Flexible Endoscope Incident Report

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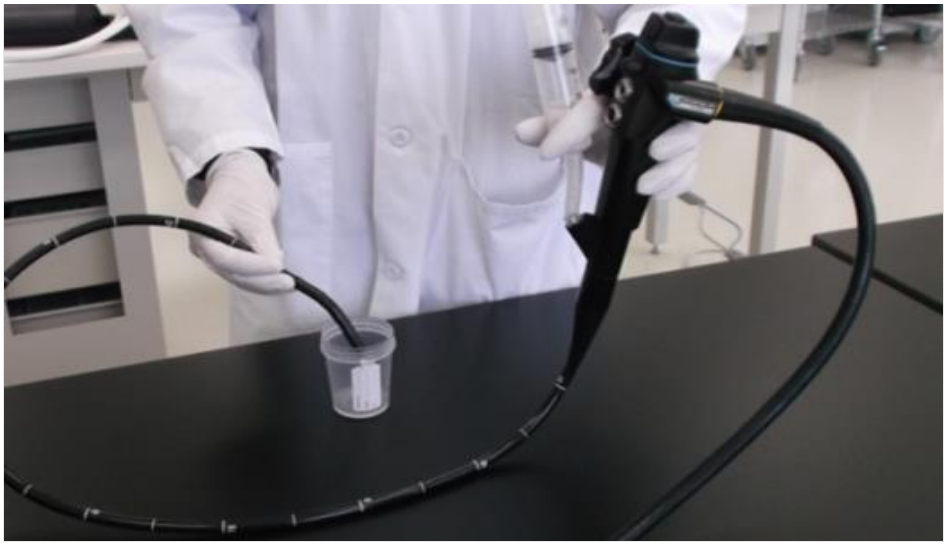

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The Flexible Endoscope Incident Report is created to be organized by topic, related by different failure modes, and is updated every quarter with new events and/or malfunctions that occur with endoscopes. The incidents in this document are found in 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 Debris was "pushed out" of the Duodenovideoscope into the patient during an ERCP from a previous ERCP, August 2022

A report in the FDA **MAUDE** database states the customer reported during a preventative maintenance inspection by an Olympus endoscopy support specialist (ESS) on the EVIS Exera III Duodenovideoscope TJF-Q190V, an Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure was completed. Debris from a previous ERCP was "pushed out" into the patient during the procedure. Patient "A" had a stent removal where the stent was removed and pulled up through the endoscope channel, part of the stent became lodged in the endoscope. The endoscope was cleaned. The scope was reused on patient "B", where part of the stent from patient "A" was introduced to patient "B". The scope was reprocessed and pulled from use, and an internal investigation is in the process at the hospital. The customer reported the debris was removed from the patient with a snare. The patient experienced no adverse effects because of this occurrence. It was reported the patient required an exposure panel (blood draw), which was negative. The patient's current condition is described as discharged home from the outpatient procedure.

The scope has been evaluated by the ESS. Preliminary findings are reported. Physical evaluation of the scope found the bending section glue was peeling and scrape marks were identified on the insertion tube. The Olympus ESS noted during the inspection the customer (following manual cleaning) is using:

- BW-412T cleaning brushes
- Scope buddy plus for aspiration and automated flushing
- Medicator advantage for automated reprocessing
- Resi-Test™ is being completed on all endoscopes.

Recommendations were made by the Olympus ESS to customer to schedule scope training as well as a reprocessing in-service to ensure all staff member are properly trained. 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=15298653&pc=FDT#

1.2 The Gastroscope was returned to Olympus service center due to air/water nozzle clogged with dark foreign material, July 2022

A report in the FDA **MAUDE** database states the EVIS Exera III Gastrointestinal Videoscope GIF-H190 was exhibiting air/water flow issues. Neither patient nor user injury were reported due to the event. The scope was returned to an Olympus service center for evaluation. Upon inspection and testing of the returned scope, it was observed the air/water nozzle was clogged with a solid and dark foreign material. This report is being submitted for the malfunction found during evaluation of the scope (foreign material). Additional details have been requested regarding the reported issue. At this time, no additional information has been provided.

The reported issue (air/water issues) was confirmed. It was observed there was no air/water flow due to the clogged nozzle. In addition, service found:

- Worn out adhesive on the bending section cover
- Scratched charge-coupled scope cover lens
- Scratched light guide lenses
- Wrinkled connecting tube
- Wrinkled universal cord
- Worn out rubber on switch button#1
- Discolored electrical contact on the scope connector
- Out of specification bending angle
- Out of specification insulation resistance value
- Discolored and scratched biopsy channel.

The investigation is ongoing; 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=15033423&pc=FDS

1.3 Moisture condensation it the CCD module caused the gastroscope to have a shadowy image, July 2022

A report in the FDA **MAUDE** database states Pentax checked the returned Pentax Video Gastroscope-EG29-I10 and confirmed the CCD module shadow in image, which was caused due to the moisture condensation in the CCD module. In addition, we confirmed a) the nozzle gluing was missing, b) a leak in bending rubber, c) a cut in the bending rubber, d) scratched objective lens, and e) a suction channel kink; however, they are not the main cause and/or irrelevant to the alleged complaint. The time of the event is unknown. There was no report of patient harm. Video image failure (cloudy).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14903188&pc=FDS

1.4 The Colonoscope had a foggy appearance and the endoscopist attempted to clear the screen with water, June 2022

A report in the FDA **MAUDE** database states Pentax medical became aware on June 14, 2022, of a customer reporting a "foggy appearance during the procedure," involving the Pentax Video Colonoscope EC38-I10NL. The endoscopist attempted to clear the screen with water and by blotting the screen on clean parts of the bowel but with no improvement. This is a known issue being tracked and is the reason the facility had the loaner endoscope so that Biomed could review our equipment for this same issue. The reported failure caused an approximate 20-minute delay in the case per physician resulting in the patient being under anesthesia for additional time. A second endoscope was required to complete the procedure. The model and serial numbers of the second scope were not provided. If additional information becomes available, a supplemental report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14767113&pc=FDF

1.5 The patient had a perforated sigmoid colon from an area of irritation caused by a Colonovideoscope during a colonoscopy procedure, June 2022

A report in the FDA **MAUDE** database states during a diagnostic esophagogastroduodenoscopy and colonoscopy using a EVIS Exera II Colonovideoscope CF-H180AL, the scope was inserted into the rectal vault and advanced to 30 cm where upon withdrawing there was an area of irritation caused by the scope on the site where it appeared that there was a linear rent in the mucosa. The submucosa was visible deep to this, and two (2) clips were used to approximate the mucosal edges. The scope was then exchanged for another scope and was passed beyond this site to the level of the cecum without difficulty.

The patient was seen in the physician's office for post-procedure follow-up and is doing well. However, when the patient was discharged from our facility, she was later sent to the hospital for observation, where she was taken to the operating room for a perforated sigmoid colon.

The colonoscope was sent to Olympus for evaluation and repair because post procedure it was noted that the distal end was chipped. Olympus performed a visual inspection/physical evaluation of the scope's received condition. Preliminary findings are reported, and the investigation is ongoing. The distal end of the scope was inspected under a microscope and found a) deep dents, b) scratches, c) chipped lenses, and d) deterioration of the glue around the lenses. The bending section cover glue was also inspected and found a crack, pinholes, and missing and chipping glue due to deterioration. Further findings per the estimation quality inspection results included: a) leaking from the auxiliary water channel, b) failed distal end cover insulation test, c) restriction at the suction cylinder, and d) low angulation, play, and clicking on the control knobs. This report will be updated upon completion of the investigation or upon receipt of additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14565895&pc=FDF

1.6 The casing on the tip of a tracheal intubation fiberscope broke off and fell into the patient's airway, June 2022

A report in the FDA **MAUDE** database states during an unspecified procedure using a Tracheal Intubation Fiberscope LF-GP, the casing on the tip of the scope broke off into the patient's airway and was retrieved. No report of adverse effects to the patient, but additional details regarding the reported event have been requested. At this time, no additional information has been provided by the customer. An Olympus onsite specialist reported no one saved any foreign body material for them to examine and there were no physical missing parts from the scope.

The scope was returned to Olympus for evaluation and (upon inspection/examination) no parts were missing from the scope. Physical evaluation of the scope:

- Leak at the instrument channel
- Cut in adhesive rubber
- Restriction in the forceps' passage
- Image has a stain
- Dent in the insertion tube
- Chemical damage to the control body
- Off-center eyepiece body
- Lower than standard angulation.

The investigation is ongoing. This report will be completed of the investigation or upon receipt of additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14852973&pc=EOQ#

1.7 Adhesive on the distal side of the bending section fell into the patient's bronchus, June 2022

A report in the FDA **MAUDE** database states during a bronchoscopy, the adhesive on the distal side of the bending section (a fragment about four [4] mm) fell into the patient's bronchus. The EVIS Lucera Elite Bronchovideoscope BF-P290 was inserted and removed several times to retrieve/remove the fragments from the patient and there was a small amount of bleeding at that time. Hemostasis was performed and the intended procedure was completed. A request for additional information is in progress.

The scope has been returned to Olympus for evaluation and investigation is in progress. The physician stated there is no relationship between the hemostasis treatment due to bleeding at the time of examination and this defect. No charge in reportability. Once the investigation has been completed, a supplemental report will be submitted with scope's evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14675651&pc=EOQ#

1.8 A stent was pushed out of the duodenovideoscope during an unspecified procedure that was left from a previous patient procedure, May 2022

A report in the FDA **MAUDE** database states during an unspecified procedure, it was reported to Olympus that a stent from a previous patient procedure was pushed out of the EVIS Lucera Duodenovideoscope TJF-260V and into the patient. The stent was successfully retrieved form the patient and is unknown how it was retrieved from the patient. The customer reported a tent (10) minute delay due to this event. Follow-up with the patient was performed and was reported to be okay. The customer reported the scope had been washed since the prior procedure. The nurse informed the decontamination staff the stent pushed out of the scope may have been from inside of the scope and a previous procedure. The facility stated the scope was brushed and nothing came out. It is suspected the brush being used is too small. The scope was returned to Olympus service center for evaluation. During the inspection and testing of the returned scope, the instrument channels were brushed, and the instrument was visually inspected for any external damage that could be attributed to the reported event. No abnormalities or associated damage were identified during the inspection. The internal channels were inspected using a slim diameter video scope and no foreign objects or internal channel damage were identified. The following defects were observed during the evaluation:

- Light guide lens was scratched, the glue around the light guide lens was worn.
- Objective lens was chipped, and glue around the lens was worn.
- Adhesive on the bending section cover was lifting, the insertion tube was delaminated.

- Connector plug was stained.
- Bending angulations did not meet specification, and the angulation control knob was loose.
- A leak was observed at the water-resistant cap.

An Olympus support manager will be visiting the user facility to provide additional training. Once the investigation has been completed, a supplemental report will be submitted with scope evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14465148&pc=FDT

1.9 Foreign material was pushed out of a Gastrointestinal Videoscope during an unspecified procedure including several areas of damage were noted on the endoscope, March 2022

A report in the FDA **MAUDE** database states the user facility reported that during an unspecified procedure a foreign material/tissue was pushed out of the EVIS Exera III Gastrointestinal Videoscope GIF-H190. This incident was disclosed to the patient. There has not been any infection or patient harm from this incident. The scope was returned to Olympus for evaluation and did not confirm the presence of foreign material in the channel of the scope. there were deep scratches noted near the biopsy opening and on the side of the plastic distal end cover. The upward and downward angulation was loose. The bending section cover glue was cracked. There was bite mark noted at 55 cm on the insertion tube. The scope has been serviced and returned to the user facility. This report will be supplemented when new information becomes available. Investigation activities have been opened to manage the actions related to this report and any required MDR reporting.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13668665&pc=FDS

1.10 The Imagina colonoscope image was blurry due to water on the lens and could not refocus when moving closer or away from object, March 2022

A report in the FDA **MAUDE** database states residual water remains on the lens of Pentax Imagina Colonoscope EC38-O10CL scopes. Camera does not refocus, and image remains blurry when moving closer and further away from an object. Purple ring shows up on screen which looks to be reflection or lens flare. There was no report of patient harm. The time of event was during use. If additional information becomes available, a supplemental report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13850024&pc=FDF

1.11 During preparation for use the bronchoscope was noted to have several areas of damage including leaking fluid, February 2022

A report in the FDA **MAUDE** database states that during preparation for use, liquid was leaking from the channel on the EVIS Lucera Bronchovideoscope BF-1T260. This did not impact the procedure or cause injury to the patient. During the evaluation, it was noted that the scope's coating at the connection tube had peeled off. The scope was returned to Olympus for evaluation and the report was confirmed. Liquid leaked due to damage of the channel tube and part of the bending cover was cut. The electrical connector was corroded due to leakage, angulation in the up direction was out of standards due to worn angle wire. Insulation resistance was out of standard due to damage to the channel tube. The light guide lens was broken, and the insertion tube was scratched, as well as the adhesive around the lenses were worn. This report is to capture the reportable malfunction of peeled coating at the connection tube noted at evaluation. The investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13534072&pc=EOQ

1.12 Several patients developed respiratory infections from the same Pentax bronchoscope, February 2022

A report in the FDA **MAUDE** database states Seven cases of respiratory infection with *Achromobacter xylosoxidans* after discovering the Pentax Fiberoptic Bronchoscope 2.2C 4.9TP 600L FB-15V had the same bacteria. One death was reported but unrelated to the event. The first analysis was initiated by the hospital and carried out on December 24, 2021. On December 31, 2021, pathogens were detected on the scope. An extended period of time elapsed between the date of occurrence and the date when Pentax was informed on January 31, 2022--the facility was unable to conclude whether the scope may have contributed to the bacterial infection that was observed in 2021. The inspection carried out at the facility at Pentax on February 2, 2022, revealed the scope was not in working condition. The scope was damaged and required a full mandatory repair. The damages are as follows: a) crushed segment, b) wrinkled insert tube, c) striped insertion tube, d) multiple point CFB image fiber (damaged fiber optics), e) pleated bonding tube. The damage observed during the inspection does not allow a conclusion whether the scope may have contributed to the bacterial contamination or not. The results of the microbiological assessment from December 24, 2021, and December 31, 2021, do indicate the reprocessing at the hospital was insufficient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13447528&pc=EOQ

1.13 It was noticed that the biopsy channel of a colonovideoscope contained a foreign object, January 2022

A report in the FDA **MAUDE** database states the user facility reported a foreign object was observed in the entrance of the biopsy channel of the Colonovideoscope CF-H170L. The event occurred during a non-specified diagnostic procedure. The device was not used on the patient. There was no delay in the procedure, and it was completed using another scope. No patient injury due to the event. The colonovideoscope was returned to Olympus service center for evaluation. The scope inspection found the:

- Foreign object in the biopsy channel was a syringe tip, which was removed.
- Angle-wire up direction was out of specification due to wear of the angle wire.
- Distal end was found to be scratched and the adhesive was worn.
- Light guide lens was discolored and scratched.
- Light guide bundle was out of specification.

The investigation is ongoing. The root cause of the 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=13385799&pc=FDF

1.14 A clip was lodged in the channel of the duodenoscope from a previous procedure and fell out into a patient during a therapeutic procedure, January 2022

A report in the FDA **MAUDE** database states the customer reported to Olympus that a Boston Scientific clip was lodged in the channel of the EVIS Exera III Colonovideoscope PCF-H190DL (from a different procedure) and fell out of the scope into a different patient, who was undergoing an unknown therapeutic procedure. The customer reported that five (5) Boston Scientific clips had been used in the previous procedure but only had become lodged in the channel. The scope went through bedside cleaning prior to being reprocessed in a Medivator. The scope was then dried and used on a new patient. The doctor was able to remove the clip. There was no report of patient harm associated with this event. The scope has been received, but the evaluation has not been completed. The investigation is ongoing and follow-up with the user facility is currently being performed. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13246951&pc=FDF

1.15 A ureteroscope had excessive broken fibers (black dots) causing image problems, January 2022

A report in the FDA **MAUDE** database states during an evaluation, a hole and protruded (metal) skeleton from the bending section cover was found. The reported issue was confirmed as the image has excessive broken fibers (black dots). The Uretero-Reno Fiberscope URF-P6 had:

- Failed the leak test (due to a large leak from the instrument channel at the distal end)
- Chipped glue of the bending section cover (with exposed threading)
- Sunken down objective lens
- Discolored eyepiece body.

The scope was last serviced via repair in 2019. The service center was informed that the uretero-reno fiberscope was returned for a reported image problem. During inspection/testing, the scope was found to have metal protruding from the bending section cover. No patient injury or harm reported to Olympus. The root cause cannot be determined at this time. This investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13287734&pc=FGB

1.16 Foreign material was seen in patient's ureter during a ureteroscopy, January 2022

A report in the FDA **MAUDE** database states the doctor visualized foreign material during a ureteroscopy in the patient's right ureter. The object appeared blue in color and was retrieved via basket and observed by staff. It was determined to be a small portion of the Storz 11278AU1 (Flex-X) Scope Ureteroscope that was in use. The scope was passed off the field and incident reported to the product rep. The damaged scope was reported to SPD and a new flexible ureteroscope was used for the duration of the case. No detachable harm to the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13251919&pc=FGB

1.17 The tip of the bronchoscope broke off outside the patient's body during preparation for use, January 2022

A report in the FDA **MAUDE** database stated, while preparing the EVIS EUS (Endoscopic Ultrasound) Ultrasound Bronchovideoscope BF-U190F for a procedure, the tip of the scope broke off (outside the patient's body) while attaching the balloon. A second scope was used to complete the procedure. The scope has been evaluated by Olympus with preliminary findings reported. Physical evaluation of the scope shows a) the probe acoustic broken, b) insertion tube has dents/buckles, and c) rubber glue is detached/cracked/peeling. The bending angle does not meet specifications. There was no impact to the patient because of the occurrence. The investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13237589&pc=PSV

1.18 The bending manipulation and insertion tube were found to be defective upon inspection on a ureteroscope, December 2021

A report in the FDA **MAUDE** database states a user facility returned the Olympus Uretero-Reno Videoscope URF-V3R due to no angulation and the control lever not flexing up or down. Upon inspection and testing of the returned scope, it was observed that the bending manipulation and insertion tube were defective. Additionally, a brown liquid was coming out of the bending cover, and the bending rubber was broken, torn, and a metal was sticking out of the scope. The scope was evaluated by Olympus. It was confirmed a) the scope was not flexing up or down, b) a brown liquid was coming out from the bending section sheath, and c) the scope image was very cloudy. The scope connector was corroded due to fluid invasion and all switches on the scope were not working. The faulty parts were replaced to meet Olympus' functional standard. The investigation is ongoing; the root cause of the reported event cannot be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13010687&pc=FGB

1.19 The bending rubber split on a ureteroscope during a case, December 2021

A report in the FDA **MAUDE** database states the Video-Uretero-Renoscope Flex XC Video Ureteroscope 11278VSUEK bending rubber split apart during a case, and the whole scope became stuck inside of patient. The surgeon used a laser to incise mucosa on the inside of the patient's ureter to remove the video ureteroscope and placed a stent, which will be left in for two weeks. The receipt and evaluation of the affected device is pending.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12968521&pc=FGB

2. Malfunctions of Single-Use Scopes and Endcaps

2.1 Two procedures where the single use distal cover came off the Duodenoscope and into patient, August 2022

A report in the FDA **MAUDE** database states two procedures during which the single-use distal cover MAJ-2315 came off the duodenoscope and into the patient. The procedures were performed by two different physicians.

Procedure 1: The distal cover was found to be missing upon withdrawal of the scope. The physician went back down with the scope to look for the distal cover and it was not found or retrieved. The physician is not certain there was a distal cover on the scope at the beginning of

the procedure. The are no reported adverse effects to the patient as a result of this occurrence. The customer was unable to provide any further information when asked.

Procedure 2: The distal cover came off the scope in the patient's upper esophagus. The physician was able to retrieve it successfully. There were no additional consequences to the patient reported. The customer was unable to provide any further information when asked.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15194115&pc=FDT

2.2 A patient developed pain in their kidney after a cystourethroscopy procedure and required a prolonged stay in the hospital, August 2022

A report in the FDA **MAUDE** database states Boston Scientific Corporation was notified, through a post-market clinical follow-up of retrospective data collection, that a LithoVue flexscope M0067913500 was used during a cystourethroscopy with left ureteral stent placement, left ureteroscopy with laser lithotripsy, right ureteroscopy with laser lithotripsy procedure performed in 2021. The patient required a prolonged hospitalization for kidney pain.

The complainant was unable to provide the scope lot number. The lot expiration and scope manufacture dates are unknown. The scope has not been received for analysis. Upon receipt and completion of the scope analysis, and any further relevant information from that review, a supplemental MedWatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15146090&pc=FGB#

2.3 After a cystourethroscopy, the patient experienced hematuria, dysuria, and urinary retention and pain, August 2022

A report in the FDA **MAUDE** database states Boston Scientific Corporation was notified, through a post-market clinical follow-up of retrospective data collection, that a LithoVue flexscope M00067913500 was used during a cystourethroscopy with left ureteral stent placement, left infundibulotomy, left retrograde pyelogram with fluoroscopic interpretation procedure in 2018. Post procedure, the patient a) experienced hematuria, b) dysuria, c) urinary retention, and d) pain. The patient presented to the emergency room with fever and nausea. It was reported after ureteral stent removal the patient still had left flank pain; however, less severe. The patient was given medications to treat these complications.

The complainant was unable to provide the scope lot number—therefore the lot expiration and scope manufacture dates are unknown. The scope has not been received for analysis. Upon receipt and completion of the scope analysis and if there is any further relevant information from that review, a supplemental MedWatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15143140&pc=FGB#

2.4 A patient developed a urinary tract infection and sepsis during a cystourethroscopy procedure, August 2022

A report in the FDA **MAUDE** database states Boston Scientific Corporation, through a post-market clinical follow-up of retrospective data collection, that a LithoVue flexscope M00067913500 was used during a cystourethroscopy with left ureteral stent removal, cystourethroscopy with right ureteral stent placement, cystorethroscopy with right ureteral stent removal, left ureteroscopy, right retrograde pyelogram with fluoroscopic interpretation, right ureteroscopy with laser lithotripsy procedure performed in 2017. During the procedure, the patient experienced urinary tract infection and sepsis. The patient was required a medication to treat the complication.

The complainant was unable to provide the scope lot number, and the lot expiration and scope manufacture dates are unknown. The scope has not been received for analysis. Upon receipt and completion of the scope analysis, and if there is any further relevant information from that review, a supplemental will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15142840&pc=FGB

2.5 The LithoVue ureteroscope and zero tip baskets were used for a procedure causing the patient to be infected with *C. difficile* and sepsis, August 2022

A report in the FDA **MAUDE** database states the event was reported to Boston Scientific Corporation, through a post market clinical follow up of retrospective data collection, that LithoVue flexscope M0067913500 and zero tip basket were used during a cystourethroscopy with right ureteral stent placement, right antegrade nephrostogram with fluoroscopic interpretation right percutaneous nephrolithotomy, right renal access and dilation, right renal ultrasound with interpretation, and right retrograde pyelogram with fluoroscopic interpretation procedure performed in 2017. The patient experienced *clostridium difficile* and sepsis. The patient stayed longer in the hospital than the intended procedure date, and medication was required to treat the complications.

The complainant was unable to provide the scope lot number, and the lot expiration and scope manufacture dates are unknown. The scope has not been received for analysis. Upon receipt and completion of the scope analysis, if there is any further relevant information from that review, a supplemental MedWatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15156183&pc=FGB

2.6 The distal cover was missing from the Duodenovideoscope and remains in the patient, July 2022

A report in the FDA **MAUDE** database states during an ERCP (using an EVIS Exera Lucera Duodenovideoscope TJF-260V and a single-use distal cover), upon withdrawal of the scope from the patient the distal cover was missing. It may have fallen into the body (the duodenum); although it cannot be confirmed, it seems that it remains in the patient's body. The physician feels the cover may have come into contact with the drainage tube and fell off. No additional consequences to the patient have been reported. Additional details regarding the reported event have been requested. At this time no additional information has been provided.

The scope was not returned to Olympus for evaluation. The definitive cause of the user's experience cannot be determined at this time. The investigation is ongoing, and 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=14886115&pc=FDT

2.7 The Fujifilm Duodenoscope endcap was missing when the scope was withdrawn from the patient, June 2022

A report in the FDA **MAUDE** database states Fujifilm corporation was informed of an incident that occurred during a procedure while utilizing Fujifilm Duodenoscope ED-580XT. It was reported that the cap was missing when the scope was withdrawn after the procedure was completed with the scope. The doctor utilized a gastroscope and performed a gastroscopy to locate the cap. They could not find the cap, and upon withdrawal of the gastroscope, the cap was found in the patient's mouth. The cap was removed from the patient's mouth and no injury was observed or reported by the doctor or nursing staff.

Fujifilm determined the root cause to be the accidental use of the DC-06D distal end cap, which is not compatible with the scope ED-580XT. The facility staff was retrained on the instructions for use (IFU). There was no death or injury reported with this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14747104&pc=FDT

2.8 A patient had a piece of the single-use distal cover stuck in his esophagus after an ERCP, June 2022

A report in the FDA **MAUDE** database states the customer reports in a voluntary MedWatch that during an ERCP (using an EVIS Exera III Duodenovideoscope and a single-use distal cover MAJ-2315), the distal cover dislodged from the housing of the scope. This was not noticed at the time of the procedure. After being discharged home, the patient called the physician complaining that he felt like something was stuck in his esophagus. The patient then coughed up a piece of

plastic. The patient sent a photo to the physician and was identified to be the single-use disposable cover used in the procedure. The patient had no residual complaints or symptoms and is doing well. No other consequences to the patient are reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14643165&pc=FDT

2.9 A piece of the distal end separated from the endoscope and was left inside the patient after an ERCP, May 2022

A report in the FDA **MAUDE** database states the distal end cover unknowingly separated from the Single-Use Distal Cover MAJ-2315 endoscope and was left inside the patient after an ERCP. After the procedure, the patient had difficulty swallowing and a decreased level of consciousness. A bedside swallow study was ordered with speech (therapy). During the swallow evaluation, the patient coughed up mucus and a piece of plastic resembling the distal end cover. After this event, the patient was able to speak more clearly and swallow better. The customer reported the staff is unable to confirm the distal end cover was 100% securely attached to the endoscope at the start of the procedure as this is a new step. The procedure was completed without any issues. This report is 1 of 2 for the distal end cover, MAJ-2315 with lot H1922 (sterile lot H219065).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14359694&pc=FDT

2.10 Distal covers were lost in two different patients during two different procedures, April 2022

A report in the FDA **MAUDE** database states the distal cover was lost during two (2) different procedures with two different patients. The customer stated it is unknown why the distal cover fell off the Single-Use Distal Cover MAJ-2315 endoscope. The customer also stated the old version of the distal cover did not have such issues. In one procedure, the distal cover remained in the patient and was an emergency situation. No additional information is available. In the other procedure, the distal cover was recovered with no additional information provided. This report is one of four for the lost distal cover that remained in the patient for MAJ-2315.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14014366&pc=FDT

2.11 A 5-centimeter tear and bleeding were presented in a patient the day after an ERCP procedure, April 2022

A report in the FDA **MAUDE** database states Boston Scientific Co. received a report that exalt model d single-use Duodenoscope M00542421 was used in a ERCP for treatment of stones. At the end of the procedure, the physician pushed the scope into the long position to capture a fluoroscopy image. The control knobs were returned to neutral position, removed the scope, and the procedure was then complete with no bleeding noted at that time. The patient presented with bleeding the next day and a 5-centimeter tear in the gastric wall was discovered. As a result, two (2) repeat procedure were required, clips were placed at the site of the tear, but the patient formed a large clot and the bleeding stopped on its own. The patient was hospitalized and is reported to be in stable condition. The physician's assessment states there was stiffness while the scope was in the long position contributed to the injury. They reported that the tear could have been caused by pushing too against the greater curvature of the stomach. The complainant indicted that the device was disposed and will not be returned for evaluation; therefore, a failure analysis of the scope could not be completed. A supplemental MedWatch will be filed if further information is identified.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14107194&pc=FDT#

2.12 Distal cap came off a Fuji endoscope during an ERCP procedure and remained in the patient, March 2022

A report in the FDA **MAUDE** database states during an endoscopy procedure, a Fuji ERCP distal cap came off a FUJI Distal Endo Cap Duodenoscope 55A4 and the cap remained in the patient. The team noticed the distal end cap was off the scope after the case. They performed another endoscopic procedure to retrieve and remove the distal cap.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13966084&pc=FDT

2.13 Two different procedures were reported were distal endcaps dislodged from the endoscope into two patients' stomachs, March 2022

A report in the FDA **MAUDE** database states two (2) different procedures the distal cover fell off the Single-Use Distal Cover MAJ-2315endoscope.

First patient event: involved the Olympus endoscope with distal cover was inserted without issues and it was noticed the clear cap stated dislodging. It seemed to correct itself as it could not be seen anymore. After completing the procedure, upon withdrawal of the endoscope form the stomach, the distal cover was identified sitting in the patient's stomach. The physician had difficulty retrieving the distal cover while grasping with forceps and pulling it back up the esophagus. Eventually a thin part of the cap ripped, and it had to be pushed back into the

stomach. The physician needed to use a roth net and had some difficulty removing the distal cover. This patient was noted to have a narrow esophagus however the physician noted this should have not occurred.

Second patient event: happened approximately 1-2 months ago on a unknown date. While the physician was inserting the endoscope, the distal cover fell off and lodged in the posterior oropharynx. It is unknown how the distal cover was retrieved. The Olympus area manager performed an in-service to all end users of the Olympus endoscope and distal cover. After the in-service, there have not been any related incidents with the distal cover falling off the endoscope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13952021&pc=FDT

2.14 A single-use duodenoscope was unable to pass in the patient's esophagus and irritation was notice in the area by the physician, March 2022

A report in the FDA **MAUDE** database states Boston Scientific Co. received a report that an exalt model d single-use Duodenoscope M005542421 was introduced for use in an ERCP procedure for treatment of a stone in the common bile duct. During the procedure, the patient was put in the prone position under general anesthesia. The physician was unable to pass the scope into the patient's esophagus. After several minutes of trying, the physician discontinued the procedure. The physician noticed irritation to the area after his attempts but did not suspect a perforation. He then referred the patient to another healthcare facility for treatment. Several day later, the patient underwent and ERCP at the referred facility and an oropharyngeal perforation was detected. The perforation was confirmed by contrast study and treated surgically. The patient was then hospitalized. Despite follow up attempts, no further information has been obtained at this time. The physician stated that since it is unclear during which procedure the perforation occurred, he is unable to determine if use of exalt contributed to the complications. He noted that the second physician also had a difficult time passing a scope into the patient's esophagus and had to use an overtube. The patient's exact age is unknown. Approximated based on the date the manufacturer became aware of the event. The complainant was unable to provide the suspect scope lot number, therefore, the lot expiration and scope manufacturer dates are unknown. The complainant indicated that the scope is not available for return; therefore, a failure analysis of the scope could not complete. Any further relevant information that is identified, a supplemental Medwatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13870205&pc=FDT#

2.15 A patient's esophagus was injured during an ERCP with a single-use duodenovideoscope and scope distal cover, February 2022

A report in the FDA **MAUDE** database states the customer reports during an ERCP for biliary stent removal (using an EVIS Exera III Duodenovideoscope MAJ-2315 and a single-use distal cover) the patient sustained a moderate mucosal tear the entire length of the esophagus. Cap assisted examination was performed and did not reveal deep penetrating injury. The patient was sent home with eight (8) weeks of twice daily proton pump inhibitor (PPI) treatment. No additional consequences to the patient were reported. Over a 21-day period, the customer reported a cluster of eight (8) similar events occurring during ERCP procedures using an EVIS Exera III Duodenovideoscope with a single-use distal cover. These events involve gastrointestinal tissue trauma and/or tissue found in the distal cover following the procedure. Events one (1) through eight (8) report the TIF-Q190V used in the procedures and the MAJ-2315 used in the procedures. Customer attributes these similar events to cracked caps (MAJ-2315). Customer reports speaking with the team, and they did report having difficulty in the beginning with cracking the caps. The caps were changed if they were found to be cracked. The customer also reported discovering a few caps were cracked when coming out of the packaging and that the scope broke off. Upon physical inspection/evaluation of the returned scope, Olympus could not confirm the customer's report. There were no pieces of the video scope broken off. The single-use distal cover (MAJ-2315) was not returned for evaluation. Olympus did note cracking on the insertion tube side of the bending section cover glue, which was still intact/attached to the video scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13518299&pc=FDT

2.16 Minor bleeding to the mucosa and trachea of a patient was caused by the suction button on a single-use bronchoscope that became stuck in the depressed position, February 2022

A report in the FDA **MAUDE** database states an event was reported to Boston Scientific that an Exalt Model B Single-use Bronchoscope M00542711 was used during a broncho-alveolar lavage (BAL) procedure performed in 2021. During the procedure, the suction tube's button became stuck in the depressed position causing minor bleeding to the bronchial mucosa and trachea. The procedure was not completed due to this event. The bleeding required no additional treatment, and the patient has recovered.

The complainant was unable to provide the scope's lot number. Therefore, the lot expiration and device manufacturer dates are unknown. The complainant indicated the scope was disposed and will not be returned for evaluation. If any further relevant information is identified, a supplemental MedWatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13602378&pc=EOQ

2.17 The cap was attached incorrectly to the single use distal cover of a duodenovideoscope prior to the ERCP procedure, January 2022

A report in the FDA **MAUDE** database states the customer reports during an ERCP procedure using an EVIS Exera III Duodenovideoscope with a single-use distal cover, the cap was not applied correctly. The was adjusted, and the procedure was started. The physician could not pass the scope into the stomach and the procedure was terminated. As the scope was being withdrawn (extubating), the patient experienced a 5–6 cm oropharynx mucosal tear (visualized with a glide-a-scope) said to be caused by the distal cover. The patient was admitted to the hospital and an ear/nose/throat (ENT) physician was consulted. The patient required additional imaging. The patient was hospitalized for six (6) days for observation/assessment of the tear. No surgery was performed to treat the tear. There were no abnormalities in the appearance of the scope/distal cover.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13260458&pc=FDT

2.18 The plastic cover came off the scope in the patient during an ERCP procedure, December 2021

A report in the FDA **MAUDE** database states it was reported to an Olympus representative that after an ERCP procedure the plastic cover was missing from the end of the scope. The scope was reintroduced into the patient—the plastic cover was identified in the second part of the duodenum and retrieved using rat tooth forceps. Additional information was requested from the customer, but none is available. It is unknown if there was patient harm or injury.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13008059&pc=FDT

2.19 Patient had a perforation in the pyriform sinus during an ERCP due to the stiffness of the single-use scope, which may have caused the event, December 2021

A report in the FDA **MAUDE** database states that the event was reported to Boston Scientific corporation involving an Exalt Model D Single-use Duodenoscope M00542420 for use in an ERCP procedure in 2021 for common bile duct stricture. The procedure was performed under general anesthesia with the patient in a semi-prone, left lateral position. The physician reported that due to the patient's morbid obesity, there was a sharp angle between the neck and body. As the physician was trying to advance the scope into the esophagus via the oropharynx, he felt a give and noticed a 6–7 mm full thickness perforation in the pyriform sinus. The procedure was then aborted. The physician stated the stiffness of the scope may have partially contributed to the event. The perforation was evaluated by an otolaryngologist and the performing physician, and they determined additional surgery was not required. The patient was admitted for observation. Post procedure, the patient complained of chest pain, but imaging did not show any significant

air or fluid. The patient was worked up for cardiac etiology of chest pain. The patient underwent a barium swallow a few days after the procedure, which did not show any leak and the patient was started on clear liquids. The patient was reported to be doing well. The complainant was unable to provide the scope—the lot expiration and manufacturer dates are unknown. The complainant indicated the scope was disposed of and will not be returned for evaluation. If any further relevant information is provided a supplemental Medwatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13001194&pc=FDT

3. Cleaning Verification Testing

3.1 A patient tested positive for *E. coli* after the same Gastroscope was used on a prior patient, who also tested positive prior to their procedure, June 2022

A report in the FDA **MAUDE** database states that Olympus was informed a patient was positive for *E. coli* after use of the same EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 on a prior patient, who had *E. coli* prior to their procedure with the scope. Patient zero was found in 2021 to be positive for multi-resistant *E. coli*. The patient underwent a sigmoid endoscope with the scope in 2022. Also in 2022, a different patient tested positive for the same microorganism, *E. coli*. Both patients were examined epidemiologically, and the common factor was the same gastroscope used. The facility cultured the endoscope and twice found bacteria. Hospital will recall patients who were examined with the same gastroscope. A request for additional information is in progress. The scope has not been returned to Olympus evaluation. The investigation is in process. Once the investigation has been completed, a supplemental report will be submitted with device evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14789139&pc=FDS

3.2 The distal tip and channels of the fiberscope were cultured and less than one (1)-CFU of a microorganism was detected, June 2022

A report in the FDA **MAUDE** database states the cleaning, disinfection, and sterilization (CDS) of the Uretero-Reno Fiberscope URF-P7 was performed by the customer. The air/water channel, auxiliary channel, balloon channel, and forceps elevator wire channel were flushed. There was an aspiration of water through the instrumentation/suction channel, as well. The instrument/suction channel, suction cylinder, instrument channel port, balloon channel, and distal end/areas around the elevator were manually cleaned with Laboratoires Anios™ Hexanios G + R pre-disinfectant detergent. The scope was manually disinfected with Anioxyde 1000. The scope was stored horizontally. The maintenance of the scope was performed by Olympus.

After the scope was returned to Olympus, it was sent out for additional testing. The hygiene microbiological investigation report indicated the channels, and the distal end of the scope were cultured. Less than one (1)-CFU of a microorganism was detected. The results obtained complied with the target level for an endoscope subjected to high-level disinfection and rinsed with sterile water. The scope has been received and is currently in the evaluation process.

The customer reported to Olympus a routine microbiological culture was performed on the uretero-reno fiberscope. The scope tested positive for one (1)- (CFU) of *filamentous fungi*. There was no reported contamination or any other serious deterioration in the state of health of any person to which the scope could have been a contributory cause. The investigation is ongoing, and the root cause 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=14732169&pc=FGB

3.3 Sampling of a colonovideoscope was taken at reprocessing and tested positive five times for pseudomonas, May 2022

A report in the FDA **MAUDE** database states the EVIS Exera III Colonovideoscope CF-HQ190L tested positive for pseudomonas five (5) times. Sampling was taken at reprocessing, before use. The user did not report any contamination or any other serious deterioration in state of health of any person, to which the scope could have been a contributory cause. The scope was returned for investigation. Upon evaluation of the returned scope the following defects were found: 1. bending angle did not meet specification; 2. bending rubber adhesive detached; 3. upward/downward angulation control knob could not be locked securely due to work out lock engagement lever. The faulty part was replaced, and scope was returned to the user facility. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14483732&pc=FDF#

3.4 Microbiological culture was performed on an ultrasound bronchofibervideoscope that tested positive for microbes, May 2022

A report in the FDA **MAUDE** database states microbiological culture was performed on the EVIS EUS Ultrasound Bronchofibervideoscope BF-UC190 and tested positive for several microbes.

Biopsy Channel	Distal End	Operating Channel	Suction Channel

(1CFU) micrococcus luteus	(1CFU) staphylococcus species	(3CFU) micrococcus luteus	(2CFU) micrococcus luteus
(1CFU) brevundimonas species	(1CFU) Moraxella species		
(3CFU) environmental germs			
(1CFU) moraxels species			

No reported contamination or any other serious deterioration in the state of health of any person, to which the scope could have been a contributory cause. The scope was returned and is currently being evaluated. The investigation is ongoing, and 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=14345047&pc=PSV

3.5 Bronchoscope used in two procedures tested positive for Roseomonsa bacteria infecting two patients, May 2022

A report in the FDA **MAUDE** database reports states the customer reported to Olympus the EVIS Lucera Elite Bronchovideoscope BF-1TQ290 tested positive for Roseomonas mucosa bacteria. The customer informed by their infection control the scope was used in procedures and two (2) patients tested positive for microbial contamination with R. mucosa bacteria. The customer reported no visible damage to the scope. It is unknow what symptoms the patient exhibited and how they are doing today. It was also reported that it is unknown when the issue was identified, and no indication of any other instrument was being used at the time. When asked if the instrument was inspected prior to use, the customer responded: critical care support or critical care assistant would only remove bronchoscope from the air filtered cabinet, place it in the carrying case to transport to the user. Any obvious damage visually would be immediately reported. As for the user, doctors, and consultants, if any damage or fault occurred or found, would be brought to the attention of a critical care support or critical care assistant for repair.

The scope was returned to Olympus for evaluation and is in progress. The Olympus service center evaluated the scope and identified the following: The scope was cultured, and results were negative for microbial contamination. The bending section rubber was porous and broken, the distal end was discolored and there is a scratch inside the channel. A supplemental report will be submitted with the scope evaluation results once the investigation is completed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14455106&pc=EOQ

3.6 A colonovideoscope tested positive for Pseudomonas aeruginosa and Klebsiella pneumoniae during a routine culture, March 2022

A report in the FDA **MAUDE** database states the EVIS Exera III Colonovideoscope CF-H185I tested positive for greater that 100 (CFUs) of P. aeruginosa and 8 (CFUs) of K. pneumoniae. All channels were sampled. The issue was found during a routine culture of the scope. Sampling was taken at reprocessing. The scope was not used on a patient during culture sample collection. The user did not report any contamination or any other serious deterioration in the state of health of any person, to which the scope could have been a contributory cause. The scope was sent to an independent laboratory for culture testing. All channels were sampled. The scope tested positive for one (CFUs) of gram-positive bacteria bacillus and two (CFUs) of unspecified microorganisms. The user facility provided additional information regarding the cleaning, the disinfection and the sterilization processes performed onsite for the endoscopes. During pre-cleaning, the customer suctions water out of the channels and flushes out the air/water, and auxiliary washing, channels. However, no detergent was used during pre-cleaning during manual cleaning. The customer used neutral disinfectant ddn9 detergent with Albyn Medical double brush (5mm, 11mm) and 5mm swab to brush the operating channel, the suction pistons/cylinders, and the instrument channel port. The scope was not manually disinfected. For AER treatment, the Soluscope 4 reprocessor along with Soluscope CLN detergent and Soluscope PAA disinfectant were used. The scope was stored horizontally in a Surestore dry cabinet and Olympus is the customer's maintenance company. The scope was not sterilized. The customer stated that no AER testing was performed. The scope was returned for investigation and upon inspection and testing of the scope, defects were found light guide rod lens cracked, bending section cover or distal sheath glue white clouded and separated bending section tube crushed/sunken folds, and biopsy channel work but no malfunction reported. The faulty parts were replaced, and the scope was returned to the user facility. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13930192&pc=FDF#

3.7 A duodenoscope tested positive for microorganisms and was quarantined after the lab informed the facility about the positive culture test, February 2022

A report in the FDA **MAUDE** database states the customer reported the EVIS Exera II Duodenovideosocpe TJF-Q180V tested positive for *Pseudomonas aeruginosa*. It is also believed that the scope is contaminated with *Carbapenemase*. The customer reported the test results of the culturing will be provided later. The intended procedure was a therapeutic duodenoscopy. The scope was quarantined as soon as the lab informed the facility about the positive culture test. The issue was found during a routine culture of the scope. The user did not report any contamination or any other serious deterioration in the state of health of any person, to which the scope could have been a contributory cause. The Olympus scope was sent to an independent laboratory for

culture testing and no microorganisms were detected. The results obtained are in conformance with the requirements. The scope was returned to Olympus for evaluation.

- Insertion tube was buckled and kinked and was also found to have surface scratches and peeled coating.
- Light guide tube was dirty and kinked.
- Light guide cover glass was discolored.
- Light guide fibers were broken.
- Deposits were found on the air/water and suctions cylinder.
- Corrosion was found on the forceps raiser and the channel ports on the scope connector.
- Cover was not attached.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13503487&pc=FDT

3.8 A total of five patients contracted a urinary tract infection following cystoscopy procedures using one of three cysto-nephro videoscopes, February 2022

A report in the FDA **MAUDE** database states the customer reports a cluster of five-patient urinary tract infections following cystoscopy procedures using three cysto-nephro videoscopes CCYF-VHR. During the procedures, the user observed foreign bodies shedding from the tips of the scopes. There are three reports.

Report 1:

This report is based on patient one of five to which the procedure was a cystoscopy. Four days following the procedure, a urinary tract infection was diagnosed via urine culture. The microorganism identified in the patient's urine was *E. coli*. The patient was treated with an unspecified antibiotic and their current condition is reported as recovered and no additional consequences to the patient have been reported.

The facility does not document which scope was used in the procedure record, so it is unknown which of the three scopes were used in this procedure. There were no scope cultures performed by the facility. The customer declined to allow an Olympus Endoscopic Support Specialist (ESS) visit to observe reprocessing procedures and provide education to the staff an indicated. The request was declined by the customer for Olympus to culture the scope as part of the investigation. The customer emphasized they cannot conclusively say the scopes caused the infections. They noted increased infections at the same time foreign bodies were observed shedding from the tips of scopes. The customer used an Sterrad AER for sterilization. Precleaning is performed immediately post-procedure following the manufacturer's recommended steps.

This scope was returned to Olympus for evaluation. Preliminary findings have been reported with the investigation ongoing. Olympus performed a visual inspection on the received condition. The scope was inspected using an Olympus fiberscope to verify the condition of the biopsy channel. The fiberscope was first inserted into the biopsy channel, starting from the distal end side. Once inside, it was noted a reddish fiber in the middle of the biopsy channel. The fiberscope was inserted farther and discovered foreign material and debris approximately 50 mm from the opening. The distal end was inspected, and multiple abnormalities were found as well as dents at the opening of the biopsy channel and cracks on one of the light guide lenses. Also noted cracked, peeling, and missing glue from both ends of the bending section. 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=13470902&pc=FAJ

Report 2:

This report is based on patient two of five, where 12 days following the cystoscopy procedure, a urinary tract infection was diagnosed via urine culture. The microorganism identified in the patient's urine was *Enterococcus faecalis*. Patient two was treated with unspecified antibiotic and current condition is reported as recovered with no additional consequences to the patient have been reported.

The scope was returned to Olympus for evaluation. Several cracks in the adhesive were found with a lift that catches cotton, and the adhesive rubber was removed due to excessive scratches. A borescope was also used to verify the channel condition, and no scratches or tears could be seen. The scope image is good with no stains found. The distal end is not detached from the bending section. This report will be updated upon completion of the investigation or upon receipt of additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13470989&pc=FAJ

Report 3:

This report is based on patient three of five, where eight days following the cystoscopy procedure, a urinary tract infection was diagnosed via urine culture. The microorganism identified in the patient's urine was *Staphylococcus aureus*. The patient was treated with unspecified antibiotics and current condition is reported as recovered and no additional consequences to the patient have been reported. The scope was returned to the manufacturer but no answer about evaluation has been provided at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13471296&pc=FAJ

Patient/Report #	UTI Causing Microorganism	Cysto-nephro Videoscope Evaluation Findings

1	*E. coli*	• Biopsy Channel:
		  ○ Dents at opening
		  ○ Reddish fiber in the middle
		  ○ Foreign material/Debris approx. 50 mm from opening.
		• Distal End—Multiple abnormalities.
		• Cracks on one light guide lens.
		• Bending Section—Cracked/Peeling/Missing glue from both ends.

2	*Enterococcus faecalis*	• Several cracks in adhesive with a lift that catches cotton. • Adhesive rubber was removed due to excessive scratches. • Channel—No scratches or tears could be seen. • Scope Image is good. • No stains found. • Distal end is not detached from the bending section.
3	*Staphylococcus aureus*	• Scope was returned to the manufacturer. • No Evaluation details provided at this time.

3.9 All channels were tested on a gastrointestinal scope and results came back positive for over 100 CFUs of *Escherichia coli,* January 2022

A report in the FDA **MAUDE** database states the EVIS Exis III Gastrointestinal Videoscope GIF-1TH190 tested positive for over 100 CFUs of *Escherichia coli*. The issue was found during a routine culture of the scope. All channels were tested. The sampling occurred during reprocessing prior to patient use. The user did not report any contamination or any other serious deterioration in the state of health of any person.

The scope was sent to an independent laboratory for culture testing. All channels were sampled scope tested positive for one (1)-colony forming unit of unspecified gram-positive bacteria. The results obtained are in conformance with the requirements. The user provided additional information regarding the cleaning, the disinfection, and the sterilization processes performed onsite for the endoscope. During precleaning, the customer suctions water from the channels and flushes the air/water and auxiliary washing channel. The customer did not use detergent during precleaning but used detergent during manual cleaning and brushes for the operating/suction channel, suction piston, port of the operating channel and the distal end/area around the elevator and using Albyn medical double brush (180 cm). The scope was not manually disinfected. For

AER, the user facility uses AER Soluscope 4 along with detergent Soluscope and disinfectant Soluscope PAA. The scopes are stored in a Soluscope drying cabinet (DCS 8000). Olympus is the customer's maintenance company. The scope was not sterilized and has been received. It is currently in the evaluation process. The investigation is ongoing. 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=13146091&pc=FDS

3.10 *Coliform bacillus* and *pseudomonas* species was detected in a colonovideoscope for one (1)–10 CFUs, January 2022

A report in the FDA **MAUDE** database states that a customer reported to Olympus, the EVIS Exera III Colonovideoscope PCF-H190DL tested positive for one (1) to 10 colony forming units (CFUs) of *Coliform bacillus* and *Pseudomonas* species. The culturing occurred during reprocessing. Multiple scopes tested positive for contamination, and the customer only has one scope that did not test positive. The customer reported that no scope would be returned for service as it is speculated whether or not the hospital water supply may have caused the issue. There were no reports of patient harm or infection as a result of this event. The investigation is ongoing, and a supplemental report will be submitted upon completion if any additional information is obtained.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13148314&pc=FDF

3.11 A duodenoscope was immediately quarantined after it tested positive for *Staphylococcus lugdunensis*, January 2022

A report in the FDA **MAUDE** database states that Fujifilm corporation was informed the Duodendoscope ED-580XT was cultured and tested positive for (one [1]-CFU) *Staphylococcus lugeunensis*. Since the endoscope 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 positive culture, the endoscope was not clinically reused. There was no death or serious injury associated with this event. This report is being submitted in abundance of caution.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13237881&pc=FDT

3.12 Lung transplant patients had BAL specimens test positive for *Mycobacterium immunogenum* after bronchoscopies using disposable and reusable endoscopes, January 2022

A report in the FDA **MAUDE** database states, several lung transplant patients have had bronchial alveolar lavage (BAL) specimens test positive for *Mycobacterium immunogenum* after bronchoscopies using disposable and reusable Olympus scopes. The BAL specimens were direct specimens that were not diluted. There is no ice/water introduced into the patients during the procedure. The customer randomly selected a bronchoscope to culture with sterile water, which was found to be positive for *Mycobacterium immunogenum*. A physician at the facility observed a bronchoscopy and the lab processes for BAL and saw no gaps in the procedures. The Medivator AER was cultured (results not provided). The customer plans to culture the remaining 52 scopes in their fleet over the next month. The customer's internal lab is currently unable to perform environmental cultures on solid surfaces (e.g., sinks and prep table) due to the type of swabs and process required. Additional details regarding the patient(s), device(s), and reported event(s) have been requested. At this time, no additional information has been provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13261716&pc=EOQ

3.13 During reprocessing a colonovideoscope tested positive for *Enterobacter cloacae* including all channels being sampled, December 2021

A report in the FDA **MAUDE** database states the customer reported to Olympus, the EVIS Exera III Colonovideoscope PCF-H190I tested positive for 97 (CFUs) of *Enterobacer cloacae* during reprocessing, and all channels were sampled. The user did not report any contamination or any other serious deterioration in the state of health of any person. The scope was sent to an independent laboratory for culture testing. All channels were sampled, and the results were determined to be conforming. The results obtained are in conformance with the requirements. The use facility provided additional information regarding the cleaning, the disinfection, and the sterilization processes performed onsite for the scopes. The customer uses detergent Anios for precleaning and manual cleaning and Olympus brushes to brush the operating/suction channel, suction piston, operating channel port, balloon channel, and the distal end/area around the elevator. The scope was not manually disinfected. For AER processing, the customer uses AER Soluscope 4 (series 4 peracetic acid), along with detergent/disinfectant Anios. The scope is stored in a drying cabinet (Dry 300). Olympus is the customer's maintenance company. The scope was not sterilized. The scope evaluation is currently in process and the investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13016062&pc=FDF

3.14 All channels (including the air/water channels and aspiration channel) of a colonovideoscope were cultured and tested positive on multiple occasions, December 2021

A report in the FDA **MAUDE** database states the reported the EVIS Exera III Colonovideoscope CF-H190I was cultured and tested positive on multiple occasions.

Sampled Channel	Tested Positive CFUs
All Channels	10 CFUs for *Stenotrophomonas maltophilia*
Air/Water Channel	10 CFUs of *Klebsiella oxytoca*
Aspiration Channel	> 100 CFUs of *Serratia marcescens* and *Pseudomonas aeruginosa*

The issue was found during a routine culture. There was no contamination or any other serious deterioration in the state of health of any person, to which the scope could have been a contributory cause. The cleaning, disinfection, and sterilization of the scope was performed by the customer. There was no patient infection. The AER was also sampled. The air/water channel was precleaned/flushed with water. There was an aspiration of water through the instrument/suction channel, as well. The instrument/suction channel, instrument channel port, and distal end were manually cleaned with Novaclean brushes. The scope was not manually disinfected. The AER used was Soluscope along with Soluscope CLN and Soluscope PAA. The customer stored the scope bagged in a plasmatyphoon. The scope was not sterilized, the scope has been received and is currently in the evaluation process. The investigation is ongoing; 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=12950770&pc=FDF

3.15 An endoscope was quarantined after initial sampling and tested positive for *Escherichia coli* and *Micrococcus luteus*, December 2021

A report in the FDA **MAUDE** database states Fujifilm was informed that the Fujifilm Duodenoscope ED-580XT was cultured and tested positive for *Escherichia coli* and *Micrococcus luteus* (total four [4] CFUs). The endoscope was quarantined after initial sampling—no patients were involved or exposed to the endoscope. Following the positive culture, the endoscope was not clinically reused. There was no death or serious injury associated with this event; this report is being submitted in abundance of caution.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13003273&pc=FDT

4. Excessive Force with Equipment

4.1 Tip of the bronchoscope broke off due to the user applying excessive force causing the bending section of the tube to tear off during removal of the scope, January 2022

A report in the FDA **MAUDE** database states the tip of the flexible video bronchoscope 478001000 tore off due to the user applying excessive force causing the bending section of the aScope™ 4 Broncho not to be in a straight position during removal of the scope and to tear off. The product risk evaluation—risk is assessed as acceptable. The bending piece became stuck in the tube and caused an airway obstruction. The user has confirmed that the tracheal tube was bent during the procedure. No remedial, corrective, or preventive actions are taken as a result of this event. Ambu will keep monitoring this issue and take actions if necessary.

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

5. Failures Due to Reprocessing Equipment (AERs)

5.1 During an inspection it was discovered the water filter for the OER-4 had not been replaced since 2020, July 2022

A report in the FDA **MAUDE** database states during an inspection, a customer found and reported to Olympus that the water filter of the Endoscope Reprocessor OER-4 has not been replaced since 2020. No harm or injury reported due to the event. The OER-4 has not been returned to Olympus for evaluation. The investigation is ongoing, and a definitive 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=15033207&pc=FEB

5.2 Two (2) Cystoscopes processed in the OER-S causing potential cross contamination leading to urinary tract infections in five (5) patients, July 2022

A report in the FDA **MAUDE** database states the customer reported over the last 1–2 months a cluster of five (5) patients have been infected with urinary tract infections after endoscopy using one of two cystoscopes CYF-VHA and CYF-VA2 that were processed in OER-S causing potential cross contamination. More than a year ago, there was something like green algae growing on the water filter. In view of this, the facility is concerned about infection caused by OER-S.

At that time, the facility staff did not find any abnormalities after the response, so the process was completed without any problems, and there was no problem with the frequency of filter replacement at the facility noted. Microbiological investigation of the reported reprocessor indicates the OER-S is not the source of infection in the reported patients. Additional details regarding the patients and reported events have been requested. At this time, no additional information has been provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15126225&pc=FEB

5.3 The facility was not checking the concentration of the disinfectant every time before cleaning a scope in the OER-S, June 2022

A report in the FDA **MAUDE** database states the customer contacted the Olympus call center to inquire how to replace the OER-6 water filter on the Olympus endoscope reprocessor. As the customer was guided, it was discovered they were checking the concentration of the disinfectant daily instead of every time before cleaning a scope. The user error occurred during reprocessing.

There was no patient involvement. The medical device report (MDR) is being submitted to capture the reportable malfunction of poor reprocessing due to inadequate water supply piping disinfection after water filter replacement as stated by reported.

The OER has not been returned to Olympus for evaluation. Due to the nature of the error, it is difficult to identify specific scopes or patients affected by the suspected reprocessing failure. Proper operation guidance has been implemented for the facility. The investigation is ongoing. If additional information becomes available, this report we will supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14653479&pc=FEB

5.4 The AER was malfunctioning due to clogging of the nozzle hose caused by insufficient cleaning, June 2022

A report in the FDA **MAUDE** database states it was reported to Olympus, the EVIS Exera III Colonovideoscope CF-H190I stopped during the wash cycle during the endoscope disinfection cycle, as it had a flow problem. Upon inspection and testing of the returned scope, foreign matter was discovered in the nozzle hose causing insufficient flow to the air/water supply. There were no reports of patient harm associated with this event. The medical device report (MDR) is being submitted to capture the reportable malfunction of the clogging of the nozzle hose caused by insufficient cleaning found during evaluation.

The scope was returned to Olympus for evaluation. Upon inspection (testing of the scope), the user's request was confirmed—there was insufficient flow due to the clogging of the nozzle hose. In addition, they found:

- Leak failure between the case unit and the plug unit—either the scope connector or the O-ring was faulty.
- Out of specification the insulation resistance value.
- Separated glue of the bending section.
- Scratched scope cover.
- Wrinkled universal cord.
- Scratched angles wires in coil pipe.
- Out of specification angulations.

The investigation is ongoing, if additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14775855&pc=FDF#

5.5 Broken connecting tube from the OER-Pro was found after seven (7) colonovideoscopes were reprocessed and used on patients, April 2022

A report in the FDA **MAUDE** database states the customer reported that the connecting tube on the OER-Pro was found broken. Seven (7) EVIS Exera III Colonovideoscopes CF-HQ190L were reprocessed in the OER-Pro with the broken connecting tube and were used on patients. One (1) scope had been used on two (2) different patients on the same day. Procedure or patient impact was unknown as the broken piece of tubing was discovered after procedures were performed. It was unknown when the tubing was broken. Patient injury or infection was unknown. However, to date, no patient harm had been reported. The broken connecting tube was replaced, the OER-Pro was fully operational, and the scopes were rewashed. The customer contacted Olympus Technical Assistance Support (TAC) via phone. No troubleshooting was performed. The customer informed TAC of the event. A letter of discontinuation for the OER-Pro was emailed to the customer. The OER-Pro will not be returned to Olympus for evaluation. An Olympus Endoscopy Support Specialist (ESS) has been 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, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14013895&pc=FDF

5.6 The OER-4 basin was taking longer than usual to fill and received an E01 error message, March 2022

A report in the FDA **MAUDE** database states the customer reported the OER-4 100V Endoscope Reprocessor received an E01 error message indicator that the filling of the basin is taking longer than usual. The facility had not changed the water filter in eight (8) months. No report of harm to

any patient. The OER is not sold in the U.S. but a similar one is. The OER was not returned so a root cause of the reported complaint cannot be determined at this time. This event is under investigation and a supplemental report will be submitted upon completion of the investigation or upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13803490&pc=FEB

5.7 The OER 4 filter had not been changed in over two years, December 2021

A report in the FDA **MAUDE** database states Olympus Medical Systems Corp. (OMSC) was informed the OER-4 filter has not been replaced for more than 2 years. There was no report of patient injury associated with the event. The event date was unknown. The OER-4 100V Endoscope Reprocessor OER-4 was not returned to Olympus. 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=12948998&pc=FEB

6. Endoscope Malfunctions

6.1 A student was sent to the emergency room for exposure to blood body fluid from the one-way valve during a bronchoscopy, August 2022

A report in the FDA **MAUDE** database states during a bronchoscopy, a student was splashed in the eye with bloody fluid from the scope's one-way valve. The needle was withdrawn, and while the respiratory therapist was flushing the sample out of the scope the patient coughed. The valve did not seal, and blood and body fluid came out through the endoscope valve (single-use adaptor biopsy value MAJ-1414) and into the student's eye. The student was sent to the emergency room for the exposure.

The scope has not been returned to Olympus for evaluation. The investigation was completed, and a report will be submitted with scope evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15175766&pc=PSV

6.2 The Visera Cysto-Nephro Videoscope was unable to pass through the stricture at the bladder neck during a diagnostic cystoscopy, July 2022

A report in the FDA **MAUDE** database states the customer reported during a diagnostic cystoscopy using a Viscera Cysto-Nephro Videoscope CYF-V2R to assess response to therapy for bladder cancer, the scope was unable to pass through a stricture at the bladder neck. Sequence of events as follows:

1. An Olympus flexible scope was connected and white balanced in a routine fashion.
2. The scope was well lubricated and subsequently the patient's urethral meatus was cannulated. The patient had a normal-appearing urethra with no masses, lesions, or polyps.
3. The prostate was absent. There were no masses, lesions polyps or areas suspicious for cancer. Neobladder without evidence of tumor.
4. Patient had a 14-fr stricture near the bladder neck. The scope was unable to pass through the stricture.
5. Upon retracting, the scope broke and appeared to loop de loop on itself. As such, it was unable to be retracted and removed.
6. The patient was taken urgently to the operating room for removal.
7. The patient's current condition is stable.
8. The customer states there were no procedural or anatomical challenges that could have caused or contributed to the reported event.

The scope has been returned to Olympus for evaluation/repair. Preliminary findings are reported, and investigation is ongoing. Olympus performed a visual inspection on the received condition of the suspect scope. The scope's cover on the control body was open and the scope already inspected by the service group. They noted:

- Multiple buckles on the insertion tube next to the bending section cover glue.
- Chemical damage to bending section cover glue and voids around the edges on both ends.
- Discolored bending section cover along with chemical damage.
- Cut (large) on the bending section cover (closer to the insertion tube side).
- (Dried) brownish residue within the opening of the biopsy channel of the distal end.
- Non-Olympus glue repair surrounding the lens of the objective lens. (Note: Small edge forming on one side of the non-Olympus glue around the objective lens.)

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=14928191&pc=FAJ

6.3 A bronchoscope withdrawn from a patient's nose was charred and smoking, December 2021

A report in the FDA **MAUDE** database states, during an unspecified procedure, an EVIS Exera III Bronchovideoscope BF-H190 was being introduced in the patient's nose causing pain. The scope was withdrawn from the patient and smoke was seen emitting from the distal end with charred pieces noted on the distal end of the scope. A different scope was used to complete the procedure with no further issue. There was no cautery or laser system in use during the procedure. There was no injury to the patient reported. The scope was sent to the customer's in-house repair facility for evaluation and repair, and no issues were found. Additional details regarding the patient and reported event have been requested. No further information has been provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12972593&pc=EOQ

7. Use Errors

7.1 The Cidex OPA bottle does not fit the customer's non-ASP reprocessor nor does the customer use test strips to verify the effective concentration, August 2022

A report in the FDA **MAUDE** database states a customer initially reported that the Cidex OPA bottle opening does not fit their non-ASP reprocessor (TD100 Tee Probe disinfector). In 2022, the customer provided additional information that their facility does not use Cidex OPA test strips to verify the minimum effective concentration and does not monitor the solution temperature when they use the Cidex OPA with the non-ASP TD100 reprocessor. The customer stated the reprocessing room is maintained at temperatures of 22 °C (72 °F) to 23 °C (73 °F). Therefore, the Cidex OPA solution is the same temperature as the room. There was no report of infection, injury, or harm to any patient(s) associated with this event; although ASP has determined in this situation high-level disinfection cannot be assured. ASP has decided to report all incidents where high-level disinfection cannot be assured, and the Tee probe was released and used on patients.

The batch recorded was reviewed. No issues were observed that would contribute to this event. The product met manufacturer specification at the time of release. An ASP representative provided customer retraining as per the Cidex OPA solution instructions for use (IFU).

The report is being submitted pursuant to the provisions of 21 CFR, part 4. This report may be based on information which has not been investigated or verified prior to the required reporting date. This report does not reflect a conclusion by advanced sterilization products or its employees that the report constitutes an admission that the product, advanced sterilization products, or its employees caused or contributed to the potential event described in this report. If

information is obtained that was not available for the initial report, a follow-up report will be filed as appropriate.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15153567&pc=MED

7.2 Two patients tested positive for *P. aeruginosa* after having procedures with three (3) different cystoscopes and treated with antibiotics, August 2022

A report in the FDA **MAUDE** database states the customer reported to Olympus two (2) patients tested positive for *pseudomonas aeruginosa* after having procedures with three (3) Olympus cystoscopes— two (2) CYF-VA2 and one (1) CYF-VA. The two (2) patients presented with a fever after surgery and were diagnosed with a urinary tract infection. Both patients were treated with antibiotics and have recovered. The cystoscopes were cultured and two (2)—one (1) CYF-VA2 and the CYF-VA—tested positive for microbial contamination with *pseudomonas aeruginosa*

The cleaning process that the facility has carried out so far is as follows:

- After use, appearance cleaning with cleaning agent.
- Immersion in protein removal detergent; rinse cleaning. (Note: Immersion is glutaral preparation; rinse cleaning.)
- In the pipeline for drying, alcohol flushing process was generally suitable, but the disposable suction valve (MAJ-209) was reused.
    - Scope operation part was not soaked.
    - Cleaning tool was inadequate.
    - T shaped tube (MAJ-891) was disassembled, cleaned, and disinfected.

The customer admitted there was a defect in their cleaning process and will proceed with improving the cleaning, disinfection process, and purchasing necessary items. In addition, the scope will be cleaned and disinfected in an improved process. After EO gas sterilized, it will be used again.

The Single Use Suction Valve MAJ-209 has not been returned to Olympus for evaluation. The investigation is in process. Once the investigation has been completed, a supplemental report will be submitted with scope evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15157190&pc=EOQ

7.3 The patient was advised by the nurse to submit the report to the FDA after developing *pseudomonas aeruginosa* strain bacterial UTI after a cystoscopy, August 2022

A report in the FDA **MAUDE** database states the patient was advised by the nurse to report the incident to the FDA to help prevention going forward. The patient reports they developed a *pseudomonas aeruginosa* strain bacterial UTI. They were hospitalized for three (3) days on IV Cefepime. They were allowed to go home with a pic line for seven (7) more days of Cefepime injections. This protocol has been ordered for 10 days total pending that they are clear of infection. They notified the physician, and the nurse assures the patient she will obtain the model number for the patient by the end of Monday. The patient will send that number in to this site. The nurse is aware the patient is making this report to the FDA and stated it is necessary step. The nurse was going to relay the information to the physician.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15322149&pc=FAJ

7.4 During an audit several precleaning inconsistencies in reprocessing an endoscope were observed, July 2022

A report in the FDA **MAUDE** database states during an audit, it was observed the facility had an incorrect reprocessing step. The precleaning of the Olympus, EVIS Exera II Duodenovideoscope TJF-Q180V was not adequate. No harm or user injury reported due to the event. The scope has not been returned to Olympus for evaluation.

During the visit at the facility, it was observed a) the insertion section was not wiped, b) suction on channel was not flushed enough (1–3 seconds) nor air-water channel flushing noted with cleaning adapter, c) auxiliary water channel was not flushed, and d) three (3) endoscopes were noted to be dirty from the day before and no pre-soaking occurred. A review of the scope history record found no deviations that could have caused or contributed to the reported issue.

Based on the results of the investigation, it is likely that the user's understanding differed from Olympus recommendation in scope handling and reprocessing steps. This issue is addressed in the instruction for use (IFU). Olympus will continue to monitor the field performance of this scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15029540&pc=FDT

7.5 An Olympus employee observed the facility did not perform leak testing or the facility using brushes for cleaning cystoscopes, July 2022

A report in the FDA **MAUDE** database states an Olympus employee was performing an in-service and observed the reprocessing of the Uretero-Reno Videoscope URF-V. The facility did

not perform a proper leak test, and brushing cystoscopes was not part of their process. There was no effect on the patient reported due to the event.

The customer acknowledged understanding of proper reprocessing steps and stated brushes would be ordered for reprocessing. The investigation is ongoing. The root cause of the 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=15042041&pc=FGB

7.6 Fiberscope had brown liquid come out from the tip when removed from the sterility pack, July 2022

A report in the FDA **MAUDE** database states during preparation for use, a brown liquid flowed out from the tip of the Uretero-Reno Fiberscope URF-P7 when it was removed from the sterility pack. There was no harm to any patient. The intended procedure was completed with a similar scope.

There was suspicion the forceps channel had a pinhole. The information provided for the customer reprocessing is as follows:

- Customer performs in-channel brushing.
- Cleaning and disinfection are performed with an Olympus OER-4 automatic endoscopy reprocessor.
- Sterrad® sterility is used.

The scope has been returned but the evaluation is not yet completed. A definitive root cause of the reported complaint cannot be determined at this time. Supplemental report(s) will be filed as any relevant new information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15041637&pc=FGB

7.7 The same cystoscope was used on three (3) patients that developed urinary tract infections and one (1)-patient developed dysuria, June 2022

A report in the FDA **MAUDE** database states the customer reported, after routine cystoscopy procedures using the same Visera Cysto-Nephro videoscope CYF-V2R, three (3) patients developed urinary tract infections (customer originally reported two patients, then later reported a third). An unspecified time after the cystoscopy procedure, the patient developed dysuria. A patient urine sample was cultured and was positive for *E. coli*. The patient was treated with antibiotics and their condition is reported as clinically improved. The patient had no pertinent health history.

The customer reported the endoscope was not sampled and cultured; however, later stated that symptoms triggered the scope sampling and culturing (no results provided). The customer stated the scope was used on a patient with known infection of the same microorganism. The customer suspects the scope is the cause of the patient infections. It is unknown what other factors may be contributory to this reported event. Environmental factors are not being investigated. No genetic testing about bacteria was detected from the endoscope and the patient. The positive urine culture was detected in 2022. The scope was taken out of service May 2, 2022. The scope was not used between the date of detection and isolation of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14573106&pc=FAJ#

7.8 The facility was performing manual cleaning in the procedure room due to the facility not having a designated room for reprocessing endoscopes, May 2022

A report in the FDA **MAUDE** database states an Olympus ESS was at the customer site to perform a facility review summary. Upon evaluation, incorrect reprocessing was noted with EVIS Exera III Colonovideoscope PCF-HQ190L. There was no patient harm or user injury reported due to the event. The ESS mentioned that the customer pre-cleans, performs leak testing, and manually cleans the scope in the procedure room. The customer did not have a designated room for manual cleaning at the facility. The ESS recommend the manual cleaning to be done in the cleaning room and advised that the doctor refrain from leaning on the scopes. The investigation is ongoing; therefore, the root cause of the reported event cannot be determined at this time, however, if additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14438066&pc=FDF

7.9 A bronchoscope was not cleaned or reprocessed after use and left out overnight, May 2022

A report in the FDA **MAUDE** database states the EVIS Exera Bronchovideoscope BF-3C160 was left out overnight without cleaning or reprocessing. It was reported the scope was later reprocessed in a Medivator reprocessor. Olympus informed the customer about delayed reprocessing and the reprocessing manual was sent with a reference to delayed reprocessing procedures. No report of patient involvement or user injury associated with this event. The scope was returned for investigation. Upon evaluation of the returned scope the following defects were found:

- Non-Olympus bending section cover
- Non-Olympus bending section cover glue
- Non-Olympus insertion tube

- Cracked objective lens
- Kinked in biopsy channel and restriction for brush passage.

The faulty part was replaced, and scope was returned to the user facility. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14515557&pc=EOQ

7.10 CCD module had fluid damage causing video image failure in a Pentax gastroscope, April 2022

A report in the FDA **MAUDE** database states the Pentax Imagina Gastroscope EG290l10C was returned, checked, and confirmed that the CCD module had fluid damage. It was also confirmed, the up/down pully wire, and the right/left pulley wire had fluid damage. The control body was broken, and the insertion flexible tube buckled. However, they are not the main cause, and/or irrelevant to the alleged complaint. The video image failure was due to fluid damage. The time of the event is unknown. No report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14216093&pc=FDS

7.11 A gastrointestinal videoscope was cleaned and reprocessed after sitting for sixteen hours after a procedure, April 2022

A report in the FDA **MAUDE** database states the EXIS Exera II Gastrointestinal Videoscope GIF-H180J was used in a procedure and then set on a counter for sixteen (16) hours without being cleaned. The scope was then cleaned and reprocessed. The customer asked that Olympus evaluate the scope to ensure it is safe to use as it was not reprocessed per the instruction manual at the facility. No harm or user injury reported due to the event. The scope was returned to Olympus with inspection and testing confirmed the scope was reprocessed with a different procedure from the instructor manual. In addition, there was a deep dent and scratches on the distal end plastic cover, the adhesive on the bending section cover was cracked and discolored, there was old glue around the objective and light guide lenses, there wear minor scratches on the insertion tube, there was minor rust on the customer label on the scope connector, there was play in the control knob, and the labels had minor peeling. The investigation is ongoing. 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=14017468&pc=FDS#

7.12 A gastrointestinal Videoscope was pre-cleaned without using the air/water channel washing adapter causing the scope to have insufficient air and water supply prior to an unspecified procedure, April 2022

A report in the FDA MAUDE database states during the inspection of the EVIS Lucera Elite Gastrointestinal Videoscope GIF-H290T, prior to an unspecified procedure, the scope exhibited insufficient air and water supply. Upon rewashing the scoop, coagulated blood came out of the attachment port of the water supply tank of the connector. A nurse at the user facility speculated that there was bleeding during the previous procedure, and the scope had been pre-cleaned without using the air/water channel washing adapter. The reported issue (insufficient air supply/water supply) was resolved after rewashing the scope. The intended procedure as successfully completed. The scope was reprocessed using an Olympus endoscope reprocessor model OER-4. There was no report of patient or user injury associated with this event. Since the customer's issue was resolved after rewashing the scope, it was not returned to Olympus for evaluation. A review of the device history record (DHR) found no deviations that could have caused or contributed to the reported issue. The scope met all specifications at the time of shipment. Based on the results of the legal manufacturer's investigation, it is likely the coagulated blood was due to insufficient reprocessing or handling of the scope after the previous procedure. A root cause could not be determined. Olympus will continue to monitor field performance for this scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14251815&pc=FDS#

7.13 An Olympus employee noticed breaches in reprocessing endoscopes after a patient infection was reported after use, April 2022

A report in the FDA **MAUDE** database states a patient infection was reported after use with an unknow Olympus endoscope. The scope has not been returned to Olympus for evaluation and the investigation is in process. The Olympus employee went on-site to the facility to observe their reprocessing practices and provide an in-service for correct reprocessing procedures. It was found the customer does not follow the instructions for use (IFU) when reprocessing Olympus endoscope. This customer transports endoscopes from the closets to the tower by hand but the cabinets are in the rooms. Scope are stationed well, but accessories are not inspected prior to putting them into the scope. They do purge lumens and check all functions of the scope. The customer stated during procedures when multiple scopes are being used, will wipe the insertion tube, suction water through the scope and set aside to be properly pe-cleaned after the procedure is completed. The proper pre-cleaning was done but not always immediately after use as per our IFU. This customer transports from the procedure room to the dirty room in green bags and then put the scope into bins n the dirty room. Sometimes more than one (1) scope is put into a bin. The Olympus employee witnessed several people carrying the green bags from the room to the dirty room without being placed in a basin; also witnessed the bags should be carried in a flat position so the scope isn't possibly damaging itself. This customer is using a Veriscan leak

tester, and they have been trained by Veriscan and are following their instructions. There are instructions hanging on the walls to support the process. Also, there are instructions from Veriscan on how to process a leaking scope, including a competency test in every staff member folder with instructions from Olympus. Electrical tape is on hand in case of a leak. The customer has a Scope Buddy Plus that releases the proper amount of detergent doses as to the amount of gallons of water in the sink. A new sponge is used for every scope and wipe down per the IFU. OEM brushes are used and following the Olympus IFU for proper brushing did not see anyone inspect prior to use. The Olympus employee stated ERCP reprocessed scopes with all steps followed as per the IFU, with additional hospital policy steps being performed. The customer is using the Medivators DSD machine. Once the investigation has been completed, a supplemental report will be submitted with the scope evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14189557&pc=FDF#

7.14 A leak tester was not used while a cysto-nephro videoscope was reprocessed at the user facility during an annual in-service with an Olympus ESS on site, April 2022

A report in the FDA **MAUDE** database states the user facility called Olympus to request their annual in-service, while onsite the ESS observed the Cysto-Nephro Videoscope CYF-V2 being reprocessed without the leak test being performed. There were no reports of death, harm or injuries related to this event. Olympus ESS was onsite and performed scope reprocessing and infection control in-service for the staff. Infection control, user manual, and the manual reprocessing of the scope. The ESS covered the importance of the leak tester and recommended the facility purchase one. Additionally, the ESS sent an email requesting a quote for the customer. The investigation is ongoing, and a definitive 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=14053452&pc=FAJ

7.15 An Olympus team member identified the user facility did not follow appropriate reprocessing steps for a cysto-nephro videoscope during an in-service, April 2022

A report in the FDA **MAUDE** database states the customer requested Olympus to provide an in-service. During the in-service, the customer reported a ‘recent issue” with an unspecified infection involving a patient. The Olympus team member also identified the facility did not follow the appropriate reprocessing steps in the IFU. The customer refuses to provide additional information. The Videoscope CYF-V2 Cysto-Nephro Videoscope has not been returned to Olympus for evaluation. The investigation is in progress and once it has been completed, a supplemental report will be submitted with the scope evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14084284&pc=FAJ

7.16 The suction channel of a gastroscope was clogged due to insufficient reprocessing at a user facility, March 2022

A report in the FDA **MAUDE** database states a Pentax Video Gastroscope- l10 SLIM DG27-l10 was returned and confirmed the operation/suction channel was clogged. Based on the result, it was caused due to the insufficient reprocessing at the facility on the operation channel. In addition, we confirmed that the remote-control buttons were leaking, the electrical connector disinfections damage, the light guide cable buckled, the light guide cable cracked, the operation channel improper adjustment, and the bending rubber broken; however, they are not the main cause, and/or irrelevant to the alleged complaint. Based on the technical report and /or the risk analysis results, it was evaluated to submit MDR. The time of event is unknown, and no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13717728&pc=FDS

7.17 Single-use biopsy valves were being reprocessed at a facility and not being disposed of correctly according to an Olympus Endoscopy Support Specialist (ESS), March 2022

A report in the FDA **MAUDE** database states the user facility requested a reprocessing in-service for the single-use biopsy valve (sterile). An Olympus ESS visited the customer and noted during the in-service, the customer was not discarding single-use biopsy but instead reprocessing them. It was reported that the customer was not using MH-948 endoscope air/water channel cleaning adapter for precleaning of equipment. There was not patient involvement, no harm or user injury reported due to the event. Additional information from the user facility confirmed that the biopsy channel was cleaned and sterilized for reprocess training purposes and the biopsy channel covers were not reused. The Olympus ESS observed the customer had been reprocessing disposable forceps plugs, instead of correctly discarding them after use. The Olympus ESS reviewed the proper cleaning, disinfection and sterilization reprocessing steps and covered pre-cleaning, leakage testing, manual cleaning, and high-level disinfecting with the customer reprocessing technicians. In addition, the Olympus ESS informed the customer reprocessing technicians that the MAJ-1555 is a single-use accessory and to be discorded after use. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13653764&pc=FDS

7.18 A gastrointestinal Videoscope was only pre-cleaned and then used on a patient, March 2022

A report in the FDA **MAUDE** database states that Olympus Medical Systems Corp. (OMSC) was informed that during reprocessing, an EVIS Lucera Elite Gastrointestinal Videoscope GIF-H290 that had been pre-cleaned by hand was set in the OER-5, but the scope was picked up without performing the cleaning and disinfection process and then used on the patient. No report of patient injury associated with the event. The exact model number was unknown. The scope was not returned to Olympus. The exact cause of the event could not be conclusively determined at this time. Unable to obtain information on the scopes model number, therefore, information related to the scope such as serial number, manufactured date is unknown. Also, there are other blank items in the MDR because of information not currently available. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13657936&pc=FDS

7.19 An Olympus ESS was requested by the customer to do a reprocessing in-service, the ESS noticed the reprocessing of scopes was being performed incorrectly, March 2022

A report in the FDA **MAUDE** database states Olympus Endoscopy Support Specialist (ESS) was dispatched to the customer site and observed the user facility's reprocessing methods. ESS observed the customer disconnecting the leak tester under the water and the leak tester cord found to me missing the O-ring. The reprocessing technician did not follow reprocessing steps as outlined in the IFU. The EVIS Exera III Colonovideoscope CF-HQ190L was not brushed at a 45-degree angle through the suction channel. The scope was flushed using a syringe with no channel plug or injection tubing. The customer transports the scope with the knobs down and the scopes are hung in the sterile processing department after reprocessing. The customer waits until later in the day to transport the scopes to storage in the operating room. This is done for proper rotation of the scopes. The ESS reviewed proper reprocessing steps for the scope with the customer and informed the customer how to reduce common repairs. Investigation activities have been opened to manage the actions related to this issue and any required MDR reporting. The investigation is ongoing and follow up with the user facility is currently being performed. Therefore, the root cause of the reported event cannot be determined at this time. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility. The customer requested reprocessing in-service for the colonovideoscope. An Olympus ESS visited the customer and noted during the in-service, the scope was being reprocessed incorrectly. There were no reports of patient harm associated with this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13837778&pc=FDF

7.20 A ureteroscope is suspected to have been insufficiently sterilized prior to using the scope according to a physician, March 2022

A report in the FDA **MAUDE** database states a study coordinator (physician) reported, after an ureteroscopy using a reusable Uretero-Reno Fiberscope URF-P6R (exact model and serial number not provided). A patient contracted hepatitis. The physician suggests insufficient sterilization prior to using the reusable ureteroscope as the possible cause. No additional consequences to the patient were reported. It is not known what intervention/treatment the patient received as a result and the patient's current condition is unknown. No further information can be requested. The report stated they did no want to be contacted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13892057&pc=FGB

7.21 It was noticed that a broken disposable brush was inside the suction channel of a gastrointestinal scope prior to use, February 2022

A report in the FDA **MAUDE** database states the user facility reported after reprocessing (while preparing the Gastrointestinal Videoscope GIF-V70 for use), it was observed that a section of a disposable brush was broken and inside the suction channel of the gastrointestinal videoscope. There was no delay in the intended diagnostic procedure, which was completed using another similar scope with no patient impact reported due to the event. The scope was returned to Olympus for evaluation confirming the customer's report and removed the broken piece of brush from the suction channel. In addition, service found additional issues:

- Suction cylinder was worn.
- Insulation resistance at the tip was out of specification due to a scratched cap cover.
- Up/down knob was loose (up direction was out of specification due to wear of the angle wire).
- Liquid leak was observed due to a damaged air/water cylinder (water pressure was out of specification due to deformation of the nozzle).
- Light guide lens was broken/light guide bundle was in poor condition.
- Adhesive rubber was broken.
- Connection tube creased.
- Corrosion was observed at the electrical connector due to leakage.
- Switch #1 was damaged.

The investigation is ongoing. A definitive 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=13506279&pc=FDS

7.22 During a biopsy procedure tissue was noticed by the physician that came out of the gastrointestinal scope before biopsies were taken, February 2022

A report in the FDA **MAUDE** database states that the physician noticed a piece of tissue came out the EVIS Exera III Gastrointestinal Videoscope GIF-H190 during a biopsy procedure. The biopsy forceps were immediately pulled back into the scope with the tissue and the scope was taken out of the patient. The intended procedure was completed with another scope with no surgical delay. The scope was inspected prior to use with no abnormalities noted. No patient harm reported. The tissue was not from the patient and was thought to be from a previous procedure or unknown because no biopsies had been taken yet. The scope was used the day prior and manually cleaned and high-level disinfected, and the channel checked negative. The scope was still contaminated after being reprocessed due to the tissue which came out. The rim could be felt when passing the brush through the scope. Olympus technical support and the customer spoke via the phone and instructed the customer to send the scope in for repair with confirmation that the scope was disinfected. The scope was returned to Olympus for evaluation and the reported issue was not confirmed. The borescope did not indicate any significant damage. There was a) a micro lens separation causing abnormal images, b) bending section cover glue had a crack, c) labeling was peeling, d) distal end plastic cover had dents and scratches inside the channel, and e) insertion tube and light guide tube had minor scratches. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13591133&pc=FDS

7.23 Patient residue came out of the air/water channel as the biomedical engineer pressed on the air/water valve, February 2021

A report in the FDA **MAUDE** database states that during preparation for use for a diagnostic procedure, the air-water channel was not working on the EVIS Exera III Colonovideoscope CF-HQ 190L and seemed blocked. A leak test was performed, and the scope was reprocessed; however, the issue persisted. The biomedical engineer pressed the air-water valve and patient residue came out of the air/water channel. The scope was reprocessed again and was working perfectly and was in usage. The procedure was completed with another colonoscopy scope. The reported problem did not impact the procedure. No patient harm reported. The customer was inquiring why patient residue was in the air/water channel.

The scope was returned to Olympus for evaluation and the reported issue was confirmed.

- Air/water channel had a piece of metal stuck inside. There was a biopsy leak.
- Distal end plastic cover had deep scratches.
- The Olympus name plate was missing.
- Light guide lenses and the bending section cover glue were non-Olympus components.
- Up/down lever on the control body had a deep scratch.
- Light guide tube had a buckle.

- Scope connector had been repaired by a third-party and had minor scratches and dents.
- Insertion tube insulation needed replacement.
- Control knob movement right/left had play and was loose, and the up/down was loose.
- Objective lens edge was chipped, and the insertion tube had multiple minor scratches.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13602471&pc=FDF

7.24 Customer was using simethicone infused water for precleaning of the colonovideoscope and was not knowledgeable of the delayed time reprocessing, February 2022

A report in the FDA **MAUDE** database states the end user was using simethicone infused water for precleaning of the EVIS Exera III Colonovideoscope CF-HQ190L. Additionally, the staff was not knowledgeable about the delayed time reprocessing and not completing all the steps of manual cleaning per the instructions for use. A total of six (6) colonovideoscopes were affected. The facility leadership was concerned residual simethicone may be in the scope channels. A concern for the harboring of bioburden and biofilm was a risk. The issue was found during maintenance. No patient harm reported.

The Olympus ESS performed a reprocessing in-service/customer competency. The ESS noted the facility utilized the Medivator's SCOPE BUDDY™ PLUS for manual cleaning and manual flushing of endoscope channels. For manual high-level disinfection, rinsing, and alcohol flush, the facility used Medivator's reprocessor. All Olympus recommended reprocessing guideline steps were reviewed following the Olympus reprocessing manuals during the in-service.

The scope was returned to Olympus for evaluation and the reported issue was not confirmed.

- Multiple leaks were found in the biopsy channel and scope connector/plug unit.
- Scrape mark was found in the biopsy channel.
- Switch #1 had a pinhole.
- Distal end plastic cover had dents.
- Bending section cover glue was cracked.
- Control knob movement had play.
- Insertion tube had minor peeling.
- Control body and the customer label on the grip had minor scratches.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13591003&pc=FDF

7.25 The leak tester was not used to perform an air leak test as it was reported to be broken, January 2022

A report in the FDA **MAUDE** database states a repair reduction observation was performed for a Cysto-Nephro Videoscope CYF-VHR at the facility. The reprocessing of the scope was observed onsite by Olympus. It was noted no leak testing was being performed during reprocessing due to a broken leak tester. Education was provided and a new leak tester was ordered. There was no patient impact related to this occurrence. The investigation is ongoing and will be updated upon completion of the investigation or upon receipt of additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13237381&pc=FAJ

7.26 Olympus ESS observed at a facility, endoscopes were not properly reprocessed and were not leak tested prior to manual cleaning, January 2022

A report in the FDA **MAUDE** database states that an Endoscopy Support Specialist (ESS) reported during an onsite reprocessing in-service at the customer's site, it was noted the Cysto-Nephro Videoscope CYF-V2 was being improperly reprocessed (bedside cleaning was not performed and they do not leak test the scope because they do not have a leak tester). . It was also noted their manual cleaning consisted of brushing the scope followed by placing only the insertion tube part of the scope into a high-level disinfectant solution (Cidex®) and then wiping the handle part of the scope with alcohol. There were no reports of harm or patient injuries reported.

The ESS performed a reprocessing in-service with the staff that covered the guidelines on reprocessing the Olympus scopes per the on-track form and reprocessing manual. The staff also performed a return demonstration to show they understood the process. The customer also understood that the Olympus reprocessing manuals are the validated source of instructions. The investigation is ongoing, and the root 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=13261801&pc=FAJ

7.27 A TEE probe was reprocessed at 17.2 ℃ instead of 20 ℃, December 2021

A report in the FDA **MAUDE** database states a customer reported an event of Cidex® OPA solution being used at 17.2 ℃ to reprocess a transesophageal echocardiogram (TEEC) probe, and the probe was released and used on a patient. As per the Cidex® OPA instructions for use (IFU), the minimum temperature for reprocessing is 20 ℃. There was no report of any injuries or human reactions. As a matter of policy since high-level disinfection cannot be assured,

Advanced Sterilization Products (ASP) have decided to report all incidents of Cidex ® OPA solution being used under the minimum reprocessing temperature and the instrument was released and used on a patient. ASP has contacted the customer to offer retraining and to request additional information, however, no further information was provided. ASP will continue to follow up for this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13046511&pc=MED

7.28 Scopes were released and used on patients after user facility stated they did not follow the Cidex® OPA solution instructions for use (IFU) for instrument rinsing, December 2021

A report in the FDA **MAUDE** database states the customer reported their facility did not follow the Cidex® OPA solution instructions for use (IFU) for instrument rinsing, and the instruments were released and used on patients. The facility confirmed there were no patient symptoms and no injuries reported. Per the Cidex® OPA solution IFU, a minimum of three (3) one (1)-minute rinses is required using large volumes of fresh water. Human contact with a medical device that was not rinsed (per Cidex® OPA solution IFU) was reported. This event is being reported as a malfunction after a previous serious injury. The customer was retrained on the correct rinsing procedure, and the customer provided that they have switched to processing with Medivator machines. The batch history record was reviewed and no issues relating to the failure mode were noted. The involved unit met manufacturer specification at the time of release.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12936937&pc=MED

7.29 The gastrointestinal scope was cultured three times and tested positive for microorganisms each time, December 2021

A report in the FDA **MAUDE** database states the customer reported to Olympus, the EVUS Lucera Elite Gastrointestinal GIF-HQ290 tested positive for microorganisms after being cultured three (3) times.

Culture #	Scope Section Tested	Positive Microorganisms (Unspecified CFUs)
1	Suction line	*Bacillus cereus*
2	• Tip • Suction line	• *Bacillus subtilis* • *Klebsiella*
3	Suction line	*Klebsiella*

The user did not report any contamination or any other serious deterioration in the state of health of any person.

The customer provided additional information regarding the cleaning, disinfection, and sterilization practices used at the facility. The scope passed the leak test and the precleaning was not delayed. The customer used a suction pump to suction water from the forceps/suction channel. The MH-948 was used to send air and water to the supply/water channel. There were observed unspecified abnormalities in the accessories used for the reprocessing. Manual cleaning was performed within one-hour after the case. In some instances, the scope is left at bedside for three to five (3–5) minutes after cleaning. During manual cleaning, Power Quick™ was the cleaning solution used by the customer. Brushes are used to clean the forceps/suction channel, suction cylinders, and forceps mouth. The customer does not perform manual disinfection. According to the customer, when the scope is being cleaned in the sink it is only being immersed under the running water and not in the sink itself. Therefore, the liquid is not being sent by the injection tube. The customer uses AERs OER-4 (manufactured by Olympus) as well as KD-1 and WM-S (manufactured by Kaigen Pharma). The customer uses Kaigen washing machines with strong acidic water during the inspection and high-level disinfection with the OER-4 at the end of the day. The customer used the cleaning solution End Quick and additional cleaning solutions by Kaigen Pharma and Olympus. The customer used antiseptic solution Aceside and hypochlorous acid water. Manufacturers used for the antiseptic solutions are Saraya and Kaigen Pharma. The disinfectant was used within the effected person and within the effective concentration range. When rinsing the endoscope cleaning and disinfecting the equipment, the customer used filtered water. The customer stores the scopes in the cabinet with a drying function.

The scope was returned to Olympus for evaluation and found a) debris on the forceps tip, b) corrosion on the scope connector metal contacts, c) stretched angle wires, d) cracked adhesive on the bending section cover, e) cracked light guide lens, f) obstructed nozzle, and g) a deformed insertion tube. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12941100&pc=FDS

7.30 During reprocessing unknown fibers were found inside the working channel of the gastrointestinal scope, December 2021

A report in the FDA **MAUDE** database states the technical service engineer was informed by the registered nurse at the user facility that foreign “unknown fibers were found inside the working channel of the scope,” during reprocessing after a procedure. It was reported the facility used a thin diameter borescope to inspect inside of the working channel. No patient injury, infection, or harm was reported. During troubleshooting via telephone, the nurse indicated the facility does not use Olympus brushes to clean the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190; instead Ruhof brushes are used. Also, a Medivators AER is used for final reprocessing. Olympus recommended for the customer to purchase Olympus brushes, which are the only validated brushes to use.

The scope will not be returned to Olympus as the customer sent the suspected scope to Steris IMS for repair/services. The investigation is ongoing; therefore, the root cause of the reported issue/malfunction cannot be determined at this time. If additional information becomes available a follow-up medical device report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12961807&pc=FDS

7.31 Foreign matter and dirt were found inside and at the mouth of the air/water nozzle of the gastrointestinal scope, December 2021

A report in the FDA **MAUDE** database states that Olympus Medical Systems Corp. (OMSC) was informed that during the incoming inspection for repair at Olympus Service Operation Repair Center (SORC), foreign matter and dirt was found inside the air/water nozzle and at the mouth of the air/water nozzle. The EVIS Lucera Gastrointestinal Videoscope GIF-XP260N had been returned to OMSC for repair because the endoscopic image had been cloudy during the procedure. There was no report of patient injury associated with the event.

OMSC reviewed the manufacturing history (DHR) of the scope and confirmed no irregularity. As a result of Fourier transform infrared spectrophotometer analysis of the foreign matter, silicone was detected and there was peak-like dimethylpolysiloxane. As a result of energy dispersive x-ray analysis of the foreign matter, silicon was detected strongly—it might be silicic acid. Based on the report of the analysis of the foreign matter, OMSC surmised that the foreign matter might be derived from antifoam agent, which contained dimethylpolysiloxane and hydrated silicon dioxide. The exact cause of the reported event could not be conclusively determined. However, OMSC surmised the reported phenomenon was attributed to accumulation of dried residue of antifoam agent and so on due to inappropriate and/or insufficient reprocess. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13007673&pc=FDS

7.32 The air/water supply of the colonovideoscope was found weak during the inspection prior to use, December 2021

A report in the FDA **MAUDE** database states during an inspection before use, the user found that the air supply and water supply of the EVIS Exera Lucera Elite Colonovideoscope PCF-H290I were weak. The user replaced the scope with another scope to complete the intended procedure. During the incoming inspection for the evaluation of the scope at Olympus Medical Systems Corp. (OMSC), it was found that a white viscous foreign material was clogged approximately 10 cm from the distal end inside the air/water channel and found a black rubber-like foreign material was clogged inside the air/water channel. There was no report of patient injury associated with this event. OMSC checked the scope and found reported phenomenon. In

addition, component analysis found that both foreign materials were silicone. OMSC reviewed the device manufacturing history (DHR) of the scope and confirmed no irregularity. Based upon the investigation result, OMSC surmised the white viscous foreign material was derived from silicone-based chemicals, such as defoamer or detergent used during the procedure or reprocessing. OMSC could not conclusively determine the origin of the black rubber-like foreign material based upon this analysis because it was used for various purposes (i.e., watertight packing, silicone-based adhesives, and silicone members). If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12931077&pc=FDF

7.33 A Pentax colonoscope was thought to have seeds in the channel and no suction during the procedure, December 2021

A report in the FDA **MAUDE** database states the customer reported “no suction” involving Pentax HDVideo Colonoscope EC-3490LI. The problem was observed in the operating room during use. The user mentioned there were possibly seeds in the channel during the initial reporting. The user responded to a good faith effort request sent by Pentax customer service via email on November 17, 2021, stating the failure occurred during the procedure and there were no accessories used, no reported injuries to the patient, and no delay in the procedure requiring medical intervention. This event meets the requirement for FDA reportability. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event.

The scope was received by Pentax medical for evaluation on November 19, 2021. The technician noted suction tube resistance confirming the customer complaint and also documented the following inspection findings: a) bending rubber with severe discoloration, b) passed wet leak test and dry leak test, c) suction tube resistance, d) bending rubber glue cracking at distal side, e) bending rubber glue cracking at insertion tube side, f) customer complaint [suction resistance] confirmed, g) hole in #2 remote control button cover, h) air/water socket O-ring chipped, i) residue on up/down control knob/lever, j) residue on right/left control knob, k) air/water nozzle glue worn.

The scope underwent repairs including the following components: a) O-rings and seals, b) bending rubber, c) suction channel LG, and d) jet socket. The scope was repaired and approved by final quality control on December 3, 2021, then was delivered to the customer. This scope has been routinely serviced at a Pentax facility since it was put into service. On November 22, 2021, a device history record (DHR) review for this model was performed by the manufacturer. The DHR review confirmed the scope was manufactured in the facility on June 3, 2011, under normal conditions, passed all required inspections, and was released accordingly. Also, there were no reworks or concessions and the dates of approval for shipment and actual date shipped were confirmed for June 3, 2011. The investigation is in-process. If additional information becomes available, a supplemental report will be filed with the latest information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13018414&pc=FDF

7.34 A brush was noted to be stuck in the channel of a colonoscope prior to use, December 2021

A report in the FDA **MAUDE** database states Pentax was made aware of an event which occurred in the Pai region involving Pentax Video Colonoscope EC38-I0L. The user stated there was a brush stuck/broken in the channel. This was noticed in the procedure room prior to use. No adverse event was reported with this complaint.

The scope was received at Pentax service facility for further evaluation. The scope was inspected where the user narrative was not confirmed. Inspection findings are as follows: a) image spots, b) customer complaint not duplicated, d) failed wet leak test, e) bending rubber glue cracking at distal side, f) bending rubber glue cracking at insertion tube side, g) failed dry leak test, h) operation channel-primary slice by accessory, i) image had mild shadow, j) hole in #1 remote control button cover, k) leak at #1 remote control button cover, l) objective cover lens scratch, and m) insertion tube root brace cut. On November 10, 2021, a device history record review for model EC38-I0L was performed and the DHR review confirmed the scope was manufactured on July 31, 2017, under normal conditions, passed all required inspections, and was released accordingly. The date of approval for shipment and actual date shipped were confirmed. The scope is in the process of being repaired where all defects found will be remediated and returned to the user upon completion. If additional information becomes available, a supplemental report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12923178&pc=FDF

7.35 A stent was unknowingly retained in a duodenoscope during an ERCP procedure, December 2021

A report in the FDA **MAUDE** database states a retained stent was discovered in a Duodenoscope TJF-Q180V in 2021 and noted during an ERCP for stone extraction. The stent was unknowingly retained after an attempt to remove a pancreatic stent by a duodenoscope. Both procedures were successful, and no harm occurred to either veteran.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13059167&pc=FDT

Gram Negative Bacteria Outbreak

8.1 A Duodenovideoscope was used on seven (7) patients and all tested positive for *pseudomonas aeruginosa* after the procedure, August 2022

A report in the FDA **MAUDE** database states the customer reported to Olympus on July 5, 2022, a patient's blood, or body fluid, culture tested positive for *pseudomonas aeruginosa* after having an unspecified procedure involving the EVIS Lucera Elite Duodenovideoscope TJF-Q290V. It is unknown if the patient was symptomatic. On July13, 2022, the facility informed Olympus an additional six (6) patients tested positive for *pseudomonas aeruginosa* after having an unspecified procedure involving the same scope. It is unknown if the patients were symptomatic. It is unknown if the scope was cultured for microbial contamination. All patients have been discharged and the customer stated no bacteria detected; although, the results have not been determined.

The scope has not been returned to Olympus for evaluation. The investigation is in process. Once the investigation has been completed, a supplemental report will be submitted with device evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15156121&pc=FDT

8.2 The same Duodenovideoscope was used on eight (8) patients that tested positive for *pseudomonas aeruginosa*, August 2022

A report in the FDA **MAUDE** database states the customer reported two (2) endoscopes were suspected of cross-contamination with eight (8) patients. The patients tested positive for *pseudomonas aeruginosa* after procedures with one of the EVIS Lucera Duodenovideoscopes TJF-260V. The facility plans to investigate whether other patients whose procedure was performed with the endoscope used by the infected patient developed an infection after the procedure.

The endoscope was tested and had a positive culture test and used after the event. The start of precleaning was delayed after the procedure. Water was not aspirated through the instrument/suction channel with a suction pump. The forceps elevator was moved to raise and lower three (3) times in water during aspiration. The air/water channel was not flushed with water and air by using MH-948. The reprocessing accessories were all normal. The manual cleaning was performed within an hour after the procedure. The endoscope passed the leak test. Brushed points (i.e., instrument and suction channel, air/water valve/suction valve, and biopsy valve) were checked. The forceps elevator was brushed, operated in the detergent solution, and flushed. The distal end was flushed with MAJ-2319. The detergent solution was Olympus EndoQuick. All channels were connected with tubes when the endoscope was set up into the AER/EWD. Disinfection solution used was before the expiration date and met the minimum effective concentration. The water filter was replaced within the specified period. The rinse water treatment system was without abnormality. After manual disinfection or AER process, the

scope is wiped with clean towel or paper, blown by compressed air, and by the dry process of the AER/EWD. The endoscope is not stored in a drying cabinet.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15288316&pc=FDT

8.3 A significant increase of infections when switching to Karl Storz cystoscopes, eight (8) cases in 10 months, July 2022

A report in the FDA **MAUDE** database states as per manufacturer incident report that was received from the factory states: initially received information from the clinic from the physician: "I have been using flexible cystoscopy in my clinic since 1997. Annually, I perform cystoscopy on the average in 300 cases. Our infection rate was very low previously; according to our records we had only two (2) cases over the last 15 years. We recently upgraded our system with a brand new two digital flexible cystoscopes (11227VH) in 2021. Unfortunately, our infection rate significantly increased after this change. We had severe infection in 8 cases in 10 months although my staff is very experienced in this procedure. We have been working together for nearly 25 years. Seven of eight (8) patients had infection with klebsiella and one (1) had *E. coli*. Previously we were using Cidex® OPA, but we recently replaced it with Sekusept™ Aktiv. I designed a stainless-steel container and sterilized this container every two weeks. I routinely use prophylactic antibiotics and perform urine culture before cystoscopy. We took culture before cystoscopy. We took culture from different parts of our procedure room and no significant bacteria growth was observed. Despite all our efforts we had a significant rate of infection by using new digital flexible cystoscopes."

Further information stated no incident happened during cystoscopy procedure. After cystoscopy procedure, the patient went to the hospital with a complaint of high fever on the same day. As a result of examination, the urinary infection was detected in patient's blood. The affected scopes and further information have been requested for the investigation. For each infection case a separate complaint was recorded, and each case will be reported separately.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=14945782&pc=FAJ#

8.4 Four patients were infected with the same endoscope after diagnostic procedures were performed, July 2022

A report in the FDA **MAUDE** database states the EVIS Exera III Bronchovideoscope Flexible Video Bronchoscope tested positive for microbial contamination with *penicillium* species. These events were previously reported in patient one (1) and in patient two (2). Olympus was also made aware of two (2) other patient infections involved to date for one Olympus endoscope.

The scope was not returned to Olympus for evaluation. The investigation is in process, and once completed, a supplemental report will be submitted with the scope evaluation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15129540&pc=EOQ#

8.5 The same Gastroscope caused infections in eight (8) patients after being cultured several times, June 2022

A report in the FDA **MAUDE** database on March 23, 2022, Olympus was informed the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 was cultured several times but still did not get clean enough to be used. The scope reportedly tested positive for *salmonella* species, serogroup 08, and *proteus mirabilis*. The gastroscope channels were previously replaced. The user facility suspected there was damage inside the gastroscope. Infection tracing is ongoing, and it is currently unknown whether additional patients have become infected.

On May 10, 2022, additional information was obtained from the reporting facility, which states that there were several patients infected by the gastroscope. The customer provided their cleaning, disinfection, and sterilization process stating the precleaning detergent is unknown and the automated endoscopic reprocessor (AER) used is a non-Olympus reprocessor. Olympus is the maintenance company.

On June 2, 2022, Olympus was informed there were eight (8) patients reportedly infected; however, no further details were provided. Eight (8) complaints were created to account for the total number of patients involved.

The scope was returned to Olympus for investigation. However, as part of the investigation of this type of report, the scope was forwarded to an off-site laboratory for microbiological testing.

- The microbiological analysis report:
    - Three (3) channels of the scope were cultured
    - Results showed no germs were detected.
- Physical evaluation of the returned scope:
    - Cracked (impact points) of the distal end cap
    - Pierced and scratched insertion tube
    - Damaged (worn out) air/water cylinder and suction cylinder.

The investigation is ongoing. 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=14785024&pc=FDS

8.6 After an ERCP procedure using one of three duodenoscopes, six patients were diagnosed with *new delhi metalo-beta-lactamose*, March 2022

A report in the FDA **MAUDE** database states the customer reports six (6) patients diagnosed with new delhi metalo-beta-lactamase 1 (ndm) producting *E. coli* after an ERCP procedures using one (1) of three (3) EVIS Exera II Duodenovideoscope TJF-Q180V. Patient six (6) (this report) in this complaint, the customer reports two days after ERCP for the indication of suspected bile leak, the patient was diagnosed with NDM producing E. coli (in peritoneal fluid). This was sent to the state lab for confirmation and sequencing. The patient was treated with Bactrim ds. The patient's current condition is reported as "alive and hospitalized". There was no malfunction of the scope during the ERCP procedures. Three of the facility scopes have been cultured (results not provided). The facility describes their reprocessing procedures as follows:

- We follow the Olympus IFU for scope reprocessing
- We use Cantel Medivators AER with Rapicide for high-level disinfection
- Use protein test for each ERCP scope
- We bring in endoscopic support specialist (ESS) and Olympus sales rep when purchasing a new scope model or if there is a change to the IFU
- We currently meet and exceed the original equipment manufacturer IFU for endoscope training to ensure patient safety.
- Clinical engineering is routinely in contact with our OEM scope vendors to monitor any changes to the IFUs.

The previous scopes have been replaced with the latest scope model with detachable single use parts. ESS training is scheduled. The customer declined offer to dispatch ESS sooner. The customer further stated we are happy to share best practices and how we improved the situation to ensure patient safety as we finalize our report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=13930031&pc=FDT