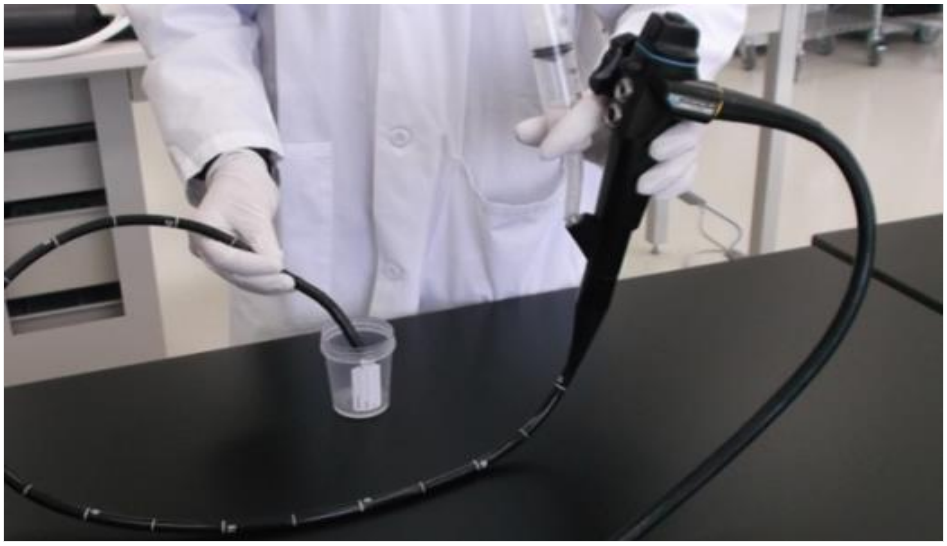
Flexible Endoscope Incident Report

April 2022

Volume V



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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 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.

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1.2 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.

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1.3 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.

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1.4 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.

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1.5 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.

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1.6 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.

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1.7 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.

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1.8 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.

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1.9 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.

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2. Malfunctions of Single-Use Scopes and Endcaps

2.1 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.

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2.2 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.

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2.3 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.

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2.4 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.

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2.5 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 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

3.2 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.

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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.

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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.

3.3 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

3.4 *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

3.5 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

3.6 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.

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3.7 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

3.8 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

3.9 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 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 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 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

7.2 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

7.3 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

7.4 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

7.5 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

7.6 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

7.7 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

7.8 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

7.9 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

7.10 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

7.11 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

7.12 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

7.13 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

7.14 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

7.15 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