used to reprocess the endoscopes. Also, bioburden was observed on the distal end of the endoscope, inside of the hookup tubing on all suction valves. While observing the incorrect processes, Medivators sales representative immediately informed the technician who cancelled the cycle and made the necessary corrections and the physician was also informed of the observations. The facility received an additional in-service training by Medivators clinical education specialist for all their Medivators products. The facility reported that they updated their products and staff were required to watch all training videos and review all ifus/user manuals. The facility also switched to using Medivators single-use disposable valves, disposable tubing and pull-thru cleaning devices. There are no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8575470&pc=NVE

3.2. Employees developed exposure symptoms from Rapiocide pa high level disinfectant that leaked from their Advantage Plus AER, May 2019

A report in the FDA's **MAUDE** database states a facility reported that employees developed exposure symptoms from Rapiocide PA high level disinfectant that leaked from their Advantage Plus AER. The AER had a leak they could not locate and the HLD ran onto the floor, then

cleaned up with towels which were then placed in the dirty laundry hamper. After a couple hours the employees reported a strong odor and noticed a haze in the room. One employee opened the hamper to find a thin cloud of fumes and reported the towels had some type of noticeable chemical breakdown. The facility used baking soda to neutralize the towels and chemical. Three employees reported symptoms of eye and throat irritation, nausea, headache and chest pain. The employees were sent to employee health and referred to ED for evaluation and reported to be fine. Medivators Field Service Engineer arrived on site and repaired the leak. The machine now runs within specification. The facility failed to follow the IFU and SDS disposal instructions for Rapicide PA HLD.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8569468&pc=FEB

3.3. A facility's DSD-201 AER and hookups were stained with green residue, April 2019

A report in the FDA's **MAUDE** database states that a Medivators field service engineer was onsite for a service visit reported that the facility's DSD-201 AET and hookups were stained with a green residue. There is potential for patient harm from exposure to the green residue and potential that endoscopes were not adequately high level disinfected. The FSE reported that the green substance is from a concentration of the detergent (orthozime) mixing with the high-level disinfectant (Cidex OPA) used in their AER. It was determined that the facility incorrectly programmed their AER for detergent use which caused the detergent to be mixed with the high-level disinfectant in the basin during reprocessing cycles. Th facility was informed by the FSE of the potential impact to patient safety due to the coating of the green substance in the AER and on endoscopes and the potential that endoscopes are not being adequately high level disinfected. The facility received in-service training on the DSD-201 AER in 2007 and 2014 by Medivators Clinical Education Specialist. It is unknow if the facility continues to use the affected AER. There have been to reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8524712&pc=FEB

3.4. A facility had not been performing water line disinfection cycles for their eight Advantage Plus AERs, March 2019

A report in the FDA's **Maude** database states, Medivators Clinical Education Specialist reported a facility had not been performing water line disinfection (wld) cycles for their eight Advantage

Plus AERs. Medivators CES discovered the facility was not performing water line disinfection and estimated it has not occurred since as early as 2014. The number of endoscopes reprocessed during this time is unknown. Medivators CES retrained the facility on the importance of completing a wld as instructed in the AER user manual. After the in-service training visit, the facility reported to Medivators CES that additional processes are now in place to ensure wld is completed per the AER user manual.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8424418&pc=FEB

3.5. Medivators observed the facility using modified hookups and the incorrect parameter set for Cidex OPA, March 2019

A report in the FDA's **MAUDE** database states that a Medivators field service engineer reported while on site, he observed the facility using modified hookups and the incorrect parameter sets for Cidex OPA in the DSD 201 AER. There is potential that endoscopes were not properly high-level disinfected, thus there is potential for cross-contamination. The facility was using Cidex OPA high level disinfectant at fifteen degrees for a twelve-minute contact time which is not in accordance with the labeling. The Cidex OPA HLD instructions for use state use a minimum temperature of twenty degrees for five minutes. The FSE adjusted the temperature of the AER and informed the facility to order the correct hookup. The facility does not have a Medivators service contract, it is the facilities responsibility to perform proper maintenance on their machine. No information was provided to Medivators regarding how many cycles or endoscopes were reprocessed. It cannot be determined if the endoscopes were properly HLD during this timeframe. It is also unknown if the facility has ordered a new hookup. There have been no reports of adverse events or patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8466920&pc=FEB

3.6. After completion of a reprocessing cycle, a black substance appeared in both basins of the facility's DSD Edge AER, March 2019

A report in the FDA's **MAUDE** database states a facility reported a black substance appeared in both basins of their DSD Edge AER after completion of a reprocessing cycle. The facility requested a Medivators Field Service Engineer to evaluate the AER and did perform a preventative maintenance service. The source of the black substance was due to degradation

of the disinfectant pumps from extended exposure to the high-level disinfectant. Medivators recommends replacing these pumps at least annually as part of the routine preventative maintenance. The facility's biomedical technician reported he was unaware when the last pm was performed on the AER. The facility does not have a contract with Medivators and the AER is normally serviced by the biomedical technicians. Per Medivators DSD Edge user manual, it is the responsibility of the facility to ensure proper servicing is performed on the AER. The biomedical technicians will perform pm services on the AER in the future. It is unknown if the endoscopes potentially exposed to the black substance were used in the patient procedures. There have been no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8387951&pc=FEB

Employee Chemical Burns

4.1. An employee experienced a burn on their fingertip while handling items that were processed in a V-Pro Max sterilizer while wearing PPE gloves, March 2019

A report in the FDA's **MAUDE** database states that an employee experienced a burn on their fingertip while handling items that were processed in a V-Pro Max sterilizer while wearing PPE gloves. A Steris account manager spoke with user facility personnel and was informed that the employee subject to the reported event was wearing nitrile exam gloves. The V-Pro Max sterilizer manual states that nitrile gloves are compatible, however they must be chemical resistant gloves. Additionally, the user facility personnel should ensure all instruments are properly dry prior to placement in the V-Pro Max sterilizer. Only dry items are to be placed in sterilization unit. The root cause of the event can be attributed to user facility personnel not wearing proper PPE. The account manager communicated over the phone to the user facility on the importance of wearing proper PPE as well as properly drying instruments. No additional issues have been reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8457485&pc=MLR

Sterilizer Malfunction

5.1. The user facility's V-Pro Max sterilizer caught fire over the weekend, March 2019

A report in the FDA's **MAUDE** database states the user facility reported that their V-Pro Max sterilizer caught fire over the weekend. No injuries associated with the subject event and the flames subsided on their own. On Monday, personnel arrived onsite and noted a "burning smell" throughout the room. Personnel inspected the V-Pro Max sterilizer and found evidence of blackened wires and compounds around the insulation of the unit. A Steris Service Technician arrived to inspect the sterilizer and found the cause to be a loose fitting on the SV5 valve. This allowed sterilant to leak from the valve onto the wires and components below causing the electrical wires to short and the reported event to occur. The sterilizer was manufactured in 2015 and is not under a Steris service agreement for maintenance activities. The facility is responsible for all maintenance activities. The reported event can be attributed to user error as facility personnel should have ensured all fittings are properly tightened following all service or maintenance activities prior to placing the unit back in service. The unit has been removed from service and no additional issues have been reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=840042&pc=MLR

5.2. A facility's Reliance endoscope processor started to smoke and caught fire, March 2019

A report in the FDA's **MAUDE** database states the user facility reported their Reliance endoscope processor started to smoke and caught fire. The department where the unit was evacuated due to the burning smell, resulting in procedure delays. A service technician arrived onsite to inspect the Reliance endoscope processor. The technician spoke with the user facility personnel and was informed that contrary to the reported event there was no fire observed, only smoke and a burning smell coming from the chamber. The root cause can be attributed to the unit's drying fan which had failed causing the heating elements in the unit to overheat and produce the smoke and burning smell. The technician replaced the drying fan and heating elements and ran several test cycles and confirmed the unit to be operating according to specification. Per the customer's request, the unit was de-installed and put into storage, and no additional issues have been reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=841857&pc=NZA

Use Errors

6.1. Four patients developed staph infection after undergoing procedure with the user facility's Uretero-Reno Fiberscopes, May 2019

A report in the FDA's MAUDE report database states that four patients develop staph infection after undergoing procedure with user facility's Uretero-Reno Fiberscopes URF-P6. The facility has multiple Uretero-Reno Fiberscopes and is unable to determine which contributed to the patient incidents. The course of treatment is unknown. The user facility reported that scope was reprocessed in a Steris 1E AER. It is unknown if the scope was returned to the service center for evaluation repair. Follow up with the user facility via telephone and in writing obtain additional information regarding the reported event but with no result.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8625182&pc=FGB

6.2. A Duodenoscope cultured positive for Staphylococcus lugdunensis after reprocessing, April 2019

A report in the FDA's MAUDE database states during a post market surveillance study the EVIS Exera II Duodenoscope TJF-Q180V cultured positive for Staphylococcus lugdunensis after reprocessing. Olympus did a follow up with the user facility regarding the reported event and was informed the facility uses Medivators Rapicide PA as cleaning and disinfection solution. The facility's reprocessing staff has changed since the last in-service as one technician has left and two new reprocessing technicians are now in rotation. All reprocessing personnel is trained on how to properly reprocess an endoscope. The facility's scope undergoes routine maintenance. An Olympus ESS was dispatched on February 26, 2019 to observe the techniques of the facility's reprocessing technician who reprocessed the pms scope. No deviations noted with the technician's method. An Olympus engineer was dispatched to observe the sampling techniques and noted that during preparation card was brought in the room. The sampler's sterile gloves were not changed after preparation step and the sampler's PPE was sliding off during sampling.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8424835&pc=FDT

6.3. The sample collected from a Duodenoscope tested positive for Enterococcus faecium and Candida glabrata, April 2019

A report in the FDA's **MAUDE** report database states a sample from an EVIS Exera Duodenoscope TJF-160VF tested positive for Enterococcus faecium and candida glabrata classified as high concern. The scope was not returned to Olympus for evaluation. The exact cause cannot be determined at this time. As part of the post market surveillance study, an Olympus engineer was dispatched to the user facility to review the sampling technique of the sampler and the facilitator who took the sample from the scope. Several deviations were noted: someone was entering or leaving the sampling room. Someone was working in the sampling room. Olympus engineer instructed the appropriate technique to the sampling staff. This investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8521080&pc=FDT

6.4. A Colonoscope had multiple microbiological testing by the user facility, microbes were detected from the samples collected, April 2019

A report in the FDA's **MAUDE** database states that OMSC was informed that as a result of multiple microbiological testing by the user facility, following microbes were detected from the sample collected from the subject device. 1. Stenotrophomonas maltophilia and Brevundimonas diminuta (>100 CFU). 2. Candida guilliermondii and Ochrobactrum anthropic (<10 CFU). 3. Stenotrophomonas maltophilia and Candida guilliermondii (<100 CFU). The EVIS Exera LLL Colonovideoscope CF-HQ190L was not returned to OMSC for evaluation. OMSC reviewed the manufacture history of the scope and confirmed no irregularities. 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=8507643&pc=FDf

6.5. Five procedures were performed on the same date with the same Gastroscope, April 2019

A report in the FDA's **MAUDE** database states that one Gastroscope FSG-2500-MC90 was used during five procedures on the same date. It was reported to Boston Scientific corporation that a fuse 1g Gastroscope was used during five Gastroscope procedures performed in 2019. Each patient was test for H. pylori and lab analysis revealed all five patients tested positive. The

physician prescribed each patient three dosages (unknown) to treat the infection. The Gastroscope was not reprocessed properly and tested by the facility's reprocessing technician. The complainant suspected the scope had a leak not detected due to improper reprocessing. It was confirmed that one technician was involved in the event, and one Gastroscope was affected and the technician was terminated. The scope was returned for analysis and a functional analysis was performed. A leak was noted in the biopsy channel and was replaced. The most probable root cause for the reported leak in unintended use error caused or contributed to events.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8524645&pc=FDS

6.6. Pentax medical Video Gastroscope was cleaned three times and failed three times using the ChannelCheck test strips, April 2019

A report in the FDA's **MAUDE** database states on March 18, 2019 a report stating "customer claims difficult" cannot clean the Pentax Video Gastroscope DG-2990I. On March 19, 2019 the customer responded to a good faith effort follow up email and stated they are using the ChannelCheck 3-in-1 test strips to verify cleaning. The scope was manually pre-clean before HLD three times and all three times test strips failed. The Gastroscope was removed from circulation and called in for service. The scope was returned on March 21, 2019 and evaluated by the service technician at Pentax medical on March 22, 2019. The technician documented a leak at the biopsy channel inlet side. Other findings included: failed wet leak test, failed dry leak test, fluid invasion in control body, air/water socket cylinder o-ring chipped, right/left angulation tight, umbilical cable single buckled under pve root brace, eto vent valve attaching screw broken, control body frame based plate coating peeling, up/down angulation tight. The Gastroscope repair is currently ongoing as of April 8, 2019.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8495252&pc=FDS

6.7. A Gastrointestinal Videoscope cultured positive for Pseudomonas after being reprocessed, April 2019

A report in the FDA's **MAUDE** database states an EVIS Exera III Gastrointestinal Videoscope GIS-H180 cultured positive for Pseudomonas in 2019 after being reprocessed. The scope had been used on a patient with a pre-existing pseudomonas infection. The scope was quarantine at the

user facility. The scope was returned to Olympus for evaluation and a visual inspection was performed and found the bending section cover and insertion tube cracked. An Olympus borescope was used to inspect the biopsy channel and scrape marks were noted inside the channel. The scope was repaired and returned to the customer.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8485458&pc=FDS

6.8. The sample collected from the Uretero-Reno Videoscope tested positive for unspecified microbes, April 2019

A report in the FDA's **MAUDE** database states during routine microbiological testing by the user facility, the sample collected from the subject device tested positive for unspecified microbes (2105 CFU/100 ml), the testing result indicated that there was *Stenotrophomonas maltophilia*. The scope was not returned to OMSC for evaluation but did review the manufacturing history and confirmed no irregularity. 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=8406619&pc=FGB

6.9. Two patients developed sepsis after unspecified procedures using the Cysto-Nephro Videoscope, April 2019

A report in the FDA's **MAUDE** database states that two patients developed sepsis after unspecified procedures using the Cysto-Nephro Videoscope CYF-VH between January 5, 2019 and January 15, 2019. The user facility conducted twelve cases of unspecified procedure using the scope between January 5th and January 15, 2019 but no other infection was reported. The scope was reprocessed with a Non-Olympus AER WD440PT Wassenburg using peracetic acid. It was also reported that the time between procedures and pre-cleaning varies day to day (the times were reportedly from 15 minutes to over an hour). The scope was not returned to OMSC for evaluation. No malfunction to the scope, OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. 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=8395053&pc=FAJ

6.10. A patient developed a liver abscess after undergoing a pancreatic stent procedure and was transferred from recovery to the ICU, March 2019

A report in the FDA's **Maude** database states Olympus was informed that a patient developed a liver abscess after undergoing a pancreatic stent procedure and was transferred from recovery to the ICU. The user facility reported that the scope used was reintroduced into service in 2019. The scope failed leak testing on February 16, 2019. Olympus followed up with the user facility to obtain additional information regarding the reported event but with no result. The EVIS Exera Duodenoscope is placed in the Medivators DSD edge AER and hung in a ventilated cabinet and no air flushed into its channel. The cause of the report cannot be determined at this time. A review of the instrument's history was performed and revealed that the scope was purchased on September 5, 2006 and no service/repair records found since the date of purchase.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8433990&pc=FDT

6.11. Four patients were reportedly infected with Mycobacterium peregrinum after undergoing a bronchoscopy procedure at the user facility, March 2019

A report in the FDA's **MAUDE** database states that four patients underwent a bronchoscopy procedure and were reportedly infected with Mycobacterium peregrinum. Patients 1, 3 and 4 were examined with the same bronchoscope model BF-1TH190. Patient 1 returned later with unspecified respiratory symptoms and was later diagnosed to be infected with Mycobacterium peregrinum which takes approximately five to eight weeks to grow. Patient 2 was also examined with the bronchoscope model BF-1TH190. The reprocessing method by the user facility includes pre-cleaning, manual cleaning followed with an OER-Pro. The clinical Endotherapy Specialist was informed the OER-Pro filters are replaced per the designated frequency. The scopes are stored in a mass medical scope locker, and the heap filter has not been changed in the last 18 months. The input charcoal like sponge filters are original as well. Each scope has undergone a BAL test, saline flushed through biopsy channel and collected. Each sample was sent to the lab for testing. The heap filter was soaked in saline and sent out for testing as well. The Bronchovideoscope was not returned to Olympus for evaluation. The cause of the patients' outcome cannot be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8394277&pc=EOQ

6.12. A Colonovideoscope underwent a routine surveillance culturing tests at the user facility repeatedly tested positive for bacteria, March 2019

A report in the FDA's **MAUDE** database states during a routine surveillance culturing tests at the user facility, the EVIX Exera LLL Colonovideoscope repeatedly tested positive for the following bacteria: the air/water channel and auxiliary channel tested positive for coagulase negative Staphylococcus (1cfu/18ml, air/water, 1cfu/20ml/auxiliary). The suction channel tested positive for Enterococcus casseliflavus, S. maltophilia and Bacillus spp. (8cfu/0.1ml in total). The test result indicated no microbial growth for the instrument channel. The suction channel tested positive for Cellulosimicrobium cellulans and E. casseliflavus (9cfu/18ml in total). No microbial growth for other channels. The scope was returned to Olympus and was sent to a third-party laboratory for additional microbiological testing. The result indicated no microbial growth to the distal end, air water channel and instrument channel of the scope. No irregularities were confirmed when Olympus reviewed the manufacturing history of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8419362&pc=FDf

6.13. During a post market surveillance study, the Duodenoscope cultured positive for Staphylococcus aureus after reprocessing, February 2019

A report in the FDA's **MAUDE** database states Olympus was informed that during a post market surveillance study the EVIS Exera II Duodenoscope TJF-Q10V cultured positive for S. aureus after reprocessing. Olympus did follow up with the user facility to obtain additional information regarding their reprocessing practices. The Olympus ALT Pro was utilized for the leak test which is not valid for the TJF-Q180V. The ESS informed the customer that it was not validated for use. The ESS reported the following deviations from the reprocessing technician who reprocessed the scope; general brushing particular to the distal tip and channels with multiple brushes. Failed to properly perform visual checks to see if debris was removed, the ALT-Pro was utilized for leak testing, external surfaces of the scope were not wiped down, minimal flushing of the elevator areas with syringe, no suction channel cleaning adapter utilizing, no

flushing of the channels. The customer stated the Medivator Advantage Plus AER eliminated several of the recommended steps. The cause of the reported event could not be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8365270&pc=FDT

Gram Negative Bacteria Outbreak

7.1. Six patients were detected to have Pseudomonas aeruginosa 3-MRGN (quinolone sensitive) in bronchial secretions, April 2019

A report in the FDA's **MAUDE** database states all patients had bronchoscopies completed with the Video Bronchoscope EB-530T. All six patients were detected to have Pseudomonas aeruginosa 3-MRGN (quinolone sensitive in bronchial secretions. Patient 1 who underwent the bronchoscopy procedure using the bronchoscope EB-530T was detected to have P. aeruginosa 3-MRGN (quinolone sensitive in the bronchial secretions. In 218 this agent could also be detected in bronchial secretions after enrichment in five samples from five different patients and have a bronchoscopy performed using the bronchoscope EB-530T. This device was discontinued and no further evidence of P. aeruginosa 3-MRGN occurred. In 2019 the EB-530T was sampled and P. aeruginosa 3-MRGN was detected. In 2019 the facility submitted the incident report to the authority of their country and the service center was informed by the authority regarding this incident. Both bronchoscopes were loaner devices owned by the service center. One of the bronchoscopes was sent to the service branch and was found to have a damaged distal end cap. A service history review was performed and prior to sending to the customer facility the inspection performed on October 25, 2018 did not show any failures; therefore, it was determined that the failure occurred during use at the facility. It is unknown if there is a casual relationship between the failure and this incident, at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8383689&pc=EQQ

7.2. A patient contracted E. coli from unidentified scope and expired after undergoing an ERCP procedure in 2015, March 2019

A report in the FDA's **MAUDE** database states that Olympus was informed that a patient contracted E. coli from an unidentified scope and expired after undergoing an ERCP procedure

in 2015. A family member of the patient reported that the patient was very ill prior to the procedure and was placed on life support due to her health declining further. The patient's treating physician reportedly diagnosed the patient with the same strain of E. coli that was identified during an outbreak at the user facility. The specific scope model/serial number was not provided. It is unknown if the Olympus Duodenoscope was returned to Olympus for evaluation. The cause of the patient's outcome cannot be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8462376&pc=FDT