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Flexible Endoscope Incident Report

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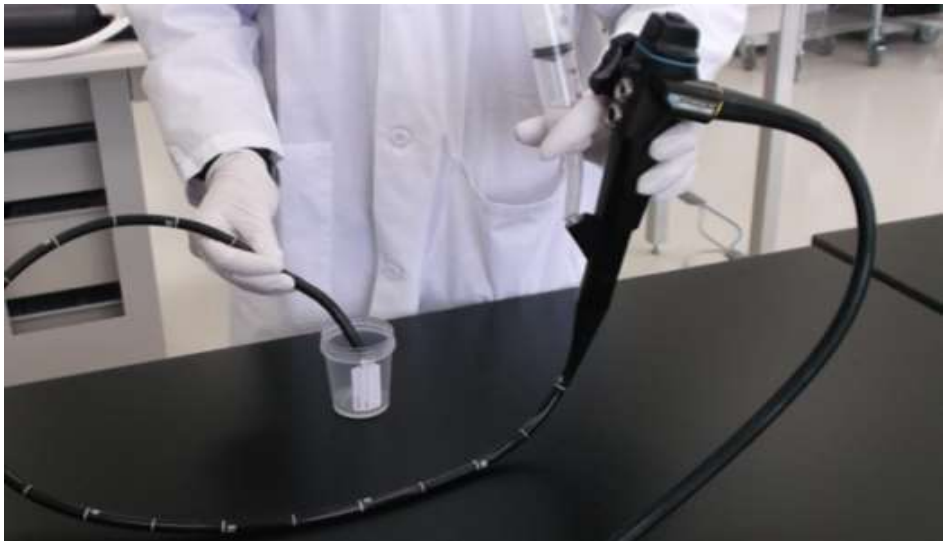

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The Flexible Endoscope Incident Report is created to be organized by topic, related by different failure modes, and is updated every quarter with new events and/or malfunctions that occur with endoscopes. The incidents in this document are found in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

1. Failure of Visual Inspection

1.1 Brown liquid came out from the instrument channel of the Uretero-Reno Videoscope during preparation for use, September 2021

During the preparation for use of the Uretero-Reno Videoscope URF-V2, brown liquid came out from the instrument channel. The scope was not returned to Olympus Medical Systems Corporation (OMSC) for evaluation but was returned to Olympus Service Operation Repair Center (SORC). SORC checked the subject device and could not duplicate the reported phenomenon. SORC also found there were pinholes on the bending rubber and inside the instrument channel. OMSC reviewed the scope's manufacture history (DHR) and confirmed no irregularity. The exact cause could not be conclusively determined. However, based upon the information from SORC, OMSC surmised it was attributed to corrosion inside the scope due to water ingress from the pinhole of the bending rubber and/or leakage point of the instrument channel. Any additional information received will be added to this report.

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1.2 Attempting to get a biopsy, the physician found a piece of tissue in the channel of the scope, August 2021

A report in the FDA's **MAUDE** database states, during an unknown diagnostic procedure the physician found a piece of tissue in the channel of the EVIS Exera II Gastrointestinal Videoscope GIF-H180J, while attempting to take a biopsy. The scope had been used earlier in the day and had been reprocessed in the AER machine. The physician does not believe the tissue was suctioned into the scope during the procedure. The patient was not harmed. This is the first

of two associated MedWatch reports filed for the event. There are two scopes involved in this event where a piece of tissue is alleged to be left behind after reprocessing: GIF-H180 and OER-Pro. The second scope is captured in MedWatch with patient identifier. The scope was not returned, a definitive root cause of the complaint cannot be determined at this time. Supplemental report(s) will be filed as the information becomes available.

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1.3 During an unspecified procedure, a clip exited the biopsy channel when the snare was inserted which came from a previous procedure, August 2021

A report in the FDA's **MAUDE** database states the Olympus Endoscopic Support Specialist (ESS) provided an onsite in-service in 2021. The customer stated that during an unspecified procedure, a non-Olympus clip exited the biopsy channel when the snare was inserted. The customer explained the clip came from a previous procedure completed on a Friday in 2021 when the scope had been used in a bleeder case. After this procedure, the scope was left over the weekend in the dirty scope room. The customer further reported that scope had not been pre-cleaned, but was soaked for an hour, brushed multiple times, and then reprocessed in the OER-Pro automatic endoscope processor before being used. This report is being submitted for improper reprocessing of the scope before being used on the patient. No clips were used in the patient's procedure. It is unknown if the clip fell into the patient. As part of the investigation, the ESS (while onsite) further discussed the scope's improper reprocessing and the daily repair prevention alert for the scope with the customer. The ESS reported that the repair history showed the scope had undergone a full refurbishment prior to this event and was returned to the customer. The scope was not returned to the service center for evaluation. An investigation is ongoing to obtain additional information regarding the reported event. If additional information is received this report will be supplemented accordingly.

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1.4 Patient was diagnosed with Salmonella two days after a colonoscopy procedure, August 2021

A report in the FDA's **MAUDE** database states, two days after a colonoscopy procedure using an EVIS Exera III Colonovideoscope CF-Hq190L, the patient was diagnosed (using stool studies) with *Salmonella*. The patient required hospitalization and IV antibiotics to treat the *Salmonella* infection. The current condition of the patient is described as "discharged" with no additional consequences to the patient reported. There is no report of device malfunction. The customer further states that a restaurant is another potential source of *Salmonella*. The scope was returned to Olympus for culturing by a third-party lab and for physical evaluation after culturing and EO sterilization. The investigation is ongoing, and the cause of the user's experience cannot

be determined at this time. The physical evaluation of the scope reveals Olympus: a.) Performed a visual inspection on the received condition, b.) Discovered stains inside the control body section of the biopsy channel using a borescope. Also, scrape marks were found throughout the biopsy channel and a tear mark was located near the middle section of the channel. The suction channel was also inspected with the borescope and a kink was located at the opening near the connector side. The scope passed the Cosmo leak test. The scope was previously refurbished on September 23, 2020.

Third-party lab culture:

Areas of Scope Cultured by the Lab	Results
1. Insertion Section	Gram negative bacteria: no growth. Blood agar: growth-microorganism identified: Bacillus idriensis.
2. Air/Water Channel	Gram negative bacteria: no growth. Blood agar: no growth.
3. Instrument/Suction Channel	Gram negative bacteria: no growth. Blood agar: no growth.
4. Auxiliary Water Channel	Gram negative bacteria: no growth. Blood agar: no growth.
Environmental monitor	Tryptic soy agar-no-growth.

This facility is scheduled to have a site visit from an Olympus Endoscopic Support Specialist (ESS) on August 23, 2021. This report will be updated upon completion of the investigation or upon receipt of additional relevant information.

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1.5 During treatment, a part of the insertion tube from the fiberopticbronchoscope fell into the patient and was retrieved the next day, August 2021

A report in the FDA's **MAUDE** database states during treatment on a pneumonia patient, the insertion part of the Pentax Fiberopticbronchoscope FB-15RBS's fell off into the patient's body. An attempt to retrieve the piece from the patient's body with another scope was unsuccessful and was retrieved the next day. The manufacturer performed a device history record (DHR) review for the scope and confirmed it was manufactured under normal conditions, passed all required inspections, and was released accordingly. There were no reworks or concessions and the dates of approval for shipment and actual date shipped were confirmed.

An evaluation summary was conducted:

- Part of the flexible tube exodermis resin (around 50 mm to 75 mm from the distal end) had peeled off –visible to the naked eye.

- Magnification (15 times) revealed/confirmed many streaky cracks, and the back side of the flexible tube exodermis resin.

A tensile comparison test was conducted between the returned product and the normal flexible tube outer skin resin. It was confirmed the returned product was not elastic and could be easily torn off. This scope was delivered in 2010 with no repair history. This was caused by the flexible tube exodermis resin deterioration over time and fell off. In addition, there was a red deposit that seemed to be blood in the conduit of the scope. There is a possibility the scope has not been sufficiently cleaned and disinfected and was reported from Pentax to PMDA on June 30, 2021. The investigation report was provided to the hospital on June 11, 2021 and was accepted on July 1, 2021. This event meets the requirement for FDA reportability; however, submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event.

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1.6 A Boston Scientific Resolution clip was stuck in the colonoscope during three procedures with three different patients, June 2021

A report in the FDA's **MAUDE** database states a Boston Scientific Resolution clip was stuck in the EVIS Exera II Colonovideoscope CF-Q180AL during three procedures with three different patients. During a diagnostic procedure, clips were used, and one (1) clip came off and was not identified in the suction container or in the patient. Central Sterile Processing was notified to flush and brush out the scope for fear of the clip being lodged in a channel. The scope went through the regular manual cleaning process, flushed out, a brush was run down the channels, and no clip was found during the process. The scope was used on a patient during a diagnostic procedure and then again on a patient during a diagnostic procedure in 2021. At the end of the procedure, during the cleaning process, the location of the clip was identified when it became dislodged from the channel and flushed out of the scope. During the procedure, there were no other scopes involved in the event. During the procedure in 2021, radial jaw biopsy forceps were also used. All the procedures were completed with the same scope and there was no patient harm or surgical delay. In speaking with Olympus technical support via the phone, the customer was advised to not use the scope until was deemed safe for use after an evaluation had been performed by the Olympus repair center to verify the channel was not damaged. A third-party was normally used to repair the scope but wanted to send the scope to Olympus. The issue was initially reported to an Olympus sales representative by email and the customer wanted to know if the clip would affect the integrity of the internal channel and what the repercussions would be. Would the clip affect the process of disinfecting, would the clip itself get disinfected, and had this happened before and what would be the course of action? The scope was returned to an Olympus service center for evaluation. A borescope was used, and a non-Olympus channel (forceps passage) was found. The channel was also kinked, cover, rubber, glue, light guide lens, nozzle, insertion tube, light guide tube, and control knob were found to be non-Olympus parts. It

was also recommended the insulation, body, and control knob be replaced. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

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1.7 Black speck was noted to be floating in the patient's bladder during a cystoscopy procedure, June 2021

A report in the FDA's **MAUDE** database states, during a cystoscopy procedure using a Cysto-nephro Videoscope CYF-VHR. At the end of the procedure, a black speck was noted to be floating in the patient's bladder. The physician believes he removed the speck from the bladder with a syringe. The scope was removed. When wiping the scope, black residual/specks were noted on the 4 x 4 gauze by the surgical technician (ST). The ST inspected the scope prior to the procedure for residual/specks and found nothing. The patient was made aware of the speck found in their bladder, and the physician ordered Amoxicillin 500 mg by mouth for one dose. No further consequences to the patient have been reported. Additional details have been requested regarding the patient and reported event. No new information currently.

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

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

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

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

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

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

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

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

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

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

A report in the FDA's **MAUDE** database states the service center was informed of tissue that remained in the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 from a previous patient and fell into another patient during an unspecified procedure. The facility verified there was no issue with the scope. The gastroscope was returned for evaluation due to verifying no issue with the scope after a piece of tissue remained in the scope after cleaning and was dislodged. Visual inspection was performed on the received condition, inspected the biopsy, and suction channels for foreign material. An Olympus borescope was used to inspect both the biopsy and suction channels. The borescope was inserted through the distal end side of the channel and numerous scrape marks were found along the wall, which start from the distal end opening and proceed into the channel at approximately 80 mm. The borescope was then inserted through the channel from the control body side and a stain was found upon entering the channel. The suction channel was also checked using the Olympus borescope (no damages or foreign material were noted). The functionality of the air/water function was also tested and verified the water flows consistently, with no stoppage, until release of the valve as intended. The videoscope passed the leak test. Olympus dispatched an Endoscopy Support Specialist (ESS) to the user facility to assess their reprocessing practices as part of the ongoing investigation. The ESS will also provide reprocessing training if necessary.

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

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

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

A report in the FDA's **MAUDE** database states the service center was informed the EVIS EXERA II Duodenovideoscope TJF-Q180V cultured positive twice for either non-pathogenic mold or bacteria. The scope was cultured twice in 2020. The facility reported all their scopes are cultured after every case. A visual inspection was performed on the scope and discovered foreign residue and stains inside the suction channel opening and biopsy channel opening. The biopsy

channel was inspected with an Olympus Borescope and foreign residue was discovered at the distal end opening of the biopsy channel. Also, brownish stain was found on the backside of the forceps elevator, when fully manipulated in the up direction. The borescope was farther inserted into the biopsy channel to find kinks located with the bending section portion as well as scrape marks found halfway into the biopsy channel. On the biopsy channel wall, a black streak was found near the control body side approximately at the 10 cm marking. There were more findings with inspection within the biopsy and suction channels, noted voids on the glue between the control body, and forceps elevator. The glue had discoloration (with pinholes and wear around the edges) on both sides of the bending section causing small gaps. The glue surrounding the objective lens was also worn with pinholes and discoloration noted. The light guide lens has reddish brown (dried) foreign material within. The videoscope passed the leak test. The investigation of this event is ongoing.

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

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

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

A report in the FDA's **MAUDE** database states that during a Ureteroscopy and laser Lithotripsy using a Uretero-Reno Videoscope URF-V2R the surgeon had resistance putting the 2.2Fr basket down. The physician repositioned the scope and managed to pass the basket, but no fibers came out. The physician was able to retrieve one of the fibers, then took the rest out of the patient and irrigated the ureter/kidney. No patient injury or infection related to this event. The scope was

received by Olympus for physical evaluation and the investigation is ongoing. Upon inspection of the returned scope, it was confirmed the scope is leaking from scrape marks found inside the instrument channel. The inspection also revealed cracks found in the bending section cover glue. The definitive cause of these issues is inconclusive. The report will be updated upon completion of the investigation, or upon receipt of additional relevant information.

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

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

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

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

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

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

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

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

A report in the FDA's **MAUDE** database states the patient had some bleeding post-procedure after the Visera Cysto-Nephro VideoscopeCYF-V2 was removed. The doctor felt more friction than normal. The scope was examined by the customer after the procedure. It was noted on the tip of the flexible portion of the scope the outer covering is raised (formed a ring) and is not smooth. The procedure was completed as planned. No treatment was required because of this, and the patient's current condition is stable with no continued bleeding. The physical evaluation of the scope was visual inspection of the condition of the scope was performed and found the bending section cover buckle/stretched. The inspector placed the bending section between two fingers and proceeded to moderately pull the bending section cover from the insertion tube side up to the distal end. After releasing the bending section cover it was noted that the cover became buckle/stretched, never returning to its original form. The inspector also tested the bending section, glue, and cover, as stated in the inspection standards. The ring gauge was passed over the distal end and obstruction was found at the section of the bending cover, which had become buckled. A review of the scope history record was conducted and confirmed there were no abnormalities in manufacturing. The scope was 13 years and nine months old. The a-rubber had deteriorated, and the buoyancy occurred when the rubber was moving during procedure. External force: there is evidence that some external force was applied to the a-rubber, damaging the a-rubber, and contributing to the movement.

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

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

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

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

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

A report in the FDA's **MAUDE** database states OMSC was informed from the user that the green sticky substances remained on a tray and on the outside of the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 after the scope was reprocessed. The following information was also shared by the user. Before the reprocessing, the gastroscope was used for the procedure in which there was an emergency case to retrieve two button batteries from a patient. Once retrieved, the scope was cleaned as per the usual procedure with a bedside cleaning with no evidence to indicate an unusual solution on or in the gastroscope. A disinfect (Rapicide A and B, Matrix disinfectant) and alcohol (70%) cycle in the Non-Olympus AER Medivators Advantage was completed to clean the scope. After the reprocessing procedure was completed, the scope was hung over night. Olympus Australia checked the scope and found the reported phenomenon could not be duplicated. No reported infection associated with this report. The gastroscope has not been returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11064744&pc=FDS

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

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

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

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

A report in the FDA's **MAUDE** database states a user facility informed OMSC because of six microbiological testings upon the sample collected from the instrument/suction channel of the EVIS EXERA LLL Colonovideoscope CF-HQ190L, which tested positive for unspecified microbes. On August 6, 2020, they detected *P. aeruginosa* (10-100 CFU) microbes in the suction

channel. Olympus checked the scope and found the suction cylinder cover port was leaking at the distal end, insulation test failed, the bending angle did not meet specification, the light guide lens was chipped/cracked, the rubber adhesive was detached, chipped, cracked, or had a burr. No report of infection associated with this report. The scope was not returned to OMSC for evaluation. The exact cause of the reported event is currently undetermined.

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

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

A report in the FDA's **MAUDE** database states the customer saw a clip coming out of the instrument channel of the EVIS EXERA LLL Colonovideoscope CF-HQ190I. The procedure did not require clips. The clip likely got stuck in the channel in the previous procedure using the same scope. The scope was not returned to OMSC for evaluation and no further details were provided. No report of patient injury associated with the event.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11044276&pc=FDF

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

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

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

2.Malfunctions of Single-Use Scopes and Endcaps

2.1 One disposable cap fell off the scope into the patient, and the second cap was broken upon withdrawal of the scope from the patient, October 2021

During an ERCP using an EVIS Exera III Duodenovideoscope TJF-Q190V with MAJ-2315 disposable cap, the cap fell off the scope and into the patient. The cap was retrieved, and a second disposable cap was used to continue the procedure. The second cap was found to be broken upon withdrawal of the scope from the patient. The patient was not injured because of this occurrence and the procedure was completed. Additional details regarding the patient and event have been requested, though none have been provided at this time. The scope will not be returned to Olympus. There was no abnormality in the appearance of the scope or cap after the cap was attached (and prior to the start of the procedure), and there were no anatomical or procedural complications that could have contributed to the difficulties experienced. The definitive cause of the user's experience cannot be determined at this time. The investigation is ongoing. Correction and preventative action investigation has been opened to further investigate this issue.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12573332&pc=FDT

2.2 The distal end cover fell into the duodenum of the patient during a procedure, September 2021

The user checked the duodenoscope TJF-260V before the procedure and found that the distal end cover of the scope could not be pulled out. During the procedure, the user found the distal end cover fell into the duodenum of the patient. The doctor tried removing the distal end cover by using forceps and talked to the patient. However, there was no response from the patient and their vital signs were not stable. The doctor stopped the procedure and started emergency treatment. After the patient's vital signs became normal again, the doctor commented that the distal end cover was out of the patient's body by natural defecation. The patient was not then discharged. The scope has not been returned to Olympus Medical Systems Corp. (OMSC), so they could not investigate the scope. Olympus was informed about the scope's condition as the following:

- Leakage of the bending cover
- Wrinkles (serious) at the insertion section
- Worn suction cylinder
- Cracked object lens.

The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12485942&pc=FDT

2.3 During an ERCP procedure, the user noticed a hemorrhagic wound in the antrum, August 2021

A report in the FDA's **MAUDE** database states, during an ERCP with the Single-Use Distal Cover MAJ-2315 and the duodenoscope, difficulties were encountered in crossing the pylorus. The user noticed a hemorrhagic wound in the antrum and the duodenoscope was removed from the patient. The lesion occurred since the endcap had opened a little in the center. The user replaced the distal cover with another distal cover to complete the procedure. Due to this problem, the procedure time was 20 minutes longer than planned. The user stopped bleeding with three clips and no further interventions were required. The user discarded the distal cover, so it was not returned to Olympus. A supplemental report will be submitted, if additional or significant information becomes available at a later time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12287493&pc=FDT

2.4 Two patients had distal end caps that fell inside of them during two separate procedures, August 2021

A report in the FDA's **MAUDE** database states a user facility's response to a good faith effort (GFE) was provided in 2021. Two dec caps detached from the scope during procedure: a.) one detached in the patient's mouth and b.) one detached in the other patient's stomach/the cap broke. Both were able to retrieve both caps.

The customer ordered a box of KUMOE-A63 for 10 distal caps. Two of the caps failed during two separate procedures. Both caps were discarded, and the customer is returning the eight remaining caps in the box. After checking the returned used caps, no visual damage or defects were observed on the used piece. Related MDR: 9620877-2021-1039. Evaluation summary: as a result of the internal investigation, it was determined this issue was not related to design or manufacturing. It was also determined that improved training and clarification of labeling (IFUs) would be helpful in ensuring proper attachment and continued safe use of the device. As a result, Pentax has updated the labeling (both distal end cap IFU and duodenoscope IFU). The instructions were updated to include new wording and illustrations for a more secure attachment of the distal end cap. In addition, they updated the IFU warning section to notify users of the associated risks with the distal end cap unexpectedly becoming detached during a procedure as well as what immediate actions should be taken in case the event occurs. These changes were cleared in 510(k), k210710, and distributed to the installed base via a 21 CFR806. Finally, a quick reference guide was created utilizing existing labeling for video processor carts at all U.S. customers of the Capa Number (b)(4). Training was completed at all sites along with producing an instructional video that was distributed accordingly. Therefore, Pentax has initiated this correction to provide the latest IFU to all U.S. customers with these Pentax duodenoscope devices. This correction actively ensures all affected customers will receive the duodenoscope IFU. Exact date of event is not known.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12350156&pc=FDT

2.5 The distal cover (MAJ-411) came off the duodenovideoscope and into the patient during an ERCP, July 2021

A report in the FDA's **MAUDE** database states, during an endoscopic retrograde cholangiopancreatography (ERCP) using an EVIS Lucera Duodenovidescope JF-260V and the distal cover (MAJ-411), it was found that the MAJ-411 came off. The user did not notice the phenomenon during and immediately after the procedure, but the patient vomited up the endcap. The user completed the intended procedure with scope. The occurrence date of the event is unknown. No report of patient injury associated with the event. The field service engineer (FSE) visited the facility and found the deterioration of the endcap. The FSE also confirmed that it can be attached and detached normally by replacing it with a new one. The FSE checked the endoscope and found no malfunction on it. The scope was not returned to any Olympus locations, so Olympus could not investigate. OMSC reviewed the manufacture history (DHR) of the scope and confirmed no irregularity. The exact cause of the reported phenomenon could not be conclusively determined. OMSC surmised this phenomenon was attributed to the endcap forcibly being attached with the instrument channel outlet of the scope being closed (the forceps elevator was raised). The endcap was not securely attached to the distal end of the scope. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12157940&pc=FDT

2.6 A single use distal cover came off the scope and retained in the patient without the physician being aware the cap was still inside, June 2021

A report in the FDA's MAUDE database states, during an endoscopic retrograde cholangiopancreatography (ERCP) using a Single-Use Distal Cover MAJ-2315, the distal cover came off the scope and was retained inside the patient. The physician was initially unaware the cap was still inside the patient. The patient's oxygen saturation began to deteriorate (drop). The anesthesiologist suctioned the patient's esophagus to remove the distal cap. This resolved the issue and recovered the oxygen saturation. No additional intervention was required. The patient's current condition is reported as still hospitalized, but due to a surgical procedure to treat necrosis of the pancreas and not the reported event. The scope/cap were assessed before and after the procedure and no abnormalities were noted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11991008&pc=FDT

2.7 Tissue was found in the top left corner of the distal cap behind the elevator during an ERCP, June 2021

A report in the FDA's **MAUDE** database states, during an endoscopic retrograde cholangiopancreatography (ERCP) with biliary stent exchange procedure using an EVIS Exera III Duodenovideoscope TJF-Q190V, tissue was found in the top left corner of the distal cap behind the elevator. The patient did well without clinical signs of complication and no medical or surgical intervention due to the occurrence. The physician called the patient the next day and the patient's mother stated the patient recovered well from the procedure.

New information is provided: The mucosa damaged the stomach. The damage was judged with endoscopy. The injury was described as moderately severe. The injury was treated with proton pump inhibitor. This tissue trapped was approximately 20 mm x 50 mm. The doctor does not routinely perform suction when withdrawing the scope. The cap was not cracked after the procedure and no abnormality with the appearance of the scope was found before or after the procedure.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11919316&pc=FDT

2.8 Cap broke and fell off the scope and into the patient during an ERCP procedure, June 2021

A report in the FDA's **MAUDE** database states, during an ERCP using an MAJ-2315, the cap broke and fell off the scope, and into the patient. The case was performed in the operating room via robotic/laparoscopic approach by surgeon, who placed a trocar catheter so that the gastrointestinal (GI) physician could gain access to the ampulla. The cap was retrieved. A second cap was placed on the scope, and it fell off into the patient's stomach—it was not retrieved, though, it was expected the patient will expel the cap. It is reported there was no injury to the patient related to this occurrence. Both caps were/will be discarded and are not available for evaluation. The packages for both caps were discarded, and no lot numbers could be provided. The patient was critically ill, and the case was complex. The procedure was unsuccessful. Further details have been requested regarding the patient and reported event. At this time no additional information has been provided. This case reports the second cap that fell off remains in the patient. The device 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. Correction and preventative action (CAPA) investigation have been opened to further investigate this issue. 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=12016152&pc=FDT

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

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

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

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

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

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

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

A report in the FDA's **MAUDE** database states Olympus Medical Systems Corp. (OMSC) was informed by the user that during an ERCP there was tissue material in the single-use distal cover (MAJ-2315) at the end of the procedure when removing the MAJ-2315. This event occurred on two procedures. The user completed the procedure with the single-use distal cover MAJ-2315.

Bleeding was observed along the lesser curvature of the stomach wall close to the pyloric sphincter, but medical intervention was not required. The procedure was not extended and there was no further issue with the patient. The MAJ-2315 caps were checked for cracks/splitting before and after each procedure but there was no problem. The user stated the tear line in the caps is hazardous because there isa slight V-shaped indent at the distal end of the tear line and could easily catch a fold in the mucosa wall and ultimately cause tissue to get trapped within the cap. The single-use distal cover was not returned to any Olympus locations, and therefore, they could not investigate the MAJ-2315. The exact cause of the event could not be concluded at this time. If additional information is received, this report will be supplemented. This event is one of two similar cases, and this report is regarding the MAJ-2315 of the first case.

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

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

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

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

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

A report in the FDA's **MAUDE** database states the single-use distal cover's tip detached during a procedure. According to the initial reporter, when they removed the cap from the patient, the distal tip was not present. Requests were made to the user on whether the segment was still in the patient and the doctor stated that if it was still in the patient, it will pass. The nurse said she did follow up with the patient two days post-procedure, and the patient was not experiencing any complications. The scope has not been returned for evaluation. If additional information becomes prior to the conclusion of the investigation, a supplemental report will be filed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.Cleaning Verification Testing

3.1 A duodenoscope was quarantined after initial sampling and tested positive for *Klebsiella pneumoniae* and *Enterococcus faecalis*, November 2021.

The Fujifilm Duodenoscope ED-580XT was cultured and tested positive for *Klebsiella pneumoniae* and *Enterococcus faecalis* (total 36 CFUs). The endoscope was quarantined after initial sampling and no patients were involved or exposed to the endoscope/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=12745083&pc=FDT

3.2 A Cysto-nephro Fiberscope cultured positive for Paracoccus yeei and Sphingomonas spp. after microbiological routine control test, November 2021.

After a microbiological routine control test, the OES Cysto-nephro Fiberscope CYF-5 cultured positive for *Paracoccus yeei* and *Sphingomonas* spp. The user facility will forward the scope to Olympus for further testing and a physical evaluation. The user did not report any contamination or any other serious deterioration in the state of health of any person. Information was provided regarding the cleaning, disinfection, and sterilization by the user facility. The biopsy valve, air valves, and suction valves are disinfected or sterilized via manual cleaning procedures and the scope is stored horizontally after reprocessing. The reported *Paracoccus yeei* and *Sphingomonas* spp. could not be confirmed since the scope tested negative. No hygiene relevant germs were found. The root cause 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=12796408&pc=FAJ

3.3 During routine culturing, the OES bronchofiberscope tested positive for microbial contamination, November 2021.

A user reported that during routine culturing of the OES bronchofiberscope BF-1T60, it tested positive for microbial contamination. 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 was reported.

The scope was sent to an independent laboratory for culture testing where cultures were taken from the distal end and suction channel. One (1) CFU of *Acinetobacter radioresistens* was identified from the suction channel. The obtained results are in conformance with the requirements. An additional culture sampling will be performed after the scope undergoes a second reprocessing cycle and then evaluated. The investigation is ongoing, and, therefore, the root cause is currently undetermined. If additional information becomes available this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12843718&pc=EOQ

3.4 Forty-three (43) CFUs of *Pseudomonas spp.* were found after a gastrointestinal videoscope tested positive, October 2021

An EVIS Exera III Gastrointestinal Videoscope GIF-H190 tested positive for 43 CFUs of Pseudomonas spp. during routine testing of the scope. The user did not report any contamination, or any other serious deterioration is 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, and coagulase-negative *staphylococci* was identified. The obtained results are in conformance with the requirements. The scope has not been received at Olympus for evaluation. The investigation is ongoing; therefore, the root cause cannot be determined at this time. Any additional information becomes available this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12615018&pc=FDS

3.5 The channels of the colonovideoscope tested positive for 56 CFUs of *Pseudomonas aeruginosa* and 56 CFUs of *Klebsiella pneumoniae* during a routine culture, October 2021

The channels of the EVIS Exera II Duodenovideoscope CF-Q180AI tested positive for 56 CFUs and of *Pseudomonas aeruginosa* and 56 CFUs of *Klebsiella pneumoniae*. The issue was found during a routine culture of the scope. 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 cleaning, disinfection, and sterilization (CDS) evaluation was performed by the customer. The last sampling was in 2021. The scope was precleaned with Salvanios Premium detergent. Asept Inmed® was used for manual treatment/bedside precleaning. The biopsy valve, air valve, and suction were disinfected by the automatic endoscope reprocessor (AER). Soluscope 4 was used as the AER along with Soluscope CLN detergent and Soluscope PAA disinfectant. The scope was stored horizontal after treatment. The maintenance was

performed by Olympus. The occupation of the reporter is unknown. A supplemental report will be submitted should additional information be made available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12656083&pc=FDF

3.6 The duodenovideoscope cultured positive three times since April for *S. aureus, S. epi/micrococcus luteus* and coagulase negative staph, October 2021

An EVIS Exera II Duodenovideoscope TJF-Q180V was cultured three (3) times since April for a) S. aureus, b) S. epi/*Micrococcus luteus*, and c) coagulase-negative staph. The customer believes there may be internal damage inside the scope. The facility's sterile processing department and scope culturing super users watch the washing and culturing process and do not believe this is where the problem is coming from. The scope was returned to the service center and is pending evaluation. In addition, further communication with the customer requested for independent laboratory testing of the scope. To date, confirmation from the customer for the independent laboratory testing/schedule has yet to been finalized. An Olympus Endoscopy Support Specialist (ESS) has been dispatched to observe the user facility's reprocessing practices from start to finish and provide reprocessing in-service training, if necessary, to correct and address any reprocessing deviations. There were no associated patient infections reported. An investigation is ongoing to obtain additional information regarding the reported event. If additional information is received, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12615805&pc=FDT

3.7 Two patients tested positive for *Klebsiella pneumoniae* as well as the bronchoscope also tested positive for *Klebsiella pneumoniae*, October 2021

The EVIS Lucera Bronchovideoscope BF-260 tested positive for *Klebsiella pneumoniae* as well as two (2) patients also tested positive for *Klebsiella pneumoniae*. The customer is doing their own investigation to determine if there is any relationship between the bronchoscope and the patient infections. Requests for additional information are in progress. The bronchoscope has not been returned to Olympus for evaluation and 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=12583841&pc=EOQ

3.8 The colonovideoscope tested positive three (3) times for microbes from the samples that were collected, September 2021

After multiple microbiological testing by the user facility, Olympus Medical Systems Corp. (OMSC) was informed that the following microbes were detected from the sample collected from the EVIS Exera LLL Colonovideoscope CF-HQ190L:

Test # / All Channels	Microbes (CFUs)
First	*Pseudomonas aeruginosa* (10 - 100 CFU)
Second	Gram-negative bacteria (> 50 CFU)
Third	*Pseudomonas aeruginosa* (< 10 CFU)

The reprocessing method was not provided. The scope was not returned to OMSC but was returned to Olympus for evaluation where they found the following:

- Bending section rubber adhesive had been worn and cracked
- Bending angle did not meet specification
- Angulation knobs had slack
- Angulation was tight and heavy due to worn bending section
- Adhesive around the distal end lenses had been worn.

The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12457796&pc=FDF

3.9 The duodenovideoscope tested positive for *Escherichia coli* after being cultured, September 2021

Fujifilm corporation was informed that the Duodenovideoscope ED-580XT was cultured and tested positive for *Escherichia coli*, two (2 CFU). The endoscope was quarantined after initial sampling and no patients were involved or exposed to the endoscope/no death or serious injury associated with this event. This report is being submitted in abundance of caution. A supplemental report will be submitted with any additional information that becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12467381&pc=FDT

3.10 Samples collected from the distal end and channel of the duodenovideoscope, September 2021

An EVIS Exera III Duodenovideoscope TJF-Q190V was microbiologically cultured and tested positive for organisms. After a therapeutic endoscopic retrograde cholangiopancreatography (ERCP) procedure and post reprocessing, samples were collected from the distal end and channel on the scope and sent to an independent laboratory for testing.

- The channel tested positive for:

    - One (1) colony of *Staphylococcus lugdunensis*
    - Four (4) colonies of *Staphylococcus epidermis*
    - One (1) colony of *Bacillus cereus.*
- The distal end tested positive for:
    - Forty-one (41) colonies of *Staphylococcus lugdunensis*
    - Thirty (30) colonies of *Staphylococcus capitis*
    - Twelve (12) colonies of *Staphylococcus aureus.*

The scope was not returned to Olympus as it was sent to an independent laboratory for destructive sampling. 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=12545874&pc=FDT

3.11 The user detected an unexpected contamination in the Ureteroscope after microbiological routine control test, September 2021

After a microbiological routine control test on the Uretero-Reno Fiberscope URF-P6, as required by regulation, the user detected an unexpected contamination during reprocessing. The user then sent the scope to the OFR subsidiary for hygiene microbiological investigation (HMI) for further investigation. The customer HMI results reported the scope tested positive with mold. The information on customers' CDS checklist is as follows:

1. Life Nova clean for preclean bedside
2. Aniosyme x3 the detergent used for cleaning
3. Anioxyde 1000 disinfectant used for disinfection
4. Autoclave for sterilization

Investigation is ongoing. The user did not report any contamination or any patient injury or patient infection. No user injury reported. This report will be supplemented accordingly following investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12637272&pc=FGB

3.12 Microbes were detected two times in the instrumental and suction channels of a gastrointestinal videoscope, August 2021

A report in the FDA’s MAUDE database states microbes were detected twice in 2021 from the sample collected by the user facility from the EVIS Exera III Gastrointestinal Videoscope GIF-H190.

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	Instrument Channel	Suction Channel
1st Time	*P. aeruginosa* (20 CFU/channel)	*P. aeruginosa* (80 CFU/channel) *K. pneumoniae* (120 CFU/channel)
2nd Time	*P. aeruginosa* (22 CFU/channel)	*P. aeruginosa* (8 CFU/channel)

The scope was reprocessed with a non-Olympus AER reprocess, ISA Medivators, using ADASPOR. No report of infection is associated with this report. The scope was not returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12286133&pc=FDS

3.13 Microbes were found two times from microbiological testing in a gastrointestinal videoscope, August 2021

A report in the FDA's **MAUDE** database states, multiple microbiological testing by the user facility, following microbes were detected two times in 2021 from the sample collected from the EVIS Exera II Gastrointestinal Videoscope.

	Microbes
1st Time	*Klebsiella pneumoniae* (between 1 CFU and 4 CFU)
2nd Time	*Klebsiella pneumoniae* and *Escherichia coli* (the total is between 5 CFU and 25 CFU)

The scope had been reprocessed with a non-Olympus AER, Soluscope Serie 4, using peracetic acid. There was no report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11919056&pc=FDS

3.14 Multiple microbes were detected from a sample collected from a Duodenovideoscope, August 2021

A report in the FDA's **MAUDE** database states, multiple microbiological testing by the user facility, microbes were detected from the sample collected from a EVIS Exera III Duodenovideoscope TJF-Q190V.

Microbiological Test #	Channel(s) Specified	Microbes Found
First	Unspecified	*Staphylococcus epidermidis* and *Staphylococcus warneri* (12 CFU/200ml)
Second	Unspecified	Filamentous fungus (2CFU/200ml)
Third	• Suction and Instrument • Air/Water	• *Staphylococcus warneri*, *Staphylococcus epidermidis* and *Kocuria sp.* (4 CFU/100ml) • *Staphylococcus warneri*, *Staphylococcus epidermidis*, and *Kocuria sp.* (3 CFU/50ml)
Fourth	• (b)(6) • Elevator channel • Unspecified channel	• *Acinetobacter lwoffii* (5CFU) • *Staphylococcus hominis* and *Micrococcus luteus* (6 CFU) • *Staphylococcus hominis* and *Micrococcus luteus* (7 CFU)

The scope had been reprocessed with a non-Olympus AER, Soluscope Serie 4, using peracetic acid. No report of infection associated with this report. The scope has not been returned to OMSC but was returned to Olympus, which sent the scope to a third-party laboratory for microbiological testing. No microbe was detected from the sample collected from all the channels and the distal end of the scope. The testing result cleared the guideline. The exact cause of the reported event could not be conclusively determined. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12334781&pc=FDT

3.15 Microbes were detected from a sample collected from the duodenovideoscope by the user facility, August 2021

A report in the FDA's **MAUDE** database reports states, with multiple microbiological testing by the user facility, microbes were detected from the sample collected from the EVIS Exera II Duodenovideoscope TJF-Q180V.

	Microbes
1st Time	• *Escherichia coli* • *Pseudomonas aeruginosa*
2nd Time	*Pseudomonas aeruginosa*

Note: The facility found that four patients were infected with Pseudomonoas aeruginosa.

The reprocessing method was not provided. The scope was sent to and evaluated at an Olympus repair center. Olympus confirmed the scope was repaired on February 17, 2021 because of a customer fault description that "The scope's controls do not work properly." Result of incoming inspection: there was leakage from the push-button box. The exact cause of the reported event could not be conclusively determined at this time. OMSC is submitting four medical device reports based on the number of infected patients. This is two of four reports. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12257429&pc=FDT

3.16 Microbes were detected from routine microbiological testing from a bronchovideoscope, August 2021

A report in the FDA's **MAUDE** database states, as a result of routine microbiological testing by the user facility, microbes were detected from the sample collected from the EVIS Exera III Bronchovideoscope BF-P190. *Stenotrophomonas maltophilia* (CFU/endoscope). Detailed information regarding the reprocessing method was not provided. The scope was not returned to OMSC but returned to Olympus—to which they sent the scope to a third-party laboratory for microbiological testing. No microbe was detected from the sample(s) collected from all channels of the scope and the testing result cleared the guideline. It could not be determined what the exact cause was of the reported event. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12317000&pc=EOQ

3.17 A bronchoscope was used on six patients and two tested positive for Muycobacterium abscessus, August 2021

A report in the FDA's **MAUDE** database states, Pentax was made aware of an event (involving Pentax Video Bronchoscope EB-1570K) to be evaluated because it could possibly have caused patients to be infected. The user facility wants the scope to be checked out completely to verify. A representative at the hospital responded to good faith efforts via email, on August 11, 2021, and provided case information for two patient cases. A unique *Mycobacterium abscessus* was identified in two sequential bronchoscopy cases (both patients have a similar strain). The scope had been used on six patients up until 2020. All patients, who did not have any radiographic evidence for *Mycobacterium* disease and were asymptomatic, in each case, had the same scope used. The facility confirmed they have seven bronchoscopes on-site. The customer owned endoscope has not been received for evaluation or testing as of August 13, 2021. The bronchoscope EB-1570K has been routinely serviced at a Pentax facility since the device was put into service. The investigation is in-process.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12321958&pc=EOQ

3.18 Three patients were infected, one died following a procedure with a bronchovideoscope, July 2021

A report in the FDA's **MAUDE** database states, an unknown time after the procedure with an EVIS Exera II Bronchovideoscope BF-1T180, a patient developed an unspecified infection and subsequently died. It is currently unknown if the infection/resulting death are related to the procedure or the Bronchovideoscope. Additional details regarding the patient and reported event have been requested. This facility has reported three patient infections following procedures using the BF-1TH180 scopes. A case with patient identifier(s) report states following a procedure using a BF-1Th180 Scope, three patients had infections—one died as a result of said infection. The scope was not returned to Olympus for evaluation and the investigation is ongoing. The definitive cause of the user's experience cannot be determined at this time. This report will be updated upon completion of the investigation or upon receipt of additional relevant information. This event has been reported by the importer on MedWatch #2951238-2021-00358.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12107073&pc=EOQ

3.19 Microbes were detected in a colonoscope after multiple microbiological testing by the user facility, June 2021

A report in the FDA's **MAUDE** database states that multiple microbiological testing, by the user facility, of the sample collected from the EVIS Exera LLL Colonovideoscope CF-H190l detected the following microbes:

	Microbes
1st Time	All Channels: *Escherichia coli* (>100 CFU/endoscope)
2nd Time	All Channels: *Escherichia coli* (8 CFU/endoscope)

The reprocessing method was not provided. No report of infection is associated with this report. The scope has not been returned to OMSC but was returned to Olympus, who sent the scope to a third-party lab for microbiological testing. As a result of the testing, no microbe was detected from the sample collected from all channels of the scope. The testing result cleared the French guideline, and there is no conclusion yet to the exact cause of the reported event. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12073555&pc=FDF

3.20 *Escherichia coli* and *Enterococcus avium* were detected from the sample collected from the colonoscope, June 2021

A report in the FDA's **MAUDE** database states, as a result of routine microbiological testing by the user facility, *Escherichia coli* and *Enterococcus avium* (>250 CFU) were detected from the sample collected from the scope. The scope was reprocessed with a non-Olympus AER, using peracetic acid. The scope was not returned to OMSC but was returned to Olympus and sent to a third-party lab for microbiological testing. *Micrococcaceae* (3 CFU/endoscope) were detected from the sample collected from all channels of the scope. The testing results cleared the guideline. The exact cause of the reported event could not be determined. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11920890&pc=FDF

3.21 A patient tested positive for *Granulicatella adiacens* after a procedure with a bronchovideoscope, June 2021

A report in the FDA'S **MAUDE** database states it was reported that two out of three patients tested positive for *Granulicatella adiacens* after a procedure with an EVIS Evera III Bronchovideoscope BF-H190. The specimen was collected at the time of the procedure. The scope was not returned to Olympus for evaluation. A definitive cause cannot be determined at this time, and the investigation is still ongoing. This report will be updated upon completion of the investigation or upon receipt of additional relevant information. This event has been reported by the importer on MedWatch #29511238-2021-00344.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11939235&pc=EOQ

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

A report in the FDA's **MAUDE** database states on April 13, 2021, Fujifilm corporation was informed that the Fujifilm Duodenovideoscope ED-580XT was cultured and tested positive for *Enterococcus faecalis*, *Klebsiella pneumoniae*, and *Bacillus flexus* (10 total CFU). As the scope was sampled and cultured as part of a post-market surveillance activity, no patients were involved or exposed to the endoscope. Per study protocol, the endoscope was immediately quarantined after initial sampling until culture data were available. Following the growth, the endoscope was not clinically reused. The scope was returned to and inspected by Fujifilm

Medical Systems U.S.A, Inc. The inspection results found no issues with the scope. The scope was sent to Fujifilm Corporation for further investigation. No death or serious injury was associated with this event. The report is being submitted in abundance of caution. If any additional relevant information is provided, a supplemental report will be submitted.

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

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

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

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

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

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

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

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

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

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

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

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

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

A report in the FDA **MAUDE** database states a patient developed a respiratory tract infection with *Mycobacterium llatzerense* 19 days post Bronchoscopy procedure with an EVIS Evera II Bronchovideoscope BF-Q180—for the indication of hemoptysis for two months and cough. This was diagnosed with bronchial alveolar lavage (BAL). The endoscope was shipped back (and forwarded) for 3rd party culturing. The definitive cause of the user's experience cannot be determined at this time. It was discovered, at the end of each bronchoscopy procedure, tap ice water was being injected through the scope with a syringe intending to reduce post-procedure bleeding. Culture results of the water supply are: (a) heterotrophic place count (HTC) having a count of (214 CFU) and (b) a total coliform *E. coli* test. The water was not tested for the specific

organism identified in the patient cultures. The water company came to culture the ice machine and could not because it was turned off. The water source was the same for the sink and ice machine. While they cultured the sink, they did not culture the ice machine (even after the machine was turned on). This investigation is ongoing, and the report will be updated upon completion of the investigator or upon receipt or additional relevant information.

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

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

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

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

The scope had been reprocessed in a non-Olympus AER, Steelco ew2, using peracetic acid. The scope has not been returned to OMSC but was returned to Olympus Europa. The scope was sent to a third-party laboratory for microbiological testing and no microbes were detected from the sample collected from the distal end and the forceps elevator and the suction, the instrument, the air/water channels of the scope. The testing result cleared the guideline. It was also confirmed in the evaluation of the scope- the adhesive of the light guide lens and the objective lens were worn; there were deposits on the distal end cover; the control section had damage; there were deposits on the air/water cylinder and suction cylinder; the adhesive part on the bending section rubber was worn out. There was no report of infection associated with this report. The exact cause of the reported event could not be conclusively determined at this time. If additional information is received, this report will be supplemented.

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

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

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

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

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

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

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

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

performed, and the history record review confirmed the endoscope was manufactured on March 4, 2009, under normal conditions, passed all required inspections, and was released accordingly. The endoscope has been routinely serviced at a Pentax facility since the device was put into service on March 24, 2009. The endoscope is pending sampling results and further evaluation.

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

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

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

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

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

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

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

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

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

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

4.Excessive Force with Equipment

4.1 Inspection was conducted on the colonovideoscope prior to use and found the auxiliary water channel was clogged with foreign material, October 2021

The user inspected the EVIS Lucera Elite Colonovideoscope PCF-H290ZI before use and found the auxiliary water channel was clogged with a foreign material (water could not be supplied from the auxiliary water channel). The user replaced the scope to another similar scope and performed the intended procedure. The scope has been reprocessed with an Olympus AER model OER-4 using peracetic acid. No report of patient injury associated with this event.

The scope was returned to OMSC for evaluation and checked the scope. The reported phenomenon was duplicated, also found that white material (silicone and a part of the auxiliary water inlet cap) was clogged inside the area approximately 23 cm from the distal end of the auxiliary water channel. As a result of exterior inspection of the scope, it was found there was no abnormality on the distal end cover near the auxiliary water channel inlet. OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. As a result of the investigation, OMSC concluded the foreign material was attributed to a part of the damaged auxiliary water inlet cap. Also, OMSC surmised that the central part of the auxiliary water inlet cap was torn off and invaded the auxiliary water channel due to repeatedly attachment/detachment of the auxiliary water inlet cap and stress applied in the licking direction during attachment/detachment. If additional information is received, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12568770&pc=FDF

4.2 A Cysto-Nephro Videoscope had a kink in the biopsy channel during a therapeutic procedure, October 2021

Customer reported the Cysto-Nephro Videoscope CYF-VH had a kink in the biopsy channel. It was unknown when the issue occurred but involved a therapeutic procedure. During the evaluation, it was noted there was a) looseness, b) deformation, c) scraping, d) rattling, and e) detachment of the instrument channel port. No patient involvement reported.

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

- Distal end unit was disconnected from the bending tube/the tip was cut from the bending tube.
- Light guide cover lens was scratched.
- Bending section cover cement was defective.
- Connecting tube was peeling off and was scratched.
- Universal cord was scratched.
- Angulation wires and knobs needed to be adjusted.

The legal manufacturer conducted an investigation. The device history records of the scope were reviewed, and all records indicated that the product was manufactured according to all applicable procedures and met final product release criteria. No abnormalities were found, and the root cause could not be identified. It was likely the tip was cut from the bending tube due to handling. This report is to capture the reportable malfunction of looseness, deformation, scraping, rattling, and detachment of the instrument channel port noted at estimation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12618470&pc=FAJ

4.3 Excessive play in the control knobs causing the angulation to measure below standards along with failed leak test from the biopsy channel, September 2021

A patient experienced a Sigmoid colon perforation said to be due to inability to retroflex of the scope during a diagnostic colonoscopy using an EVIS Exera III Colonovideoscope PCF-H190L. The patient was transferred to the main hospital via ambulance where she was triaged in the emergency room and later taken to the operating room for surgical closure of the Sigmoid colon. The patient's current condition is reported as stable to recovering. The scope has been evaluated by Olympus. The definitive cause of the user's experience cannot be determined at this time.

Olympus evaluated (performed a functional inspection) the scope. While the definitive cause of the user's experience cannot be determined at this time, the physical evaluation revealed:

- Excessive play on the control knobs (occurring in every direction) causing angulation to measure below standards in all directions.
- The video scope failed the leak test inspection (caused by leak from the biopsy channel—according to estimation's inspection results).

- Further findings include a snaking insertion tube.

Once confirming the user's report of retroflex issues, Olympus proceeded to perform advanced diagnostics by pulling down the grip unit on the control body confirming the angle wires were stretched. There are no signs of fluid within the control body section. The last service event for the scope was in 2018. The videoscope was resold on December 5, 2018. 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=12471293&pc=FDF

4.4 Duodenoscope tested positive for *Pseudomonas*, and extensive damage upon evaluation, June 2021

A report in the FDA's **MAUDE** database states, the EVIS Exera Duodenovideoscope TJF-160VF was cultured and tested positive for *Pseudomonas*. Later, the scope was used for an endoscope retrograde cholangiopancreatography (ERCP). Seventeen days after the ERCP procedure, the patient exhibited feverish peaks with unspecified patient cultures obtained. (Results were not provided). The scope was reprocessed, and a culture was taken, which tested positive for *Pseudomonas*. The patient was treated with antibiotic therapy. This event did not affect the patient's discharge from the hospital. The scope was returned to Olympus for evaluation with preliminary findings. The definitive cause of the user's experience cannot be determined at this time. The investigation is ongoing. Physical evaluation of the scope revealed:

- Damage due to physical stress.
- Stretched angle wires.
- Insufficient cleaning of the scope.
- Damage to the angulation control/knob.
- Worn out adhesive part on the bending rubber.
- Caught/Pinched part of the insertion tube.
- Peeling scope coating likely due to aging/chemical stress/water invasion.

No additional information has been reported but 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=12048032&pc=FDT

4.5 The control lever on two aScope™ 4 bronchos from the same batch broke during a fiberoscopy, June 2021

A report in the FDA's **MAUDE** database states the control lever of an aScope™ 4 broncho broke during a fiberoscopy. The health professionals immediately tried another aScope™ 4 broncho from the same batch, but the control lever of that Flexible Video Bronchoscope, Single-Use 47800100 also broke. Due to the prolonged procedure, the patient desaturated. The endoscopy was then performed with a functional endoscope. Patient saturation level returned to normal. No long-term serious health deterioration for the patient was reported. The defective scope has been received for investigation. Ambu® was able to verity the reported failure and investigated the defective sample found that the control lever was loose due to a detached steering wire on the inside of the endoscope. With the wire detached, the endoscope will not function as intended and won't be able to bend the tip. Investigation of the defective sample and the retention sample from the same lot suggest that the wire has been detached due to excessive force of the lever. The wire was shown to have the specified diameter and the crimping was observed to be fully compresses on the defective endoscope. Pull strength tests were performed on both the defective endoscope and the retention sample and both devices passed the test. Ambu® has ruled out defective steering wire and improper crimping as cause of the defect. The complaint states that the defect was only detected after the endoscope had been used. A precheck is prescribed, it is evaluated the fault occurred as a result of the user applying excessive force due to having difficulties maneuvering the endoscope within a smaller space. This is characterized as rough handling in the product risk evaluation. In the product risk evaluation that breakage of the aScope™ 4 broncho due to rough handling by the user will not pose a serious risk or harm to the patient or user. The user is advised to had suitable back up ready in case of a defective endoscope. Two consecutive endoscopes broke due to rough handling, which lead to the hazardous situation and desaturation of the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11940894&pc=EOQ

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

A report in the FDA's **MAUDE** database states the tip of an Ambu® aScope™ single-use slim Flexible Video Bronchoscope 476001000 broke off inside the endotracheal airway tube of a patient. The physician retrieved the broken piece, and the patient was not affected. No sample was returned for investigation and Ambu® has not been able to verify the failure. The expected cause of the failure is mishandling, where the bending section was not in straight (neutral) position during extraction of the bronchoscope from the Double Lumen Endotracheal Tube (DLT) and excessive force was applied to pull out the scope causing the distal end to break off. It is stated in the IFU, the distal tip must be set in a neutral or non-deflected position when being withdrawn and excessive force should be avoided. The reported problem is included in the product risk analysis.

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

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

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

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

5. Failures Due to Reprocessing Equipment (AERs)

5.1 Thirteen (13) patients had procedures performed with affected instruments processed with expired Cidex OPA concentrate, November 2021

A report in the FDA's MAUDE database states thirteen (13) patients were reported to have procedures performed with the affected instruments processed with expired Cidex OPA concentrate by two (2) EVOTECH® ECRs at the facility; however, it is unclear which EVOTECH® ECR was involved for each patient. Advanced sterilization products will continue to follow-up for additional information regarding this event. Per the Cidex OPA concentrate's instructions for use (IFU), the facility was advised lot number and the expiration date must be manually entered into the EVOTECH® ECR. The customer reported that the facility unit was retrained. A batch record review was performed and no issues relating to the failure mode were noted. The involved batch met manufacturer specifications at the time of release. The expired disinfectant was in use for approximately four (4) weeks before the error was discovered, and the affected instruments were released and used on thirteen (13) patients. There was no report of any injuries or human reactions. As a matter of policy, advanced sterilization products (ASP) have decided to report all cases (where a customer uses expired product and releases it for use on patients) since high-level disinfection cannot be assured.

This report (2084725-2021-00435) is for EVOTECH® #2 and patient #2.

Refer to the manufacturer report number 2084725-2021-00434 for the report on EVOTECH® #1 and patient #1.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12861933&pc=MED

5.2 The disinfectant solution concentration level was not checked every time, October 2021

User did not check the disinfectant solution concentration level every time when disinfecting. Other detailed information was not provided, and no patient injury associated with the event. The OER -4 100V Endoscope Reprocessor was not returned to Olympus for evaluation or to Olympus medical systems (OMSC) for investigation. Device history record indicates the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. When the OER is used, the disinfectant solution concentration level should be checked every time by the test strip.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12708427&pc=FEB

5.3 The water filter of the OER-4 has never been changed since the installment in 2017, September 2021

The user facility reported to Olympus Information Center by phone that the water filter of the OER-4 100V Endoscope Reprocessor has never been replaced since it was installed on its delivery date July 5, 2017. In addition, the user facility reported the dealer representative had never been pointed out about replacing the water filter when checking the OER. There was no report of patient injury associated with the event. The OER was not returned to any of Olympus locations. Olympus explained to the user about the replacement of the water filter via the dealer, but the Olympus sales representative will explain the replacement of the water filter to the user again. The exact cause of the reported event could not be conclusively determined at this time. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12523910&pc=FEB

5.4 An error e99 occurred on the AER, the user did not check the concentration of the disinfectant solution with test strip, August 2021

A report in the FDA's **MAUDE** database states the user was reprocessing when an e99 error occurred on the AER OER-3 100V Endoscope Reprocessor. The user did not check the concentration of the disinfectant solution with the test strip. Therefore, it was unknown whether the concentration of the disinfectant solution was effective or not. Also, OMSC was informed that the user had not checked the concentration of the disinfectant solution each time with the test strip. There was no patient injury associated with this report. The AER was not returned to any of Olympus locations, so Olympus could not investigate the AER. The exact cause of the reported event has not been determined at this time. If additional information is received, this report will be supplement.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12351888&pc=FEB

5.5 Five endoscopes were washed with chemicals later tested to be harmful to the human body, August 2021

A report in the FDA's **MAUDE** database states, the user facility has been using liquid chemicals other than those specified by Olympus in the alcohol bottle for reprocessing and washed five endoscopes. During the preparation for use, the user found that these chemicals have a problem. The user tested the chemical and found it was harmful to the human body. There was no report of infection associated with this report. The OER-AW 240V Endoscope Reprocessor was not returned to Olympus Medical System Corp. (OMSC) for evaluation. The exact cause of the reported event could not be determined at this time. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12376687&pc=FEB

5.6 Two patients were infected with a Carbapenem-resistant *Enterobacteriaceae* infection after undergoing an endoscopy procedure on the same day, August 2021

A report in the FDA's **MAUDE** database states, the user facility reported two patients underwent an endoscopy with the EVIS Exera Lucera Elite Duodenovideoscope TJF-Q290V on the same day were infected with a Carbapenem-resistant *Enterobacteriaceae* infection. Bile culture tester were performed on both patients by the user facility and found the infection.

	Case #1	***Case #2***
Sex of Patient	Male	Male
Procedure	Endoscopic Retrograde Cholangiapancreatography (ERCP)	Endoscopic Cholangiolithotomy
User's Action	Inspected the scope before using it and completed the procedure	The scope was inspected before using it and completed the intended procedure.
Patient's Symptoms	Patient had no symptoms of the infection	Patient had no symptoms of the

		infection and was discharged.
Treatment	Hospitalized for treatment of the primary disease as of August 6, 2021. Doctor prescribed the patient with antibacterial agent.	The doctor prescribed the patient an antibacterial agent.

The scope had been reprocessed with an Olympus automated endoscope reprocessor mode OER-4 after precleaning. The doctor was concerned about structural issues with the scope, as their Olympus endoscope TJF-260 series has never experienced a similar incident. The infection control department at the facility said that if no bacteria are detected on the reprocessed endoscope, it suggests these consecutive infection incidents accidentally occurred. However, they also said that if the endoscope tests positive, it means there is a problem with the Olympus cleaning machine. Olympus Medical System Corp. (OMSC) is submitting two medical device reports, according to the number of infected patients. The scope was returned to OMSC for evaluation and is currently in progress. The exact cause of the event could not be determined at this time. If additional information becomes available, this report will be supplemented. This is the first of two reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12390494&pc=FDT

5.7 The water filter had not been replaced in the AER since October 2019, June 2021

A report in the FDA's **MAUDE** database states the user facility had not replaced the water filter of the AER OER-4 100V Endoscope Reprocessor since October 2019. The user also reported that they have conducted the diagnostic procedure one or two cases a day. There was no report of patient injury associated with this event. The AER has not been returned to any Olympus locations. Therefore, Olympus could not investigate the AER. 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=11999186&pc=FEB

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

A report in the FDA's MAUDE database states the user had not replaced the water filter of the OER-4 100V Endoscope Reprocessor since 2016. Other detailed information was not provided. The OER was not returned to Olympus Medical Systems Corp. (OMSC) for evaluation and could not be investigated. The device history record review (DHR) indicates the product was

manufactured and tested in accordance with all applicable procedures and met all final product release criteria. There was not report of patient injury associated with the event.

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

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

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

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

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

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

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

6. Endoscope Malfunctions

6.1 A Ureteroscope was advanced into the patient's kidney and became stuck with multiple attempts but failed, November 2021

During a procedure, the Ureteroscope 1127VSUE was advanced up to the ureter into the kidney. After pyeloscopy was performed, the ureteroscope was pulled back. However, it was unable to be removed at the level of the distal ureter. More attempts were made to remove the scope using a combination of techniques but failed from the antegrade fashion. Procedure was then converted to percutaneous nephrolithotomy (PCNL). During this time, the rubber sheath—which appeared to have been pancaked/flattened—was sliced up to facilitate extraction of the ureteroscope and distal sheath. The rubber sheath was torn and ripped at the tip of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12786441&pc=FGB

6.2 The customer attempted to remove the bronchoscope that became stuck in the ET tube and unraveled into a "slinky-style" manner, October 2021

A Glidescope BFLEX 5.8 bronchoscope began to unravel in a "slinky-style" manner after becoming stuck in the ET tube when the customer attempted to remove the bronchoscope at the end of a patient procedure. The ET tube was removed and replaced without incident. No harm to the patient or user was reported. The customer declined the option to have their Glidescope BFLEX 5.8 bronchoscope returned to Verathon for evaluation. Since the device was not returned, the root cause could not be determined. Corrective action is not required at this time. Verathon will continue to monitor for trends.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12658563&pc=EOQ

6.3 A "milky image" occurred prior to use on a gastroscope and reported to Pentax by the user, August 2021

A report in the FDA's **MAUDE** database states, a "milky image" involving Pentax Imagina Gastroscope EG29-I10C. The event was reported to have occurred prior to use. No further information was provided at the time of the report. The scope was returned to Pentax Medical service workshop in Germany, where the following was confirmed: a.) Foggy misty image, b.) Moisture under the LED cover lenses. If additional information becomes available, a supplemental report will be filled with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12332030&pc=FDS

6.4 The video ureteroscope was being used when the picture went out, the physician tried to remove the scope but was unsuccessful, August 2021

A report in the FDA's **MAUDE** database states, the customer was using a Video Ureteroscope, 8.5 FR. X 675MM with the picture went out, the physician tried to remove the scope, but was unable to pull the scope out of the ureter. They had to cut off part of the scope's shaft and a significant portion of the distal remained lodged in the patient's ureter.

The scope has not been returned (at this time). Karl Stroz Endovision representation was informed that the patient had the scope's separated piece removed successfully from their ureter in a procedure over the weekend at Good Samaritan Medical Center (separate hospital) and stated the scope had been at end-of-service since December 31, 2019. The scope was sent to a third-party by IMS. After multiple attempts, this information has not been able to be confirmed with the customer. If the scope is returned and evaluated, a supplemental report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12375207&pc=FGB

6.5 After a procedure, it was noticed that the tip of the scope was missing after it was removed from the patient, August 2021

A report in the FDA's **MAUDE** database states, during the procedure the Ambu® aScope™ Bronchoscope 4 Broncho Large Size 5.8/2.8 became very difficult to remove. When the scope was removed it was observed the tip of the scope was missing. A second bronchoscopy was performed with a smaller size Ambu® disposable scope without incident. During the second procedure, the tip of the first scope (foreign object) was found in and retrieved from the patient's lung using an Ambu® disposable bronchoscope 4 size 5.0/2.2. FDA safety # 575948.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12280797&pc=EOQ

6.6 A complaint to Pentax about a colonoscope that had an "unresolvable blurry image reported to Biomed", July 2021

A report in the FDA's **MAUDE** database states, on June 3, 2021, Pentax Medical was made aware of a complaint that a Pentax Video Colonoscope EC38-I10NL had an "unresolvable blurry image reported to Biomed." No other information was received with the complaint. The investigation is underway, and this event meets the requirements for FDA reportability. However, submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event. 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=12256180&pc=FDF

6.7 A colonoscope had condensation of moisture which caused poor image quality and water droplets on the LED cover glass, July 2021

A report in the FDA's **MAUDE** database states, a Pentax Imagina Colonoscope EC38-I10CL had poor image quality, blurry foggy video images, plus water droplets issue on the LED cover glass. The evaluation summary confirmed it was caused due to a condensation of moisture in the CMOS unit by changing of the temperature.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12222402&pc=FDF

6.8 A bronchoscope's camera housing broke off in the patient's lung during an emergency care procedure, July 2021

A report in the FDA's **MAUDE** database states, the customer reported, during an emergency care procedure, while using a Glidescope BFLEX 5.8 Bronchoscope, the camera's housing broke off in the patient's lung. The patient had to go into surgery to get the scope camera housing removed. The scope was returned to Verathon for evaluation. A Verathon technical specialist representative (TSR) evaluated the bronchoscope and confirmed the missing camera housing. The scope was forwarded to Verathon Canada for further investigation. Verathon continues to investigate the reported event and a supplemental report will be submitted in accordance with 21 CFR 803.56 when additional information becomes available. Corrective action is not required at this time. Verathon will continue to monitor the trends.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12122759&pc=EOQ

6.9 The bending rubber burst on a gastroscope during an endoscopy, June 2021

A report in the FDA's **MAUDE** database states, an event occurred in South Korea within the APAC region during use. The information provided indicated that during the endoscopy procedure the bending rubber burst and a screw fell out. The endoscope was withdrawn right away, and another endoscope was inserted to remove the screw that fell out involving Pentax Medica Video Gastroscope, EG29-I10C. After returning this endoscope, it was inspected, and the other two screws were found in PMK by the service team. Currently, the endoscope is awaiting repair. The investigation is in process.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11988815&pc=FDS

6.10 The Uretero-Reno Videoscope could not be withdrawn, and the up/down angulation control lever was stuck during a ureteroscopic lithotomy procedure, June 2021

A report in the FDA's **MAUDE** database states, during a ureteroscopic lithotomy, the Uretero-Reno Videoscope URF-V2 could not be withdrawn, and the up/down angulation control lever was stuck. The user performed x-ray inspection and found the distal end and bending section for the scope were in the bending state. The sheath of the flexible ureteroscope can withdraw normally when it is tilted but it cannot withdraw when it is stuck. The user cut the insertion section of the scope and still could not withdraw. The user withdrew the scope by the laparotomy. The scope was not returned to OMSC for evaluation, but it was returned to Olympus and confirmed the scope was cut and the bending section was in bending state. The exact cause of the reported event could not be determined at this time. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12006651&pc=FGB

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

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

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

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

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

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

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

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

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

were no abnormalities that occurred on other endoscopes including the Olympus 290 series that the user facility owns. This is the second of two reports.

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

7. Sterilizer Malfunction

7.1 Eye irritation potentially related to sensitivity to the Sterrad® 100NX sterilizer affected three health care workers, July 2021

A report in the FDA's MAUDE database states, two females and one male health care workers experienced eye irritation potentially related to sensitivity to the Sterrad® 100NX. The health care workers left the room and their eye irritation resolved within a few hours. They did not seek or receive any medical attention/treatment and were reported to be "fine." An ASP field service engineer was dispatched to assess the unit on-site and identified an odor emitting from the Sterrad®. A field service engineer was dispatched to the customer site. The catalytic converter and oil mist filter were replaced to resolve the odor/smell issue. Unit meets specifications and was returned to service. If information is obtained that was not available for the initial report, a follow-up report will be filed as appropriate. This event is being reported as a malfunction after a serious injury.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12145683&pc=MLR

8.Use Errors

8.1 A patient was infected following the use of an unknown scope, October 2021

A patient was infected following the use of an unknown scope. The customer states the automated endoscope leak tester did not detect a leak on the scope used with the patient. A request for additional information is in progress.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12562285&pc=PCV

8.2 A brush was found clogged in the channel of the gastrointestinal videoscope during the preparation for use, October 2021

User found a brush clogged in the channel of the EVIS Lucera Gastrointestinal Videoscope during the preparation for use. The brush was removed by cleaning. No patient injury associated with the event. The scope was not returned to OMSC for evaluation. The scope was checked, and

the reported phenomenon could not be duplicated because the clogged brush had been removed. The exact cause of the event could not be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12603732&pc=FDS

8.3 Air and water channel had brownish dirt in the nozzle of the gastrointestinal scope while being inspected for use, October 2021

During the preparation for use of the Gastrointestinal Videoscope GIF-1200N, which was reprocessed using End Cleanse, air and water could not be supplied. The scope was returned to OMSC for evaluation and found that there was a "brownish dirt" in the nozzle. Component analysis of the "brown dirt" revealed they were proteins—organic silicones and iron oxide. The manufacturing record was reviewed and found no irregularities. OMSC presumed that each component was found due to the following possible causes.

- Proteins: blood or other body fluids
- Organic silicone: anti floating agent
- Iron oxide: rust generated by the adhered body fluid not being washed

There was no report of patient injury associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12588655&pc=FDS

8.4 Incorrect reprocessing of a gastrointestinal scope was discovered during a visit by an Endoscopy support specialist, September 2021

During an Endoscopy Support Specialist (ESS) facility visit, incorrect reprocessing of the EVIS Exera III Gastrointestinal Videoscope was discovered. The ESS noted that the facility staff was not using the bite block while performing the procedure. Furthermore, the customer did not protect the distal tip and allowed it to impact the tower while performing precleaning. During the precleaning, the air was not suctioned, the air/water channel cleaning adapter was not used, and the auxiliary water port was not finished.

Additional information related to this event and patient was requested but was unavailable. There was no patient harm or consequence reported because of this event. At this time, the scope is not scheduled for return. The Olympus ESS is planning to work with the customer to set up a reprocessing in-service, according to the Olympus instructions for use (IFU) along with the repair findings from the facility. Should additional information become available prior to the investigation conclusion, a supplemental report will be provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12461267&pc=FDS

8.5 Sample collected from the instrument channel of the gastrointestinal videoscope for microbiological testing showed *Pseudomonas aeruginosa* were detected, September 2021

A report in the FDA's **MAUDE** database states A user performed microbiological testing of a sample collected from the instrument channel of the EVIS Lucera Elite Gastrointestinal Videoscope GIF-H290T and detected *Pseudomonas aeruginosa*. The scope had been reprocessed with an Olympus AER model OER-5. The user facility did not provide other detailed information, such as the number of microbes. There was no report of infection associated with this report. The scope was returned to OMSC for evaluation. They found a) foreign material adhered to the auxiliary channel, b) the distal end was dirty, and c) the instrument channel scratched. The scope was then transferred to the Olympus Service Operation Repair Center (SORC). The exact cause has been under investigation and has not yet been conclusively determined. Additional information will be supplemented when it becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12510912&pc=FDS

8.6 The nurse found a piece of unidentified tissue inside the patient's body during a diagnostic gastroscopy and was removed with forceps, September 2021

Olympus Medical Systems Corp. (OMSC) was informed that while using an EVIS Lucera Elite Gastrointestinal Videoscope GIF-HQ290, a nurse found a piece of the unidentified tissue inside the patient's body during diagnostic gastroscopy. The user was not sure whether the tissue was from the patient or from the endoscope. The user removed the tissue using forceps and then replaced the scope to complete the intended procedure. There was no delay in the procedure. The scope was used in combination with the Olympus 290 series scopes.

The user inspected the scope before use and found no defect at the time. The scope had been reprocessed with manual and a non-Olympus AER. The scope was evaluated at Olympus in Ireland and the following was confirmed:

- Leakage from the remote switch due to perforation
- No abnormalities were found during scope brushing and flushing during the cleaning and disinfection process
- Insides of the suction and biopsy channels were inspected with an Olympus industrial endoscope I-plex
    - No evidence of tissue was found in the channels
    - A scratch was found inside the biopsy channel.
- The light transmitting lens was damaged
- Part of the light guide lens was chipped
- Evidence of liquid intrusion was found inside the scope.

As a precautionary measure, both the suction channel and the biopsy channel were replaced.

- Adhesive on the objective lens and light guide lens was loose.
- Leakage was found at the endoscope connector and an excess of liquid flowing in.
- Angulation in all directions was out of the standard value and there was play in the angulation.

The exact cause of the reported event could not be conclusively determined at this time. There was no report of patient injury associated with the event. In addition, the patient had no health hazard after the procedure.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12420148&pc=FDS

8.7 A poly-loop initially used in the first case was unknowingly left in the colonovideoscope and fell out during the third case, and debris expelled into the patient, September 2021

The customer reported possible cross-contamination involving three (3) patients in which the EVIS Exera LLL Colonovideoscope CF-HQ190L that was used was reprocessed incorrectly.

Patient Case	Event Report Description
First Patient	A poly-loop was initially used in an unspecified procedure
Second Patient	Scope used on the first patient's procedure was incorrectly reprocessed, and the poly-loop remained in the scope channel unknowingly
Third Patient	Debris was expelled into the patient and removed

The patient experienced no adverse effects because of this occurrence. The scope has been returned to Olympus for evaluation. Physical evaluation of the suspect device revealed the(re):

- brush passage was okay.
- device passed the dunk test.
- are minor scratches on the camera switch.
- angulation is low.
- cover plastic has dents and scratches.
- adhesive rubber glue is cracked.
- is minor shakiness in the insertion tube.

An endoscopic support specialist (ESS) was dispatched to the facility to offer education and observation of the current reprocessing procedures. The customer expressed that they are planning a skills day to educate all the staff, and the customer declined an onsite visit from the ESS to observe the staff reprocessing at this time. The ESS sent information to the customer to emphasize the proper inspection techniques of the instrument channel as well as a list of compatible EndoTherapy devices for inspection. Investigation activities have been opened to manage the actions related to this issue and any required MDR reporting.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12548140&pc=FDF

8.8 An Olympus endoscopy support specialist became aware that a green colored bile substance was found in the instrument channel, September 2021

During an in-service, the Olympus endoscopy support specialist became aware of a green colored bile substance found in the instrument channel of an EVIS Exera III Colonovideoscope CF-HQ190L that was hanging in the drying cabinet. No death, injury, or infection was reported to Olympus. No scope will be returned. The investigation is ongoing. Therefore, the root cause of the reported issue/malfunction cannot be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12752396&pc=FDF

8.9 During a procedure, the bridge's wire/forceps raiser was not sufficiently taut on the EVIS Exera II Duodenovideoscope, November 2021

During a procedure, the bridge's wire/forceps were not sufficiently taut on the EVIS Exera II Duodenovideoscope TJF-Q180V. The procedure was completed with another duodenovideoscope. No patient harm was reported. After the scope was disinfected and within the endoscope dry cabinet (EDC) for a while, the facility felt the bridge was working better than during the procedure. During the evaluation of the scope, it was noted there was residue/foreign material under the forceps' raiser due to insufficient cleaning.

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

- The forceps raiser had no function.
- The plastic distal end cover had leakage between the up/down/right/left knobs.
- There was residue/foreign material under the forceps raiser/arm.
- The charge-coupled scope glue lens had discoloration.
- The up/down/right/left knobs had play.

It was not possible to see other leakage. The corrosion under up/down/right/left knobs may have been related to the leakage. The contact person/occupation of the reported is unknown. A supplemental report will be submitted should additional information be made available. The investigation is ongoing. This report is to capture the reportable malfunction of residue/foreign material under the forceps raiser due to insufficient cleaning noted as estimation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12795345&pc=FDT

8.10 A nurse found feces remained on the distal end of the colonovideoscope while in storage, September 2021

A nurse found feces remained at the distal end of the EVIS Lucera Colonovideoscope while in storage. The date of occurrence is unknown. The nurse stated that before the reprocessing of the scope by the unspecified AER, precleaning and manual cleaning were performed appropriately (especially the precleaning, which was carried out longer than usual). The was no confirmation whether the scope was used on a patient without noticing the feces. The nurse doubted that immediately before the reprocessing, the pump of the AER had malfunctioned. It might be caused due to insufficient reprocessing. The nurse also stated that the periodical maintenance indicator and the box-shaped indicator of the AER had lit up.

The nurse informed Olympus Customer Information Center by phone anonymously. Olympus asked the nurse their name, facility name, the detail of the devices (model name), and so on. However, the nurse refused to answer them. The scope was not returned to any Olympus locations. Therefore, Olympus could not investigate the scope. OMSC could not review the manufacture history of the scope because the model name and serial number were not provided. The cause could not be conclusively determined. However, OMSC surmised that the reported phenomenon was attributed to wrong reprocessing, abnormality (failure). No report of patient injury associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12533265&pc=FDF

8.11 A deviation in the scope cleaning process was observed during an in-service of the fiberscope CYF-5, September 2021

During an in-service reprocessing of the Cysto-nephro Fiberscope CYF-5, a deviation was observed in the scope cleaning process, as the customer mentioned they do not do any precleaning on their urology scopes. Customer also does not conduct an extended soak if the scopes sit longer than an hour. The issue was noticed during reprocessing training. The Olympus representative covered and explained the precleaning process following Olympus guidelines on reprocessing with the customer. The precleaning in-service included all cleaning, disinfection, and sterilization information contained in the Olympus manual. There was no harm, infection, or user injury reported due to the event. The investigation is ongoing. The root cause of the reported event cannot be determined at this time, and additional information will be supplemented as needed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12516613&pc=FAJ

8.12 Black spots were present on the image during preparation for use in the Ureteroscope along with additional damage to the scope, September 2021

The customer originally returned the Olympus Uretero-Reno Fiberscope URF-P6R due to black spots present on the image during preparation for use. According to the initial report, a different scope was used to complete the procedure without patient impact. During the scope evaluation, it was discovered that the bending section of the scope was broken and had exposed metal through the distal end. This report is being submitted to capture the damaged distal end and exposed metal.

The scope was returned, and an initial evaluation was conducted by Olympus; however, the investigation is ongoing. During the initial evaluation, the user report was confirmed.

- Scope had seven (7) broken fibers in the image.
- (As noted,) the bending section of the scope was broken, and had exposed metal at the distal end.
- A crack was noted in the plastic cover
- A pinhole was noted in the distal end causing the unit to fail the leak test.

If additional information becomes available following device evaluation, a supplemental report will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12469040&pc=FGB

8.13 During an onsite in-service, an Endoscopy Support Specialist (ESS) observed an EBUS scope improperly reprocessed, September 2021

An Endoscopy Support Specialist (ESS) was onsite for an in-service and observed an EBUS Ultrasonic Bronchofibervideoscope BF-UC180F had been improperly reprocessed noting a piece of a balloon and a dried substance on the s-body (distal tip) of the scope. As part of the investigation, the ESS discussed the finding with the facility's respiratory therapy lead and recommended an in-service with him on reprocessing and scope handling—including extended soaking instructions. The ESS also explained how there was a high potential for bioburden on this EBUS scope. The scope was not returned to the service center for evaluation. An investigation is ongoing to obtain additional information regarding the event and will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12481744&pc=PSV

8.14 An Ambu® endoscope become stuck in the distal tracheostomy disposable inner cannula causing the patient to have an anxiety cardiac arrest, September 2021

A single-use bronchoscope 478001000 became stuck during a bronchoscopy procedure in the inner cannula on XLT distal tracheostomy and the patient expired. During the investigation, the nurse clarified that the bronchoscope did not cause the death of the patient, as the scope was

successfully removed while the patient was still alive. The nurse further clarified it was the patient's underlying conditions that led to his unfortunate death. The scope is therefore not related to the death of the patient. However, the incident did lead the patient to have an anxiety cardiac arrest.

There was no sample returned nor lot number provided for investigation. The test was performed on a retention sample and information provided by the user was used as input for the investigation. It was stated by the user the bronchoscope got stuck in the XLT distal tracheostomy disposable inner cannula during the procedure. Based on the simulation results from a retention sample, the suspected cause of the reported failure could be due to insufficient lubricant applied on aScope™ when inserting the scope in the DLT. As prescribed in the IFU, the insertion cord should be lubricated with a medical grade lubricant before the endoscope is inserted into the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12422315&pc=EOQ

8.15 Dirt could be seen in the facility's water supply from the well water, 13 scopes could possibly be contaminated, August 2021

A report in the FDA's **MAUDE** database states dirt/sediment could be seen in the water supply (from well water) at the facility. Thirteen Pentax Video Colonoscopes (EC38-l10L) were either not cleaned after the procedure or they were cleaned with dirty water. *There was no patient involvement*. It was confirmed the hospital was cleaning the scope according to the IFU but could not clean due to dirty water. Therefore, the scopes were not processed with polluted water. The event only happened once (one day) and did not occur repeatedly. Evaluation summary: it was caused due to improper reprocessing at the hospital. It was not a product failure.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12322703&pc=FDF

8.16 Due to staff shortages, scopes are not cleaned immediately after use and are left overnight, July 2021

A report in the FDA's **MAUDE** database states, the customer called service center to request reprocessing education and demonstration of an EVIS Exera II Gastrointestinal videoscope GIS-H180. An Olympus ESS arrived at the facility to provide in-service to staff. ESS was notified by staff during the demonstration that, due to staffing shortages, the scope is not cleaned immediately after use. The staff confirmed the scopes, "on occasion," are left overnight and cleaned the next day before use. Additionally, staff stated there "is no time for presoak." The in-service was completed for proper reprocessing procedures (e.g., leak testing, cleaning, brushing, rinsing and pre-soak) according to the Olympus manual. There have been no reported patient infections or harm at the time of the report. This report is for two of three scopes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12165803&pc=FDS

8.17 Patient developed *Pseudomonas aeruginoisa* bacteremia three days after ERCP procedure, July 2021

A report in the FDA's **MAUDE** database states, three days after the patient's ERCP procedure, the patient developed *Pseudomonas aeruginoisa* bacteremia. The facility received the typing results June 17, 2021, which showed the strain from the patient matched the one isolated from the Duodenoscope ED-580XT. The scope has been reprocessed several times since use on this patient but not used on any other patients. No death or other serious injury is associated with this event. Inspection of this scope is scheduled. If any additional relevant information is provided, a supplemental report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12239546&pc=FDT

8.18 Patient started running a fever, and chills 24 hours after a cystoscopy, July 2021

A report in the FDA's **MAUDE** database states a patient started running a fever, chills, and feeling bad all over 24 hours after a cystoscopy. The patient was admitted to the hospital with a sepsis diagnosis. It was brought to the patient's attention the FDA is investigating reports of infections associated with reprocessed urological endoscopes. Original test result is available upon request. Assessment comment: severe sepsis secondary to UTI vs. prostatitis.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12161045&pc=FAJ

8.19a Two patients were infected after a diagnostic cystoscopy using an OES Cystonephrofiberscope, July 2021

A report in the FDA's **MAUDE** database states, after a diagnostic cystoscopy using an OER Cystonephrofiberscope CYF-5R, two patients were infected. This case reports on patient one of two. Three days after the procedure using an OES Cystonephrofiberscope (for the indication of microscopic hematuria), the patient developed a urinary tract infection (diagnosed with a urinalysis obtained in the emergency room). The patient was treated with Cipro 500 mg and resolved the symptoms.

The scope was not cultured by the facility and was not returned to Olympus for evaluation. The definitive cause of the user's experience cannot be determined at this time and the investigation is ongoing. June 29, 2021, an Olympus Endoscopic Support Specialist (ESS) completed a virtual in-service regarding cleaning and care of urology scopes. The ESS covered infection control information referenced in the user manual and reprocessing manual. The customer states they

manually high-level disinfect (HLD) their scopes with alcohol. The ESS explained to the customer that they should follow the alcohol IFU for specific instructions for HLD. It was discovered the facility was not previously precleaning, or leak-testing their scopes after each use (they were not previously submerging the scope for leak-testing using a hand-held leak-tester). 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=12165544&pc=FAJ

8.19b Second patient infected after diagnostic cystoscopy using an OES Cystonephrofiberscope, July 2021

A report in the FDA's **MAUDE** database states, after a diagnostic cystoscopy using an OER Cystonephrofiberscope CYF-5R, two patients were infected. This case reports patient two of two. An unknown period after a diagnostic cystoscopy using an OES Cystonephrofiberscope (for the indication of microscopic hematuria), the patient developed a urinary tract infection. This was diagnosed on an unknown date at an urgent care facility. The patient was treated with an unspecified antibiotic and the symptoms resolved. The scope was not cultured by the facility. The scope has not been returned to Olympus for evaluation. The definitive cause of the user's experience cannot be determined at this time and the investigation is ongoing. June 29, 2021, an Olympus Endoscopic Support Specialist (ESS) completed a virtual in-service regarding cleaning and care of urology scopes. The ESS covered infection control information reference in the user manual and reprocessing manual. The customer stated they manually high-level disinfect (HLD) their scopes with alcohol. The ESS explained to the customer that they should follow the alcohol IFU for specific instructions for HLD. It was discovered the facility was not previously precleaning their scope or leak-testing their scopes after each use (they were not previously submerging the scope for leak-testing using a hand-held leak-tester). 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=12165459&pc=FAJ

8.20 The distal end of a cleaning brush fell into the patient during an unspecified procedure, June 2021

A report in the FDA's **MAUDE** database states, the user informed Olympus Medical Systems Corp. (OMSC) that, during an unspecified procedure, it was found the distal end of a brush, which had remained in the instrument channel of the EXIS Exera III Gastrointestinal Videoscope GIF-H190, fell off into the patient. There was no report of patient injury associated with the event. The scope was not returned to any Olympus locations. Therefore, Olympus could not investigate the scope. OMSC could not review the manufacturing history record (DHR) because the serial number was unknown. Based on the information from the user, it was considered this

phenomenon might be attributed the following: Cleaning the instrument channel with the cleaning brush the distal end of the brush was damaged and remained in the instrument channel. Subsequently, the scope was used for the next procedure with the distal end of the cleaning brush remaining in the instrument channel. The cause of the brush being damaged could not be determined but it might be the fatigue (i.e., the bending of the brush, the scratches, or the stress of repeated use.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11981398&pc=FDS

8.21 It was reported that incorrect reprocessing of the GI scope during the repair reduction observation by an Endoscopy Support Specialist, June 2021

A report in the FDA's **MAUDE** database states that an Endoscopy Support Specialist (ESS) reported reprocessing of the EVIS Exera II Colonovideoscope CF-Q180AL during a repair reduction observation. There was no patient involvement, harm, or user injury reported due to the event. The ESS performed a repair reduction observation and noticed the customer failed proper control over the distal end of the scope when removing it from the cabinets and knocked the distal end on the bottom of the cabinet. The customer failed to move the lock to a neutral position during precleaning and only suctioned detergent for approximately 10-15 seconds. Afterwards, the customer did not suction air. Throughout the air/water cleaning adapter step, the customer placed the air/water cleaning adapter in the scope but did not depress the air water cleaning adapter. Furthermore, the customer had the air flow on low during the process of the air water cleaning adapter step as well as failing to flush the auxiliary water channel. The customer placed the scope in the transportation bin, but the scope was not properly positioned because its connector was placed on top of the distal end and the insertion tube. During leak-testing, the customer situated the scope in the sink (which did not have enough water to completely submerge it) and left out the scope connector. The customer proceeded to check the MU-1 and the leakage tester cord before attaching the scope connector. However, the customer did not place the scope connector in the water. Therefore, the control knobs were not covered during the leak test process. After the leak-test was completed, the customer left the scope in the water and turned off the leak tester to decompress the scope prior to disconnecting. The customer used a non-Olympus brush (but only brushed the channels), while avoiding the channel openings. Additionally, the customer had the control body out of the water, while brushing the scope, and failed to perform the suction step. Lastly, the customer moved the scope from the detergent water to an empty sink and flushed the scope pairing with detergent, water, and air. The ESS informed the manager of all findings and scheduled an in-service reprocessing appointment to address all the cleaning concerns. The scope has not been returned to Olympus and 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=11921732&pc=FDF

8.22 Bronchoalveolar lavage (BAL) was performed with one patient testing positive for *P. aeruginosa* as well as 30 patients were examined with same the bronchoscope, June 2021

A report in the FDA's **MAUDE** database states, Fujifilm corporation was informed on May 28, 2021, of an incident involving the Bronchoscope EB-580S. Bronchoalveolar lavage (BAL) was performed on a patient, and the collected sample tested positive for *Pseudomonas aeruginosa*. The patient was treated with medication. There was no death or other serious injury associated with this event. The facility injected saline into the forceps' channel from the operation part of the bronchoscope and sent the sample collected from the tip of the endoscope to tissue culture– the result was negative. The bronchoscope was sent to the local distributor, where they performed an air-tightness test and found no abnormalities. The suction cup could not be investigated because it was discarded at the facility. It was discovered that the facility was reusing the suction button (a single-use accessory). Thus, it was determined the BAL samples were contaminated with *P. aeruginosa* due to the reuse of the single-use suction button. Approximately 30 patients were examined by this scope. Aside from the patient for which this MDR is being submitted, the BAL samples taken from the three patients examined with this scope in 2021 also tested positive for *P. aeruginosa*. Separate MDRs will be submitted for each of these patients. If any additional relevant information becomes available, a supplement report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12040110&pc=EOQ

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

A report in the FDA's **MAUDE** database states Olympus Medical Systems Corp. (OMSC) was informed by the user that after reprocessing the EVIS Exera Lucera Duodenovideoscope TJF-260V, yellow liquid (possibly bile) came out of the distal end of the scope. The scope was reprocessed with an Olympus automated endoscope reprocessor (AER) model OER-3, OER05 (not available in the United States) using peracetic acid. No other detailed information was provided. The Duodenoscope was not returned to Olympus Medial Systems Corp. (OMSC). The exact cause has been under investigation. There was no report of patient injury associated with the event. A supplemental report will be submitted if additional or significant information becomes available later. This is the first of the two reports.

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

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

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

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

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

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

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

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

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

patient injury associated with the event. If additional information becomes available, this report will be supplemented.

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

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

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

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

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

A report in the FDA's **MAUDE** database states the user found a clip in the suction channel of the Evis Lucera Colonovideoscope CF-H260DL, which had been reprocessed at the preparation for use. It was also reported the scope was used in the unspecified procedure, left overnight, and reprocessed the next morning. The hemostasis clip (Nova clip) came out from the scope during manual cleaning. The scope was used for one or possibly two patients. Then another clip came out from the scope. However, no clips were used during the procedures in the endoscopy. The scope was not returned to OMSC but returned to the service department of Olympus for evaluation. The service department checked the instrumental and suction channels of the scope, but nothing was found as the user reported; even inside the channel was checked using the thinnest industrial videoscope. No damage and blockages could be found with the channels and no clips were present. No report of patient injury associated with this event. The exact cause of the reported event could not be conclusively determined at this time. If additional information is received, this report will be supplemented.

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

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

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

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

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

A report in the FDA's **MAUDE** database states while preparing for a procedure, an EVIS Exera II Gastrointestinal Videoscope GIF-2TH180 was pulled from the cabinet and there was blood dripping from it. The scope was reprocessed the day before and was not used on any other patients. It was stated at times, a scope would be reprocessed and when moved from the washer to the transfer case, debris would leak out of it, at which time the scope was reprocessed.

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

training to correct and address any reprocessing deviations. Also, the ESS sent delayed reprocessing instructions and the correct connection information when using and OER-Pro. The scope was not returned for evaluation, so the scope evaluation could not be completed at this time. The investigation is ongoing.

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

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

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

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

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

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

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

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

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

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

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

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

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

On February 23, 2021, an ESS was dispatched to the user facility to observe the facility's reprocessing practices and provide an in-service. During training a manager from the user facility timed the process starting from the precleaning until the high-level disinfectant (HLD). The ESS was informed by the manager the staff does not perform any precleaning or hanging of the

scopes. The ESS observed the scopes are set in a distilled water basin (after the HLD and rinse) with the tip submerged in the distilled water for up to an hour before it is used again. It is unclear how often the water was changed. The ESS reported the reprocessing issues were discussed with the facility's manager. The manager informed the ESS that the problems with the cleaning and reprocessing of the scopes will be discussed with the doctor. The scope will not be returned to the service center for evaluation. The investigation is ongoing, and, therefore, the root cause of the reported event cannot be determined at this time. If additional information becomes available this report will be supplemented accordingly.

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

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

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

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

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

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

- Leak testing was conducted without operating the far end
- Detergent was used during the leak test

- During manual cleaning, compatible detergents were not prepared as recommended by the manufacturer and water was not filled to the fill line
- The diameter of the cleaning brush may not fit the channel because it did not use the sponge or the cloth without thread scraps
- Flushing by syringe was not done.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A report in the FDA's **MAUDE** database states the user facility reported to Olympus that they had utilized expired Acecide disinfectant in the endoscope reprocessor OER-PRO. The facility has a five-day limit on the usage of the disinfectant, but they utilized the reprocessor with the expired disinfectant on day six. Although the disinfectant was expired, the reprocessed scopes passed efficacy checks. One of the reprocessed scopes was used on a patient, which was reported on related MedWatch 8010047-2020-05979. The facility reported to Olympus that (to their knowledge) no patient injury or infection resulted from this event. The other scopes that were reprocessed with the expired disinfectant were reprocessed again with unexpired disinfectant. An Olympus Endoscopy Support Specialist (ESS) had a meeting with the endoscopy nurse manager to provide staff training on proper reprocessing and changing Acecide on or before day five of the validation. The device history record was reviewed, and it was verified the device was manufactured in accordance with documented specifications. A Corrective and Preventative

Action(s) (CAPA) has been opened to manage the actions related to remediation of this issue and any required Medical Device Reporting (MDR). The device was not returned.

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

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

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

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

9.Gram Negative Bacteria Outbreak

9.1 The HFH team was notified of an NDM (New Delhi metallo-beta-lactamase 1) in one inpatient that matched the strain of another patient at another facility in July, September 2021

The State notified the HFH team of an NDM (New Delhi Metallo-beta-lactamase 1) producing *E. coli* strain in one of their patients that matched the strain of another patient tested at a different facility in July. During the investigation, the other patient was a previous patient at HFH. HFH started investigating the week of September 27. Worked with lab to see if this organism was identified in any other patients at HFH. Three (3) other patients at HFH identified with NDM producing *E. coli*. Chart reviews began to find any commonalities between the five (5) patients. One of the commonalities discovered was that all patients had endoscopic retrograde cholangiopancreatography (ERCP). One ERCP scope appeared to be common. The scope was sequestered, and the State was updated. The State requested the other three isolates be sequestered.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12736742&pc=FDT

9.2 A duodenovideoscope was of potential inspection after being notified by the Maine CDC that they were dealing with a CRE organism with three patients testing positive, September 2021

The customer reported the Olympus the EVIS Exera II Duodenovideoscope TJF-Q180V was a scope of potential infection after being notified by the Maine Center for Disease Control (CDC) that they were dealing with a *Carbapenem-resistant enterobacter* (CRE) organism. The scope was cultured by the customer in 2020, and three (3) times in 2021. In 2021 the scope was tested after a known CRE case. The scope tested negative after each culture in 2020 and three (3) different times in 2021. The epidemiologist was made aware of a cluster of patients that were infected over one (1)-year ago with CRE (highly resistant CP-CRE organism). A "few patients" tested positive; however, the reprocessing department was never informed. The reprocessing department was instructed to pull the scope out of service in 2021. The scope was cultured in 2021 after it had been disinfected numerous times as the patient infection occurred in July 2020 and the culture was negative. The customer further reported that they had three (3) patients who had been examined by this scope and were genetically identical *E. cloacae*.

First report (2951238-2021-00417)

Patient number one (1) of three (3) was diagnosed with *Klebsiella pneumoniae* carbapenemase (KPC) producing *Enterobacter cloacae bacteremia* 10 days after an unknown procedure using the scope referenced in this report. The patient required intensive care services for sepsis and required several interventional radiology (IR) drains to drain infected pus from unknown abscess sites that tested positive for KPC-*Enterobacter cloacae, Enterococcus faecali*s, and *Streptococcus anginosus*. The patient is currently alive. No further information was provided by the customer regarding the patient's current condition.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12547817&pc=FDT

Second report (2951238-2021-00421)

Patient number two (2), who is a female with a medical history of pneumonia, hypertension, hypothyroidism, paroxysmal atrial fibrillation, and peptic ulcer disease. The patient was scoped twice in 2020 with the scope for biliary obstruction and cholangioca. The patient was later diagnosed with sepsis after her blood was cultured and tested positive for KPC-E. cloacae in 2021. The patient received IV antibiotics for sepsis and her status is reported as living.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12557860&pc=FDT

Third report (2951238-2021-00422)

Patient three of three, who is a female with a medical history of anemia, biliary obstruction, type 2 diabetes mellitus (on insulin), a gastrointestinal hemorrhage, coronary artery disease, transaminitis and hyponatremia. The patient was scoped in 2020 for a gastrointestinal hemorrhage and an abnormal cat scan of the pancreas showing a mass at the tail. The patient was

diagnosed with an infection after her gallbladder culture was positive for *Klebsiella pneumoniae carbapenemase* (KPC)-producing *Enterobacter cloacae* in 2021. She was treated with intravenous antibiotics and her reported status is living.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12558238&pc=FDT

Patient	Sex	Scope Procedure	Medical History	Infection Type(s)	Medical Care	Status
1	Unknown	Unknown	Unknown	• KPC-*Enterobacter cloacae* • *Enterococcus faecalis* • *Streptococcus anginosus*	• Intensive care services for sepsis • Required several IR drains from unknown abscess sites	In 2020, patient was living. Unknown current condition.
2	Female	• Biliary obstruction • Cholangioca	• Pneumonia • Hypertension • Hypothyroidism • Paroxysmal atrial fibrillation • Peptic ulcer disease	Sepsis/ KPC-E. cloacae	IV antibiotics for sepsis	Living
3	Female	• Gastrointestinal hemorrhage • Pancreatic mass on tail	• Anemia • Biliary obstruction • Type-2 Diabetes mellitus (on insulin) • Gastrointestinal hemorrhage • Coronary artery disease • Transaminitis • Hyponatremia	*Klebsiella pneumoniae carbapenemase* (KPC)-producing *Enterobacter cloacae*	IV antibiotics	Living

9.3 Six gastroenterology patients have been diagnosed with the same strain of CPPA in a six-month period, July 2021

This is the first of six reported in case with patient identifier in the FDA's **MAUDE** database states: the customer reported after being notified by the state board of health, a cluster of six gastroenterology patients have been diagnosed with the same strain of carbapenemase-producing *Pseudomonas aeruginosa* (CPPA) during a six-month period. All six patients were found to have undergone procedures using the same EVIS Exera III Gatronintestinal Videoscope GIF-1TH190.

1) Patient one's case:

Two days after an esophagogastroduodenoscopy (EGD) with an EVIS Exera III Hastrointestinal Videoscope, the patient had sputum culture results showing: *P. aeruginosa*, carbapenem-resistant (carbapenemase-producer). The patient required unspecified treatment due to the infection. The indication for the EGD was upper gastrointestinal (UGI) bleeding, which was not active at time of the exam. However, a nodule with erosion was noted and clipped. The patient's history was significant for:

- Open sternal wound infection.
- Prosthetic valve endocarditis.
- Aortic root debridement then replacement of automatic implantable cardioverter defibrillator (AICD).
- Congestive heart failure (CHF).
- Anemia.
- Paroxysmal atrial fibrillation.

The patient's current condition: Deceased.

The patient's cause of death is not known to be associated with the device at this time. Cause of death has been requested but not provided at the time of this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12180700&pc=FDS

2) Patient two's case:

Eight days after an endoscopic ultrasound (EUS)/esophagogastroduodenoscopy (EGD) with stent placement (using an EVIS Exera III Gastrointestinal Videoscope GIF-1TH190), the patient had blood culture results showing: *P. aeruginosa*, Carbapenem-resistant (carbapenemase-producer). The patient required unspecified treatment due to the infection. The indication for the procedure was: a.) malignant tumor of the head of pancreas, b.) gastric outlet obstruction, c.) duodenal stenting, and d.) staging of malignant ascites. The patient's history was significant for:

- Metastatic pancreatic adenocarcinoma
- Gastric outlet obstruction
- Diabetes mellitus (DM)
- Vancomucin resistant enterococcus (VRE) bacteremia (Admission from hospice care).

The patient's current condition: Deceased.

The patient's cause of death is not known to be associated with the device at this time. Cause of death has been requested, but not provided at the time of this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12180793&pc=FDS

3) Patient three's case:
Twenty-two days after an upper gastrointestinal (GI) endoscopy/fluoroscopy using an EVIS Exera III Gastrointestinal Videoscope GIF-1TH190, the patient had urine culture results showing: *P. aeruginosa*, carbapenem-resistant (carbapenemase-producer). The patient required unspecified treatment due to the infection. The indication for the procedure was suspected post-surgical (Whipple) anastomotic stenosis vs. neoplastic obstruction. The procedure disclosed acute angulation without obstruction. No endo therapy was employed. The patient's history was significant for:
    - Pancreatic cancer.
    - Diabetes mellitus (DM).
    - Hypertension.
    - Cirrhosis of liver.
    - Hemochromatosis (hereditary).
    - Anemia.
    - Poor oral intake.

    The patient's current condition is reported as at home.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12180856&pc=FDS

4) Patient four's case:
Two days after esophagogastroduodenoscopy (EGD) using an EVIS Exera III Gastrointestinal Videoscope GIF-1TH190, the patient had sputum culture results showing: *P. aeruginosa*, carbapenem-resistant (carbapenemase-producer). The patient required unspecified treatment due to the infection. The indication for the procedure was melena, presumed upper gastrointestinal (UGI) bleed. The EDG identified a large duodenal ulcer (DU) requiring interventional radiology (IF) embolization. The patient's history was significant for:
    - Diabetes mellitus (DM) infected foot ulcer.
    - Sepsis.
    - Hypertension.
    - Gastrointestinal hemorrhage.

    The patient's current condition is reported as "at home."

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12180999&pc=FDS

5) Patient five's case:
Seventeen days after esophagogastroduodenoscopy (EGD)/upper gastrointestinal (UGI) procedure using an EVIS Exera III Gastrointestinal Videoscope GIF-1TH190, the patient had bronchial alveolar lavage (BAL) culture results showing: *P. aeruginosa*, carbapenem-resistant (carbapenemase-producer). The patient required unspecified treatment due to the infection. The indication for the procedure was management of a.) anastomotic fistula, b.) gastropleurobronichial fistula, and c.) nausea with vomiting. The procedure was most recently performed in 2021 (the patient had numerous procedures). The patient's history was significant for:

- Lymphoma.
- Malignant neoplasm of the esophagus-s/p (Ivor Lewis procedure) complicated by gastro-pleural-bronchial fistula with intrahepatic abscess.
- Adult respiratory distress syndrome (ARDS).

The patient's current condition: Deceased.
The patient's cause of death is not known to be associated with the scope at this time. Cause of death has been requested, but not provided at the time of this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12181035&pc=FDS

6) Patient six's case:
Seven days after esophagogastroduodenoscopy (EGD) using an EVIS Exera III Gastrointestinal Videoscope GIF-1TH190, the patient had sputum culture results showing: *P. aeruginosa*, carbapenem-resistant (carbapenemase-producer). The patient required no treatment due to the infection. The indication for the procedure was an exchange of direct percutaneous endoscopic jejunostomy (DPEJ) with placement of retrograde vacuum catheter through the fistula. The procedure (six in total over 18 months) was most recently performed in 2021. The patient's history was significant for:

- S/P roux-en-y gastric bypass (RYGB).
- Malnutrition.
- End-stage renal disease (ESRD) dialysis dependent.
- Bronchoesophageal fistula.
- Pleural abscess.

The patient's current condition is reported as "at home."

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12181158&pc=FDS

In all of six reported cases, the customer verified there was no malfunction of the Olympus scope during the procedure. The customer reports, after becoming aware of these events, the scope was immediately quarantined. The suspect scope was cultured, and all cultures were negative for *P. aeruginosa*. The customer also reports the suspect scope was carefully examined with no

abnormalities noted. No breaches were found from standard high-level disinfection (HLD) processes.

9.4 Six cases of urinary tract infection after cystoscopy procedures using cystoscopes had been identified, July 2021

A report in the FDA's **MAUDE** database states several patients were infected.

Six patient cases of urinary tract infection after cystoscopy procedures using cystoscopes CYF-5 had been identified as follows:

- 5 *Pseudomonas aeruginosa* infections
    - 4 required hospitalizations
    - 2 presented bacteremia
    - 1 required intensive care
- 1 with a Proteus mirabilis infection required hospitalization (possible endogenous patient flora).

There were no deaths resulting from the infections and all patients had been discharged from the hospital.

The correspondence between infected patients and used cystoscopes (cyf-5) was as follows:

- Three cases of infection without knowledge of the used cystoscopes (two procedures performed and one procedure performed); with one case of *Pseudomonas aeruginosa* infection.
- Another procedure performed with one case of *Pseudomonas aeruginosa* infection after using a cystoscope with a different serial number.
- The results of microbiological tests, performed by the user facility, on used cystoscopes were as follows:
    - Tests performed before cystoscopy procedures (serial numbers not shown in report)
    - *Pseudomonas aeruginosa*
- The other four cystoscopes:
    - No microbes were detected
    - Cystoscopes were sterilized.
- Other cystoscopes (serial numbers not shown in report) had microbes were found:
    - *Stenotrophomonas maltophilia*
    - *Pseudomonas aeruginosa*
    - *Pseudomonas luteola*
    - *Stenotrophomonas maltophilia*.
- Three other cystoscopes (with serial numbers not shown in report):
    - No microbes were detected
    - Cystoscopes were sterilized.

Other cystoscopes had been manually reprocessed using peracetic acid and reprocessed with a non-Olympus AER, Sterado. The user facility performed the microbiological test of sample collected from the examination room—where the procedures had been performed—and no bacteria was detected. The user facility was using an Olympus irrigation plug MAG-891.

The scope was not returned to any Olympus locations. Therefore, Olympus could not investigate the cystoscope. OMSC could not confirm the manufacturing history (DHR) of the scope because the serial number was unknown. Based upon information from Olympus, OMSC surmised the reported event was caused using the cystoscope with bacterial residue to patients. It was also surmised that since the validity of the reprocessing methods of the cystoscope at the user was confirmed, the cause of the bacterial residue was not attributed to the cystoscope. The results of the of the microbiological tests performed by the user facility in 2021, showed no microbes were detected on any cystoscopes (CTY-5), so it was also surmised that inappropriate reprocessing just before this event might have resulted the bacterial residue on the cystoscope. 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. This report is regarding CYF-5; serial number unknown (2 of 3).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12107963&pc=FAJ

9.5 A facility has linked patient infections to the Ultrasonic Bronchofibervideoscope, June 2021

A report in the FDA's **MAUDE** database states the facility has linked patient infection(s) with the EVIS Exera II Ultrasonic Bronochofibervideoscope BF-UC180F. The customer reports that the scope is out of service and will be sent to Olympus for evaluation and culturing. Additional details regarding the scope and reported event(s) have been requested from the customer, but at this time no information has been provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=12089150&pc=PSV

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

A report in the FDA's **MAUDE** database states the user facility commented that five Lucera Bronchovideoscope BF-F260 were possibly infected with *Klebsiella*. The physician at the facility operated a procedure using these endoscopes for some of the patients. The user facility did confirm that a patient was infected with *Klebsiella*. The source of the infection and the number of infected patients is unknown. Information (i.e., the reprocessing method) was not provided. The endoscope has not been returned to Olympus Medical Systems Corp. (OMSC) for evaluation. The exact cause of the reported event could not be conclusively determined at this

time. OMSC is submitting five medical device reports according to the number of infected endoscopes. This is one of five reports.

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

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

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

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

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

A report in the FDA's **MAUDE** database reports the attending physician reported nine patients were examined by the same Cysto-nephro Fiberscope CYF-5. The patients' urine samples were cultured and an ESBL and *E. coli* had been recovered and the patients were treated with antibiotics. The physician stated some of the patients have had a) urine retention, b) hematuria, c) septic issues, and d) UTI after the procedures, which triggered him to have the urine cultured. The cystoscope was returned to Olympus for evaluation to see if there had been any damage to the scope. It was reported the scope has been manually reprocessed and soaked in Cidex® OPA. The user facility did report there had been no cultures performed prior to returning the scope to Olympus. The scope was sent to an off-site lab for microbiological testing. As part of the investigation, an ESS was sent out to visit the user facility to perform a scope reprocessing and infection control in-service for the staff. The ESS covered infection control information referenced in the manual and reprocessing manual. The ESS also requested the staff to show him each step in the use and reprocessing of the scope. The ESS observed the staff was not currently:

a) using correct transport bins; b) precleaning; c) leak testing after each case; d) reprocessing stopcock; e) replacing saline bag or irrigation tubing between each case; f) reprocessing reusable brushes; g) soaking scope in detergent for recommended amount of time; h) properly rinsing the scope. The ESS communicated the findings to the facility staff and provided a list with recommended proper reprocessing techniques, proper handling, and storage of the scope.

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