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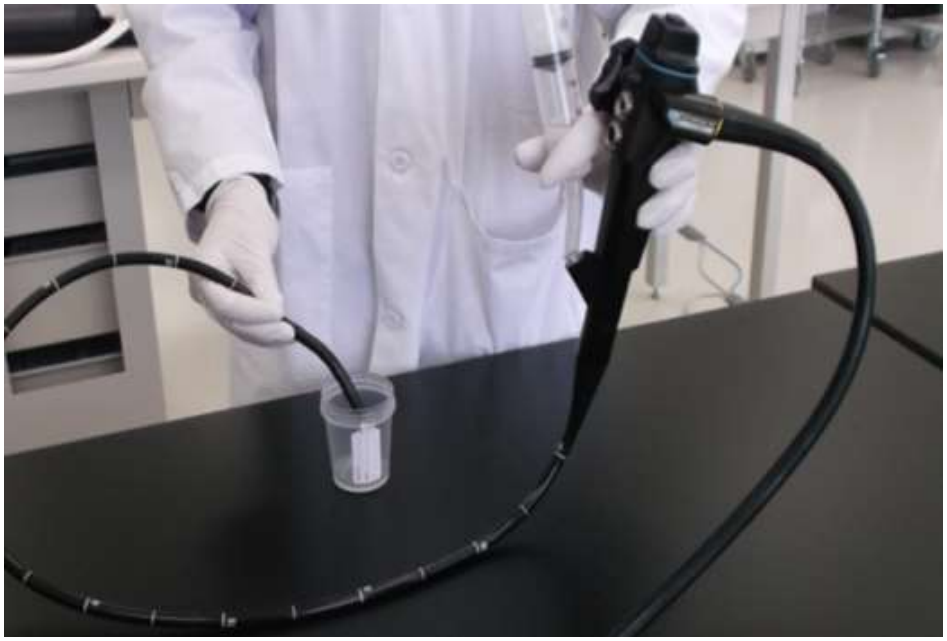
Flexible Endoscope Incident Report

October 2019

Volume II



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

1.Failure of Visual Inspection

1.1. After a procedure, patient was experiencing pain and a scratching of the throat from the Rhino-Laryngofiberscope, August 2019

A report in the FDA's **MAUDE** database states there was a tear at the bottom of the scope causing the patient pain and scratching of the throat. The Fiberscope "ENF-P4" Rhino-Laryngofiberscope ENF-P4 was returned to the manufacturer and an evaluation was conducted. A microscope was used for visual inspection on the scope and note that the bending section cover glue was bumpy and lifted. It was rough to the touch when tactile force was applied. The bumpy/lifted bending section cover glue was most likely what the patient was experiencing. There were scratch mark streaks on the bending section cover glue. Also, the bending section cover was noted to be stretched causing it to overlap with the distal end tip. There was no evidence of tears and passed the leak test.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8865103&pc=EOB

1.2. A scope came apart while in a patient during an unspecified procedure, July 2019

A report in the FDA's **MAUDE** database states during an unspecified procedure, the EVIS Exera II Colonovideoscope CF-H180AL came apart while in the patient. It is unknown if the intended procedure was completed. A follow up the facility via telephone and in writing to obtain additional information was performed but with no result. A visual inspection was performed on the scope when returned to the service center for evaluation. During visual inspection it was

found that the bending section broken near the insertion tube side. It is completely separated for the insertion tube revealing the internal elements, which include the cdd, light guide bundle, channels and angle wires. The non-manufacturing bending section cover is torn and fully detached form the bending section cover glue which is also non-manufacturer. The insertion tube is also non-manufacturer. The likely cause of the bending section become detached is due to non-manufacturer parts and repairs. The instruction manual does warn users as repair performed by person who are not qualified by Olympus could cause patient or user injury and/or equipment damage.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8760651&pc=FDF

1.3. Patient had a mucosal tear when the scope was removed during a Colonoscopy procedure, July 2019

A report in the FDA's **MAUDE** database states the physician reportedly observed a mucosal tear upon removing the EVIS Exera III Colonovideoscope PCF-H190L. The patient experienced discomfort despite additional sedation. The physician applied clips and proceeded to come out of the colon to finish the procedure. It was noted that there was redness on the colon wall. At bedside cleaning, the nurse found a complete separation of the rubber near the distal end of the scope, exposing wires and metal sheath. The scope was returned to the manufacturer and a visual inspection was performed and found the bending section cover at the distal end was torn at the joint section between the bending section and the passive bending section; the torn bending cover is partial missing. The bending section was found detached and the internal elements were exposed. Foreign materials residing on a screw, sharp metal edge lifting on the passive bending section joint end, and excessive broken/frayed wires on the bending mesh. There was evidence of 3rd party parts assembled onto the scope by an unauthorized repair. Insertion tube, light guide tube, light guide lens, light guide bundles, bending cover and bending cover adhesive. The passive bending section and the bending section were assembled by 3rd party. Based on the evaluation, the unauthorized 3rd party repairs and parts can contribute to the reported event as 3rd repairs/parts can compromise the functionality of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8846032&pc=FDF

1.4. A piece of tissue from the biopsy channel fell into the patient during an unspecified procedure, July 2019

A report in the FDA's **MAUDE** database states that during an unspecified procedure, a piece of tissue from the biopsy channel of the EVIS Exera III Gastrointestinal Videoscope GIS-H190 fell into the patient and the tissue was retrieved. The doctor and nurse were unable to determine if the tissue was from the current of previous procedure. On May 16, 2019 an ESS was dispatched to the user facility to provide an in-service to the reprocessing staff. The ESS reminded the user that the IFU instruction states to confirm that the endotherapy accessory extend smoothly from the distal end. The scope was not returned to the service center for evaluation. The cause of the event cannot be determined. There was no injury to the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8687563&pc=FDS

1.5. During an Ureteroscopy, user facility had trouble angulating the Uretero-Reno Videoscope and retrieval from the patient, July 2019

A report in the FDA's **MAUDE** database states Olympus was informed that during an Ureteroscopy of the left kidney. The motion of the bending section of the Uretero-Reno Videoscope URF-V3 was blocked twice with the distal end angulated. The facility experienced difficulty in the retrieval of the scope. The scope was retrieved using a Non-Olympus guidewire.

The scope was returned to Olympus France and evaluated the scope and did confirm the curve of the bending section was not smooth. Also, a part for guiding of angulation wire was unstuck from the bending section tube after disassembling of the bending section tube. The instrument channel was kinked at the same location when the cable support was unstuck. OMSC confirmed no irregularity when reviewing the manufacturing history of the scope. The exact cause of the event could be not conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8835041&pc=FGB

1.6. There was resistance when pulling the Naso-Pharygno-Laryngoscope out from the nose of the patient, July 2019

A report in the FDA's **MAUDE** database states a reported complaint on June 25, 2019 that occurred when pulling the Pentax Nasopharyngolaryngoscope VNL-1570STKout from the nose

of the patient, the doctor found it was hard to pull out and after doing so the doctor found there was a little blood inside the patient's nose . the patient felt a bit of pain and medication was applied. The distributor visited the hospital and detailed the events that the doctor used the scope on the patient. The doctor did notice the surface on the bending rubber was broken. Photos were provided by the facility and contacted the distributor of the damaged scope. The distributor documented the scope was not inspected prior to use and did not have leak testing done prior to usage. Also, the facility has not been performing inspection, leak testing daily maintenance. On April 4, 2019 Pentax medical made a major repair of the scope replacing an aging venting connector, light prong, pve connector, lcb and body cover grip. The scope was repair and returned to the customer.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8805112&pc=EOB

1.7. Pieces' of the Laryngoscope fell into pieces of a patient's mouth, July 2019

A report in the FDA's **MAUDE** database states the customer complaint alleges the MAC 3 Laryngoscope, Rigid 004551003 fell into pieces while being used on a patient. All the pieces were retrieved from the patient's mouth. The patient was not harmed and is in stable condition.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8889566&pc=CCW

1.8. A hemostasis clip from previous day was expelled into colon of patient, June 2019

A report in the FDA's **MAUDE** database states while using the Colonoscope CF-HQ190L the hemostasis clip from previous day was expelled into colon of patient. The scope had been cleaned and reprocessed per manufacturer recommendations and hospital policy, yet hemostasis clip remained in the scope channel until next use.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8802866&pc=FDF

1.9. Something like patient tissue came out of the Gastroscope at the same time forceps came out of the working channel, June 2019

A report in the FDA's **MAUDE** database states the OMSC was informed that something like patient tissue came out of the EVIS Exera III Gastrointestinal Videoscope GID-HQ190 at the same time the forceps came out of the working channel. The patient was tested for Hepatitis B, Hepatitis C and HIV and confirmed all negative. The scope was not returned to OMSC. During the evaluation the: Ccd lens scratched, Lg/ccd lens adhesive wear and tear, distal end cover scratched, bending section scratched and slightly kinked, instrument channel kinked. The exact cause could not be determined. There was no injury to the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8742783&pc=FDS

1.10. The single use distal cover detached from the Duodenovideoscope fell into the patient's stomach, June 2019

A report in the FDA's **MAUDE** database states that the single use distal cover detached from the subject device fell into the patient's stomach during the biliary catheterism. The distal cover was retrieved from the patient body using unspecified fiberscope and foreign body extractor. The admission time of general anesthesia for the patient was prolonged and no report of further patient injury with the event. It was reported the distal cover was not kept by the user facility. The facility had asked Olympus to provide training on how to install the distal cover. On February 22 and Mach 1, 2019, Olympus representative visited the user facility for training. During the training, Olympus representative concluded that the user facility did not attach the distal cover to the subject device properly. The scope 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=8730287&pc=FDT

1.11. The ring and shaft from the Laryngoscope detached and fell into the patient's cavity, May 2019

A report in the FDA's **MAUDE** database states during a laparoscopic procedure, the ring and shaft of the Endo Catch Gold Laryngoscope, Endoscope 173050G detached and fell into the

patient's cavity and was retrieved. Another bag was used for retrieval of the specimen. There was no injury to the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8624105&pc=GCI

1.12. Monarch aspirating biopsy needle was difficult to keep extended to obtain biopsies, the needle popped off into the wall of the patient's airway, May 2019

A report in the FDA's **MAUDE** database states an EBUS scope was used first to obtain fine needle aspiration samples from lymph nodes. On site pathology could not confirm diagnostic cells from these samples. The Robotic Bronchoscope was set up and the Pulmonologist navigated to the lesion in the right lower lobs of the lung. Several samples were obtained using the Monarch Aspirating Biopsy needle 24 ga. The needle was visualized coming out of the scope but was difficult to keep extended. The pressure from the airway wall was pushing it back into the sheath. The needle popped into the wall of the airway. No additional pressure added besides extending the needle with the turn dial. Six passes with the needle were done and visualized the broken needle on Fluoroscopy. The Robotic Bronchoscope was removed and a flexible Bronchoscope was used to attempt to visualize the needle in the airway. With several attempts, using Fluoroscopy they were unable to visualize the needle. The patient was extubated and transferred to the PACU and discharged the same day.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8764086&pc=EOQ

1.13. Three to four attempts were taken to obtain a third biopsy sample with a Bronchoscope but suspected the needle had detached inside the patient, May 2019.

A report in the FDA's **MAUDE** database states during the physician's third or fourth attempt to obtain a third biopsy sample with the Aspirating Biopsy Needle Bronchoscope. It was suspected that the needle had broken when the physician encountered difficulty obtaining the sample. The staff used a Fluoroscopy and confirmed the tip of the needle had detached inside the patient. The physician retracted the scope which brought the needle tip back the patient's trachea where it fell out of the scope into the trachea. A Non-Auris Bronchoscope was used to retrieve the needle tip from the trachea.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8660822&pc=EOQ

1.14. A black plastic piece came out of the Bronchovideoscope and fell into the patient's lobes of their lung, May 2019

A report in the FDA's **MAUDE** database states that during in unspecified procedure a black plastic piece came out of the EVIS EXERA III Bronchovideoscope BF-XP190. The facility reported the piece had disappeared off the screen and could not be removed. It was reported from the user facility the patient did not suffer any injuries. The scope was not returned to OMSC for evaluation. The manufacturing history was review for this device and confirmed no irregularity. The reported event could not be conclusively determined what the exact cause was.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8653265&pc=EOQ

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

A report in the FDA's **MAUDE** database states the user facility aborted a therapeutic procedure since the insertion tube was bent and they could not withdraw the Cysto-Nephro Videoscope CYF-VA2 from the stenosis in the patient's urethra. The scope was removed from the patient by cutting the insertion tube of the scope and inserting a metal rod into the urethra to straighten the bent insertion tube.

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

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

A report in the FDA's **MAUDE** database states that an Olympus Endoscopy Support Specialist conducted observations with bronchoscopes being used in procedures and found a damaged scope was not removed from rotation and was used on a patient in an unspecified diagnostic procedure. The scope was damaged with a missing bending section glue (showing separation from the insertion tube). The ESS provided instructions to the user facility to perform an inspection of their scopes and on what to look for prior to using in procedures. No information was obtained when Olympus followed up with the user facility for detailed information regarding the reported event and reprocessing of the scope. The scope was returned to Olympus for evaluation and was confirmed that the entire bending section cover glue at the

insertion tube side was missing on the scope. The scope failed a leak test with a heavy dent on the bending section. Due to the leak it also caused the electrical continuity test failure. The scope was purchased on August 23, 2014 and last repaired on October 22, 2018. The missing bending section cover glue cannot be confirmed.

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

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

A report in the FDA's **MAUDE** database states that Pentax of American initiated a field correction which included inspection of the suction arm on affected models pursuant to predefined inspection criteria. This was to locate part C255-AB171 (suction arm) and verify it is not loose. If it is found to be loose, the device was considered to fail the inspection criteria. On March 14, 2019 the device was returned to Pentax from a customer and inspection was performed on March 18, 2019 where the quality control inspector found the following: suction arm loose, insertion tube non-Pentax material, leak at pve connector, failed wet leak test, umbilical cable non-Pentax material, up/down brake lever cracked, distal body chipped, up/down control knob/lever cracked, lightguide prong scratched/pitted, failed dry leak test, lightguide prong cover glass set scratched, light carrying bundle broken, lightguide prong cover glass set dented, chemical residue buildup on control body, primary operation channel resistance, ccd circuit board poor solder technique, hole in #2 remote control button cover, image blackout. The inspection of the suction arm was performed, and the device failed the inspection criteria. The part that were replaced: o-rings and seals, distal end with cc-m pb-free/ntcs, insertion flex tube with seg pb-free, bending rubber, distal attaching pin, segment steel braid, light guide cable, electrical connector assy, light guide prong imp-1, large prong insulation ring, large prong attaching nut, light guide prong washer imp-1, large cover glass set (lens type), friction lever assy, angle lever assy, insertion/s-nipple attaching screw, suction connection tube.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8497605&pc=EOQ

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

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

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

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

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

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

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

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

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

1.21. During an Endobronchial ultrasound procedure, there was a visible break noted at the distal tip on the Bronchofibersvideoscope, March 2019

A report in the FDA's **MAUDE** database states that Olympus was informed that during an Endobronchial ultrasound procedure, and after sampling was performed, there was a visible break noted at the distal tip on the Bronchofibervideoscope BF-UC180F. To obtain more information, Olympus followed up via telephone and in writing regarding the scope, procedure and patient involved but no information was obtained. The scope was returned to Olympus for

evaluation and confirmed the scope has a break on the bending section area near the distal tip. Visual inspection on the scope found the bending section separated approximately 25mm from the distal end; there are no signs of impact (dents). A small portion of the bending section cover is missing at the same location where the separation of the bending section has occurred. The separation of the bending section produced sharp edges from the exposed bending section skeleton. The balloon channel was also detached from the distal end and both the ccd unit and light guide bundle have visible kinks. The image was observed to have excessive ig breakage with very dim light when the image was displayed on the monitor. This can be attributed to excessive force (pulling) is applied to the distal end or bending section.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8436918&pc=PSV

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

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

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

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

A report in the FDA's **MAUDE** database states that Pentax of America initiated a field correction that included inspection of the seal around the distal body and distal cap of the Duodenoscope ED-3490TK pursuant to predefined inspection criteria. The objective was to verify there were no defects/discontinuities in the seal between the distal body and distal cap. The customer device was previously returned to Pentax medical from a customer on February 6, 2019 and

inspection of the unit was performed on February 11, 2019 where the quality control inspector found the following: distal tip-fixed types failed seal integrity inspection, operation channel twisted in bending section, failed dry/wet leak test, lightguide prong cover glass set loose, bending rubber pinhole, umbilical cable single buckled under pve root brace, operation channel-primary slice by accessory.

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

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

A report in the FDA's **MAUDE** database states during a diagnostic Colonoscopy the doctor noticed minor bleeding near the proximal sigmoid. The EVIS Exera LLL Colonovideoscope CF-HQ190L was partially withdrawn several centimeters and the doctor observed that the patient's mucosa was lacerated in three areas. The doctor stopped the procedure and upon completely withdrawing the scope, the doctor observed its bending section was torn open with exposed metal coils. There were no sharp instruments inserted into the scope at any point of the procedure. No additional treatment or hospitalization was required for the patient, the intended procedure was completed with a similar device. It is unknown if the scope was inspection prior to use. The scope was sent back to Olympus for evaluation and a visual inspection was performed and found 1 cm of the scope's bending section cover is torn off and missing but the missing bending section was not returned. The bending section is detached from the insertion tube side causing the elements inside to be exposed. The screw that holds the bending section together is missing which attributed to the detachment of the bending section and was noted to be stripped. There were non-Olympus repairs identified with the distal end, bending section cover, bending section cover glue, the objective lens glue and light guide lens glue. This is most likely what caused the torn bending section cover and detached bending section.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8438810&pc=FDF

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

A report in the FDA's **MAUDE** database states during a Colonoscopy procedure with biopsy, the user facility reported that a foreign tissue was pushed out of the biopsy channel at the distal end of the scope before patient's tissue was biopsied. The nurse did not see the foreign tissue fall into the patient but was uncertain if the foreign tissue was suctioned or where it went. A visual inspection was performed by Olympus and found kinks noted on the suction channel and at the instrument channel wall from the distal end area. There were no signs of foreign objects/materials inside the instrument/suction channel. The cause of the kinks is potentially due to handling from excessive force applied to the scope. A review of the EXIS Exera III Colonovideoscope PCF-H190DL history indicates the scope was purchased on August 9, 2015 and last repaired on February 15, 2019. There was no patient injury reported.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8463180&pc=FDF

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

A report in the FDA's **MAUDE** database states that during an unspecified endoscopy procedure using the EVIS Exera III Gastrointestinal Videoscope GIF-H185, the user facility found a brush head came out from the scope and fell off within the patient. The brush head was safely removed from the patient and no injury associated with this report. The scope was reprocessed with a Non-Olympus AER, Wassenburg. The facility reported that the scope was used the day before the procedure without any problem and the brush head was not from the brushes used by the user facility. The scope was not returned to OMSC for evaluation but review the manufacture history of the device and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8415543&pc=FDS

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

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

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

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

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

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

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

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

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

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

A report in the FDA's **MAUDE** database states that during an Esophagogastroduodenoscopy (EGD) procedure, pieces of a reprocessing brush fell out of the scope into the patient. The fragments were retrieved using a basket and forceps. No additional bleeding observed, and the procedure was completed with the same device with no patient injury reported. The EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 was returned to Olympus for evaluation and a borescope was used to inspect the biopsy channel for any objects or foreign material within, the evaluation did not locate any foreign material inside the biopsy channel. However, Multiple kinks inside the channel starting at 20cm up until the 40cm mark from the bending section. The scope could not be leak tested since it had already been opened by estimation. The quality inspection results noted the scope passed the water dunk test.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8380633&pc=FDS

2. Cleaning Verification Testing

2.1 A sixth patient involved in the event of a Duodenoscope testing positive for Klebsiella spp., CPE New Delhi Metallo-Beta-Lactomase, July 2019

A report in the FDA's **MAUDE** database states that a sixth patient involved in the event with an EVIS Exera Duodenoscope TJF-160VR that tested positive for Klebsiella spp., CPE and New Delhi Metallo-Beta-Lactomase or Klebsiella pneumoniae after a procedure using the scope between February 8th and February 20, 2019. Five other patients tested positive also when samples were collected. Olympus reviewed the service history for the subject device. Olympus subsidiary had received the subject device for repair from the user facility in March 2019 before aware of the reported event. The evaluation results of the scope are as follows; there was air leakage from the distal end. The instrument channel had worn and scratches. The adhesive on the rubber of the bending section had wear and tear. The distal end had scratches and the also on the light guide lens. The scope has not been returned to OMSC for evaluation. OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time. OMSC is submitting one initial MDR for the sixth patient and five follow-up MDRs for the rest of the patients. This is the initial MDR for the sixth patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8820754&pc=FDT

2.2 A Duodenoscope failed ATP monitoring during reprocessing, May 2019

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

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

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

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

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

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

A report in the FDA's **MAUDE** database states the Olympus was informed that the samples collected from five patients were tested positive for Klebsiella spp., CPE, New Delhi metallo-beta-lactamase or Klebsiella pneumoniae after a procedure using an Olympus Evis Exera Duodenovideoscope TJF-160VR in 2019. First patient underwent a procedure for replacement

of prosthesis after a migration using the device in 2019. Klebsiella spp., and NDM were detected from the bile sample collected from the patient. The second patient underwent an ERCP using the device in 2019 and was reported that CPE NDM and klebsiella pneumoniae were detected from the bile and rectal samples collected from the patient. Third patient underwent a procedure for replacement of prosthesis using the subject device in 2019. Klebsiella pneumoniae, CPE and NDM were detected from the rectal sample collected from the patient. The fourth patient underwent and ERCP using the device in 2019 and Klebsiella pneumoniae, CPE and NDM were detected from the bile sample collected from the patient. The fifth patient underwent a procedure for replacement of Biliary pneumoniae using the device in 2019, Klebsiella pneumoniae, CPE and NDM were detected from the rectal sample collected from the patient. The Duodenoscope was reprocessed with a Non-Olymypus AER, Soluscope Serie 3, using peracetic acid. Olympus subsidiary had received the device for repair from the user facility in March 2019 before aware of the reported event. The results of the evaluation of the device were as follows: air leakage from the distal end, instrument channel had wear and scratches, the adhesive of the rubber of the bending section has wear and a tear, scratches on the distal end, and scratches on the light guide lens. OMSC reviewed the manufacturing history of the device and confirmed no irregularity. The exact cause could not be conclusively determined at this time.

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

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

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

and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8538524&pc=FDT

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

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

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

3. Excessive Force with Equipment

3.1. A black piece of plastic peeled off from near tip of scope and fell into the patient's bladder, June 2019

A report in the FDA's **MAUDE** database states during a diagnostic Cystoscopy procedure, a black piece of plastic peeled off from near the tip of the scope and fell into the patient's bladder. The fragment was retrieved and sent to the hospital's lab for confirmation of material. The procedure was completed with the same scope with no patient injury. The scope was returned to the service center for evaluation and the black piece was confirmed from the customer's complaint. A visual inspection was performed on the returned device and found damage to the scope. An Olympus borescope was used to inspect the instrument channel and found scratch marks inside the channel from the bending section side. The distal end was also inspected and noted the bending section cover glue was cracked and partial peeled off. The evaluation showed the cause of the scratches inside the channel and the partially damaged bending section cover glue is due to mishandling.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8687479&pc=FAJ

3.2. During an in-service with Olympus, the distal tip of a Ureteroscope was damaged due to excessive force by the operator, June 2019

A report in the FDA's **MAUDE** database states during an in-service conducted by Olympus, the distal tip of the Uretero-Reno Videoscope URF-V3 was damaged as the up angulation was not working. No patient involvement with the scope. The scope was returned to Olympus and visual inspection was performed. An irregular shape on the bending section at the distal tip. It appears both in the neutral and up angulated positions. When engaging the control lever the movement of the bending section is abnormal in the up direction; the down angulation has no response while attempting to manipulate the lever. It was discovered the some of the cable supports have detached from the up and down angle wires or partially detached when inspection was performed with a microscope on the skeleton of the bending section. The damage to the cable support pins can potentially occur if excessive force is used to manipulate the bending section whenever it becomes stalled. The scope was also leaking from the biopsy channel to which a borescope was used to inspect and found multiple tear marks at the opening of the channel from the distal end side at approximately 20mm. The scope was put in use only seven times since being purchased in 2019.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8680235&pc=FGB

3.3. The user facility reported to Olympus the scope's distal tip is broken, May 2019

A report in the FDA's **MAUDE** database states that Olympus was informed the Ureteroscope-Reno Videoscope URF-V2 distal tip is broken. The scope was returned to the service center for evaluation. A visual inspection was performed on the scope and found that the bending section cover had no signs of metal protruding. The bending section was removed and found the bending skeleton broken, which most likely caused the cut on the bending section cover. The bending section tab was fully broken/detached at the insertion tube area. The were no sharp areas noted with the broken/detached skeleton. The scope failed the leak test due to leaking from the bending section cover, there is a cut on the bending section cover that cause the leak. The instrument history was performed and found the scope was returned for service and was overhauled on May 13, 2019

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8708453&pc=FGB

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

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

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

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

A report in the FDA's **MAUDE** database states that Olympus was informed that these valves snap off in the same place every time. This event delays cases by 10 minutes to which the customer keeps plyers in the room so they can remove these valves at the end of their cases. The intended procedures were still completed and had to open another valve of the same model. The breakage is on the elbow of the device. The suction valve was not returned to Olympus for evaluation and did not confirm the customer's complaint of the suction valve snap off. The most likely cause of the reported phenomenon was attributed to excessive force applied to the suction connector. The OEM investigation the reported increase of complaints was observed since the manufacturing process and molding supplier for the suction valve were changed or replaced in August 2018. The OEM reported that the suction valves that were manufactured prior to and post the changes meet the product's standard for stiffness. When the unexpected large load or excessive force is applied to the suction connector, the OEM

confirmed that the product before the changes did not break, but the products that were manufactured after the changes were breaking or may break.

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

4. Failures Due to Reprocessing Equipment (AERs)

4.1. A facility's printer for the Advantage Plus AER was repaired, an endoscope was not properly reprocessed and used on a patient, August 2019

A report in the FDA's **MAUDE** database states a Medivators FSE repaired the printer of the Advantage Plus AER, it was recognized that an endoscope was not properly reprocessed and was used during a patient procedure. The facility determined that the endoscope was not properly reprocessed while reviewing the printouts from previous cycles when the printer was not working. It is the facility's responsibility to review cycle logs after each cycle to ensure endoscopes achieved adequate HLD. Medivators district manager followed up with the facility about this incident in which they confirmed only one endoscope was impacted. No report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8851958&pc=FEB

4.2. During an in-service training at a facility incorrect processes were observed when reprocessing endoscopes with their Advantage Plus AER, August 2019

A report in the FDA's **MAUDE** database states Medivators CES performing an in-service training at a facility incorrect processes were observed when reprocessing endoscopes with their Advantage Plus AER. Incorrect processes observed include incorrect manual cleaning, flushing and leak testing. The facility has also not been replacing internal filters of their AER. The staff was seen handling endoscopes with contaminated gloves. The minimum required concentration of the HLD used in the AER reprocessing cycle was not being checked following the cycle which is required to ensure that HLD of the endoscope is achieved. The CES informed the facility of the proper procedures and the facility confirmed that they would be implemented. No reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8910503&pc=FEB

4.3. A facility reprocessed their endoscopes in the AER using two Rapicide PA part A bottles, August 2019

A report in the FDA's **MAUDE** database states a facility reported reprocessing endoscopes in their Advantage Plus AER using two Rapicide PA High Level Disinfection part A bottles. The AER is intended for use with one bottle of Rapicide PA part A and one bottle of Rapicide PA part B to product the required use-solution mixture for endoscope disinfection. There is a potential for chemical exposure from using endoscopes in patient procedures that were reprocessed with double the concentration of Rapicide PA part A. Medivators regulatory followed up with the facility to which it was reported that they identified all affected endoscope and reprocessed them correctly. One endoscope may have been used in a patient procedure that was reprocessed incorrectly with the two bottles of Rapicide PA part A. The issue was escalated to the facility's management which resulted in retraining staff and putting up sign reminding operators to verify correct usage of both part A and part B in the AER.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8876406&pc=FEB

4.4. An employee obtained injury from hot water from the user facility's 1E processor was leaking water onto the floor, July 2019

A report in the FDA's **MAUDE** database states a user facility reported that their System 1E processor was leaking water onto the floor and an employee obtained an injury from the hot water. No medical treatment was administered. Procedure delays occurred as facility personnel cleaned up the water. A Steris service technician arrived onside to inspect the System 1E processor and found the fitting that connects the facility's water line to the un filter had detached, allowing water to leak onto the floor. The technician re-installed a new fitting, tested the unit, confirmed it to be operating according to specification, and returned it to service. The unit is approximately seven years old installed in 2012.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8807117&pc=MED

4.5. During a clinical visit for the DSD-201 AER, there was black fluid dripping from endoscopes, June 2019

A report in the FDA's **MAUDE** database states Medivators clinical education specialist reported during a clinical visit for the DSD-201 AER that there was black fluid dripping from endoscopes.

There is a potential that endoscopes were not adequately high-level disinfected, a potential for patient harm. Medivators CES and Medivators field service engineer visited the facility and both has observed process and hygiene issues. The CES performed an in-service training and the FSE was onsite to test the machine. Medivators CES and FSE identified that the pre-filters in the machine were black and needed replacing. The facility was not following recommended maintenance of these filters to be changed every 6 months per the DSD-201 AER service manual. The facility reported since their external water filters were changed the black residual fluid is no longer leaking out of their endoscopes. The black substance was not identified. Medivators CES reported that the facility was using the endoscopes with the "black residual" in patient procedures. No reports of harm to the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8744924&pc=FEB

4.6. An employee ran a diagnostic cycle instead of a processing cycle to process a scope, May 2019

A report in the FDA's **MAUDE** database states the user facility reported that an employee ran a diagnostic cycle instead of a processing cycle to process a scope in their system 1E processor. The facility inquired whether a scope processed in this manner would be sterile as the employee had placed a cup of S40 in the processor prior to initiating the cycle. The hospital was informed by Steris that scopes cannot be guaranteed as sterile or patient ready. Steris service technician inspected the unit and verified that the system 1E processor was operating properly. After a test cycle the chemical indicator evidenced passing results. A refresher in-service training was offered but the hospital declined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8656334&pc=MED

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

A report in the FDA's **MAUDE** database states a Medivators sales representative reported observing the facility's technician incorrectly reprocessing endoscopes in their CER-2 Optima AER. The required AER hookup connectors were not being used to reprocess the endoscopes. Also, bioburden was observed on the distal end of the endoscope, inside of the hookup tubing on all suction valves. While observing the incorrect processes, Medivators sales representative

immediately informed the technician who cancelled the cycle and made the necessary corrections and the physician was also informed of the observations. The facility received an additional in-service training by Medivators clinical education specialist for all their Medivators products. The facility reported that they updated their products and staff were required to watch all training videos and review all IFU's/user manuals. The facility also switched to using Medivators single-use disposable valves, disposable tubing and pull-thru cleaning devices. There are no reports of patient harm.

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

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

A report in the FDA's **MAUDE** database states a facility reported that employees developed exposure symptoms from Rapicide PA high level disinfectant that leaked from their Advantage Plus AER. The AER had a leak they could not locate and the HLD ran onto the floor, then cleaned up with towels which were then placed in the dirty laundry hamper. After a couple hours the employees reported a strong odor and noticed a haze in the room. One employee opened the hamper to find a thin cloud of fumes and reported the towels had some type of noticeable chemical breakdown. The facility used baking soda to neutralize the towels and chemical. Three employees reported symptoms of eye and throat irritation, nausea, headache and chest pain. The employees were sent to employee health and referred to ED for evaluation and reported to be fine. Medivators Field Service Engineer arrived on site and repaired the leak. The machine now runs within specification. The facility failed to follow the IFU and SDS disposal instructions for Rapicide PA HLD.

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

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

A report in the FDA's **MAUDE** database states that a Medivators field service engineer was onsite for a service visit reported that the facility's DSD-201 AET and hookups were stained with a green residue. There is potential for patient harm from exposure to the green residue and potential that endoscopes were not adequately high level disinfected. The FSE reported that the green substance is from a concentration of the detergent (orthozime) mixing with the high-

level disinfectant (Cidex OPA) used in their AER. It was determined that the facility incorrectly programmed their AER for detergent use which caused the detergent to be mixed with the high-level disinfectant in the basin during reprocessing cycles. Th facility was informed by the FSE of the potential impact to patient safety due to the coating of the green substance in the AER and on endoscopes and the potential that endoscopes are not being adequately high level disinfected. The facility received in-service training on the DSD-201 AER in 2007 and 2014 by Medivators Clinical Education Specialist. It is unknow if the facility continues to use the affected AER. There have been to reports of patient harm.

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

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

A report in the FDA's **MAUDE** database states, Medivators Clinical Education Specialist reported a facility had not been performing water line disinfection (wld) cycles for their eight Advantage Plus AERs. Medivators CES discovered the facility was not performing water line disinfection and estimated it has not occurred since as early as 2014. The number of endoscopes reprocessed during this time is unknown. Medivators CES retrained the facility on the importance of completing a wld as instructed in the AER user manual. After the in-service training visit, the facility reported to Medivators CES that additional processes are now in place to ensure wld is completed per the AER user manual.

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

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

A report in the FDA's **MAUDE** database states that a Medivators field service engineer reported while on site, he observed the facility using modified hookups and the incorrect parameter sets for Cidex OPA in the DSD 201 AER. There is potential that endoscopes were not properly high-level disinfected, thus there is potential for cross-contamination. The facility was using Cidex OPA high level disinfectant at fifteen degrees for a twelve-minute contact time which is not in accordance with the labeling. The Cidex OPA HLD instructions for use state use a minimum temperature of twenty degrees for five minutes. The FSE adjusted the temperature of the AER

and informed the facility to order the correct hookup. The facility does not have a Medivators service contract, it is the facilities responsibility to perform proper maintenance on their machine. No information was provided to Medivators regarding how many cycles or endoscopes were reprocessed. It cannot be determined if the endoscopes were properly HLD during this timeframe. It is also unknow if the facility has ordered a new hookup. There have been no reports of adverse events or patient harm.

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

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

A report in the FDA's **MAUDE** database states a facility reported a black substance appeared in both basins of their DSD Edge AER after completion of a reprocessing cycle. The facility requested a Medivators Field Service Engineer to evaluate the AER and did perform a preventative maintenance service. The source of the black substance was due to degradation of the disinfectant pumps from extended exposure to the high-level disinfectant. Medivators recommends replacing these pumps at least annually as part of the routine preventative maintenance. The facility's biomedical technician reported he was unaware when the last pm was performed on the AER. The facility does not have a contract with Medivators and the AER is normally serviced by the biomedical technicians. Per Medivators DSD Edge user manual, it is the responsibility of the facility to ensure proper servicing is performed on the AER. The biomedical technicians will perform pm services on the AER in the future. It is unknown if the endoscopes potentially exposed to the black substance were used in the patient procedures. There have been no reports of patient harm.

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

5. Employee Chemical Burns

5.1. An employee experience discoloration on their hands after removing a broken Steris HP biological indicator, June 2019

A report in the FDA's **MAUDE** database states an employee experienced discoloration on their hands after removing a broken Steris HP biological indicator from a V-Pro Max sterilizer following a completed sterilization cycle. The BI was broken which allowed hydrogen peroxide to become trapped and remain after the cycle. The employee sought medical treatment and received bandages. A Steris technician arrived onsite following the reported event to inspect the V-Pro Max sterilizer, the facility was unable to identify which of the two units on site was subject of the reported event. It was confirmed all units were found to be operating properly. Based on the description of the event, the BI must have been damaged prior to the cycle. The account manager counseled facility personnel on the importance of wearing proper ppe, specifically gloves while operating their V-Pro Max sterilizer.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8693427&pc=MLR

5.2. An employee experienced a burn while handling items processed n a V-Pro 60 sterilizer, May 2019

A report in the FDA's **MAUDE** database states the user facility reported that an employee experienced a burn while handling items that were processed in a V-Pro 60 sterilizer. The employee sought medical attention. The technician inspected the sterilizer and found the unit to be operating properly. The employee was not wearing proper ppe, specifically gloves as stated in the operator manual. The technician counseled facility personnel on the importance of wearing proper ppe, specifically gloves while operating their V-Pro 60 sterilizer and properly drying instruments.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8574795&pc=MLR

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

A report in the FDA's **MAUDE** database states that an employee experienced a burn on their fingertip while handling items that were processed in a V-Pro Max sterilizer while wearing PPE

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

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

6. Sterilizer Malfunction

6.1. User facility's V-Pro Max sterilizer caught fire, June 2019

A report in the FDA's **MAUDE**database states the user facility reported their V-Pro Max sterilizer had caught fire. The department was evacuated, and the fire department was dispatched, and the fire department extinguished the flames. Procedures were cancelled as the department shut down. Facility personnel were sent to the emergency room for evaluation. A Steris service technician arrived onsite following the event to inspect the sterilizer, however the facility did not allow the technician to perform a full investigation as they wanted to conduct their own investigation first. A root cause could not be determined at this time as Steris does not have access to the V-Pro Max sterilizer.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8693477&pc=MLR

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

A report in the FDA's **MAUDE** database states the user facility reported that their V-Pro Max sterilizer caught fire over the weekend. No injuries associated with the subject event and the flames subsided on their own. On Monday, personnel arrived onsite and noted a "burning smell" throughout the room. Personnel inspected the V-Pro Max sterilizer and found evidence of blackened wires and compounds around the insulation of the unit. A Steris Service Technician arrived to inspect the sterilizer and found the cause to be a loose fitting on the SV5

valve. This allowed sterilant to leak from the valve onto the wires and components below causing the electrical wires to short and the reported event to occur. The sterilizer was manufactured in 2015 and is not under a Steris service agreement for maintenance activities. The facility is responsible for all maintenance activities. The reported event can be attributed to user error as facility personnel should have ensured all fittings are properly tightened following all service or maintenance activities prior to placing the unit back in service. The unit has been removed from service and no additional issues have been reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8400428&pc=MLR

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

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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8418572&pc=NZA

7. Use Errors

7.1. Two patients developed Colitis after undergoing a routine Colonoscopy procedure with same Fujifilm Endoscope, August 2019

A report in the FDA's **MAUDE** database states two patients have developed Colitis after undergoing a routine Colonoscopy procedure with the same Fujifilm Video Endoscope EC-600WL. Patient 1: female, routine Colonoscopy completed and no indication that there was anything wrong with the endoscope at the time of the procedure. Patient 1 presented with

abdominal pain and fever and was admitted to the hospital. CT and lab testing were performed, and Colitis was not verified. The patient was treated and discharged. Patient 2: female, had routine Colonoscopy completed, no indication that there was anything wrong with the endoscope at time of procedure. Patient 2 presented with abdominal pain, evidence of rectal bleeding and vomiting; patient was admitted to the hospital. CT results indicated that the appearance of colon was most consistent with Ischemic colitis. Blood and stool cultures were all negative. No indication at the time of the procedures that anything was wrong with the endoscope. The endoscope was clean and sterile at the time of procedures and no operators had reported any issues. Patient 2 status was asked for but not provided by customer. The scope was taken out of service and sent for evaluation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8857115&pc=FDF

7.2. Incorrectly reprocessed Gastroscopes were used in a total 998 procedures, July 2019

A report in the FDA's **MAUDE** database states Pentax medical became aware of a report on June 26, 2019 that the forward water jet channel on three customer-owned Pentax medical Gastroscope EG29-10 were not cleaned or reprocessed in accordance with the Pentax reprocessing IFU. The facility learned of the issue on June 26, 2019 and communicated to Pentax the issue dates back to when the scope was first placed into service in 2018. The facility communicated that foreign liquid was evacuated from at least on of the scopes upon flushing to forward water jet channel. On July 12, 2019, Pentax learned that one Pentax-owned loaner scope was paced into service at the facility during normal repair of one of the facility-owned scopes, and then removed from the account, reprocessed and inspected by Pentax personnel before being placed back into the loaner pool. The facility electronic health records, Pentax was informed that the three facility-owned scope and one Pentax-owned scope were used in a total of 998 procedures. An MDR is being filed for each of these procedures. The scope involved in the MDR has not been returned to a Pentax facility for repair/service since the scope was put into service in 2018. The Gastroscope were packaged with RIFU and product bulletin. Pentax service completed an in-service with the facility on June 28, 2019 for the Gastroscope and during the in-service, Pentax documented the facility's use of a Boston scientific enzymatic detergent that was not evaluated for compatibility with Pentax endoscope and Endochoice cleaning brushes that were not validated for use with Pentax endoscopes. Pentax Gastroscope was received by Pentax on July 1, 2019 and inspected the same day. Inspection findings include: Operation channel-primary slice by accessory; air/water socket cylinder o-ring chipped; air nozzle clogged with inorganic debris; insertion tube mild scratches at stage 1; sluggish air delivery function. The sampling performed yielded the following results:

forward water jet channel (1) negative rods-Cupriavidus species, (2) negative rods-Stenotrophomonas pavanii/pseudomonas geniculate. There have been no reports of patient infection or death from this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8811666&pc=FDS

7.3. A Duodenovideoscope cultured positive for P.aeruginosa after reprocessing, July 2019

A report in the FDA's **MAUDE** database states during a post market surveillance study, the EVIS Exera Duodenovideoscope TJF-160VF cultured positive for Pseudomonas aeruginosa after reprocessing. The scope was not sent back to the service center for evaluation. The ESS visited the facility on June 25, 2019 to observe the reprocessing practice of the staff and provide training for the TJF-160VF. The were no deviations when the ESS observed the reprocessing and all the steps in the user manual were followed. The investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8781626&pc=FDT

7.4. During a post market surveillance study, a Duodenovideoscope cultured positive for microbes after reprocessing, July 2019

A report in the FDA's **MAUDE** database states during a post market surveillance study, an EVIS Exera Duodenoscope TJF-160VF cultured positive for Klebsiella pneumoniae, Escherichia hermannii, Enterococcus faecalis after reprocessing. The scope was not sent back to the service center for evaluation. An Endotherapy Support Specialist contacted the user facility to offer an in-service, during the in-service at the facility, the ESS observed the reprocessing of the scope. The ESS observed no deviations from the reprocessing steps. All special brushes and cleaning adaptors were used during the cleaning.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8760368&pc=FDT

7.5. Duodenoscope tested positive for microbes after microbiological testing, July 2019

A report in the FDA's **MAUDE** database states as of a result of microbiological testing by the facility, the EVIS Exera III Duodenovideoscope TJF-Q10V tested positive for Stenotrophomonas

maltophilia (>100cfu/100ml), P.aeruginosa ((>100cfu/100ml), E.coli (17cfu/100ml), Enterobacter (26cfu/100ml). It was not reported what portion on the scope the microbes were detected. The scope was disinfected using a Non-Olympus AER with peracetic acid. The scope was not returned to OMSC, the manufacturing history of the scope was reviewed by OMSC and confirmed no irregularity. The exact cause could not be conclusively determined at this time. No report of patient infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8792131&pc=FDT

7.6. Patient's urine tested positive for Carbapenem-resistant Enterobacteriaceae after a Colonoscopy procedure, June 2019

A report in the FDA's **MAUDE** database states a patient's urine tested positive for Carbapenem-resistant Enterobacteriaceae sometime in 2019. The EVIS Exera II Colonovideoscope CF-H180AI was not returned for evaluation. The scope would be sent to an independent lab for culture testing noted by the user facility. The facility reported the scope was sent for repair after the December procedure and had a leak. The scope was repaired and returned at the time. An ESS was requested to be dispatched to the user facility to observe the facilities reprocessing practice and to provide reprocessing training. The following deviations were found: during leak testing procedure, angulating of the bending section and proper removal and disconnection from the MU-1 device. Manual cleaning- a deviation in the order of brushing and how many times the steps are being performed with the scope out of the detergent solution. Several occasion where the channel opening was brushed first, then the suction channel. Inconsistent drying of the scope before placement in the AER. The cause of the patient infection cannot be confirmed. The facility acknowledged the improvements needed in the reprocessing steps and will conduct competency checks on staff more often.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8683917&pc=FDF

7.7 The sample collected from a Gastroscope tested positive for yeast/fungi, June 2019

A report in the FDA's **MAUDE** database states the EVIS Exera II Gastrointestinal Videoscope GIF-H180 tested positive for yeast/fungi after a sample was collected. OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. The exact cause 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=8681909&pc=FDS

7.8 Microbes were detected from a sample collected from a Gastroscope, June 2019

A report in the FDA's **MAUDE** database states that the EVIS Exera III Gastrointestinal Videoscope GIF-H190 had microbes that were detected from the sample collected. First time- all channels: P. aeruginosa (100cfu); Second time- instrument channel: P. aeruginosa (5cfu), suction channel: P. aeruginosa (5cfu); Third time- air/water channel, P. aeruginosa (300cfu) and suction channel: P. aeruginosa (29cfu). The scope was reprocessed with a Non-Olympus AER, Soluscope 4 using peracetic acid. The scope was returned to Olympus and sent to a third-party lab for microbiological testing. The sample that was collected from all channels tested positive from Gram-positive bacteria (1cfu). The testing result cleared the guideline. There was no irregularity when the manufacturing history was reviewed. The reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8694384&pc=FDS

7.9. The instrument channel of the Gastroscope tested positive for Enterobacter cloacae esbl, June 2019

A report in the FDA's **MAUDE** database states as a result of routine microbiological testing by the user facility, the sample collected from the EVIS Exera III Gastrointestinal Videoscope GIF-H190 tested positive for E. cloacae esbl (182cfu/100ml). The scope was reprocessed in a Non-Olympus AER Wassenburg 440 using peracetic acid. The scope was returned to Olympus and sent to a third-party lab for microbiological testing. No microbe was detected from the sample collected. The testing cleared the French guideline. There was no report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8706738&pc=FDS

7.10. Microbiological testing by the user facility, the Duodenovideoscope tested positive for microbes, June 2019

A report in the FDA's **MAUDE** database states Olympus was informed that as a result of microbiological testing by the user facility, the EVIS Exera II Duodenovideoscope TJF-Q180V tested positive for the microbes as follows: Enterobacter cloacae and Klebsiella pneumoniae (number of microbes was not reported); total in the elevator channel (300cfu); enterobacter cloacae and Klebsiella pneumoniae. Total (300cfu); Klebsiella pneumoniae. The microbial test that was performed on the scope, which had been stored in a non-medical cabinet for 39 hours and 10 minutes after the high disinfection. The scope has not been returned to OMSC, the manufacturing history was reviewed and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time. There was no report of patient infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8720810&pc=FDT

7.11. Routine microbiological testing by the user facility the sample collected from the instrument channel tested positive, June 2019

A report in the FDA's **MAUDE** database states that as a result of routine microbiological testing by the user facility, the sample collected from the instrument channel of the subject device tested positive for P. aeruginosa (5cfu/100ml), Stenotrophomonas maltophilia (100cfu/100ml), Acinetobacter denitrificans (40cfu/100ml) and Klebsiella oxytoca (100cfu/100ml), and the suction channel of the subject device tested positive for Ochrobactrum anthropic (5cfu/100ml), P. putida (100cfu/100) and Stenotrophomonas maltophilia (5cfu/100ml). The EVIS Exera Duodenovideoscope TJF-160VR had been reprocessed with an Olympus AER Model ETD-3. The scope has not been returned to OMSC but was returned to Olympus and was sent to a third-party lab. for microbiological testing. No microbe was detected as a result of the testing from the sample collected from the scope. The testing result cleared the guideline. OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8665084&pc=FDT

7.12. Cultures tested positive for the Duodenovideoscope after being serviced and prior to being used on a patient, June 2019

A report in the FDA's **MAUDE** database states the EVIS Exera II Duodenovideoscope TJF-Q180V cultured tested positive for Staphylococcus cohnii ssp urealyticum, Staphylococcus haemolyticus and Staphylococcus aureus after being serviced and prior to being used on a patient. There was no patient involvement as this scope has not been in used as it kept coming back with positive cultures. Per the nurse manager at the user facility further information indicated the scope had been EO sterilized, repaired and returned on May 14, 2019. Upon return, the scope channel culture was positive for unknown microbes. The scope was then reprocessed in the AER Medivator machine and the scope channel culture tested positive on May 17, 2019 for Staphylococcus cohnii ssp urealyticum and Staphylococcus haemolyticus. The scope channel culture tested positive for Staphylococcus aureus. The user facility is performing pre-cleaning immediately after procedure; following the manufacture guidelines and steps for scope reprocessing. ESS last conducted an in-service on April 1, 2019. There were no staff changes and all reprocessing personnel are trained and certified in cleaning. The EES observed there were several steps being omitted on the forceps elevator during pre-cleaning and manual cleaning process. The ESS discussed observation with nurse manager, clinical educator and the infection control director. The technicians were provided with cleaning steps guide from the ESS. The scope has not been returned to Olympus for evaluation, the cause of the reported positive culture cannot be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8712959&pc=FDT

7.13. Rigid scope was occluded by debris, which caused the 0 top basket to shear off in patient, June 2019

A report in the FDA's **MAUDE** database states the 4 French port on the Wolf Semi Rigid Ureteroscope Ureteroscope and Accessories Flex/Rigid 8708517 was occluded by debris and causing the tip on the 0 top basket to shear off in the patient. Foreign body retrieval by the physician was successful. The patient was not harmed. The user facility did state the scope was not properly cleaned and handled down in prep and sterile.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8735288&pc=FGB

7.14. A sample collected from a Bronchofiberscope tested positive for Stenotrophomonas maltophilia, June 2019

A report in the FDA's **MAUDE** database states the user facility informed OMSC that as a result of routine microbiological testing, the sample collected from the Bronchofiberscope BF-PE2 tested positive for Stenotrophomonas maltophilia (88CFU). The reprocessing method was not provided, and no report of infection associated with this report. The scope was not returned to OMSC but was returned to Olympus. The scope was sent to a third-party lab for microbiological testing. The instrument channel had unspecified microbes (5CFU/Channel). Air/water channel unspecified microbes (19CFU/Channel). The testing result cleared the guideline. The OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8669698&pc=EOQ

7.15. A Bronchoscope cultured positive for Mycobacterium peregrinum when contaminated ice had been used with the saline during a Bronchoscopy procedure, June 2019

A report in the FDA's **MAUDE** database states that a loaner scope was sent to the user facility on March 4, 2019 and returned to the manufacturer on April 26, 2019. An Olympus sales territory manager reported that after a Bronchoscopy procedure the EVIS EXERA III Bronchovideoscope BF-1TH90 was cultured positive for Mycobacterium peregrinum after reprocessing and the patient was also infected. The service quality inspection report was reviewed and passed the water leak test and found to be within specification. The manufacture was not informed until May 14, 2019 about the infection. An Olympus ESS was requested to be dispatched to the facility to observe the reprocessing practice and provide reprocessing training. The visit has not been finalized. On June 7, 2019 the facility further reported per their internal investigation they have narrowed the cause down to the ice that is used with the saline and the ice had been contaminated. The Mycobacterium peregrinum takes 5 to 8 weeks to grow and the scope was stored in a mass medical scope locker.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8685517&pc=EOQ

7.16. Microbes were detected in a Colonovideoscope from samples collected from microbiological testing, May 2019

A report in the FDA's **MAUDE** database states the EVIS Exera LLLColonovideoscope CF-HQ190I had microbes that were detected from the sample collected as a result of microbiological testing. Suction channel: K. pneumoniae, air/water channel: microbes (17cfu). The scope had been reprocessed with an Olympus AER model minietd2 using peracetic acid. No report of infection associated with this report. Additional microbiological testing was performed, and no microbe was detected from the sample collected. Although, microbes were reported to have been attached in the past from the scope. 2017- Olympus air/water channel: P. aeruginosa. 2017 user facility- instrument channel: P. aeruginosa. 2018- Olympus no microbes detected. 2018- user facility- instrument channel: K. pneumonia. 2018- Olympus no microbes detected. 2018- user facility- instrument channel: P. aeruginosa, suction channel: K. pneumoniae. 2019- user facility- suction channel: P. fulva. The scope was not returned to OMSC for evaluation. OMSC reviewed the manufacturing history and confirmed no irregularity. It could not be conclusively determined at this time the exact cause of the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8653260&pc=FDF

7.17. A Gastroscope tested positive twice for microbes, May 2019

A report in the FDA's **MAUDE** database states the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 culture tested positive twice: Serratia marcescens and Stenotrophomonas maltophilia after it had been reprocessed in their AER, OER-Pro. The user facility noted precleaning process was followed. A review of the scope's instrument history record indicates the scope was last repaired on May 9, 2018. The ESS was dispatched to the user facility to observe the facility's reprocessing practice and to provide a reprocessing training. The visit has not been finalized. The scope will be sent to an independent lab for microbial testing. No patient infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8645333&pc=FDS

7.18. Microbes were found with multiple microbiological testing on a Gastroscope that was performed by the user facility, May 2019

A report in the FDA's **MAUDE** database states that multiple microbiological testing by the user facility on an EVIS Exera III Gastrointestinal Videoscope GIF-H190 with the following microbes that were detected from the sample collected. First time- unspecified channel: E.cloacae (53cfu); Second time- instrument channel: E.cloacae (2cfu), suction channel: E. cloacae (3cfu). The scope was reprocessed in a Non-Olympus AER, Soluscope 4, using peracetic acid. The scope was returned to ODE. It was confirmed through an evaluation the distal end of the scope detached from the insertion tube. It could not be conclusively determined what the exact cause of the reported event is at this time. No report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8648998&pc=FDS

7.19. The Uretero Reno Fiberscope tested positive with multiple microbiological testing, May 2019

A report in the FDA's **MAUDE** database states that Olympus was informed as a result of multiple microbiological testing by the user facility, the following microbes were detected from the sample collected from the Ureteroscope Reno Fiberscope URF-P6. First time: Coagulase-negative staphylococci (<9cfu). Second time: mold species (<9cfu). The scope was not returned to OMSC for evaluation. The manufacturing history was review with no irregularity. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8657633&pc=FGB

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

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

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

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

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

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

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

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

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

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

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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8507643&pc=FDF

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

A report in the FDA's **MAUDE** database states that one Gastroscope FSG-2500-MC90 was used during five procedures on the same date. It was reported to Boston Scientific corporation that a fuse 1g Gastroscope was used during five Gastroscopy procedures performed in 2019. Each patient was test for H. pylori and lab analysis revealed all five patients tested positive. The physician prescribed each patient three dosages (unknown) to treat the infection. The Gastroscope was not reprocessed properly and tested by the facility's reprocessing technician. The complainant suspected the scope had a leak not detected due to improper reprocessing. It was confirmed that one technician was involved in the event, and one Gastroscope was affected and the technician was terminated. The scope was returned for analysis and a functional analysis was performed. A leak was noted in the biopsy channel and was replaced. The most probable root cause for the reported leak in unintended use error caused or contributed to events.

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

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

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

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

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

A report in the FDA's **MAUDE** database states an EVIS Exera III Gastrointestinal Videoscope GIS-H180 cultured positive for Pseudomonas in 2019 after being reprocessed. The scope had been used on a patient with a pre-existing pseudomonas infection. The scope was quarantine at the user facility. The scope was returned to Olympus for evaluation and a visual inspection was performed and found the bending section cover and insertion tube cracked. An Olympus borescope was used to inspect the biopsy channel and scrape marks were noted inside the channel. The scope was repaired and returned to the customer.

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

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

A report in the FDA's **MAUDE** database states during routine microbiological testing by the user facility, the sample collected from the subject device tested positive for unspecified microbes

(2105 CFU/100 ml), the testing result indicated that there was Stenotrophomonas maltophilia. The scope was not returned to OMSC for evaluation but did review the manufacturing history and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8406619&pc=FGB

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

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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8395053&pc=FAJ

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

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

the scope was purchased on September 5, 2006 and no service/repair records found since the date of purchase.

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

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

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

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

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

A report in the FDA's **MAUDE** database states during a routine surveillance culturing tests at the user facility, the EVIX Exera LLL Colonovideoscope repeatedly tested positive for the following bacteria: the air/water channel and auxiliary channel tested positive for coagulase negative Staphylococcus (1cfu/18ml, air/water, 1cfu/20ml/auxiliary). The suction channel tested positive for Enterococcus casseliflavus, S. maltophilia and Bacillus spp. (8cfu/0.1ml in total). The test result indicated no microbial growth for the instrument channel. The suction channel tested positive for Cellulosimicrobium cellulans and E. casseliflavus (9cfu/18ml in total).

No microbial growth for other channels. The scope was returned to Olympus and was sent to a third-party laboratory for additional microbiological testing. The result indicated no microbial growth to the distal end, air water channel and instrument channel of the scope. No irregularities were confirmed when Olympus reviewed the manufacturing history of the scope.

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

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

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

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

8. Gram Negative Bacteria Outbreak

8.1. Two patients infected after an endoscopy procedure with New Delhi metallo Escherichia coli, August 2019

A report in the FDA's **MAUDE** database states the manufacturer became aware of this incident front the CBC Marketplace Link: htpps://www.Cbc.Ca/marketplace/episodes/2017-2018/tesing-shrimp-for-superbugs, the manufacturer is submitting two additional reports regarding the two patient infections after an endoscopy procedure. It was reported that the infection was from

New Delhi metallo Escherichia coli, which is a carbapenase-producing organism. The Manufacturer did make over five attemps to obtain detail from the facility, including more information about the model and manufacturer of the involved scope(s). The procedures were ERCP in the timeframe of July or August of 2016. The manufacturer still does not know the model/manufacturer of the scopes involved; this report is submitted to represent the second patient involved. The manufacturer does not have information about the model or producer of the device(s) involved in the reported endoscopy procedures. However, this hospital has previously purchased endoscopy equipment. The manufacturer is also aware that the facility has used other servicing providers for repairs and cannot rule out third party repair work or third-party parts as a contributing factor to this event. This is complaint number 2 of 3.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8867731&pc=FDF

8.2. Three patients were infected with Pseudomonas after Cystoscopy procedure using the Cystonephrofiberscope, August 2019

A report in the FDA's **MAUDE** database states that three patients were infected with Pseudomonas after a Cystoscopy procedure using the Cystonephrofiberscope CYF-5. It was reported that one of the three patients died. It is unknown if the relationship between the death of the patient and the scope and infection are connected. The condition of the two patients are unknown. The user facility returned the scope to Olympus for repair because the subject did not pass a leak test. The scope was cleaned with a non-Olympus single use brush (mi-cb-sweep-port, Cantel) and reprocessed the subject device using a non-Olympus AER (Medivators Rapidaer, Cantel), using a non-Olympus disinfectant (Rapicide part a and Rapicide part b, Cantel). OMSC is submitting three medical device reports according to the number of the infected patients. The scope has not been returned to Olympus but was returned for evaluation and repair and is in progress. The exact cause of the reported event could not be conclusively determined at this time. This is one of three reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8854159&pc=FAJ

8.3. Two patients developed MDR Pseudomonas after undergoing Bronchoscopy procedures, August 2019

A report in the FDA's **MAUDE** database states that two patients developed MDR Pseudomonas after undergoing Bronchoscopy procedures with a Bronchovideoscope BF-XT-160. The Medwatch report states the scope underwent appropriated SPD cleaning prior to being used on the second patient. The scope tested positive for MDR Pseudomonas after it was removed from service. The Scope was sent to the manufacturer who exchanged/replaced a few worn internal components. Per Steris, they do not think these components could house an organism. Infection control did witness cleaning/sterilization (Medivators) process and processed different scopes in the same manner. With a second culture performed after the scope was returned to the vendor and cultured positive. The scope continued to produce positive for the organism after being cleaned/sterilized. The Infection Control at the user facility reported since there were no similarities revealed in patients, procedure room, provider, staff, that is scope is defective. This report is for patient 2.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8856947&pc=EOQ

8.4. A Duodenoscope tested positive for Klebsiella pneumoniae blse after samples collected from microbiological testing came back positive, July 2019

A report in the FDA's **MAUDE** database states On June 6, 2019 Olympus received a lettered associated with this event from competent agency and was informed that as a result of microbiological testing by the facility, the sample collected from the EVIS Exera Duodenovideoscope TJF-160VR testing positive for Klebsiella pneumoniae blse. It was informed that two patients were infected with Klebsiella pneumoniae blse after procedures at the user facility using the subject device. It was reported the first patient was already infected with K. pneumoniae blse before the unspecified procedure before using the scope. Also, it was reported that the second patient underwent the ERCP using the scope in 2019 and was diagnosed with K. pneumoniae blse seven days after the ERCP. The user facility suspects that there is a possibility of cross infection by the Duodenoscope and has been quarantined by the facility. Olympus reviewed the service history for the scope and the last maintenance was conducted for the scope in December 2017 and no irregularity. Since then, maintenance has been conducted for the scope by a third-party company. The Duodenoscopy has not been returned to OMSC for evaluation. Olympus reviewed the manufacturer history and confirmed

no irregularity. The exact cause could not be determined at this time. OMSC is submitting one medical device reports regarding the second patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8751568&pc=FDT

8.5. Three patients were developed septicemia after being infected with P. aeruginosa after Duodenoscopies, June 2019

A report in the FDA's **MAUDE** database states three patients were infected with Pseudomonas aeruginosa after Duodenoscopies using the EVIS Exera II Duodenovideoscope TJF-Q180V between April 26 and May 16, 2019. It was also reported that the three patients developed septicemia, suspected nosocomial. The three patients were colonized P. aeruginosa. Those strains isolated in the patients were identical. The facility had cleaned the scope using an Olympus single use cleaning brush (BW-412t) with a non-Olympus detergent and an Olympus single-use brush (MAJ-1888) was also well used. After cleaning, the scope was reprocessed using a non-Olymypus AER Soluscope series 4, with peracetic acid. Olympus reviewed the service for the subject device. The scope was returned on July 10, 2018 for the most recent repair and no repair required. On June 11, 2019 a Olympus representative visited the user facility to review the reprocessing process at the user facility. There was no dirt on and around the forceps elevator. Also, there was no deviations of reprocessing practice noted. The scope was not returned to OMSC for evaluation but review the manufacturing history and confirmed no irregularity. The exact cause of the event could not be conclusively determined at this time. OMSC is submitting three medical device reports according to the number of the infected patients. This is one of three reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8730280&pc=FDT

8.6. Six patients contracted Salmonella infections in their bladder after undergoing Cystoscopy procedures, June 2019

A report in the FDA's **MAUDE** database states six patients contracted Salmonella infections in their bladder after undergoing Cystoscopy procedures with the facility's Cysto-Nephro Videoscope CYF-VH. The physician reported that this has led to sepsis in some of the patients. The bacteria have been tested and found to be the same genic bug in each case. The user

facility also identified 35 additional patients that will need to be notified as they also were in contact with the scope. The physician also reported the scope passed the leak test and appeared in satisfactory condition upon quick visual inspection. A close visual inspection was performed by the facility and observed a break, separation or perforation along the insertion tube of the scope. The scope was cultured and tested positive for Salmonella. The scope was not sent back to the service center for evaluation. The user facility did not provide a specific serial number for the scope therefore no further review of the instrument history can be performed. This is one of six reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8701602&pc=FAJ

8.7. Two patients confirmed to have tested positive for MDR Pseudomonas following a Bronchoscopy, June 2019

A report in the FDA's **MAUDE** database states that one patient developed MDR Pseudomonas following a Bronchoscopy. The next patient had the same Olympus Bronchoscope BF-XT-160 used during their procedure. Appropriate SPD cleaning was conducted. The first patient was already positive for pseudomonas and two confirmed cases after using the same Bronchoscope. The scope was removed from service and tested for pseudomonas. The scope was sent to the manufacturer and exchanged/replaced worn internal components. Per Steris they do not think these components could house an organism. Infection control witnessed the cleaning/sterilization (Medivator) process and different scopes in the same manner. A second culture was sent out to vendor and came back positive. Cleaning and sterilization continued to produce positive MDR Pseudomonas the scope was removed from service.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8707411&pc=EOQ

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

A report in the FDA's **MAUDE** database states all patients had bronchoscopies completed with the Video Bronchoscope EB-530T. All six patients were detected to have Pseudomonas aeruginosa 3-MRGN (quinolone sensitive in bronchial secretions. Patient 1 who underwent the bronchoscopy procedure using the bronchoscope EB-530T was detected to have P. aeruginosa

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

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

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

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

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