

Flexible Endoscope Incident Report

May 2019

Volume I

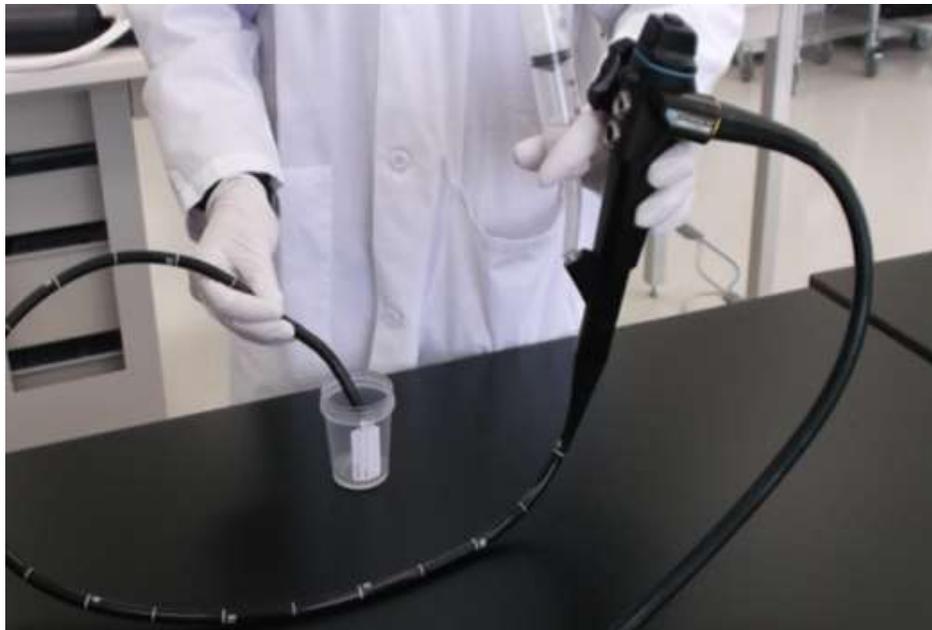




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1. Failure of Visual Inspection

1.1 The gastrointestinal wall of a patient was damaged and bled when the subject device contacted to the wall, March 2019

A report in the FDA's **MAUDE** report states that during a diagnostic procedure, the gastrointestinal wall of the patient was damaged and bled when the subject device contacted to the wall. The facility reported there was no health hazard by the bleeding so far, but gastric ulcer possibly would occur. It was reported that after the procedure the facility found that the bending section of the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 did not angulate enough. The scope was not returned to OMSC for evaluation. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8342522&pc=FDf

1.2 During an EGD procedure, it appeared the biopsy forceps pushed out a 1 mm piece of dried tissue or solid material from the interior channel, February 2019

A report in the FDA's **MAUDE** database states a year-old female referred to clinic for Dysphagia following a motor vehicle accident with blunt thoracic aortic injury. An EGD was performed showed chronic gastritis. When using the forceps during the EGD procedure, it appeared that the forceps pushed out a 1 mm piece of dried tissue or solid material from the interior channel. It was thought that the material was picked up as the forceps passed through the channel of the EGD scope. The physician attempted to obtain the material with the forceps and immediately removed and sequestered the scope. When the scope was removed, no material was found to be in forceps. The forceps did contain a small amount of blood mixed with mucus. Forceps were wiped with gauze to obtain any remainder of the material. The scope was flushed with sterile water and no gross debris was found. The flush and brush tips used to clean the channel and the gauze were sent to an off-site lab for DNA testing and is still pending. Scope was processing according to the manufacturer's instructions and no processing issues were

identified. To visualize the inside of the channel a micro-camera was used to find any defects or bioburden. Approximately where the tube boot attaches to the grip inside the control body, severe buckling is note that could conceivably trap bioburden. The manufacturer was notified, and the scope was sent to manufacturer for repair. The patient was notified of the material seen on the endoscope during the procedure and that a full investigation was being conducted. The patient was also notified about the damage to the scope during the follow-up clinic appointment in 2019. Baseline serologies were drawn and the results show no active infection and she responded to successfully to the vaccine. During the investigation, the scope had been previously used on a patient in 2019. This patient is also to be brought in for baseline serologies. DNA testing on the sterile water flush, the brush tips and the gauze is still pending with expected results in four weeks. The scope was purchased in August 2018 and sent out for repair on 11/20/2018. The repair work that was done on the scope included bending the sect. Distap tip file, re-glue and air/water cylinder replacement. Work was completed by the manufacturer on 11/20/2018 and returned to the organization.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8371996&pc=FDS

1.3. A foreign material fell out of the scope into the patient during a therapeutic colonoscopy procedure, February 2019

A report in the FDA's **MAUDE** database states that during a therapeutic colonoscopy procedure, foreign material fell out of the EVIS EXERA II Colonovideoscope PCF-HJ180AL. Olympus was informed of the incident. The material was retrieved with suction through the scope's channel and no unusual bleeding was observed with no additional intervention was required. The patient was discharged in good condition. The device was returned to Olympus for evaluation. A borescope was used to perform a visual inspection on the scope and found a yellow discoloration inside the scope's instrument channel from the biopsy port side. Kinks were found inside the channel from the bending section side and a scratch mark inside in the middle section of the channel when the instrument channel was inspected. With further inspection from the control body side noted kinks in the outer wall, as well as the suction channel was inspected with no abnormalities noted. The nozzle was disassembled and found not evidence of obstruction or foreign material in the channel. The image was found normal. However, the scope did fail the leak test, and based on the investigation the user's complaint was not confirmed as there was evidence of foreign material found inside the instrument channel or suction channel. Olympus did follow up with the facility regarding the event and was informed the at the scope is pre-cleaned immediately after the procedure. It is flushed with 500ml of endozyme solution, wiped with a sponge on the outside, air water cleaning adaptor is inserted

into the scope and the auxiliary irrigation channel is flushed with water. The scope is then transported in a covered bin to the processing area where the scope is leak tested with an Olympus MU-1. The scope is cleaned with an Olympus bw-412t brush to clean the channels. Suction cleaner adaptor is applied and 500 ml of endozone is again suctioned through the scope. The scope and all the channels are connected to the scope buddy for 35 seconds with endozone soap is flushed through the scope, then 35 seconds of water is flushed through the scope and then 35 seconds of air is flushed through the scope prior to being placed on the Medivator DSD Edge AER with Rapicide pa. Scope is hung in a cabinet with hepa air filters. The last AER preventive maintenance was performed in November 2018 and the facility participated in an in-service in 2017 and 2018. All reprocessing staff is reportedly trained to properly reprocess an endoscope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8313579&pc=PDF

1.4. During a Ureteroscopy procedure the distal wrap of the scope came apart inside the patient's bladder, January 2019

A report in the FDA's **MAUDE** database states the distal wrap of the Uretero-Reno-Fiberscope R11278AUK1 came apart inside the patient's bladder. The piece was retrieved, and the procedure was completed with no impact on the patient. The scope was evaluated, and it was found with multiple cuts and tooling/grab marks throughout the length of the angle cover. The damage was at the distal thread wrap and continues back to the proximal thread wrap. The damage may be caused by instrument used during the procedure. The distal head weld had completely separated on one side and partially separated on the other. The damage to this scope would have been done with excessive force. The Ureteroscope has been in use for approximately 5 months.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8313098&pc=FGB

1.5 Patient's ureter stuck to the scope and was avulsed during procedure, a Nephrectomy was performed, January 2019

A report in the FDA's **MAUDE** database states that during a procedure the Ureteroscope 27011L was placed into the ureter and advanced toward the kidney and during removal the ureter stuck to the scope and was avulsed. The ureter could not be repaired, and a Nephrectomy was

performed. The Semi-rigid Ureteroscope was evaluated and the distal end was a little rough from long uses. The scopes shaft is bent and with approximately 60% broken light fibers. The Ureteroscope was in use for about 12 years, it was purchased in 2007.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8379098&pc=FGB

1.6. A staple fell into a patient's duodenum during an EGD procedure that was left in the scope undetected after reprocessing from the previous procedure, January 2019

A report in the FDA's MAUDE database states that a scope that was used in two separate procedures and in the first it was reported that an unspecified staple was suctioned but became stuck inside the scope. During reprocessing the staple was not found. In the second EGD procedure, the staple presented itself as the staple fell out of the scope and into the patient's duodenum. It was retrieved using non-Olympus forceps. The procedure was completed with another EVIS EXERA III Gastrointestinal Videoscope GIF-H190. The patient had no injury and the facility also reported the previous patient had no known infectious disease. The second patient was tested, and results were negative. It is unknown if the user inserted an endotherapy device prior to procedure. The scope was returned to Olympus for evaluation and the event could not be confirmed as the suction channel was inspected and no foreign object, debris or damage was noted. The instrument channel was inspected and excessive scratches and peeling along the channel wall were found at the biopsy port, bending section and distal end areas. The scope did pass the leak test and the scope was repaired and returned to the facility. The scope was purchased on February 13, 2018 and service on October 30, 2018. There is a caution/warning in the instruction manual which states to confirm that the endo therapy accessory's distal end is closed or completely retracted into the sheath. Otherwise, the biopsy valve or instrument channel may be damaged and pieces of it could fall off. The person in charge of medical equipment maintenance in each hospital should inspect the items specified in the manual periodically. All channels and accessories must be cleaned and high-level disinfected or sterilized after each patient procedure, even if channels or accessories were not used.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8253524&pc=FDf

1.7. A blood clot and unspecified model clip were retained in the scope's biopsy/instrument channel following a GI bleed procedure, January 2019

A report in the FDA's **MAUDE** database states following a GI bleed procedure that a blood clot and an unspecified model clip was retained in the scope biopsy/instrument channel. The EVIS EXERA II Gastrointestinal Videoscope GIF-H180 was reprocessed and used in a bariatric procedure with the clot and clip still inside undetected. This procedure did not involve the use of the instrument channel. Following the procedure during manual cleaning the channel was flushed and the clot and clip were dislodged from the scope. No reported patient injury or infection from the event. Cook advised Olympus that the use of hemospray with suction is not recommended. The scope was not returned to Olympus for evaluation. The scope instructions manual has a pre-procedure inspection instructions which does include passing a test device down the instrument channel regardless of the procedure type. The instructions also warns that during use, avoid aspirating solid matter or thick fluids; clogging can occur in the instrument channel suction channel, or suction valve. An ESS will be dispatched to observe the facility's reprocessing practice and provide additional retraining if necessary.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8229785&pc=PDF

1.8. During a diagnostic Sigmoidoscopy, an unspecified tissue came out from the instrument channel of the device, January 2019

A report in the FDA's **MAUDE** database states Olympus Medical Systems corp. was informed that during a diagnostic Sigmoidoscopy, an unspecified tissue came out from the instrument channel of the device when they inserted an unspecified biopsy forceps into the channel and advanced the forceps through the channel. It was confirmed by the facility that it was human tissue and 1/2mm cube in size. No report of patient injury or infection from the event. The scope was cleaned manually and reprocessed in a non-Olympus AER and no abnormality in the AER and reprocessing procedure. It was also reported by the user facility that the scope had no irregularity during the previous procedure and inspection prior to. The scope has not been returned to OMSC but was returned to Olympus for evaluation which confirmed no blockage or restriction in the channels of the scope. Flow rates of the channels were within specification except for the aspiration channel, which was below specification. The manufacturing history was review of the scope with 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=8291988&pc=PDF

1.9. A stent was deployed but remained inside the scope undetected during a Biliary stent placement procedure and even after reprocessing, January 2019

A report in the FDA's **MAUDE** database states that in 2018 a female underwent a Biliary stent placement procedure with pre-existing Choledocholithiasis. The clinician believed the stent was deployed but remained in the scope undetected. It was reported via Voluntary medwatch mw5080812 that the patient required hospitalization but no adverse event. During the reprocessing of the EVIS EXERA II Duodenovideoscope TJF-Q180V, the stent was still not detected or removed even though a brush was passed through. The scope was used the next day in a second ERCP procedure involving a separated hydrotome device. The stent dislodged when the hydrotome was passed through the channel. The patient did not suffer from infection or injury and no reported positive culture. The procedure was cancelled and was performed at a later time. Olympus did not receive the Duodenoscope for evaluation and the complaint cannot be confirmed. The failure of the clinician to verify the stent placement in the first procedure and inadequate inspection of the endoscope channel prior to the second procedure. An in-service was performed by Olympus Endotherapy support specialist personnel to train the staff how to inspect the endoscope channel prior to a procedure and with what equipment is specified for use in the inspection and also how to verify stent placement in the patient as well. The scope instruction manual does advise running a test device through the scope prior to use. Need to make sure no foreign objects come out of the distal end and endotherapy accessory extends smoothly from the distal end. A review history shows the device was last serviced by Olympus in March 2016 to which service included repairs to several areas of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8262977&pc=FDT

1.10. A Bronchoscope detached at the distal end, leaving approximately 1 foot of internal mechanism exposed to the patient from the trachea to the opening of the patient's mouth, January 2019

A report in the FDA's **MAUDE** database states that a Bronchoscope BF-Q190 had detached at the distal end leaving approximately 1 foot of internal mechanism exposed to the patient from the trachea to the opening of the mouth. There were no issues throughout the procedure, except at the end is when the patient incident occurred. There were visible pieces of plastic the required retrieval and all pieces were successfully retrieved using another scope. No patient injury or further medical intervention was required. Olympus was informed that at an unknown date the user facility had specified a patient incident associated with an unknown

model Olympus H190 series Bronchoscope. The device was not returned to Olympus for evaluation and the cause of the report cannot be confirmed. Investigation is currently on going and Olympus will continue to work with the customer to obtain more information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8192285&pc=EOQ

1.11. Reprocessed and new Olympus scopes were inspected with a borescope revealed black and red spots within the Cystoscopes, December 2018

A report in the FDA's **MAUDE** database states the inspection of Olympus Cystoscopes after reprocessing and brand-new scopes not yet used on patients revealed black and red spots/markings were visible within. Olympus stated they have received complaints from other devices user facilities in the country regarding these same spot's user facilities identified in the scopes. Olympus referred to them as "manufacturing details" but declined to put in writing as a form of explanation. It was discussed with the manufacturer to send all scopes back for investigation, Olympus discouraged this as the outcome will be the same with the markings still being present and visualize with a borescope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8183896&pc=FAJ

1.12. During an unspecified procedure the control lever of the scope did not work, and the bending section could not be angulated, December 2018

A report in the FDA's MAUDE database states the control lever of the Uretero-Reno Videoscope URF-V2 did not work and the bending section could not be angulated during an unspecified procedure. The scope was replaced with the same model but another endoscope and the procedure was completed and no injury to the patient. The scope was returned to OMSC for evaluation and confirmed the reported event and a pinhole at the instrument channel of the device. The inside of the control section of the scope was significantly corroded. There was no damage found on the bending section and the angulation wire of the scope. It was confirmed there was no irregularity to the scope and OMSC concluded the cause was corrosion in the control section which was highly likely caused by the solution which was used during reprocessing and invaded through the pinhole portion of the instrument channel. Based on investigation, the pinhole possibly occurred due to an insertion of endo therapy accessory by excessive force.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8198240&pc=FGB

1.13. During a laser Lithotripsy procedure, the scope became stuck in the patient's ureter, December 2018

A report in the FDA's MAUDE database states that during the middle of a Ureteroscopy with laser lithotripsy, the doctor was utilizing a non-Olympus access sheath and laser to break the exterior of the stone. Make his way towards the middle of the stone, the doctor pulled the stone back then the Uretero-Reno Fiberscope URF-P6R became stuck at proximal location of the patient's ureter. He cut the scope in half with sheers and left half in the patient. Prior to the reported event, there was nothing unusual from the scope's behavior. Resistance was felt when withdrawing the scope. Unexpected bleeding to the patient which was controlled via saline irrigation and the patient was given additional anesthesia. Insufficient information was provided by the user facility regarding the event with multiple attempts made to obtain additional information from the user facility but with no results. The scope was returned to Olympus for evaluation and could not confirm the event as the scope is in working condition and receive intact with no significant damage. It was inspected and noted multiple non-Olympus third party repairs on the insertion tube, eyepiece body, and bending section cover glue. The scope did pass the leak test. The scope instrument history shows the scope was purchased in 2014 with no records of Olympus service repairs. Olympus sales rep confirmed the user facility had sent the scope to a non-Olympus vendor for repair/service prior to returning to Olympus. The cause of the reported event could not be confirmed and with no service history, improper maintenance cannot be ruled out as contributory factor.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8192500&pc=FGB

1.14. During a Lithotripsy procedure, a spark occurred when the laser was applied, December 2018

A report in the FDA's MAUDE database states Olympus was informed that during a Lithotripsy procedure, the scope device was in use with separate unknown model guidewires and a holmium PF-120 laser Lithotripsy device. When the laser was applied a spark occurred. Another spark occurred when the surgeon pulled back. It was reported that the outside of the tip of the scope pulled back, and then the scope could not longer be angulated completely. It wasn't until after the use of the laser that there was an angulation problem. The scope then

became stuck in the patient, but the surgeon was able to withdraw the scope. The left ureter became torn and urine leakage developed. Stents and a Nephrostomy tube were placed in the patient during the procedure and has gone home with the Nephrostomy tube implanted. No anomalies were found when the scope was inspected prior to use. The Uretero-Reno Fiberscope URF-P6R has not been returned to Olympus for evaluation. The cause of the reported complaint cannot be confirmed. To mitigate against patient injury, both the scope operation manual and instructions for safe use documents contain warnings and directions to address loss of angulation. A review of the scope history shows no Olympus service performed on the scope since at least 2016.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8188063&pc=FGB

1.15. The angulation of the bending section of the Uretero-Reno Fiberscope did not work in the down direction, July 2018

A report in the FDA **MAUDE** database states that during percutaneous Nephrolithotripsy, the user facility noticed the angulation of the bending section did not work in the down position, that it remained in a U shape. The Uretero-Reno Fiberscope URF-P6 was removed from the patient to inspect it when they felt something wrong with the endoscopic image. There was not a spare device available, so the procedure was abandoned. The Fiberscope was brand new. The device was sent to OMSC for evaluation, the section kept angulation for the down direction without operation of the up/down angulation control lever. There was also a leak from the instrument channel with many scratches inside of the instrument channel. There was no irregularity when OMSC reviewed the manufacturer history of the Fiberscope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7766300&pc=FGB

1.16. The bending section of the Uretero-Reno Fiberscope broke inside the patient with a non-Olympus laser probe inserted into the channel of the Fiberscope, May 2018

A report in the FDA's **MAUDE** database states during and RIRS (retro intrarenal surgery) procedure the bending section of the Fiberscope URF-P6 broke off inside the patient. The Fiberscope was safely removed from the patient, but a part of the laser fell off into the patient. The user facility performed an open surgery in order to retrieve the part of the laser from the patient. There was no complication and the patient is doing well. The Fiberscope was

delivered to the facility in 2018. The exact cause of the event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7644574&pc=FGB

1.17. The shaft of a LithoVue scope used in a Ureteroscopy procedure bent over onto itself and locked during the procedure, May 2018

A report in the FDA's **MAUDE** database states that a single use Digital Flexible Ureteroscope M0067913600 shaft of the LithoVue scope bent over onto itself and locked during the a Ureteroscopy procedure while inside the patient. The scope was not constrained in the patient's anatomy and the shaft could not be straighten when articulating, a super stiff wire was used to manipulate the shaft and the scope was removed from the patient. The deflection mechanism works fine when not inside the patient. Another LithoVue scope was used to complete the procedure with no complications to the patient. The scope was disposed and will not be returned for evaluation and a failure analysis of the device could not be completed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7592382&pc=FGB

1.18. Pentax Duodenoscope failed a cleaning verification test three times using 3M Clean Trace and sent to Pentax were several areas of scope had wear and tear, May 2018

A report in the FDA's **MAUDE** database states Pentax Video Duodenoscope ED-349TK failed a cleaning verification test three times using the 3M Clean Trace at the elevator site to detect ATP/Bioburden. First tech, tested and failed, rewashes and tested by a second tech and failed, third time a third tech cleans the scope and retests. The scope was sent in for inspection of integrity and possible repair. The user facility stated endoscopes are cleaned in accordance with Pentax instructions for use and test after every use. Pentax findings include the following: primary operation channel resistance, hole in #1 and #3 remote control button cover, bending rubber, severe discoloration. The scope passed the dry/wet leak tests. The objective lens scratched. Umbilical cable was bent, elevator body cut and deformed, light carrying bundle, distal cover glass middle chipped, the insertion tube mild crush at stage 1, distal cap-fix typed failed seal integrity inspection. The Duodenoscope is currently undergoing repairs.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7582735&pc=FDT

1.19. During an unspecified Transnasal bronchoscopy, the rhinal mucosa of the patient was injured with a small amount of bleeding, May 2018

A report in the FDA's **MAUDE** database states that the patient was injured with a small amount of bleeding and treated by astringent using gauze. The device was sent to Olympus Sales & Service Co., LTD. for evaluation and confirmed a projection on the bending section rubber of the device and an air leakage around the projection. The bending section rubber was disassembled and confirmed that several metal filaments of the inner parts of the bending section rubber frayed and broke at the leakage point. OCM reviewed the service history of the device the insertion portion of the Bronchoscope BF-1T260 was replaced due to an air leakage from the instrument channel, scratches on the insertion portion, and wear and tear of the insertion portion. Also, the bending section rubber was replaced due to the leakage from the bending section rubber. The exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7599661&pc=EOQ

1.20. During an unspecified procedure, a wire was found sticking out of the insertion tube, May 2018

The Ureteroscope URF-V2R was returned to Olympus for evaluation after an unspecified procedure a wire was found sticking out of the insertion tube. Olympus performed a visual inspection on the scope and found the bending section skeleton completely broken/detached with damages found on the angle wires, the biopsy channel, and the charge couple device unit. Upon removing of the bending section cover, one side of the angle wires was found broken with a sharp surface noted. The exposed biopsy channel was found kinked from the bending section area of the scope. Olympus was unable to perform leak testing due to the condition of the scope. The Ureteroscope was serviced and returned to the user facility. There was no patient injury reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7503395&pc=FGB

1.21. A rubber piece from Ureteroscope fell off inside the patient's ureter at the beginning of a kidney stone procedure, May 2018

A report in the FDA's **MAUDE** database states at the beginning of a kidney stone procedure, a rubber piece from the scope fell off inside the patient's ureter. The rubber piece was retrieved,

and the procedure was completed using the same Ureteroscope URF-V. It was further reported the device was inspected during reprocessing, prior to the procedure, and no anomalies were found. The scope was returned to Olympus for evaluation and a visual inspection was performed on the scope and found the bending section cover glue was broken off and missing from the distal end side and insertion tube side. The missing portion of the glue on both the distal end and insertion tube of the scope were not returned to Olympus. Due to the missing glue, the thread assembly from the bending section was found exposed. The scope failed leak testing as a result to the damages on the bending section cover glue. The Ureteroscope was serviced and returned to the user facility. User handling and improper maintenance of the scope could not be ruled out as contributing factors to the reported event. There was no patient injury reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7520909&pc=FGB

1.22. During the reprocessing of the Ureteroscope, the distal tip was noted to have sharp edges and was found broken, May 2018

A report in the FDA's **MAUDE** database states Olympus was informed that during the reprocessing of the Ureteroscope URF-V2R, the distal tip was noted to have sharp edges and was found broken. Olympus made multiple follow ups with the user facility by telephone and in writing in an attempt to gather further information on the reported event. No additional information was obtained. The Ureteroscope was returned to Olympus for evaluation and confirmed the reported device issue. The bending section was found damaged/torn with the metal ribs exposed. In addition, the bending section rubber glue was found with a hole/cut and in critical condition causing the scope to fail leak testing. The scope was serviced and returned to the user facility. Based on similar reported events and performed investigation findings, the cause of the reported device issue could be attributed to the operator(s) technique. The OEM has conducted a field corrective action including a distribution of instructions for safe use to mitigate the potential risk of patient injury. There was no patient injury reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7543473&pc=FGB

1.23. Multiple microbiological testing by the user facility, following microbes were detected from a Bronchovideoscope BF-1T180, May 2018

A report in the FDA's **MAUDE** database states the instrument channel of the Bronchovideoscope BF-1T180 tested for unspecified microbes >300cfu/20ml. The air/water channel of the scope tested for unspecified microbes >300cfu/20ml, the instrument channel of the scope tested for >300cfu and unspecified microbes >300cfu. No report of infection associated with this report. The Bronchovideoscope was not returned to Olympus medical systems corp. and reviewed the manufacturing history of the subject 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=7555702&pc=EOB

1.24. An unspecified number of patient infections occurred at a user facility with the use of Olympus Cystoscopes during an unspecified number of procedures, May 2018

A report in the FDA's **MAUDE** database states the types of infections are unknown and the exact model and serial number of the Cystoscope that caused or contributed to patient infections are also unknown. A total of three Cystoscopes are in use at the user facility. Olympus was informed and made multiple follow ups the user facility by telephone and in writing in an attempt to gather information on the reported event. The Cystoscope CYF-V2 has not been returned to Olympus for evaluation. A review of the scope history was performed and found that the scope was purchased on November 30, 2010 and last serviced at Olympus on August 30, 2016 for a bending section issue. The scope was returned unrepaired. An ESS provided a routine reprocessing in-service and found that the user facility does not have a leak tester and are not leak testing the scopes and not using detergent. The staff was using reusable brushes and not sterilizing in between uses. Recommendation were made by the ESS to purchase a leak tester, detergent, to sterilize the reusable brushes or purchase single use brushes. The ESS also recommended switching from Cidex OPA to Aldahol. The user facility declined from purchasing a leak tester but did however purchase Aldahol and were returned. On May 10, 2018 the ESS returned to the user facility to follow up on initial recommendations and found that the user facility is now sterilizing their reusable brushes and following correct cleaning and disinfection process. The ESS found that the reprocessing area is also located in the same room where procedures take place. In addition, the scopes are stored in a different procedure room and not in an enclosed ventilated cabinet. The ESS recommended to staff to follow the reprocessing protocol as stated in the instruction manual and to also consult with an

infection control preventionist and have a designated separate room as their reprocessing area to prevent cross contamination. The user facility declined a reprocessing in-service during this visit. Based on the ESS findings, most likely the cause for the infections is likely related to mis-reprocessing and improper maintenance of the scope. Olympus was informed on May 10, 2018 that there were three pseudomonas infections and a potential urinary tract infection uti/pid. Olympus is filing three reports to account for the three infected patients and reported Cystoscopes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7543476&pc=NWB

1.25. An unspecified number of patient infections occurred at a user facility with the use of Olympus Cystoscopes during an unspecified number of procedures, May 2018

A report in the FDA's **MAUDE** database states the types of infections are unknown and the exact model and serial number of the cystoscope that caused or contributed to the patient infections are also unknown. A total of three Cystoscopes are in use at the user facility. Olympus was informed and made multiple follow ups with the user facility by telephone and in writing in an attempt to gather information on the reported event. The Cystoscope CYF-VH has not been returned to Olympus for evaluation. During the investigation, a review of the device service history was performed and found no service information on the reported scope. An ESS provided a routine in-service at the user facility on January 18, 2018 to observe the facility's reprocessing practice and to provide a reprocessing training. ESS found the user facility did not have a leak tester and was not leak testing as stated in the instruction manual as well as not using detergent. A recommendation to purchase a leak tester and detergent, to sterilize their reusable brushes or purchase single use brushes, switch from Cidex OPA to Aldahol as Cidex is not recommended for sure. Facility declined to purchase a leak test but did purchase Aldahol and were returned. The ESS returned to the user facility for a follow up and found the user facility is now sterilizing their reusable brushes and following the reprocessing protocol as stated in the instruction manual. A recommendation was made to the user facility to consult with an infection control preventionist and have a designated separate room as their reprocessing area to prevent cross contamination. The user facility declined a reprocessing in-service during this visit. Based on the ESS findings, most likely the cause for the patient infections is likely related to misreprocessing and improper maintenance of the scope. Olympus was informed that there were three pseudomonas infections and a potential urinary tract infection uti/pid. The urinary tract infection incident has not been confirmed. Olympus is filing three reports to account for the three infected patients and reported Cystoscopes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7543483&pc=NWB

1.26. Several patients became infected after ERCP procedure with the same Duodenoscope, May 2018

A report in the FDA's **MAUDE** database states that several patients have been exposed to the same Duodenoscope ED-3490TK in 2018. Patient B underwent Endoscopic Retrograde Cholangio-Pancreatography for primary sclerosing cholangitis with a Pentax Duodenoscope. Patient B returned to the emergency room two days later with right upper quadrant pain, body aches, shaking chills and fever of 101.8. Six days post initial ERCP, the patient underwent another ERCP; a bile duct aspirate grew out multi-drug resistant *Pseudomonas aeruginosa*, which patient B had no prior history of this organism. Infection control was alerted to patient B by the infectious disease consult physician seeing the patient fourteen days post initial ERCP. Patient A was identified by the infection control unit investigation had undergone an ERCP in early 2018 with the same scope who was known to carry a MDR PSA prior to the procedure. Patient C had an ERCP in mid-2018 with the Pentax Duodenoscope developed bacteremia with MDR PSA with no known history. To determine if the infections were similar, the *Pseudomonas* isolates were sent out for genomic analysis including multilocus sequence typing and whole genome sequencing in mid-2018. Seven days post testing, preliminary results demonstrated the isolates from patients B and C were highly related to patient A. In mid-2018 an additional patient D underwent ERCP with the same scope was found to have a positive bile culture for PSA in early 2018. Both MDR PSAs from patient D have the same antibiogram as patient A. The Pentax Duodenoscope was sequestered and taken out of service pending further investigation near the end of 2018.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7548459&pc=FDT

1.27. The lens of an ERCP Duodenoscope was discovered to be green, May 2018

A report in the FDA's **MAUDE** database states that the facility cleaning and drying according to the manufacturer's instructions discovered the lens of an ERCP Duodenoscope TJF-Q180V was green. Six of twenty-two lenses were found green and two of the six had distorted images and were sent out for repair. An Olympus field rep. responded to the facility that the green discoloration around the lens of the scope was due to the glue used by the scope manufacturer for securement. The scope was changed out for one without lens discoloration.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7518011&pc=FDT

1.28. A Cystonephrofiberscope was noted as having approximately 3cm of its covering missing as it was being removed from the patient, April 2018

A report in the FDA's **MAUDE** database states that Olympus was informed by the facility that at the end of a second stage Buccal Urethroplasty with suprapubic placement procedure using a Cystonephrofiberscope CYF-5 was missing approximately 3cm of its covering as it was being removed from the patient and exposing the metal mesh of the scope. The missing piece was retrieved, and all parts accounted for, the procedure was completed using the same scope. Prior to use, the scope was inspected with no anomalies were found by Olympus. The scope was cleaned using Steris and with the concentration check daily with each load in the Olympus AER with no noted problems. Precleaning is performed after each procedure and leak checked prior the manual cleaning with an Olympus leak tester and a brush is using during manual cleaning with an Olympus single use brush. The scope is sterilized Sterrad® in an Aptimax tray and stored until use. All personnel are properly trained. No service information was found for this scope and was not returned to Olympus for evaluation. User handling and the operator(s) technique during use could not be ruled out as a contributing factor.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7575593&pc=FAJ

1.29. Ureteroscope became stuck within the ureter of the patient during withdrawal of the device, April 2018

A report in the FDA's **MAUDE** database states Olympus was informed that the Ureteroscope URF-P5 became stuck with the ureter of the patient during withdrawing the scope with a ureteral access sheath at the end of the transurethral lithotripsy. The access sheath could be withdrawn but the device could not. The user facility tried to withdraw the device under x-ray fluoroscopic image. A part of the ureter was retrieved and withdrawn with the subject device. The facility immediately changed the procedure into a laparotomy surgery to repair the ureter and completed the procedure. The patient's hospitalization was prolonged.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7457357&pc=FGB

1.30. During an unspecified Ureteroscopy procedure, the tip of the scope broke off into pieces inside the patient, April 2018

A report in the FDA's **MAUDE** database Olympus was informed that during an unspecified ureteroscopy procedure, the tip of the scope broke off into pieces inside the patient. It was reported that a Holium laser was used with the Ureteroscope URF-P5 during the procedure. The physician was unable to retrieve all of the device fragments from the patient and will be scheduling another endoscopic procedure to retrieve the remaining device fragments. Olympus made multiple follow ups with the user facility to telephone and in writing in an attempt to gather additional information on the reported event. No additional information was obtained. The user facility further reported that the reported scope will be sent to a non-Olympus third party entity for evaluation and service. The device service history was performed and found that the scope was purchased in 2018 and was never returned to Olympus for evaluation. The cause of the reported device based on similar reported events is that it is likely related to the operator technique.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7478078&pc=FGB

1.31. During the reprocessing process of the Ureteroscope, the bending section was found with a broken rib/skeleton protruding through the bending section, April 2018

A report in the FDA's **MAUDE** database states that during the reprocessing process of the Ureteroscope URF-V2R, the bending section was found with a broken rib/skeleton protruding through the bending section rubber. No patient/user injury reported. Olympus performed a visual inspection and found a portion of the bending section with a sharp edge and exposed/protruding bending skeleton metal tab causing the scope to fail leak testing. Upon the removal of the bending section cover, the bending section skeleton was found completely broken/detached with a sharp edge. The cause of the protruding/lifting skeleton metal tab could be attributed to the operator(s) technique. The original equipment manufacturer (OEM) has conducted a field corrective action including a distribution of instruction for safe use to mitigate the potential risk of patient injury.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7425455&pc=FGB

1.32. During an unspecified procedure, the Ureteroscope bending section broke, April 2018

A report in the FDA's **MAUDE** database states the bending section cover was found with a hole/cut and the bending section skeleton ribs were found broken. The scope was returned to Olympus and an evaluation found the bending section in critical condition. Based on similar reported events and investigation findings, the cause of the protruding/lifting skeleton metal tab could be attributed to the operator(s) technique. The original equipment manufacturer (OEM) performed investigations related to this device issue. As a result, the OEM has conducted a field corrective action including a distribution of instruction for safe use to mitigate the potential risk of patient injury.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7463113&pc=FGB

1.33. During the reprocessing of the Ureteroscope, the bending section skeleton rib was found broken and punctured a hole on the bending section rubber, April 2018

A report in the FDA's **MAUDE** database states that the Ureteroscope URF-V2R was returned to Olympus for evaluation and performed a visual inspection and found the bending section skeleton broken causing an abnormal movement with he up and down angulation. A cut was found on the bending section cover where the broken bending section skeleton is located. Upon removing the bending section cover, the bending section skeleton metal tab was found broken/detached. The scope was serviced and returned to the user facility. Based on similar reported events and investigation findings, the cause of the protruding/lifting skeleton metal tab could be attributed to the operator(s) technique. There was no patient injury reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7467189&pc=FGB

1.34. Patient suffered trauma to the left vocal cord, suffered submucosal hemorrhages, April 2018

A report in FDA'S **MAUDE** database states Olympus was informed that during a bronchoscopy left upper lobe lavage procedure, the patient suffered trauma to the left vocal cord, suffered submucosal hemorrhages, and experienced a sore throat post procedure as the bronchoscope did not advance in the trachea and into the patient as it was stuck in a retroflexed position and took 20 minutes to the Bronchoscope BF-H190 to gently extend into a neutral position. It was also reported the upon inspection of the scope post procedure an indentation mark/kink about

2 inches from the distal tip of the scope was found. The physician did not notice the kink prior to the procedure. Olympus made multiple follow ups with the user facility by telephone and in writing in an attempt to gather additional information on the reported event. The scope was not returned to Olympus for evaluation. Olympus performed a device service history review and found that the scope was purchased in 2014 and was last serviced at Olympus in 2017. Based on similar reported events, improper maintenance of the device could not be ruled out as a contributing factor to the reported event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7466505&pc=EOQ

1.35. Failures with dry and wet leak test when the distal cap and distal body failed seal integrity with a deformed biopsy insulation ring on the Duodenoscope, April 2018

A report in the FDA's **MAUDE** database states Pentax of America initiated field correction 2017-001-c which included inspection of the seal around the distal body and distal cap of the Duodenoscope ED-3490TK pursuant to predefined inspection criteria. The inspection was to verify there were no defects/discontinuities in the seal between the distal body and distal cap. The customer owned device was previously returned to Pentax medical from a customer on April 13, 2018 with a concern of fail dry leak test. On April 16, 2018 an inspection was performed where the quality control inspector found a bending rubber pinhole, prism scratched, distal cap/case cracked, biopsy insulation ring deformed, failed wet leak test, segment steel braid twisted, failed dry leak test, distal cap-fixed type failed seal integrity inspection. The device is currently in the repair process.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7447400&pc=FDT

1.36. Failure to form a seal between the distal body and distal cap of the Duodenoscope, April 2018

A report in the FDA's **MAUDE** database states Pentax of America initiated field correction 2017-001-c which included inspection of the seal around the distal body and distal cap of the Duodenoscope ED-3490TK pursuant to predefined inspection criteria. The inspection was to verify there were no defects/discontinuities in the seal between the distal body and distal cap. The customer owned device was previously returned to Pentax medical from a customer on April 9, 2018 with a complaint of bending rubber tear at distal end. On April 10, 2018 an

inspection was performed where the inspector found failures: bending rubber pinhole, prism scratched, distal cap, fixed typed failed seal integrity inspection, image shadows, failed dry/wet leak test, lightguide prong scratched, customer complaint confirmed, umbilical cable bump under pve root brace, bending rubber leak at middle section, lightguide prong glass set scratched. The scope is currently pending repair.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7447416&pc=FDT

1.37. Failure to form a seal between the distal body and distal cap of the Duodenoscope, April 2018

A report in the FDA's **MAUDE** database states Pentax of America field correction which included inspection of the seal around the distal body and distal cap of the Duodenoscope ED-349TK pursuant to predefined inspection criteria. The inspection was to verify there were no defects/discontinuities in the seal between the distal body and distal cap. The customer owned device was previously returned to Pentax medical from a customer in 2018 and inspected on order where the inspector found the following failures: distal cap fixed type failed seal integrity inspection, air/water socket cylinder o-ring chipped, prism scratched, passed dry/wet leak test, distal cap/case chipped, ETO vent valve loose inner shaft, middle light carrying bundle distal cover glass cracked, elevator body screw loose. Operation channel-primary mild resistance, image mild spot, insertion tube mild scratches at stage 3, insertion tube mild scratches at stage 10. The scope is currently pending repair.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7447401&pc=FDT

1.38. A Duodenoscope tested positive for multi-drug resistance pseudomonas during a routine surveillance culturing conducted by the user facility, April 2018

A report in the FDA's **MAUDE** database states that during a routine surveillance culturing conducted by the user facility, the Duodenoscope TJF-Q180V was test positive for multi-drug resistant Pseudomonas (1cfu/100ml). The scope used on the patient who was a known Pseudomonas carrier. The scope was used on two patients which the user facility identified on one of two patients the same Pseudomonas strain as on the carrier patient. The Duodenoscope had been reprocessed using Soluscope 4, a non-Olympus AER model. Visual inspection confirmed the following; chips and scratches on the adhesive of the bending section and

adhesives discolored to gray. There were dents and scratches on the distal end cover, wear and tear, brown parts, cracks and two pinholes on the adhesive of the distal end. The adhesive color was gray, cracks and missing part on the adhesive around the air/water nozzle and adhesive was gray in color. There were cracks inside of the light guide lens, pinholes on the adhesive around the objective lens and light guide lens and were peeled off. Annual inspection was conducted on the scope in 2017 and minor repair was conducted in 2017.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7424492&pc=FDT

1.39. Object pushed out of Olympus Gastroscope by tech in room, April 2018

A report in the FDA's **MAUDE** database states that an Olympus GIF-H180 seemed clogged. The tech in the room did a backflush of the scope after the case and was being cleaned pushed out an object. The object was given to the endoscopy supervisor.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7498451&pc=FDS

1.40. An unspecified Olympus 160 model endoscope was found leaking on the control buttons during an unspecified procedure, April 2018

A report in the FDA's **MAUDE** database states an unspecified Olympus 160 model endoscope was found leaking on the control button during an unspecified procedure and the patient contracted a stomach infection. It is unknown if the leaking scope is what caused the infection in the patient or the reprocessing of the scope. A different scope was used to finish the procedure. Olympus made multiple follow ups with the user facility by telephone and in writing in an attempt to gather more information on the reported event. Since not model or serial number was provided, Olympus was unable to perform a device service history review. It could be conclusively determined the cause of the reported patient infection.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7419845&pc=NWB

1.41. During an endoscopic procedure, a part of the distal end of the Olympus ligating device broke and lodged inside the endoscope, April 2018

A report in the FDA's MAUDE database states the Olympus was informed that during an unknown procedure involving an unknown make and model endoscope, a part of the distal end of the Olympus ligating device broke and lodged inside the endoscope. The endoscope was reprocessed using an unknown process and third-party brush made by US Endoscopy. A second procedure was done with the same endoscope which the broken off piece of Olympus ligating device was pushed in the second patient and the broken piece was retrieved with no further reported incident or adverse event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7554919&pc=FDT

1.42. Two patients' digestive tract mucosa turned white after contact with the insertion tube during an unspecified Endoscopy, April 2018

A report in the FDA's MAUDE database states that during two unspecified Endoscopy, the facility noticed the digestive tract mucosa of two patients changed their colors into white after contacted by the insertion tube of the Colonovideoscope CF-Q180Al. The facility thought the events were due to a rinsing problem (insufficient rinse during reprocessing) since the facility manually disinfected the scope with Peracetic acid. The scope was not returned to Olympus Medical Systems Corp. and the exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7555464&pc=FDF

1.43. Two patients' digestive tract mucosa changed color to white after contact by the insertion portion of the Colonovideoscope, April 2018

A report in the FDA's MAUDE database states during an unspecified Endoscopy, two patients' digestive tract mucosa changed color to white after contact by the insertion portion of the Colonovideoscope CF-Q180Al. the events were due to a rinsing problem (insufficient rinse during the reprocessing). The facility had manually disinfected the scope with peracetic acid. The facility followed up the patients by phone after the procedure and confirmed they are doing fine. The scope has not been returned to Olympus Medical System Corp.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7555563&pc=FDF

1.44. The user facility found that the bending section of the Ureteroscope broke during a therapeutic procedure, March 2018

A report in the FDA's **MAUDE** database states the Ureteroscope URF-V2 was returned to OMSC for evaluation and confirmed that air leak from the bending section of the device and the metal part was exposed from the bending section rubber. The OMSC also confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time as the evaluation has not been completed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7463398&pc=FGB

1.45. An unspecified number of patients Bronchoalveolar Lavage (BAL) washings tested positive for mycobacterium porcinum, March 2018

A report in the FDA's **MAUDE** database states Olympus was informed by the user facility that an unspecified number of patients' bronchoalveolar lavage (BAL) washings tested positive for Mycobacterium porcinum involving three different Olympus Bronchoscopes. Further reports states that the scopes were not cultured. The scopes are pre-cleaned after each procedure in the OR and manually cleaned and channels of the scopes are brushed with a non-Olympus Halyard single use dual-ended cleaning brush, leak tested with an Olympus leak tester, then processed in a non-Olympus Steris 1e AER machine. The last preventative maintenance on the AER machine was March 20, 2018 with no problems reported. The scopes are hung in a ventilated scope cabinet. The patients are fine and have been discharged. The Bronchovideoscope BF-H190 was returned to Olympus for evaluation and is still in progress and pending results. The scopes will be sent to an independent lab for microbial testing and ETO sterilization. An Endoscopy support specialist (ESS) was requested to be dispatched to the user facility to observe the facility's reprocessing practice and to provide a reprocessing training. The ess visit has not been finalized.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7442054&pc=EOQ

1.46. An unspecified number of patients Bronchoalveolar Lavage (BAL) washings tested involving three different Olympus Bronchoscopes, March 2018

A report in the FDA's **MAUDE** database states Olympus was informed by the user facility that an unspecified number of patients Bronchoalveolar Lavage (BAL) washings tested for involving

three different Olympus Bronchoscopes BF-H190. It was reported that the scope was not cultured. The scopes are pre-cleaned after each procedure in the OR and manually cleaned and the channels of the scopes are brushed using a non-Olympus Halyard single use dual-ended cleaning brush. The scopes are leak tested using an Olympus leak tester and reprocessed in a non-Olympus Steris 1E AER machine. The scopes are hung in a ventilated scope cabinet. The scope was returned to Olympus for evaluation and is still in progress and pending results. The scopes will be sent to an independent lab for microbial testing and ETO sterilization. An Olympus endoscopy specialist (ESS) was requested to be dispatched to the user facility to observe the facility's reprocessing practice and provide training.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7442058&pc=EOQ

1.47. Post procedure, Patient was admitted to the ICU after a Cystoscopy was performed, March 2018

A report in the FDA's **MAUDE** database states the physician performed a Cystoscopy procedure on patient with a 11272NVU Cystoscope. Patient was admitted to the ICU post procedure. Patient's urine was cultured and confirmed *Pseudomonas aeruginosa* infection. Patient was treated by an outside doctor and clinic does not have any information on treatment, patient most likely received antibiotics.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7418170&pc=FBO

1.48. Debris on distal lens and distal tip of the Cystoscope, patient's urine tested positive for *pseudomonas aeruginosa* infection, March 2018

A report in the FDA's **MAUDE** database states allegedly, the physician performed a Cystoscopy procedure on patient. Patient's urine was cultured, and *pseudomonas aeruginosa* infection was confirmed from the lab results. Patient was given antibiotics by a doctor from an outside clinic, doctor reported patient is doing fine. An evaluation was conducted and concluded there was debris on the distal lens and distal tip, of the Cystoscope 11272VNU, angle cover is cracked and has debris on it as well as the shaft marker rings are discolored. A nick was found on the handle housing. The evaluation suggests the user error can be linked to the physical condition of the instrument.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7418124&pc=FBO

1.49. A blue banding device from the previous case dislodged from the biopsy channel, March 2108

A report in the FDA's **MAUDE** database states that a patient having upper endoscopy, while advancing biopsy forcep down biopsy channel, a blue bending device from previous case dislodged from Gastroscope GIF-H180J. The band was removed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7475382&pc=FDS

1.50. Patient was perforated during a diagnostic Colonoscopy procedure, February 2018

A report in the FDA's **MAUDE** database states a patient was perforated during a diagnostic Colonoscopy procedure using a Colonovideoscope CF-HQ190L which was found post op. the patient received additional hospitalization and surgery to treat the perforation. The scope was returned to Olympus for evaluation and found the scope bending section discolored. The glue on the bending section was found lifted. There was also deep scratches and indentations on the distal end cover. A review of the scope service history was performed and found it was returned to Olympus multiple times for similar bending section issues. Based on the evaluation results, improper maintenance of the scope could not be ruled out as a contributing factor to the reported event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7546799&pc=PDF

1.51. Patient had undergone a diagnostic upper endoscopy with a Gastrointestinal Videoscope, felt pain in the left breast and back, February 2018

A report in the FDA's **MAUDE** database states that a patient returned to the user facility five hours with pain in the left breast and back after a diagnostic upper Endoscopy with an Evis Lucera Gastrointestinal Videoscope GIF-PQ260. There was possibility that abnormality in the esophageal exterior wall of mediastinum. The patient visited another facility for a CT scan, a perforation of the esophagus was found and was fixed by an endoscopic clipping procedure. It

was reported by the user facility that during the insertion of the upper endoscopy procedure, the distal end of the scope was retroflexed and when the facility tried to release the retroflex of the distal end, a laceration occurred in the esophagus at the location of 35 cm from the oral. The procedure continued since there was no bleeding from the laceration the procedure was completed and no bleeding during the withdrawal of the scope. The scope has not been returned to OMSC for evaluation and the exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7556063&pc=FDS

1.52. A pancreatic stent was pulled out of a Duodenoscope with tweezers during the cleaning process after an ERCP procedure was performed, December 2017

A report in the FDA's **MAUDE** database states that a pancreatic stent was found in the suction channel of the Duodenoscope ED-3490TK and retrieved with tweezers. The pancreatic stent had not been placed or attempted to be placed in the patient during this procedure or prior procedures. Pentax Medical became aware of a voluntary medwatch adverse event report forwarded by the FDA's office of surveillance and biometrics. Prior use several weeks earlier, the scope was documented as being cleaned per manufacturers recommendations. Pentax medical followed up with the facility to gather additional details on the event and to obtain the serial number of the Duodenoscope involved. The facility contact stated, that not portion fell into the patient and there was evidence of patient harm. The scope was returned to the manufacturer and did not find any problems with the scope and it was returned to use.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7399329&pc=FDT

1.53. Pentax Medical became aware of a cleaning issue and several malfunctions on the Duodenoscope ED-3490TK, November 2017

A report in the FDA's **MAUDE** database states on January 16, 2018, Pentax medical became aware of the identification results of sampling performed on 2017 on Pentax ED-3490TK. The sampling showed a total of 106 CFU of Pseudomonas Aeruginosa, the scope was returned to Pentax on November 14, 2017. When Pentax inspected the scope, the findings included: distal cap- failed seal integrity inspection, hole in and leak at #4 remote control head cover, hole in and leak #2 remote control button cover, air/water socket cylinder o-ring chipped, elevator

body, screw loose, failed wet/dry leak test. Repairs were performed and replacement of the biopsy inlet t-piece pb-free, air/water tube, deflector body, deflector body link, deflector operating wire, operation channel, bending rubber, distal cap/case, remote control button (1), deflector body attaching screw, deflector op wire adjusting screw. On January 12, 2018, the Duodenoscope was shipped back to the customer.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7448206&pc=FDT

2: Failures Due to Automatic Reprocessors (AERs)

2.1. User facility incoming water contained a black substance and causing the internal filter of the AER to turn black, February 2019

A report in the FDA's **MAUDE** database states that a Medivator FSE was on site to repair the facility's DSD-201 AER reported the incoming water contained a black substance, causing to 0.2 micron internal filter of the AER to turn black. The facility reported changing the filter more frequently due to buildup of the unknow substance. The Medivator FSE advised the facility to discontinue reprocessing in the AER until issue is resolved. The facility continues to use the AER. At the time the facility noticed the black substance, the city that the facility is located in had been issued a boil water order due to a local water main break. The facility collected samples and sent out for testing. Medivators FSE has been out multiple times and the AER is operating according to specification and is not the cause of the black substance. They are also in the process of obtaining water samples from the facility to perform chemical testing. The facility uses a third-party internal filter and is not the same as the 0.2 micron absolute filter recommended by Medivators. The facility is looking into a new pre-filter system to resolve the issue. There have been no reports of patient harm. Medivators remain in close contact with facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8336708&pc=FEB

2.2. A facility was using expired test strips to check the Rapiocide high-level disinfectant and disable one side of the DSD-201 AER, February 2019

A report in the FDA's **MAUDE** database states that a Medivator Field Service Engineer reported a facility had been using expired test strips to check the minimum required concentration of Rapiocide high-level disinfectant used in their DSD-201 AER. The FSE reported brown

discoloration of the intercept detergent used with their AER. The facility removed parts, disabling one side of their AER and is unable to perform water line disinfection which there is potential for contamination or inadequate HLD of the endoscopes prior to use in patient procedures. Rapicide HL test strips instructions warns users not to use the test strips after the expiration date (open or unopened). When the FSE noticed the discolored detergent, they disabled the optional wash phase of the AER and disposed of the discolored intercept detergent. It is unknown how many endoscopes were reprocessed using the discolored intercept detergent. The source of the discoloration is unknown. The facility removed parts and disabled side a of the AER only using side b due to the low volume of endoscopes being reprocessed. The IFU for the DSD-201 it is required to perform a water line disinfection after changing a water line and after any service is performed on the water supply system. No reports of patient harm. This complaint will continue to be monitored.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8368486&pc=FEB

2.3. Facility reported that smoke was coming from their Reliance Vision Washer, January 2019

A report in the FDA's **MAUDE** database states a facility reported that smoke was emitting from their Reliance Vision Washer. A Steris Service Technician arrived on site to inspect the washer and found the drying components overheated causing the event to occur. The overheating was due to on the of the unit's heater contactors "had become" stuck in the closed position causing the drying components in the washer to overheat. The service technician replaced the drying manifold and contactor, ran a test cycle confirmed it to be operating according to specification and returned it to service. The expected annual usage of the Reliance Vision Washer is 2,000 cycles. Although the washer ran 5,855 cycles in ten months.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8219844&pc=MEC

2.4. An employee developed exposure symptoms from Rapicide peracetic acid that leaked from the AER in their facility, January 2019

A report in the FDA's **MAUDE** database states the facility reported an employee developed exposure symptoms from Rapicide pa HLD that leaked from the AER. Employees at the facility reported a strong smell of fumes coming from the AER, and one employee reported getting a rash from the HLD exposure. A Medivator FSE was called on site and found a puddle of HLD

and water mixture at the bottom of the aer. It was determined the poa pump, that pumps HLD from the basin, was leaking and replaced it. He also replaced the AERs spray heads, bearing and gaskets. The AER was then tested and ran within specification. The facility does not have a service contract with Medivators and performs their own maintenance on their machine. The employee did seek medical attention the same day of the exposure and is doing fine now.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8214665&pc=FEB

2.5. The spray arm in the right side of the AER was not spinning during a reprocessing cycle due to lid sensors were reversed which disable the spray arm pump when the lid was closed, January 2019

A report in the FDA's MAUDE database states the user facility reported the spray arm in the right side of the Advantage plus AER was not spinning during a reprocessing cycle. Medivators FSE was dispatched to evaluate the AER, it was determined the lid sensors were reversed which disable the spray arm pump when the lid was closed and did not present an error message or alarm on the machine. There is potential that endoscopes reprocessed in the right basin did not achieve adequate HDL, which is cause for potential for cross contamination. Also, the exterior parts of the endoscopes that were not fully submerged in the basin during reprocessing were not properly high-level disinfected. The facility does perform proper bedside pre-cleaning and manual cleaning of endoscopes. The facility participated in in-service trainings provided by Medivators CES for their AERs which includes familiarity with the AER spray arms. The lid of the AER is transparent, and the spray arm is visually and audibly detectable, making it obvious to a trained operator if the spray arm is not spinning during a reprocessing cycle. There have been no reports of patient harm to date. It is unknown what endoscopes were reprocessed during this timeframe and what type of procedures were performed with potentially affected scopes. Complaint records and machine history records indicate that this is an isolated event and no similar complaints were reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8287300&pc=FEB

2.6. An operator experienced respiratory ailment from exposure to Rapicide peracetic acid HDL fumes when the lid of the AER opened during the waterline disinfection cycle, December 2018

A report in the FDA's **MAUDE** database states that a facility reported an operator experienced a respiratory ailment from exposure to Rapicide peracetic acid fumes when the lid opened of the AER during a waterline disinfection cycle. Medivators FSE dispatched to evaluate the AER. The FSE noticed fluid residue on the circuit board and a cracked coupling within the AER which may have caused a leaking during the waterline disinfection cycle. The leaking component may have caused an electrical short in the circuit board causing the lid to open during the waterline disinfection cycle. The concentration of the peracetic acid is approximately 0.2% which presents a low risk of adverse effects if exposed. The FSE repaired the AER and is now working to specification. A follow-up was made by Medivators regulatory to the facility and the sterile processing supervisor did confirm the operator was exposed to the fumes. When the lid opened during the waterline disinfection cycle due to fluid contacting the circuit board the cycle stopped and presented an error message as designed. Medivators has performed an assessment of this failure mode and has determined that the risk is acceptable and appropriate risk control measures are in place.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8180192&pc=FEB

2.7. Green slimy substance was forming on the spray arm filter of the user facility's Advantage Plus AER, December 2018

A report in the FDA's MAUDE database states the facility reported a green slimy substance forming on the spray arm filter of the Advantage Plus AER and green specks in the basin of the AER, other components in/around the basin was turning green. When the facility switched back to their normal detergent used during pre-cleaning the green substance went away. They were using pure enzymatic detergent during pre-cleaning at the time the green substance appeared. The facility also had their water tested and the results indicated high concentration of copper. Due to the quality of the facility water, the facility's biomed reported they have to change their water filters more frequently than the minimum, required schedule. The green substance remains unknown, and there are no reports of patient harm. It is unknown if the endoscopes contained the unknown green substance.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8200992&pc=FEB

2.8. Five endoscopes were reprocessed and used in patient procedures when Intercept detergent was accidentally added to the alcohol bottle used the facility's AER, December 2018

A report in the FDA's **MAUDE** database states a facility reported that Intercept detergent was accidentally added to the alcohol bottle used in their Advantage Plus AER. Five endoscopes were reprocessed and used in patient procedures after Intercept detergent was added to the alcohol bottle. There is potential that patients were exposed to the detergent during procedures. It is unknown how much detergent was added to the alcohol bottle. Medivators provided the facility with the SDS for the Intercept detergent and they provided the facility with assistance with cleaning out their AER and returning the unit to service after the incident. The facility did not follow the Advantage Plus user manual. Medivators regulatory followed up with the facility and they reported no patient adverse reaction and no medical attention was sought by the five potentially affected patients.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8180300&pc=FEB

2.9. Unknown yellow residue was found in the basin and drain screens of a user facilities AERs, July 2018

A report in the FDA's **MAUDE** database states a user facility reported an unknown yellow residue that was found in the basin and drain screens of their Advantage Plus Automated Endoscope Reprocessors with potential patient exposure to the residue during endoscopic procedures. A Medivator engineer did visited the facility to evaluate and clean the units to remove the residue and thoroughly inspect and samples taken for analysis by Medivators R&D. The residue was identified as a silicone-based substance which Medivators technical specialist and FSE confirmed this substance could not be introduced by any component from the AER. The residue was notice for the first time recently after having the AER for about a year and a half. It is unknown how many endoscopes have been reprocessed and if there were changes in the process. The facility is now keeping the drain screens clean and monitoring their units closely. There has been no additional information with the follow up from Medivators.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7765051&pc=FEB

2.10. A Duodenoscope has tested positive for bacteria during repeated culturing tests at the user facility, July 2018

A report in the FDA's **MAUDE** database states that an Evis Exera II Duodenovideoscope TJF-Q180V repeatedly test positive for bacteria during surveillance culturing tests at the user facility. The scope tested positive for Enterobacter cloacae pseudomonas spp. (>100 cfu/100 ml), Bacillus spp. (24 cfu/100 ml), Sphingomonas paucimobilis (1 cfu/100 ml), Acinetobacter calcoaceticus (1 cfu/100 ml), Acinetobacter species (2 cfu/100 ml) and shigella (2 cfu/100 ml). The scope was also tested positive for gram positive Bacillus (6 cfu/100 ml) and tested positive for unspecified gram-positive bacteria (35 cfu/100 ml). The user facility reprocessed the scope in an Olympus AER ETD-3 and ETD-4. The scope was returned to OMSC and sent to a third-party lab for additional testing which resulted with no microbial growth. It was confirmed that no irregularity was found with the scope. Exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7730215&pc=FDT

2.11. AER caught fire during reprocessing, May 2018

A report in the FDA's **MAUDE** database states that a Medivator DSD edge caught fire during reprocessing of an endoscope. No other information was provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7633335&pc=NVE

2.12. Customer incorrectly installed their Medivators CER-2 Optima AER, resulting in HLD being pulled through the machine, May 2018

A report in the FDA's **MAUDE** database states the customer installed their CER-2 Optima AER incorrectly, which resulted in HLD being pulled through the machine during the air purge of the endoscope reprocessing cycle. The residual left behind could potentially cause patient chemical colitis. The AER does not require a Medivators personnel to install the machine. The AER was receiving leak errors with a complaint filed by the facility. A Medivators service engineer was called onsite to investigate the complaint and discovered the AER was incorrectly installed by the facility. The machine was returned to Medivators and was confirmed the air tube was hooked up to the HLD tank, thus not following the IFU for install. The AER was used for about two weeks during the time in which their machine was installed incorrectly with potential for patient chemical colitis. It was reported that employees felt ill from the HLD being

leaked into the machine with no specific symptoms being reported. A new machine was ordered with a Medivators field service engineer present to install and ensure following the IFU.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7575765&pc=FEB

2.13. There was a burning odor emitting from the AER light socket and a small flame coming from the light socket, May 2018

A report in the FDA's **MAUDE** database states the user facility stated that a burning odor was emitting from the unit and observed a small flame coming from the light socket. The Steris technician was on site and inspected the washer and identified that the light socket was damaged. The Steris technician reported the issue is attributed to improper insertion of the light bulb into the light socket causing an electrical arc to occur. The light socket was replaced by the technician and ran a test cycle, confirmed the unit was operating properly. The technician counseled the facility personnel on the proper way to insert the light bulb, ensuring it is fully seated in the socket. The unit was installed in 2010 and is under Steris service agreement for maintenance activities.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7607056&pc=MEC

2.14. Blue residue remaining in Endoscopes and hookup tubing after reprocessing in the Advantage Plus Automated Endoscope Reprocessors, April 2018

A report in the FDA's **MAUDE** database states the facility reported blue residue remaining in Endoscopes and hookup tubing after reprocessing in their Advantage Plus Automated Endoscope Reprocessors. The detergent used during the manual cleaning phase of reprocessing is not getting rinsed out of their endoscopes. There is potential for chemical exposure to patients which could cause chemical colitis. The clinical education specialist reported the blue residue has only been observed when using certain hookups. The CES also reported the staff were not properly flushing the endoscopes after using intercept detergent. The Medivators specialist confirmed proper operation of their Advantage Plus AERs.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7519503&pc=FEB

2.15. During a yearly in-service with Medivators clinical education specialist reported the facility was using the incorrect hookups for endoscopes, March 2018

A report in the FDA's **MAUDE** database states the clinical educator from Medivators was performing a yearly in-service at the facility and reported they were using the incorrect hookups with their endoscopes while reprocessing in the DSD-201 AER. There is potential that the endoscopes were not properly high level disinfected, and potential for patient cross contamination. The CES educated the users on correct hookup use and placement as well as provided information documentation. There have been no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7392268&pc=FEB

2.16. Facilities experiencing a white residue being left on Olympus endoscopes after reprocessing in AERs, March 2018

A report in the FDA's **MAUDE** database states Medivators received information from facilities which are experiencing a white residue being left on Olympus endoscopes after reprocessing in Advantage Plus AERs and other AERs. The facility temporarily suspended all elective GI procedures to investigate cause and identify the residue. The residue was identified as a silicone-based compound when numerous tests were performed by third party labs. Medivators performed an internal investigation after requesting a copy of the test reports performed by each lab. The results identified the residue as poly butyl methacrylate which is a chemical commonly used as the adhesive compound on the back of tape, labels and stickers. It was noted that when the AERs were removed from the HLD process and replaced by manual HLD, the residual was still found. All endoscopes are being inspected after reprocessing and removing any remaining residual using isopropyl alcohol prior to using for procedures. To date there have been no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7421179&pc=FEB

2.17. SD-201 Automated Endoscope Reprocessor was programmed with the incorrect number of rinses required for HLD, December 2017

A report in the FDA's **MAUDE** database states that their DSD-201 AER was programmed with the incorrect number and contact time of rinses for the HLD that was being used. Metricide HDL requires 3 minutes at 1 minute each, with the facility that was reprocessing the

endoscopes had the program set at 2 rinses at 30 seconds each. Over the phone, Medivators instructed the facility how to set the machine back to the correct program. The DSD-201 user manual states that the user is instructed to verify the program settings are appropriate for the disinfectant being used prior to reprocessing scopes. There is potential chemical colitis or irritation to patients that come into contact with improperly rinsed scopes and there have been no reports of harm to patients.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7200127&pc=FEB

3. Employee Chemical Burns

3.1 Two employees experience a burn while handling items that were processed and not wearing chemical-resistant gloves (PPE). January 2019

A report in the FDA's **MAUDE** database states that two employees experience a burn while handling item that were processed in a V-Pro 1 Sterilizer. One employee did receive medical treatment and the other did not. A Steris service Technician arrived on site to inspect the sterilizer and found the unit to be operating properly and was returned to service. The two employees were not wearing proper PPE, specifically gloves when using the sterilization unit. The V-Pro 1 Sterilizer does state "danger chemical injury hazard..." and also states "dry all items thoroughly...". A Steris account manager offered in-service training on the importance of wearing proper PPE however, the user facility declined. No additional issues have been reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8219836&pc=MLR

3.2 Several employees experienced irritation from an oil mist emitting from their V-Pro Max Sterilizer producing a haze throughout the room, January 2019

A report in the FDA's **MAUDE** database states the user facility reported several employees experienced irritation from an oil mist emitting from their V-Pro Max Sterilizer. They sought medical treatment and returned to normal work duties the next scheduled workday. During the time of the event the sterilizer was running a cycle when the unit began to produce a "haze" throughout the room. A Steris technician arrived onsite to inspect the sterilizer and found that one of the o-rings, located on the oil mist eliminator became dislodged. As the o-

ring became dislodged this allowed for oil to build up around the filter housing and the reported event to occur. The o-ring was replaced, and the unit was tested by the technician. It was confirmed to be operating to specification and the unit was returned to service.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8271708&pc=MLR

3.3. An employee experienced a burning sensation while unloading instruments that were processed in a V-Pro Max sterilizer, June 2018

A report in the FDA's **MAUDE** database states that at a user facility an employee experienced a burning sensation while unloading instruments that were processed in a V-Pro Max sterilizer. The employee was not wearing proper PPE and there was no medical treatment sought or administered. There are two V-Pro Max sterilizers at the user facility and could not confirm which unit the reported event occurred on and reviewed the units cycle printouts confirms that the cycles completed successfully for both units. A Steris service technician inspected the sterilizers and found both units to be operating properly with no issues of the functions or operations were identified and were returned to service. The technician counseled the personnel on the importance of thoroughly drying instruments and wearing proper PPE while operating their V-Pro Max sterilizer. No additional issues were reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7627367&pc=MLR

3.4. An employee received a burn on their hand while unloading instruments from their V-Pro Max, June 2018

A report in the FDA's **MAUDE** database states that at a user facility an employee received a burn on their hand while unloading instruments from their V-Pro Max sterilizer. The employee rinsed off their hand with water and returned to work. A Steris service technician arrived onsite and found the sv4 (injection valve) and sv5 (reservoir valve) did require replacement, causing the instrument packs to not fully dry. The sc4 and sc5 were replaced and ran a test cycle, the unit is operation according to specifications and returned it to service. The Steris technician confirmed the employee was not wearing PPE specifically chemical resistant gloves while removing the instruments. The Steris account manager provided a full in-service training on the proper use and operation of the V-Pro Max sterilizer and wearing appropriate PPE.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7701012&pc=MLR

3.5. A customer reported an event of a strong odor emitting from the Sterrad® 100NX Sterilizer after the cycle completes, May 2018

A report in the FDA's **MAUDE** database states a customer reported an even of a strong odor emitting from the Sterrad® 100NX Sterilizer after the cycle completes, and the chamber door is opened. A healthcare worker experienced burning in both eyes but did not seek or receive any medical attention because the pain subsided once they left the room. It was advised to turn off the machine and leave the room. Based on information received, the healthcare workers symptoms suggest the event was not serious and resolved without medical attention. A field service engineer was dispatched to the customer site and the vacuum pump and vacuum pump control were replaced to resolve the odor/smell issue.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7541293&pc=MLR

3.6. A V-Pro Max sterilizer was found to be emitting a mist that filled the room with “haze”, May 2018

A report in the FDA's **MAUDE** database states that a V-Pro Max sterilizer was found to be emitting a mist that filled the room with “haze” activating the facility's fire alarm. The Steris service technician arrived at the facility to inspect the sterilizer and observed that the oil filters were saturated with oil and oil residue. The vacuum pump oil is non-toxic and not considered hazardous. The valves and filters were replaced and ran a test cycle and found the unit to operating according to specifications. The unit was returned to service with no additional issues.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7561010&pc=MLR

4. Water Quality Issues

4.1. Olympus was Informed Several Bronchoscopes Model #s BF-260, BF-1T260, and BF-F260 Tested Positive for Fungus as a result of Microbiological Culturing Testing by the Facility, March 2018

A report in the FDA's **MAUDE** database states that the sample collected from three BF-260 and one BF-1T260 tested positive for fungus. The Olympus Bronchoscopes were used on seven out of eight patients who tested positive for fungus. It was reported that six patients were doing well, but one patient was still ill. There is no information about the other patients' outcome. The Bronchoscopes were used to obtain bal samples, however Olympus is unsure as to whether the ball samples were positive or negative. Reports 1-4 of 4.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7463725&pc=EOQ

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7463723&pc=EOQ

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7463729&pc=EOQ

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7463730&pc=EOQ

The sample collected was from one BF-F260, two BF-260 and one BF-1T260 tested positive for fungus. The customer had been investigating causes of a possible outbreak of environmental contamination in a number of Bronchoalveolar lavage (bal) samples taken using flexible bronchoscopes and non-Bronchoscopes and non-Olympus Bronchoscopes in the last four months. Model BF-260 was used on patient one, two and seven. Model BF-F260 was used on patients three, four, five and eight. Patient six a non-Olympus rigid scope was used. It was confirmed there was no irregularity of the subject device when Olympus reviewed the manufacturer history. However, Olympus communicated with the user facility and obtained additional information that the Bronchoscopes are dried for a min. of 2 hours and vacuumed packed per normal reprocessing process. A shelf life of 21 days, one Bronchoscope was used in an endoscopy procedure 14 days after expiry date. The hospital is undertaking extra testing to identify where the source of the bacteria Basidiomycetes came from. There is mold in the endoscopy unit and walls were damp where the mold was. The user conducted weekly water samples from the washer. There was a water failure in December, January, and beginning of February where the washer was taken out of use with no water failures have occurred. The user facility conducted environmental test after cleaning. The test results came back as: high levels of mold grew from pre-assessment rooms and corridor outside, lower levels readings of mold grew from the procedure rooms where the bronchoscopy procedure was conducted, the recovery room, clean scope room and the reprocessing room. A microbiological testing was

conducted by a third-party laboratory with results as follows: BF-1T260 tested positive for Staphylococcus and Bacillus (total 7 cfu), BF-260 tested positive for Staphylococcus (11 cfu), BF-F260 tested positive for Gram Negative Bacteria (2 cfu), BF-260 tested positive for Staphylococcus (5 cfu). An exact cause could not be determined at present. Reports 5-7 of 7.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7595226&pc=EOQ

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7595227&pc=EOQ

5. Use Errors

5.1. With multiple microbiological testing by the facility, microbes were detected from the sample collected from a Fiberscope, February 2019

A report in the FDA's **MAUDE** reports states with multiple microbiological testing by the user facility, microbes were detected from the sample collected from all channels of the Fiberscope CYF-5 in 2018. First time: Micrococcaceae (18 cfu/endscope); second time: Staphylococcus coagulase negative (1 cfu/endscope); third time: Micrococcaceae (2 cfu/endscope); Fourth time: Pseudomonas alcaligenes (7 cfu/endscope). The results do not clear the guideline. The scope has been manually reprocessed using peracetic acid and no report of infection with this report. The scope was sent to OMSC for evaluation and the manufacturing history confirmed no irregularity. The exact cause could not be conclusively determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8194526&pc=FAJ

5.2. Two patients developed Kelbsiella pneumonia infections after undergoing Cystoscopy procedures using two of the facility's Cystonephrofiberscopes, February 2019

A report in the FDA's **MAUDE** database states that after undergoing a Cystoscopy procedure using two of the facility's Cystonephrofiberscope CYF-5R that two patients developed Kelbsiella pneumonia infections. Both patients were treated with intravenous antibiotics. The facility reported they use enzyme and aldaol cleaner to disinfect and clean the scope. The minimum effective concentration is being checked every 2 weeks. The scope channel is being brushed

during manual cleaning using a reusable brush and is precleaned immediately after the procedure. The scope is not being leak tested prior to manual cleaning and no known issue with the facility's AER. The last in-service with an Olympus ESS was on Feb. 5, 2019. No changes to the facility's reprocessing staff since last in-service. All reprocessing staff were trained properly on how to reprocess an endoscope according to the user facility. The scope was returned to Olympus and is pending evaluation and microbial testing which will be sent to an independent lab for microbial testing. On Feb. 4, 2019 an Olympus ESS was dispatched to the facility's reprocessing practices and provide training. The ESS was informed the facility did not have a leak tester and wanted the in-service to be scheduled for a later date. Date has not been finalized. This is 2 of 2 reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8364744&pc=FAJ

5.3. An EVIS EXERA II Colonovideoscope (CF-H180AI) tested positive for microbes three different times for microbial growth, February 2019

A report in the FDA's MAUDE reports states in 2018 the subject device tested positive three times. First time: Klebsiella pneumoniae (1.89 cfu/ml), Pseudomonas aeruginosa (2.7 cfu/ml); second time: Klebsiella pneumoniae (12.8 cfu/ml); third time: Pseudomonas aeruginosa (8.8 cfu/ml). There was no information regarding the reprocessing method and no report of infection associated with this report. The device was not returned to OMSC but returned to Olympus and sent the device to a third-party laboratory for microbiological testing. The sample that was collected from the distal end of the scope tested positive for microbe of Pseudomonas aeruginosa group (1 cfu). There was no irregularity of the device when OMSC reviewed the manufacturing history. 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=8309513&pc=FDf

5.4. An EVIS EXERA III Colonovideoscope (CF-H185I) tested positive for microbes several times, January 2019

A report in the FDA's MAUDE reports states in 2018 the subject device tested positive for microbes. Klebsiella pneumoniae (1 cfu/200ml) and Pseudomonas aeruginosa, Enterobacter aerogenes and Klebsiella pneumoniae (7 cfu/200ml in total). The area of the device were the

microbes were detected were not reported. The scope had been disinfected using peracetic acid and no patient infection associated with this report. The device was not returned to OMSC but was returned to Olympus. With additional testing, the testing indicated no microbial growth for the scope. The manufacturing history was reviewed and confirmed no irregularity. The exact cause of the event could not be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8269955&pc=FDf

5.5. An EVIS EXERA II Duodenoscope TJF-Q180V cultured positive for a high concern microorganism, E. coli after reprocessing, January 2019

A report in the FDA's **MAUDE** database states Olympus was informed that during a post market surveillance study the Duodenoscope culture positive for a high concern microorganism, E. coli after it was reprocessed. A Medivators Edge AER machine is what the user facility uses for high level disinfection. The scope was not returned to Olympus for evaluation. The ESS reported an in-service on reprocessing was last performed at the user facility two years ago and utilizes non-Olympus vendors for repair and for education Prezio Health. The reprocessing practices were observed by and ESS and also to provide training if necessary. The visit has not been finalized. The cause of the reported event could not be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8169509&pc=FDT

5.6. During a post market surveillance study, the Duodenoscope TJF-Q180V cultured positive for Klebsiella pneumonia after reprocessing, January 2019

A report in the FDA's **MAUDE** database states Olympus was informed that during a post market surveillance study the scope cultured positive for K. pneumoniae after reprocessing. The EVIS EXERA II Duodenoscope was returned to Olympus for evaluation and followed up with the user facility. The endoscope is leak tested prior to manual cleaning with an Olympus mu-1 and mb-155. The user facility is using enzymatic Prolystica detergent for manual pre-cleaning, channel is brushed during manual cleaning with an US endoscopy single brush. The pre-cleaning is performed immediately after each procedure. For high level reprocessing the facility uses an OER-PRO with acecide c. The AER's minimum effective concentration is being checked after each cycle. On June 9, 2018 the user facility participated in a reprocessing in-service and November 27, 2018 conducted by an Olympus endoscopy support specialist. Since the last on-

site in-service there have been no changes with the facility's reprocessing personnel. There are no known issues with the AER and the exact cause of the reported event cannot be determined at this time. An ESS was sent out to the facility to observe the reprocessing routine of the technician who reprocessed the scope prior to the sampling and provide training if necessary. The visit has not been finalized.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8265956&pc=FDT

5.7. Pentax Medical became aware of a report about a video Duodenoscope model ED-349TK which became a high concern with bacterium after sampling, January 2019

A report in the FDA's **MAUDE** database states that in 2018 Pentax Medical became aware of a report for Pentax Medical video Duodenoscope model ED-3490TK had yielded a high concern for bacterium after sampling performed in 2018. The sampling that was performed identified six colony forming units: Positive rods- unidentified, Filaments mold-Cochilobolus kusanoi/Curvularia lunata, positive cocci- Staphylococcus petrasii, positive cocci- Staphylococcus lugdunensis.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8261460&pc=FDT

5.8. Patient died due to what the user facility considered an infection in the patient caused by the remained stones after an ERCP procedure of bile duct stone extraction, January 2019

A report in the FDA's **MAUDE** database states that Olympus medical systems corp. was informed that a patient developed a fever and sepsis after an unspecified Endoscopic retrograde cholangiopancreatography (ERCP) procedure using the EVIS EXERA II Duodenovideoscope TJF-Q180V. An Olympus representative visited the user facility to obtain detailed information on the reported event and it was informed that the patient had several health problems and died due to infection which caused by some remained stones after the procedure for bile duct stone extraction. The facility commented there was no relationship between the death of the patient and procedure using the Duodenoscope or the Duodenoscope itself. The patient had undergone several procedures for the bile duct extraction in 2018 and had a bladder tumor. Once a month a microbiological culturing tests were done by the facility for the Duodenoscope TJF-Q180V and it was reported that unspecified microbes were detected during the testing and after the procedure. The

Duodenoscope had been reprocessing using a non-Olympus AER model Soluscope 3 with peracetic acid. Olympus followed up with the user facility and receive additional information about the patient. The patient developed multiple organ failure and sepsis after the ERCP procedure. The facility thought the disorders were caused from the residual stones in the procedure, they then conducted additional treatment using another Duodenoscope TJF-Q180V. The result of the microbiological test on the Duodenoscope used for the additional treatment no microbes were detected. The patient did have symptoms prior to the procedure and no microbe was detected. Olympus has determined that this device was not likely the cause of the reported event. The results of the microbiological test on the TJF-Q180V that *P. aeruginosa* was detected from the forceps elevator and *Conidia parapsilosis* was detected from the air/water channel. Symptoms of the patient did not improve with further treatment and blood tested positive for *Enterobacter cloacae*. The reprocessing practice in the user facility had been deviated from the Olympus instructions. The forceps elevator was brushed using Olympus cleaning brush for channel-opening (model mh0507) the facility was provided with the maj-1888 as the cleaning brush for the forceps elevator. The model mh-507 brush was also used to clean the biopsy valve, suction valve, and the air/water valve which is not instructed as the brush for valves. The biopsy valve, suction valve and air/water valve were not removed before storage after reprocessing. A non-Olympus reusable cleaning brush (model cle1-c2-30-16-280) was used to clean the instrument channel. This brush was disinfected at the end of the day with peracetic acid. These devices were not returned to OMSC for evaluation. OMSC reviewed the manufacturing history of the device and confirmed no irregularity. The exact cause of the culturing test result could not be determined. This report will be supplemented if more information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8201799&pc=FDT

5.9. Customer claims it is difficult to clean or cannot clean Gastroscope during reprocessing, December 2018

A report in the FDA's **MAUDE** database states Pentax medical customer service department received a customer complaint in 2018 claiming difficult to clean or cannot clean during reprocessing of the Pentax Video Gastroscope EG29-I10. The customer forwarded a response email to a good faith effort he received from another department in 2018, that they do perform their operational check before each use and there were no issues notes prior to the procedure at bedside. They responded that after the procedure in which biopsy forceps, were used, the scope failed ATP testing three times at the biopsy channel after each cleaning and the Gastroscope was removed from circulation and subsequently called in for service. The brushes were unable to be used to clean the Gastroscope. They also documented

their reprocessing steps. The scope was returned in 2018 and is pending evaluation by the service repair team.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8165725&pc=FDS

5.10. Pentax Medical became aware of a report about Model ED-3490TK became a major concern with bacterium, December 2018

A report in the FDA's **MAIDE** database states that on November 20, 2018 Pentax Medical became aware of a report for Pentax Video Duodenoscope model ED-3490TK had yielded a major concern. Bacterium was found after sampling was performed in 2018. The sampling identifying colony forming units. As TNTC (too numerous to count) comprising of: negative rods- P. aeruginosa. Pentax received the duodenoscope for evaluation on December 3, 2018.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8181129&pc=FDT

5.11. Four patients were tested positive for CRE, Enterococcus faecium or E. Coli after an ERCP procedure at the user facility using an Olympus Duodenoscope TJF-Q180V between June 2018 and December 2018, December 2018

A report in the FDA's **MAUDE** database states that Olympus Medical Systems was informed that the samples collected from four patients were tested positive for CRE, E.faecium or E. Coli after and ERCP at the user facility using an Olympus EVIS EXERA II Duodenovideoscope TJF-Q180V between June 2018 and December 3, 2018. 1.) Patient had common bile duct stone and underwent ERCP and due to the distal common bile duct obstruction, the facility repeated other ERCP in 2018. The patient developed fever and tested positive for CRE after blood test and was treated at the facility, the patient's condition is getting better. 2.) Patient had an obstructive jaundice symptom and underwent the ERCP with Duodenoscope TJF-Q180V in 2018 and a duodenal plastic stent 7FR. 12cm was inserted. Patient developed a fever and blood test indicated CRE and E.faecium positive and was treated at the facility, the patient's condition is getting better. 3.) Patient has unspecified disease in right lobe liver with obstructive jaundice and underwent the ERCP with Duodenoscope with patient developing a fever. The patient's blood tested positive for CRE and E. coli. Patient was admitted and treated in ICU and it was reported that the patient died in 2018. 4.) Patient had multiple CBD stones and underwent an ERCP procedure with a Duodenoscope TJF-Q180V three times in 2018. The facility changed procedure to an open surgery after the last ERCP due to a large stone. Patient was admitted for

post-op follow up and a culturing test was done for the bile which indicated E. coli and E. faecium positive and a blood test indicated microbial growth. Patient was admitted and treated in ICU and was getting better. The Duodenoscope was reprocessed in an Olympus AER, OER-AW with .55% Ortho-phthalaldehyde. The user facility has five Duodenoscope TJF-Q180V but the serial number that was used for each ERCP could not be identified. All five Duodenoscopes had microbiological testing to which two of the five tested positive for microbe: CRE, unspecified microbe was detected when samples were collected from the instrument channel, but no microbe was detected after additional reprocessing. There was no microbial growth for the other Duodenoscopes. Olympus did review the service history for the Duodenoscope. An annual inspection was conducted on May 3, 2018 but the other four are waiting for inspection. An Olympus representative from Thailand visited the facility the user facility for reprocessing training and assessment for the reprocessing practice at the facility. The facility informed that they reuse Olympus single use cleaning brush maj-1888. The instruction manual has warned that the instrument is intended for single use only, do not attempt to reuse it. The serial number is unknown for this device and OMC could not confirm the manufacturing history. The exact cause of reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8201861&pc=FDT

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8201871&pc=FDT

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8201863&pc=FDT

5.12. A sticky film was discovered on the outside of a Colonoscope (CF-HG-109I) after reprocessing, November 2018

A report in the FDA's **MAUDE** database states that GI techs, reprocessing the endoscopes in the GI lab, reported finding a "sticky film" on the outside of a Colonoscope (CF-HQ 109I0 after it was removed from the AER performing high level disinfection. The film appeared in different areas of the insertion tube in a very thin layer and dull in appearance and was sticky to the touch. There was a concern that the scope was not cleaned adequately for patient use and went through repeated reprocessing with no effect on the residue. Dawn was used as recommended by Olympus for substances that may not be removed with enzymatic detergent routinely used. The scope was quarantined due to the concern it was not cleaned properly for patient use. The GI tech at the time did not recall noticing the stickiness during manual cleaning. The next day two GI techs reprocessing endoscopes reported that two additional endoscopes were found to have sticky film on the endoscope, they were a pediatric Colonoscope (PCF-H-190I) and a Gastroscope (GIF-HQ190) which was visually noticeable but not localized to a particular area on the endoscope. In questioning the GI techs there could have been an endoscope the previous week with some stickiness on it, nothing was investigated as the techs felt they removed it when drying the scope. All the scopes were visualized under magnification and the sticky film was only found on the three scopes. Olympus reps were in the department and completed a full circle review of their workflow. No "red flags" were identified and the GI team was commended for hardwired processes. The Medivators DSD Edge reprocessors were evaluated and they were all up to date on all preventative maintenance, internal and external filter changes. No changes to the chemical used in the machines and no chemical changes used in other steps of the cleaning process. The Olympus assisted in removing the sticky film with alcohol, adhesive remover, and more aggressive friction. The Olympus rep. reported that she feels the scopes can now be placed back into service.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8189428&pc=FDA

5.13. A Bronchoscope was reported to have seven positive cultures following seven Bronchoscopy procedures on seven patients, August 2018

A report in the FDA's **MAUDE** database states that the first patient of seven was a morbidly ill male with pre-existing pneumonia and the Bronchoscopy took place in 2018. The user facility reported that the patient expired due to the pre-existing condition. The culture following the first patient had *Stenotrophomonas*, *Achromobacter* and an unknown species yeast. An

Olympus ESS was dispatched to the user facility to observe the facility and training of user facility personnel. The ESS found the facility to occasionally use a standard bronchoscope in the same procedure before using the Olympus EBUS scope. When the scope is removed it is not immediately precleaned, it is placed asided in a case potentially used again in the procedure. The ESS advised the facility to discontinue this practice and use a new scope after the EBUS scope. The facility clarified the positive culture for the patient involved was s. Maltophilia and yeast only. After the procedure for precleaning, the scope was wiped on the outside. Bedside cleaner was used to clean the scope and sent through the channel and hand washed on the outside. For manual cleaning, a single use endoscopy brush model 00711-609 was used and placed in an Olympus OER-Pro reprocessing system. The OER-Pro was checked before use and has no reported reprocessing issues. The scope was stored in a hanging cabinet and air drying. The user facility has not had any reprocessing in-service since the OER-Pro was purchased and since have new reprocessing personnel. An Olympus ESS will be dispatched to the user facility to observe the reprocessing practices and provide training as necessary.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7831439&pc=EOQ

5.14. A Gastrointestinal Videoscope tested positive for unspecified drug-resistant bacteria after being reprocessed twice, August 2018

A report in the FDA's **MAUDE** database states OMSC was informed during a surveillance culturing test by the facility that the Evis Exera III Gastrointestinal Videoscope GIF-H190 test positive for unspecified drug-resistant bacteria (number and type of bacteria were not informed) after being reprocessed twice. The scope was cleaned with peracetic acid (neodic septo pac). No other details were given by the facility and there was no report of patient infection associated with this report. OMSC reviewed the manufacturer history report of the scope and confirmed no irregularity and the exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7761072&pc=FDf

5.15. User Facility is unsure whether a patient had an existing infection with Klebsiella pneumoniae Carbapenemase or Duodenovideoscope was the cause of the infection, July 2018

A report in the FDA's **MAUDE** database states that OMSC was informed about a potential patient infection with Klebsiella pneumoniae Carapenemase which the patient also underwent

an ERCP procedure using the Evis Exera II Duodenoscope TJF-Q180V. It is unclear whether the reported infection was the cause of the scope or already existing before the procedure. The user facility has started its own investigation and is presently unclear where the infection comes from. There was no reprocessing deviation confirmed by the facility. OMSC was informed that during a periodically microbiological testing by the facility, microbes were found on the scope: Klebsiella pneumoniae Carbapenemase, pseudomonas Aeruginosa and Citrobacter freundii with the number of microbes unknown. The user reprocessed the scope with a non-Olympus AER using non-Olympus chemicals. This scope has been returned to Olympus and sent the scope to a third-party laboratory for microbiological testing. The results from testing the sample collected from the air/water channel of the subject device tested positive for the unspecified microbes (1 cfu/ml). After reprocessing the scope was sent to a third-party again for additional testing and no microbe was detected. No irregularity was confirmed for the history of the scope when reviewed by OMSC. Exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7745807&pc=FDT

5.16. One of three scopes cultured positive after reprocessing three different times, July 2018

A report in the FDA's **MAUDE** database states three Evis Exera II Gastrointestinal Videoscopes (2 GIF-H180J scopes) and (1 GIF-XTQ160 scope) were cultured positive (bacteria unknown) after reprocessing three different times. The cause of the event could not be determined, and evaluation is still in progress. The scopes were sent to an off-site independent lab for microbial testing and ethylene oxide sterilization. An ESS was dispatched to the user facility to observe the reprocessing practice and provide training and is still in progress.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7724278&pc=FDf

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7724337&pc=FDf

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7724153&pc=FDS

5.17. A Gastrointestinal Videoscope test positive during a surveillance culturing test at the facility, June 2018

A report in the FDA's **MAUDE** database states OMSC was informed the Evis Exera II Gastrointestinal Videoscope GIF-2TH180 tested positive for bacteria during a surveillance culturing test at the facility. Biopsy channel 1: Staphylococcus aureus (990 cfu/ml), biopsy channel 2: Staphylococcus aureus (1 cfu/ml), auxiliary channel: Staphylococcus aureus (990 cfu/ml). Also, during additional testing the scope tested positive for the following bacteria (18cfu/endoscope). Biopsy channel 1: Coagulase negative staphylococcus (1 cfu/ml), air/water channel: Staphylococcus aureus (990 cfu/ml), auxiliary channel: Micrococcus (1cfu/ml). The reprocessing method at the user facility was not provided from the facility and no report of patient infection associated with the event. OMSC reviewed the manufacture history of the scope and confirmed no irregularity and exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7576653&pc=FDF

5.18. A Duodenoscope tested positive for Escherichia coli, Coagulase negative staphylococcus and Bacillus, June 2018

A report in the FDA's **MAUDE** database states that an Evis Exera II Duodenoscope TJF-Q180V culture tested positive for Escherichia coli, Coagulase negative staphylococcus, and Bacillus which Olympus had been informed by the user facility. A mh-507 Olympus brush was used for sampling behind the elevator and the sterile water flush was collected from the tip of the scope. The Duodenoscope was high level disinfected and pre-cleaned twice after each patient use with no patient infection. The scope was returned to Olympus with the evaluation still in progress and will be sent to an independent lab for microbial testing and ethylene oxide sterilization. An Olympus Endoscopy Support Specialist visited the facility to observe the reprocessing practice and provide a reprocessing training. The ESS found no deviation during the visit.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7575724&pc=FDT

5.19. A Pentax Duodenoscope cultured positive after sampling was performed and yielded a total of 187 CFU, June 2018

A report in the FDA's **MAUDE** database states a Pentax model ED-3490TK cultured positive after sampling was performed yielded a total of 187 cfu comprised of the following four isolates: positive rods- Planococcus species, positive cocci- Staphylococcus epidermidis, positive cocci- Micrococcus luteus, positive cocci- Micrococcus luteus. The scope was returned to Pentax Medical for evaluation. The scope was reprocessed and resampled in accordance to Pentax medical procedures. The resampling yielded 135 cfu with the following three isolates: positive cocci-Kocuria koreensis, positive cocci-Kocuria koreensis, positive cocci-Staphylococcus saprophyticus. On July 2, 2018 the scope was inspected by Pentax Medical service with findings including: channel improperly installed with gap distal body opening, distal cap, fixed typed passed epoxy seal integrity inspection, passed dry/wet leak tests, primary mild scratch inside. The Duodenoscope is currently undergoing repairs.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7683552&pc=FDT

5.20. A foreign body of “biological appearance” was expelled through the distal end of the instrument channel of the Colonovideoscope, June 2018

A report in the FDA's **MAUDE** database states that during a colonoscopy procedure for Polypectomy, a foreign body of “biological appearance” was expelled through the distal end of the Evis Exera LLL Colonovideoscope when a snare was pushed through the channel. There was no patient infection and the procedure was completed successfully. The scope was reprocessed by manual cleaning and a non-Olympus endoscope reprocessor (Soluscope) two days prior to the incident and not use until day of procedure. The scope was returned to Olympus for evaluation to which the manufacturer history was reviewed of the scope and confirmed no irregularity and the exact cause could not be determined because evaluation is still in progress.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7730225&pc=FDf

5.21. During a routine culturing test conducted on March 12, 2018, the Colonovideoscope tested positive for bacteria, May 2018

A report in the FDA's **MAUDE** database states that during a surveillance culturing test conducted on March 12, 2018 by the facility, the Colonovideoscope tested positive for the following bacteria. Suction channel: Micrococcus spp. (2 cfu/50 ml), environmental bacteria (1 cfu/50 ml). Air/water channel: Micrococcus spp. (2 cfu/50 ml), Staphylococcus epidermidis (1 cfu/50 ml). Auxiliary channel: environmental bacteria (1 cfu/50 ml). There was no microbial growth for the instrument channel. With additional surveillance culturing test by the user facility the, Colonoscope tested positive in the Auxiliary channel: Staphylococcus xylosus (3 cfu/30 ml), instrument channel: Staphylococcus spp. (28 cfu/30 ml), Staphylococcus xylosus (7 cfu/30 ml), suction channel: Staphylococcus spp. (1 cfu/30 ml), Kocuria Kristinae (3 cfu/30 ml). No microbial growth in the air/water channel with additional testing. A non-Olympus AER (Soluscope 3, Soluscope 4) with peracetic acid was used to reprocess the Colonovideoscope. The scope was returned to Olympus and sent to a third-party lab for additional microbiological testing, which the scope tested positive for Bacillus spp. (2 cfu/100 ml) but test result cleared French guideline. No irregularity with manufacturing history of the scope. The exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7633145&pc=FDf

5.22. A Colonovideoscope tested positive after multiple microbiological testing by the user facility, May 2018

A report in the FDA's **MAUDE** database states that a user facility performed multiple microbiological testing by the user facility with microbes found from the sample collected from the Colonovideoscope CF-H180AI. The scope was reprocessed using peracetic acid with no report of patient infection. First test unspecified microbes (59,375 cfu/100 ml), second time (556 cfu/100 ml), third time (1,176 cfu/100 ml), geotrichum number of microbes is unknown. Fourth time, suction channel unspecified microbes (5,000 cfu/100 ml), auxiliary water channel: no microbe air/water channel: no microbe: no microbe, fifth time, unspecified microbes. The scope was returned to Olympus and sent to a third-party lab for additional microbiological testing. The testing indicated no microbial growth for all channels. No irregularity with the manufacturing history of the scope. The exact cause could not be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7722320&pc=FDf

5.23. During a Polypectomy, fine dark grey graphite powder leaked out from the Colonovideoscope, May 2018

A report in the FDA's **MAUDE** database states that a Colonovideoscope had find dark grey graphite powder leaked out and fell off within the bowel of the patient. The patient did not incur injury associated with this event. It was reported that the powder fell off from the subject device and air leakage was noted during the cleaning process after the procedure. OMSC did not receive the scope however, the manufacturing history of the scope was reviewed and confirmed no irregularity. The exact cause could not be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7612920&pc=FDf

5.24. Olympus sent device testing positive for Micrococcaceae to a third-party laboratory after repeated test were performed, May 2018

A report in the FDA's **MAUDE** database states the European Version Cystonephrfiberscope CYF-5 was sent to a third-party laboratory for microbiological testing. The scope was sent to Olympus and not OMSC. The testing results from the sample collected from all channels of the scope tested positive for Micrococcaceae (1 cfu). The results did not clear the French guideline. The repair history shows the insertion section of the scope has been replaced in September 2017. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7649488&pc=FAJ

5.25. A Cystonephrofiberscope tested positive for Staphylococcus aureus after microbiological testing, May 2018

A report in the FDA's **MAUDE** database states the OMSC was informed of the results of microbiological testing by the user facility, the Cystonephrofiberscope CYF-5 tested positive for Staphylococcus aureus. The scope was returned to Olympus and was sent to a third-party lab for testing, no microbe was detected from the sample collected from all channels of the scope. The user facility manually processed the scope with peracetic acid and no report of infection. OMSC reviewed the scope history and confirmed no irregularity. Exact cause of reported event could not be determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7676726&pc=FAJ

5.26. Gastrointestinal Videoscope tested positive during a surveillance culturing test by the facility, April 2018

A report in the FDA's **MAUDE** database states that OMSC was informed that during a surveillance culturing test by the facility of an Evis Exera III Gastrointestinal Videoscope GIF-H190, the suction and auxiliary channel tested positive for bacteria. Suction channel: pseudomonas aeruginosa (>100 cfu/100ml), Enterobacter (>100 cfu/100 ml). Auxiliary channel: unspecified bacteria (3 cfu/100 ml). the result indicated not microbial growth for the air channel. The scope had been reprocessed using a non-Olympus AER (Wassenburg wd440) with peracetic acid. No patient infection reported with the event. The scope was returned to Olympus and sent to a third-party lab for additional microbiological testing and the results indicated no microbial growth for the scope and cleared guideline. The manufacture history was reviewed and confirmed no irregularity. Exact cause could not be determined at present.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7594962&pc=DFD

5.27. Multiple testing by the user facility, microbes were detected from sample collected, April 2018

A report in the FDA's **MAUDE** database states Olympus was informed as a result of multiple testing by the user facility, microbes were detected from the sample collected from the Cystonephrofiberscope CY-5. The first time tested 1 cfu/100 ml, second testing 3 cfu/100 ml, third testing 8 cfu/100ml all unspecified microbes. Pseudomonas 1 cfu/100 ml, and Stenotrophomonas 1 cfu/100 ml were found. The scope had been manually reprocessed using peracetic acid with no reports of infection associated with this report. The scope was not returned to OMSC for evaluation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7576659&pc=FAJ

5.28. Patient experiencing fever and chills post procedure went to the ER after a Ureteroscopy and stent placement, April 2018

A report in the FDA's **MAUDE** database states a patient went to the ER experiencing fever and chills, was found to have an infection and was treated with augmentin-antibiotics. The performed procedure was a Ureteroscopy with left laser lithotripsy and stent placement. The Ureteroscope used was a Uretero-Renoscope Semi-Rigid Ureteroscope 27010KA and was returned for microbial testing, customer believes the scope may have been involved with a patient infection. The customer indicated the scope did not malfunction and no physical issue with it. The scope was received at Karl Storz Logistic Center where the channels were sampled with a brush-flush-brush technique with sterile water and a new cleaning brush to recover potential contamination inside the scope. Sterile water from the channels was collected in a sterile sample cup and negative control sample was prepared using same lot of sterile water, cleaning brush and sample cup. Sample from device and negative control sample labeled and shipped to Nelson Labs for microbial analysis. There were no colony forming units detected within the channels of the endoscope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7623587&pc=FGB

5.29. The user facility conducted a microbiological test on the suction channel of a Colonovideoscope, April 2018

A report in the FDA'S **MAUDE** database states the user facility conducted microbiological testing and the Colonovideoscope CF-H190I tested positive for bacteria of Staphylococcus aureus, Enterobacteria, Pseudomonas sp, Stenotrophomonas maltophilia, Acinetobacter sp and Candida (>200cfu/endoscope). The scope was disinfected using non-Olympus AER Soloscope series 4 with peracetic acid. The Scope was sent to a third-party laboratory for additional microbiological testing and tested positive for bacteria gram positive (3cfu/100ml) but testing result cleared guideline.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7536153&pc=FDf

5.30. Guidewire and a laser probe could not pass through the instrument channel of the Ureteroscope, February 2018

A report in the FDA's **MAUDE** database states that Olympus was informed of the incident that during a tul (Transurethral Ureterolithotomy) procedure, a guidewire and a laser probe could not pass through the instrument channel of the Uretero-Reno Videoscope. The Uretero-Rneo Videoscope URF-V has been returned to Olympus Medical Systems Corp. for evaluation due to a hole on the instrument channel at 47cm from the distal tip, and an air leak was found at the point. Shavings were piled up inside the instrument channel which clogged the channel. The conclusion was made that the instrument channel might be shaved due to inserting endo therapy accessory forcibly which causes the shavings to clog the instrument channel that caused the reported event. There was no injury to the patient with this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7243322&pc=FGB

5.31. Baystate Medical Center warns patients after unclean Colonoscope discovered, Massachusetts, January 2018

SPRINGFIELD- Baystate Medical Center has warned 49 patients who received bowel surgery that the colonoscope used in their surgeries may not have been cleaned properly. One single channel on a colonoscope had not been cleaned properly. This was a similar incident that had happened at Baystate Nobel Hospital in Westfield that occurred in 2015. The colonoscope in question has been in limited use over the past few years. Patients were notified by Baystate staff members over the phone and by letters and were given a number to call to which the hospital did not make public.

In 2015, 293 patients who had colonoscopies at Noble Hospital during from June 2012-April 2013, were notified by Baystate Health stating that "their procedures had put them at risk to exposure to blood-borne pathogens such as hepatitis B, hepatitis C, and HIV". The technicians at Noble failed to sterilize the one channel on the colonoscope.

The Republic documents obtained from the Department of Public Health, in a public record request showed that an employee tried to get Noble management to address the issue before going to the Massachusetts Department of Health.

Jim Kinney, jkinney@repub.com (Jan 30, 2018), The Republic, Baystate Medical Center warns patients after unclean colonoscope discovered, from

https://www.masslive.com/news/index.ssf/2018/01/baystate_medical_center_warns.html

5.32. Twenty-Three patients Test Positive for Mycobacterium chelonae from Bronchoalveolar lavage samples, January 2018

A report in the FDA's **MAUDE** database states the 23 patients tested positive for Mycobacterium chelonae from bronchoalveolar lavage (BAL) samples. A total of 19 bronchoscopes were reportedly used to examine the patients. The user facility did not provide specific information regarding the mode/serial number of the bronchoscopes used on patients. It is unknown if the positive bal samples are due to pre-existing conditions of the patients or due to unspecified laboratory issues. The Olympus BF-XT160 Bronchovideoscope has not been returned to Olympus for evaluation. An Olympus endoscopy support specialist was sent to the user facility on 2017, where several reprocessing deviations was noted during the visit: facility was not precleaning, leak testing was not done properly, the leaker tester was removed from the scope while submerged in the water.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7180785&pc=EOQ

5.33. Nine patients tested positive for mold spores after undergoing unspecified Bronchoscope procedures, January 2018

A report in the FDA's **MAUDE** database states that limited information was obtained when Olympus made multiple follow up telephone calls to the user facility and in writing to gather additional information on the reported events. An Olympus endoscopy support specialist (ESS) was sent to the facility to observe the reprocessing practice and provide additional training. The scope was returned to Olympus on February 2, 2018 for unspecified damage which had critical dents on the insertion tube. The scope was serviced and returned to the facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7267525&pc=EOQ

5.34. Samples show that Mycobacterium Tuberculosis grew from two patients after a bronchoscopy procedure, January 2018

A report in the FDA's **MAUDE** database states that Olympus was informed of two patients were examined by the same bronchoscope on two different dates. The facility reported that the bronchoalveolar samples collected from both patients tested positive for Mycobacterium. An

Olympus field service engineer visited the facility to evaluate the device and provide preventative maintenance, and reprocessing training on the AER (Automated Endoscope Reprocessor). In January 2017, the field service engineer looked at the error log files of the oer-pro and assisted the staff in obtaining water samples to be tested at an independent lab for microbial testing. It was discovered that the last water line disinfection was performed on October 8, 2015. The field engineer found the drain hose pushed down into the water drain trap, coming into contact with water found inside the trap. An in-service was conducted to demonstrate the proper use of the AER to the staff at the user facility on January 23, 2018.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7272402&pc=FEB

5.35. Three patients infected with the association of two contaminated Bronchoscopes, January 2018

A report in the FDA's **MAUDE** database states that Olympus was made aware of that two Bronchoscopes BF-H190 may have been contaminated and likely caused three separate patients to become infected with Mycobacterium abscessus. The Bronchoscopes were returned to Olympus for evaluation with the results pending and the investigation is ongoing. The user facility reported that in 2017 that two Bronchoscopes were sent to the lab for culturing due to possible cross-contamination and tested positive for Mycobacterium abscessus. It was reported by Olympus personnel that the facilities reprocessing practices were not being followed: with incorrect leaking testing and the duration was too short, the angulation levers were not turned during the leak test as well as the duration of suction of detergent/water through the channels was too short, and not wiping of the insertion tube. The endoscopes were placed in the AER incorrectly with the insertion tube pressed up against the lid of the AER during the reprocessing cycle. The patients received treatment and their condition is unknown.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7202843&pc=EOQ

5.36. The distal end of the Uretero-Reno Videoscope broke inside the patient and caused injury to the patient, January 2018

A report in the FDA's **MAUDE** database states that the distal end of the Uretero-Reno Videoscope URF V-2 broke inside the patient and there was injury to the patient during an

unspecified procedure. Additional medical intervention was required to remove the subject device from the patient and the procedure time was extended. Olympus was notified of the incident and has not been returned to Olympus Medical Systems Corp.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7185154&pc=FGB

5.37. Guidewire coating chipped away during procedure while using a Ureteroscope, January 2018

A report in the FDA's **MAUDE** database states that after the doctor asked for a second guidewire, he ran the semi-rigid Ureteroscope WA02946A over the wire. He tried to remove the wire through the scope with little difficulty, but once it was removed he notice some of the coating was chipped away. There was a lot of edema and the doctor used the scope to verify that none of the coating had chipped off, so a stent was placed inside the patient.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7221086&pc=FGB

5.38. Three times cultures were found on a Colonoscope that was conducted by the user facility, January 2018

A report in the FDA's **MAUDE** database states surveillance culturing was conducted on an EVIS EXER LLL Colonovideoscope CF-H190I by the user facility and microbes were detected three times. First time microbes were found >100 CFU Aeromonas hydrophila, Aeromonas caviae, Klebsiella oxytoca. Microbes were found a second time in the Colonoscope with >100 CFU Bacillus and Burkholderia cepacian complex. The third surveillance culturing found >100 CFU Bacillus, Burkholderia cepacian complex and Citrobacter freundii. The scope was reprocessed in an AER Serie 3 with peracetic acid according to the instruction manual. The exact cause of the event could not be conclusively determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7265863&pc=FDf

5.39. Endoscope Reprocessing Technician experienced chemical exposure symptoms after handling an endoscope, January 2018

An Endoscope Reprocessing Technician suffered from chemical burns and skin discoloration after handling an endoscope and other items that were reprocessed in their Advantage Plus AER. It was determined that the technician improperly reprocessed the scope which caused the chemical exposure. The facility's biomedical service technician and Medivators field service engineer evaluated the AERs and conducted test cycles, concluding that the units operated within specification. During the FSE's visit, a plastic container of reusable valves, buttons and other items were placed in the AER along with the scope for reprocessing in place of using a mesh bag that the Medivators provide with the AER. The plastic container is not validated for the use with the Advantage Plus AER which could potentially cause the accessories to not be properly high level disinfected.

Medivators regulatory affairs followed up with the facility's biomed and stated the chemical exposure was due to a handling issue during the reprocessing process and have changed their process accordingly. The technician received medical attention at their hospital and is recovering well.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7293237&pc=FEB

5.40. Blue residual fluid dripping from Olympus Endoscopes while hanging in a storage closet, January 2018

A report in the FDA's **MAUDE** database states that a facility reported blue residual fluid dripping from their Olympus endoscopes while hanging in their storage closet after it was reprocessed in their Advantage Plus AER. The facility did continue to use the endoscopes on patient with the fluid dripping from the scopes. A Medivators field service engineer confirmed the AER was properly functional and instructed the facility to collect a sample of the blue fluid if it occurs again. The FSE also noted that manually leak testing was not being performed prior to disinfection as instructed per the IFU. Leak testing is performed to detect any leaks or tears in the endoscope which can allow fluid to accumulate and cause cross contamination. No harm to patients has been reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7293173&pc=FEB

5.41. Facility reported a waxy green substance in the basin of their Advantage Plus AER,
January 2018

A report in the FDA's **MAUDE** database states a facility reported a waxy green substance in the basin of their Advantage Plus AER and on the endoscopes, which can cause potential harm to patients. The Medivators field service engineer evaluated the facility and took samples of the waxy green substance to be analyzed. The FSE noticed that maintenance was not being performed on the unit specifically the basin drains when they cleaned the build up from the basin. He informed the facility that maintenance is done on a monthly basis that is stated in the user manual. It is still unknown what is causing the waxy green substance in the AER and Medivators are working continuously with the facility to investigate what it is and where it is coming from. There has been no harm done to patients.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7293173&pc=FEB

5.42. Five patients that acquired infections from a contaminated Fiber Bronchoscope,
December 2017

A report in the FDA's **MAUDE** database states that Pentax medical was made aware of a report for the medicines and health products safety of cross contamination of a fiberscope FB-18RBS to five patients. Two cases of pneumonia acquired lung disease under ventilator (vap) to pseudomonas aeruginosa and stenotrophomonas maltophilia. The bronchial fiberscope was removed in 2017 and an antibiogram indicates a pseudomonas aeruginosa and stenotrophomonas maltophilia was present. Three of the five patient are deceased but did not attribute to vap, one patient was discharged, and one patient is in the intensive care unit. In 2018, Pentax received the device for service requested by the customer, which revealed a perforated bending rubber and a crushed/buckled insertion flexible tube. The hospital staff did not comply with Pentax instructions for use when reprocessing the bronchoscopes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7287335&pc=EOQ

6. Gram Negative Bacteria Outbreaks

6.1. Three patients developed a Carbapenem-resistant enterobacteriaceae infection after undergoing procedures, February 2019

A report in the FDA's MAUDE database states that Olympus was informed that three patients developed a CRE infection after undergoing procedures using the facility's Colonoscopes and Gastroscopes. According to the user facility's director of Perioperative services, the first patient underwent an upper/lower examination in 2018. In 2018 multiple procedures including an upper examination were performed on the second patient using three different scopes. Third patient underwent an upper examination in 2018. The post urinalysis of all three patients were positive for the New Delhi strain (CRE) and all were all treated with antibiotics. The director reported that state linking these cases to a rehabilitation/nursing facility with 20 miles of this hospital. The state is also requesting that the facility send the three scopes out to be cultured. The Colonoscope was sent to a third party for culturing and tested negative for growth. An Olympus ESS was dispatched to the facility to observe the facility's reprocessing practices and provide training if necessary. The ESS noted reprocessing deviations: steps were missed, improper use of cleaning adapters and cleaning burhs, cinch sacks were being used to transport dirty scopes and no gloves were used during the transportation of clean scopes. An in-service to review proper reprocessing methods will be scheduled for a later date. This is 3 of 6 reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8242610&pc=FD
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6.2. Stenotrophomonas maltophilia were detected in bal samples collected from a total of seven patients using an Olympus Bronchoscope BF-TE2, February 2019

A report in the FDA's MAUDE database states that Stenotrophomonas Maltophilia were detected in bal samples collected from a total of seven patients using an Olympus Bronchoscope BF-TE2. 2018 the samples were collected from the first two patients, who underwent the bal procedure using the subject device in 2018 which tested positive for Stenotrophomonas Maltophilia. Next the user facility conducted microbiological culturing testing on the device again. The device tested positive for Enterobacter Cloacae, Stenotrophomonas Maltophilia, Serratia Marcescens, and Klebsiella pneumoniae. No microbes were detected in the last testing during the last microbiological culturing. The subject device stopped being used and an investigation on the culturing results in other bal samples were conducted and collected. The results of the investigation identified that Stenotrophomonas maltophilia had been detected from the bal samples of a total of seven patients including the

first two patients since 2018. The Bronchoscope BF-TE2 has been reprocessed using a non-Olympus AER (soluscope type v3 or v4) and sometimes manually disinfected with peracetic acid. No microbes were detected from the rinse water of the AER. The Bronchoscope was stored horizontally within a stock pack and not vertically. This device has not been returned to OMSC for evaluation. The manufacturer history of the device that was reviewed by OMSC and confirmed no irregularity. There is no repair service record at Olympus since September 2014.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8183581&pc=EQ
[Q](#)

6.3. AN outbreak between 2013 and 2016 involving 20 patients with 19 patients that developed an infection of unspecified drug resistant organisms and 1 patient expiring after and ERCP, January 2019

A report in the FDA's **MAUDE** database states that Olympus was informed about an outbreak between 2013 and 2016 that involved 20 patients. 19 of those patients reportedly developed an infection of an unspecified drug resistant organisms and one patient expired during and ERCP procedure using an unidentified EVIS EXERA Duodenoscope TJF-160VF. The patients also developed sepsis and liver abscess during this time. In 2016 patient #1 was found to have a fever and cholangitis. An ERCP was done to retrieve a sample and cultured positive for Enterococcus faecium, Vancomycin resistant (VRE). Patient stroked and expired. Since 2018 the facility reported eight more patient infections and one patient death (patient #2) after ERCP procedures due to drug resistant organisms like Enterobacter, VRE and CRE. Patient did develop pancreatitis and Cholangitis after procedure. In 2018 patient's blood was cultured and tested positive for CRE and e Coli resistant organisms. Patient developed hypotension and necrosis of all limbs and resulted in loss of multiple fingers and toes. Patient expired in late 2018 due to liver failure. Treatment and current conditions of the remaining 27 patients is unknown. A physician at the user facility believed that a delay in the pre-cleaning of the facility's ERCP scopes maybe a contributing factor. No specific number were provided for the scopes used during the procedures. It is unknown if the scopes were returned to Olympus for evaluation and service. Olympus did follow up by telephone and in writing to the user facility an attempt to gather more detailed information regarding the events, limited information was provided. In December 11, 2018 and ESS and regional service director visited the facility to observe the facility's reprocessing practices and provide training if necessary. The ESS and regional service director were able to observe the sterile room or reprocessing room and noted that three endoscopes sat for at least 30 minutes for leak testing and manual cleaning. Also, the Medivators AER that was used to reprocess the scopes has had issues in November 2018. The ESS informed the director of nursing was informed there was a delay in reprocessing on a

previous visit, which the nursing director stated that this was not a concern as the staff was aware of the delayed reprocessing instructions. On December 2018 the ESS provided an in-service to the user facility's nursing staff. The ESS noted the staff using the scope buddy during periods of high volume the facility may run out of air/water cleaning adapter and suction cleaning adapters. The reprocessing staff would skip steps and continue without the use of any cleaning adapters. Suction adapter was not cleaned properly and placed loosely inside the Medivators AER. After the procedures, the used scopes sat for an extended period of time without undergoing an extended soak per the delay reprocessing instructions. Reprocessing staff carried out more than one scope in the same hand without protective gloves. Also, the scopes were stacked by twos in a tub and transported. (Report 29 of 30)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8207609&pc=FE
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6.4. Olympus was informed of three additional patients that were identified to have developed CRE infections since August 2018 after ERCP procedures at that user facility, January 2019

A report in the FDA's MAUDE database states that three additional patients were also identified to have developed CRE infections since August 2018 after ERCP procedure at that facility. It was reported that the staff at the facility observed scopes sitting for over one-hour before being pre-cleaned. The EVIS EXERA Duodenovideoscope TJF-160VF are repaired by a third party. The patients' current condition and course of action is unknown. The user facility had experienced an outbreak between 2013 and 2016 in which 19 patients developed drug resistant organisms and one patient expired after an ERCP procedure using a Duodenoscope. The facility reported that patient 1 in 2016 was found to have a fever and cholangitis. The patient subsequently stroked and expired. Additionally, the facility reported since August 2018 there have been eight more patient infections and one patient death after ERCP procedures due to drug resistant organisms: Enterobacter, VRE and CRE. According to the Texas health department inspected the facility's GI lab and found no abnormalities; however, the facility's pre-cleaning was not observed. Since that visit a gastroscope was recently cultured and tested positive for an unknown organism. The scope is currently quarantined at the user facility. There are no specific number provided for the scopes used during the procedures. It is also unknown if the scopes were returned to Olympus for evaluation and service. (Report 1 of 3)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=8379810&pc=FD
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6.5. Patient tested positive for Enterococcus casseliflavus infection after undergoing an ERCP procedure, July 2018

A report in the FDA's **MAUDE** database states that patient upon admission presented with a positive blood stream enterococcus casseliflavus infection prior to undergoing an ERCP with an Evis Exera II Doudenovideoscope TJH-Q180V. A second patient had the same scope used on them two days later and has tested positive for the same bacterium. The patient's course of treatment and condition is unknown. The nurse reported the source infection is unknown the scope cannot be ruled out. Pre-cleaning was performed and transported to the endoscopic room in an approved transport bin. An ESS visited the user facility to observe the reprocessing practice on August 15, 2018. It was noted a minor deviation as the staff used a 60 cc or 20 cc (2x) syringe for flushing the elevator area after brushing. The staff was advised the TJF-Q180V manual recommends a 30cc syringe to be used, and at all other reprocessing steps were performed in accordance with the manufacturer's recommendations. The scope was returned to Olympus for evaluation and still in progress. The scope will be sent to an independent lab for microbial testing and ethylene oxide sterilization.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7791919&pc=FDT

6.6. Carbapenem-resistant Enterobacteriaceae outbreak with multiple patients infected and reported to Olympus, May 2018

A report in the FDA's **MAUDE** database states physicians are unsure if the Bronchovideoscope BF-P190 caused or contributed to the patient infection outbreak. Olympus made multiple follow ups with the user facility by telephone and in writing in an attempt to gather additional information on the reported event. The scope was returned to Olympus for evaluation, the device evaluation is still pending completion. The scope will be sent to an independent laboratory for microbial testing and ethylene oxide (ETO) sterilization. An Olympus endoscopy support specialist visited the user facility to observe the facility's reprocessing practice and provide reprocessing training. The specialist observed one minor deviation the staff used a 30cc syringe to aspirate 90cc of fluid into the scope. The specialist provided the user facility staff a reprocessing wall chart and aDVD step by step video on how to reprocess a bronchoscope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7559224&pc=EOQ

6.7. Samples Were Taken from Ten Patients that were growing Pseudomonas Aeruginosa, Serratia Marcescens, April 2018

A report in the FDA's **MAUDE** database states that C&S obtained during a bronchoscope procedure model 1T180 of ten patients were all growing pseudomonas Aeruginosa, Serratia marcescens. This was traced back to index patient with these organisms including Chryseobacterium indologenes in the sputum. Three of the patients cultured included Chryseobacterium indologenes, and three grew Enterobacter and one grew strep pneumonia. With further investigation, the bronchoscope was used on all the aforementioned patients. The cultures of the bronchoscope revealed 2+ Serratia marcescens, 2+ Chryseobacterium indologenes, 2+Enterobacter cloacae, and 2+pseudomonas aeruginosa. The Bronchoscope 1T180 also had a loose cap on biopsy port and was cultured to reveal 2+ growth of Serratia marcescens, 2+ growth of Chryseobacterium indologenes, 2+ growth of Enterobacter cloacae, and 2+ growth of pseudomonas aeruginosa. No patients developed an infection related to this issue and no issues were identified related to high level disinfection.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7784255&pc=EOQ

6.8. Foreign material was found present in a Colonoscope during a diagnostic Colonoscopy, December 2017

A report in the FDA's **MAUDE** database states the user facility reported that during a diagnostic Colonoscopy, the user experienced difficulty passing a biopsy forceps through the channel of the colonoscope. It was reported that a hard, white, crusty substance came out with the retracted biopsy forceps. Patient was exposed to foreign material, but it is unknown if the substance had fallen inside the patient. A different scope was used, and the procedure was completed, the patient was help at the operating room for monitoring. The Colonoscope PCF-H180AL was returned to Olympus for evaluation and found that the scope failed a leak test due to a damaged biopsy channel (cut/hole), which is due to user mishandling. A small white foreign material was noted inside the biopsy channel port size approximately 1x1 .5mm but the material is not hard or crusty looking. Both the foreign material and the biopsy channel will be forwarded to an off-site lab for analysis.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7208536&pc=DFD

6.9. Four Patients Tested Positive for Drug-resistant *Klebsiella pneumonia* After Having Undergone ERCP, October 2017

A report in the FDA's **MAUDE** database states that four patients tested positive for OXA-48 producing *Klebsiella pneumonia* after having undergone endoscopic retrograde cholangiography (ERCP) with an Olympus TJF-Q180V duodenoscope in a foreign healthcare facility. OXA-48 is an enzyme that breaks down carbapenem, one of the antibiotics used to treat multidrug-resistant bacterial infections. The duodenoscope had its forceps elevator replaced in 2016.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=7027139&pc=FDT

6.10. An Olympus Colonovideoscope Linked to *Salmonella zanzibar* Infection, October 2017

A report in the FDA's MAUDE database states that *Salmonella zanzibar* was found in fecal samples of all five patients who underwent colonoscopies with a particular Olympus colonovideoscope, model CF-HQ190I. Evaluation of the device showed no irregularities and the exact issue could not be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7047861&pc=FDf

6.11. An Endoscope With a 'Design Issue' Has Been Linked to Probable Transmission of a Colistin-Resistant Superbug, U.S., April 2017

A regulatory report filed by Pentax with the FDA reveals that an ED-3490TK duodenoscope was likely responsible for the transfer of a colistin-resistant strain of CRE from patient to patient. Colistin is an antibiotic known as the "last resort" antibiotic. This is the first known case of a colistin-resistant strain of CRE being linked to patient to patient transfer via duodenoscopy. As many as five patients may have been exposed to the contaminated duodenoscope.

Muscarella, L. F. (2017, December 08). A Duodenoscope Has Been Linked to 'Probable Transmission' of a Colistin-Resistant Superbug. Retrieved March 16, 2018, from <https://www.lfm-hcs.com/2017/12/an-endoscope-with-a-design-issue-has-been-linked-to-probable-transmission-of-a-colistin-resistant-superbug/>

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=6789702&pc=FDT

6.12. Carbapenem-Resistant *Klebsiella pneumoniae* Cluster Associated with Gastroscope Exposure among Surgical Intensive Care Unit Patients at University of Pittsburgh Medical Center, Pennsylvania, October 2016

At the University of Pittsburgh medical center, an increase in carbapenem-resistant *Klebsiella pneumoniae* (CR KP) isolates was observed in the surgical intensive care unit. Three new cases were identified in one month compared with the average of 0.5 new cases/month from the previous year. Three additional cases were identified who had exposure to the surgical intensive care unit, but whose CR KP isolates were recovered in another unit. Review of the 6 cases found that all cases were exposed to the same OR gastroscope. Boroscopy revealed several deep scratches and luminal debris in the gastroscope. It then underwent channel replacement and cultured negative prior to going back into service. No further cases were identified.

http://ofid.oxfordjournals.org/content/3/suppl_1/248.full

6.13. Nurse claims University of Cincinnati Health failed to stop infectious outbreak, Ohio, June 2016

A University of Cincinnati Health nurse filed a lawsuit against the health system, claiming it failed to prevent the spread of multidrug-resistant bacteria and covered up its role in the outbreak.

According to the report, as many as 100 patients may have developed an infection as a result of the care, they received at UC Health. The lawsuit claims UC Health launched an investigation after recording a spike in the number of infections in patients who had undergone a bronchoscopy. Allegedly, the nurse suggested reaching out to an outside agency to investigate the medical devices and infections but was told "no" because the organization didn't want an audit.

The news reported that the health system decided to simply deal with the patient infections rather than tackling the root of the problem, which were the bronchoscopes being used for the procedure.

The health system had stopped checking the bronchoscopes. By no longer checking the scopes the system wasn't going to find any problems so there would be no need for an outside audit.

Michael Baldwin (June 21, 2016), Fox19Now, Nurse claims University of Cincinnati Health failed to stop infectious outbreak, from <http://www.fox19.com/story/32266508/nurse-claims-uc-health-failed-to-stop-infectious-outbreak>

6.14. CRE death linked to ERCP procedure at Lehigh Valley hospitals, Pennsylvania, April 2016

A patient at the Lehigh Valley hospital in PA underwent an ERCP procedure and soon thereafter was diagnosed with severe sepsis, septic shock and acidosis. She was admitted to the intensive care unit and, weeks after the procedure the doctor delivered the news that she had been infected with antibiotic resistant bacteria from a contaminated endoscope. She died a few weeks later.

The patient was one of as many as 350 patients at 41 medical facilities in the United States and worldwide who were infected or exposed to contaminated scopes from Jan. 1, 2010, to Oct. 31, 2015, according to a U.S. Food and Drug Administration document obtained by the House Committee on Oversight and Government Reform and made public in mid-April.

Jon Harris (June 18, 2016), The Morning Call, Lehigh Valley hospitals guard against tainted scopes, from <http://www.mcall.com/business/mc-olympus-scopes-lehigh-valley-20160618-story.html>

6.15. Multidrug-Resistant *E. coli* Infects Patients at University of Colorado Hospital, Colorado, January 2016

Nine University of Colorado Hospital patients developed infections after undergoing surgeries with a duodenoscope. Three of the patients have died, although it is unclear what role these infections played in their deaths. The hospital has notified patients, families, and other patients who had undergone surgery with the same suspect endoscope. A visual inspection of the scope at Olympus found "the bending section adhesive was whitish in color and had open gaps at each side of the bending section cover, the glue around the nozzle had signs of cracks and gaps," and "the insertion tube had multiple buckles throughout the entire length." A microscopic inspection also discovered brown stains.

Olinger, D. (2016, May 9). Surgical tool used at University Hospital linked to infections, deaths Retrieved May 13, 2016, from http://www.denverpost.com/news/ci_29870102/surgical-tool-used-at-university-hospital-linked-infections

6.16. Heat-resistant *Klebsiella pneumoniae* in endoscope-mediated outbreak in Norway, January 2016

A study conducted involving the genetic marker, *clpK*, which increases the heat resistance of a strain of *Klebsiella pneumoniae*, revolved around a recent outbreak in Norway. Five patients and one intubation endoscope were found to have the *clpK* marker at an intensive care unit in a secondary care hospital. The bacteria survived within the endoscope despite going through a chemothermal disinfection process in a decontaminator. The study found, through testing after heat treatment, the survival rate was strongly dependent upon the *clpK* marker. Due to the

potential of heat resistance of certain strains of *K. pneumonia*, this allows for possible spreading and infection to other areas of the hospital.

Heat-resistant, extended-spectrum β -lactamase-producing Klebsiella pneumoniae in endoscope-mediated outbreak, Jørgensen, S.B. et al., Journal of Hospital Infection, Volume 93, Issue 1, 57 - 62 [http://www.journalofhospitalinfection.com/article/S0195-6701\(16\)00070-0/abstract](http://www.journalofhospitalinfection.com/article/S0195-6701(16)00070-0/abstract)

6.17. Pseudomonas outbreak at Huntington Hospital in Pasadena, California, August 2015

On August 19th, 2015 Olympus contacted Huntington Hospital after a news report about patients being sickened after scope procedures at the hospital. The hospital informed Olympus that the patients had died. At least 3 patients are reported dead. It is not clear how many were exposed and whether only three have passed. The report in the FDA database shows a different scope than the one recalled in January.

Peterson, M. (2016, May 5). 3 patients died in a Pasadena outbreak possibly caused by medical scopes Retrieved May 13, 2016, from <http://www.latimes.com/business/la-fi-olympus-scope-pasadena-20160504-snap-story.html>

6.18. E. coli outbreak at Hartford Hospital, Connecticut, March 2015

On March 4th, 2015 Hartford Hospital in Connecticut contacted 281 of their patients who could have been exposed to a strain of *Escherichia coli* (*E. coli*). Two scopes that could have infected 281 patients were removed from service in December. The hospital has been active, calling the patients to let them know and ask them to come in for screening. Dr. Rocco Orlando of Hartford Hospital stated that there is a defect in this particular scope that makes it nearly impossible to be completely disinfected and that the process for cleaning their endoscopes was followed. The medical device that was used was the same one that officials at Ronald Reagan UCLA medical center said was used when seven patients were infected by the “superbug”. Hartford hospital has notified the Department of Public Health and that they are monitoring the situation.

Covner, J. (2015, March 4). Hartford Hospital Says Patients Might Have Been Exposed To E. coli. Retrieved March 9, 2015, from <http://www.courant.com/health/hc-hartford-hospital-e-coli-20150304-story.html>

6.19. CRE Outbreak at Cedars-Sinai in Los Angeles, California, March 2015

On March 4, 2015, health officials at Cedars-Sinai hospital in Los Angeles announced that 4 patients were infected with CRE (Carbapenem-Resistant Enterobacteriaceae) and that 67 additional patients might have been exposed as well. Investigators started testing for CRE after a similar outbreak occurred at UCLA Medical Center last month. A single ERCP (Endoscopic

Retrograde Cholangiopancreatography) scope was identified as the source of the outbreak and was used from August 2014 – February 2015. Officials at Cedars have since removed the scope from use and have decided to increase the safety measures associated with all scopes. As with other cases across the country, health officials found no cleaning flaws and that the cleaning was performed according to the manufacturer’s directions.

Terhune, C. (2015, March 4). Superbug outbreak extends to Cedars-Sinai hospital, linked to scope. Retrieved March 5, 2015, from <http://www.latimes.com/business/la-fi-cedars-sinai-infections-20150304-story.html>

6.20. CRE Outbreak in Carolinas Healthcare, North Carolina, February 2015

In North Carolina on February 22, 2015, officials made a statement that two people died from CRE and infected a dozen others. So far this year, three people have acquired CRE at Carolinas Healthcare System hospitals and additional 15 have come into hospitals with existing CRE infections. CRE affects sick patients who are in facilities for a long time or who use devices like ventilators, urinary catheters, and endoscopes. Carolinas HealthCare has changed how they clean their devices. Because of the increase, officials said that the Charlotte-based hospital systems have started screening patients who likely have CRE, once they are identified; these patients are isolated from other patients and once they are released, extra steps are being taken to decontaminate their rooms.

Wootson Jr, C. (2015, February 22). Carolinas HealthCare System steps up efforts against ‘superbug’.

6.21. CRE Outbreak at University of California, Los Angeles (UCLA), California, January 2015

At UCLA’s Ronald Reagan Medical Center, five patients were infected with CRE and two others died from CRE infections. These infections are all associated with contaminated endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes. 179 other patients also received treatment with these scopes and may have been exposed to CRE. UCLA says that the dirty scopes were washed according to the directions provided by the manufacturer. UCLA has now implemented a new decontamination process for the scopes that “goes above and beyond the manufacturer and national standards.” The CDC is assisting the L.A. County Department of Public Health look into these infections at UCLA. According to the FDA, work is being done to prevent the spread of infections while still allowing these tools to be used.

Terhune, C. (2015, February 18). Superbug linked to 2 deaths at UCLA hospital; 179 potentially exposed.

6.22. A Genetic and Epidemiological Analysis of Antibiotic-Resistant Enterobacteria Identifies an Endoscope as the Possible Source of an Outbreak, France, 2012-2014

A genetic investigation of OXA-204, an enzyme that breaks down carbapenem, led researchers to trace the origin of an outbreak. Carbapenem is an antibiotic that is prescribed to treat patients with multidrug-resistant bacterial infections. Bacteria with the gene that produces OXA-204 are resistant to carbapenem. Isolates of bacteria with OXA-204 were sent to the National Reference Center for Antibiotic Resistance during 2012-2014. Seventeen patients that had bacteria with the OXA-204 gene isolated from them had direct contact with a specific endoscope. In February 2014, the endoscope was retired from use and colonization of patients by the bacteria in question stopped. No bacteria with OXA-204 were recovered from the device, but gram-negative bacteria were cultured.

Potron, A. et.al (2017). Analysis of OXA-204 carbapenemase-producing Enterobacteriaceae reveals possible endoscopy-associated transmission, France, 2012 to 2014. Eurosurveillance, 22(49), 17-00048. <http://doi.org/10.2807/1560-7917.ES.2017.22.49.17-00048>

6.23. CRE Outbreak at Seattle Hospital, Washington, 2012-2014

The Virginia Mason Medical Center in Seattle, Washington blames the contaminated endoscopic ERCP duodenoscopes for the infection of at least 35 patients. These dirty scopes may also have contributed to the death of 11 people. The outbreak occurred between 2012 and 2014. Officials at Virginia Mason did not believe it was necessary to notify the patients. Investigators say the scopes had been properly sterilized according to the manufacturers' Instructions for Use. Virginia Mason now quarantines all reprocessed scopes 48 hours prior to scheduled procedure to ensure that there is no bacterial contamination.

Burger, J. (2015, January 23). Outbreak at Seattle Hospital Infects at Least 35, Suspected in 11 Deaths.

6.24. CRE Outbreak at Lutheran General Hospital in Park Ridge, Illinois, December 2013

243 patients underwent the Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure, which is a specific procedure looking at bile ducts and pancreas were screened for potentially being exposed to the bacteria CRE. 105 of 243 patients who may be infected have come in contact with the hospital for screening. The ERCPs involve a process of high-grade disinfectants and brushes in order to effectively clean them. The hospital has since permanently moved to the use of gas sterilization for better cleaning efficacy.

Peterson, E. (2013, December 27). Lutheran General finds and stops bacteria source.

6.25. Outbreak of Hospital Infection from Biofilm-embedded Pan Drug-resistant *Pseudomonas aeruginosa*, Due to a Contaminated Bronchoscope, Turkey, October 2013

An outbreak of colistin-resistant *Pseudomonas aeruginosa* occurred at a hospital in Ankara, Turkey on October 13, 2013. Fifteen patients were infected after undergoing bronchoscopy. *P. aeruginosa* was isolated from the bronchoscope. The hospital's disinfection and cleaning protocols were modified, but infections still occurred. Ethylene oxide sterilization was introduced to the disinfection protocol, and infections stopped. Scanning electron microscopy was used to confirm the presence of biofilm in the bronchoscopes taken out of use.

Alipour N. et. al. (2017) Outbreak of Hospital Infection from Biofilm-embedded Pan Drug-resistant Pseudomonas aeruginosa, Due to a Contaminated Bronchoscope. J Prev Med Vol.2 No.2:1. doi: 10.21767/2572-5483.100014

6.26. Gram-Negative Pneumonia Death Linked to Contaminated Scope, Washington, February 2013

A lawsuit over the death of a retired Navy chief petty officer was filed in November 2015. The lawsuit claims that Veteran Affairs Puget Sound Health Care System contributed to his death by failing to properly sterilize bronchoscopes. The suit claims that the veteran underwent at least two procedures with bronchoscopes from 2009 to 2012 that had not been disinfected according to the manufacturer's instructions. A nurse, Barbara Deymonaz, who worked at the Puget Sound VA from 2012 to 2013 said that she complained many times about lapses in procedures that may have potentially put patients at risk. The amended lawsuit mentions that the VA used scope-washing machines manufactured by Custom Ultrasonics.

Aleccia, J. (2015, November 16). Navy vet's death blamed on contaminated medical scopes Retrieved May 16, 2016, from <http://www.seattletimes.com/seattle-news/health/navy-vets-death-blamed-on-contaminated-medical-scopes/>

6.27. CRE Outbreak at University of Pittsburgh Medical Center, Pennsylvania, November 2012

In November 2012, an investigation was started at UPMC Presbyterian after multiple patients tested positive for CRE. None of the patients died as a direct result of the infection. As a result of the investigation, 18 patients had matching cultures to an infected scope used in ERCP procedure. During the investigation, UPMC realized that due to a new design, disinfectant was unable to reach all parts of the scope. They have started using ethylene oxide gas sterilization as a new way to clean all gastrointestinal scopes.

Fabregas, L. (2014, October 13). Scope disinfection failure suspected in superbug cluster, leads UPMC to alter methods.

6.28. CRE Outbreak National Institute of Health (NIH), Maryland, June 2011

In June 2011 staff members at the National Institutes of Health's Clinical Center started a 6-month fight with antibiotic-resistant *Klebsiella pneumoniae* that eventually infected 17 patients. The staff attempted to contain the infection after they noticed the first patient became sick, but a few months later a second, third and fourth patient became ill with the same strain of bacteria. After the second round of infections occurred, the infection prevention staff implemented extreme measures including monitoring every patient, swabbing all surfaces, implementing an extreme hand hygiene policy and even disposing reusable equipment after one use. The staff struggled to treat the infected as well. The bacteria quickly developed resistance to experimental antibiotics as well as antibiotics that were thought to be too harmful to the patients. After six months, the infection-control finally caught up to the infections, and the spread of the bacteria was stopped. Ultimately, the most important aspect to stopping outbreaks in hospitals is surveillance.

Vastag, B. (2012, August 22). 'Superbug' stalked NIH hospital last year, killing six.

6.29. Emergence of Glutaraldehyde-Resistant *Pseudomonas aeruginosa*, Switzerland, November 2009

In November 2009, at the University Hospital of Basel in Basel, Switzerland, staff conducted a routine sampling of endoscopes. The routine sampling was to monitor the efficiency of the endoscope-cleaning procedure at the hospital. During this procedure *Pseudomonas aeruginosa* (gram negative) was detected. From 40 tested endoscopes in November 2009, 23 of 73 samples detected *P. aeruginosa*. In the following samples from November through December 2009, *P. aeruginosa* was detected in 29 of the 99 samples. It was found in the rinsing water and in the drain of 1 of the automated endoscope reprocessors. 2 distinct *P. aeruginosa* strains were revealed, one in each reprocessor. The glutaraldehyde-based disinfectant showed no activity against the 2 pseudo outbreak strains when it was used in the recommended concentration under standard conditions. 63 patients who underwent endoscopic procedures from April through November 2009 tested positive for *P. aeruginosa*. The epidemiologic investigations failed to find a relation in 20 of 63 patients. After medical chart review by 2 infectious disease specialists, lower respiratory tract and bloodstream infections possibly caused by the pseudo outbreak strain were detected in 6 patients. The surveillance of the endoscopes were increased by sampling the rinsing water from the automated reprocessors twice weekly and sampling endoscopes twice monthly.

Tschudin-Sutter, S. (2011). Emergence of Glutaraldehyde-Resistant Pseudomonas aeruginosa. Infection Control and Hospital Epidemiology, 32(12), 1173-1178.

6.30. Multidrug-resistant *Klebsiella pneumoniae* outbreak after ERCP, France, December 2008 – August 2009

Gram negative bacteria: *Klebsiella pneumoniae* was the culprit producing extended-spectrum beta-lactamase outbreak. The investigators reviewed all medical data associated with patients and collected microbiological data from environmental sources and Duodenoscopes. The investigators identified 16 patients that were colonized with *Klebsiella pneumoniae* that produced extended-spectrum beta-lactamase type CTX-M-15. All 16 of these patients had previously undergone ERCP between December 2008 and August 2009 at Hospital G. Montpied in France. The ultimate source for the infection was identified as one Duodenoscope. Audits show that the cleaning and drying was insufficiently performed. After strictly following the cleaning guidelines, the outbreak ended.

Aumeran, C. (2010). Multidrug-resistant Klebsiella pneumoniae outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy, 42, 895-899.

6.31. Early Identification and control of carbapenemase-producing *Klebsiella pneumoniae*, originating from contaminated endoscopic equipment, June 2008- January 2009

A total of seven patients became infected with *Klebsiella pneumoniae* at two hospitals between June 2008 and January 2009. All seven patients had previously received ERCP within the past two months. Infection control measures were implemented to help prevent the transmission to other patients. There appears to be a link between all seven patients. They all had ERCP done at the same endoscopy center. It was discovered that there was an inadequate cleaning step at the endoscopy center. Investigators found bioburden in the elevator channel of the implicated scope. After identifying this flaw, 46 patients were invited for testing and an extra three patients were identified to be colonized with with carbapenemase-producing organisms. The identification of the problem, the source of the problem and implementing infection control measures led to the prevention of an outbreak.

Alrabaa, S. (2013). Early Identification and control of carbapenemase-producing Klebsiella pneumonia, originating from contaminated endoscopic equipment. American Journal of Infection Control, 41, 562-564

6.32. *Pseudomonas aeruginosa* outbreak in The Netherlands, 2008

In 2008, an outbreak of multidrug-resistant *Pseudomonas aeruginosa* occurred at the University Medical Centre Groningen at the University of Groningen in The Netherlands. Three patients became infected with this bacterium after undergoing ERCP procedures. Using both microbiological and epidemiological techniques, the investigators found the source of the infection: one individual ERCP scope. They found no bacterial contamination in the washer-disinfectors, tubing, or anywhere else in the hospital. The isolates found infecting the patients were linked to the isolates from the scope through molecular characterization. Luckily the

routine screening of both patients and scopes prevented this outbreak from becoming a larger problem. The surveillance protocol needs to be tightened up to prevent all cases and prevent cross contamination between patients who underwent ERCP.

Kovaleva, J. (2009). Is bacteriologic surveillance in endoscope reprocessing stringent enough? Endoscopy, 41, 913-916.

6.33. *Pseudomonas aeruginosa* outbreak in The Netherlands, 2008

There was a small outbreak of *Pseudomonas aeruginosa* infections in June and July of 2007 at Grady Memorial Hospital in Atlanta, Georgia. Isolates were obtained from respiratory cultures of 12 patients. All of the cultures had the same unique antibiogram pattern. The investigators cultured all bronchoscopes at the hospital and identified one as the source of the infection. As soon as this bronchoscope was identified as the source, it was removed from use. After removal of the bronchoscope, there were no more cases of *Pseudomonas aeruginosa*. 55% of patients exposed to that specific bronchoscope during those two months developed an infection, as opposed to 2% of patients exposed to other bronchoscopes in the same time period. The bronchoscope was evaluated, and there was visible damage to the bronchoscope that prevented effective high-level disinfection. It was determined that the occasional inspection for damage might be required in order to ensure effective high-level disinfection.

DiazGranados, C. (2009). Outbreak of Pseudomonas aeruginosa Infection Associated with Contamination of a Flexible Bronchoscope. Infection Control and Hospital Epidemiology, 30(6), 550-555.

6.34. An outbreak of *Pseudomonas aeruginosa* infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor, Japan, May - June 2003

In May and June 2003 an outbreak of *Pseudomonas aeruginosa* occurred after thoracic surgeries in Kyushu University Hospital in Fukuoka, Japan. Seven patients were reviewed, and it was revealed that the bronchoscopes were used during endotracheal intubation for one-lung ventilation in most patients. *P. aeruginosa* was recovered from the sputum of these patients at a very early stage after the operation. Samples from the bronchoscopes and an automated endoscope reprocessor were cultured and *P. aeruginosa* was recovered from all the samples obtained. The sterilization cycles of the bronchoscopes were inspected, and it revealed unsuitable management of bronchoscopes and a flaw in the AER. The detergent tank was contaminated and once it is contaminated it was not possible to disinfect it.

Shimono, N. (2008). An outbreak of Pseudomonas aeruginosa infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor. Japanese Society of Chemotherapy and The Japanese Association for Infectious Diseases 2008, (14), 418-423.

6.35. Unusual implication of biopsy forceps in outbreaks of *Pseudomonas aeruginosa* infections and pseudo-infections related to bronchoscopy, France, January – April 2003

Between January and April 2003, it was observed at the University Teaching Hospital of Montpellier, France an increase in positive respiratory tract samples for *Pseudomonas aeruginosa*. The samples were cultured from patients who had a bronchoscopic procedure. 61 bronchoscopic procedures were performed in 36 patients with two different bronchoscopes. 16 patients became infected and the infections were traced back to two bronchoscopes. After inspecting the bronchoscopes damage to the internal channel was observed. This damage was caused by defective biopsy forceps and prevented proper cleaning and disinfection of the bronchoscopes. The outbreaks stopped after the inner channels was replaced, and the hospital switched to disposable biopsy forceps.

Corne, P. (2005). Unusual implication of biopsy forceps in outbreaks of Pseudomonas aeruginosa infections and pseudo-infections related to bronchoscopy. Journal of Hospital Infection, 60, 20-26.

6.36. Multidrug-Resistant *Pseudomonas aeruginosa* Cholangitis after ERCP, Illinois, July 2002

In July 2002, three patients developed sepsis due to a *Pseudomonas aeruginosa* infection at Northwestern University Feinberg School of Medicine in Chicago, Illinois. All three patients had previously received ERCP treatment. This small outbreak was surprising because Northwestern is diligent about routine surveillance of their endoscopes. The infection control investigators believed that all three patients had received their ERCP treatment with the same scope. They confirmed that hypothesis by testing all of the available scopes and linked the isolates from the patients to the isolates from one scope. This scope had been cultured about a month prior, and the culture was negative for bacterial growth. With that being said, it is possible that infections can still occur even if the surveillance cultures are negative. The screening and surveillance processes have to become more stringent to prevent infections from occurring.

Fraser, T. (2013). Multidrug-Resistant Pseudomonas aeruginosa Cholangitis After Endoscopic Retrograde Cholangiopancreatography: Failure of Routine Endoscope Cultures to Prevent an Outbreak. Infection Control and Hospital Epidemiology, 25(10), 856-859.

6.37. Outbreak of *Pseudomonas aeruginosa* Infections Associated with Flexible Bronchoscopes, Maryland, June 2001 – January 2002

At Johns Hopkins Hospital in Baltimore, approximately 1000 flexible bronchoscopic procedures are performed yearly. More than half of the procedures include bronchoalveolar lavage, where sterile saline is instilled in the lower airways and then extracted to obtain samples. Between June 2001 and January 2002, the rate of isolation of *P. aeruginosa* from bronchoalveolar-lavage

samples was three times higher than the usual rate. 414 patients had a bronchoscopy during the outbreak. It involved 48 infections of the upper and lower respiratory tracts and bloodstream among 39 of the 414 patients. In 66.7% of these infections *P. aeruginosa* was found. The contaminated bronchoscopes might have been related to a loose biopsy-port cap which could have had a part in the death of three patients.

Srinivasan, A. (2003). An Outbreak of Pseudomonas aeruginosa Infections Associated with Flexible Bronchoscopes. The New England Journal of Medicine, 348(3).

6.38. An outbreak of multidrug-resistant *Pseudomonas aeruginosa* infection associated with contamination of bronchoscopes and an endoscope washer-disinfector, England, October – November 1998

In the course of a two-month period at the St Thomas Hospital in London between October and November 1998, two strains of *P. aeruginosa* were isolated from eight patients on the intensive care unit and three patients from other units. 11 patient's cultures came from respiratory samples and eight of the patients had a bronchoscopy. The possible cause of the outbreak appeared that the hospital purchased automated, closed washer-disinfectors due to the health and safety concerns over the use of open-trough glutaraldehyde. The machine had lime scale and biofilm deposits on its internal plumbing. 20 out of 21 samples from the washer-disinfector showed various bacterial contaminants including *Pseudomonas*. 1 specimen grew *P. aeruginosa*. Once the washer-disinfector was removed from service and the bronchoscopes had been cleaned, there was no patient cultures identified with ceftazidime- and azlocillin-resistant *P.aeruginosa*.

Schelenz, S. (2000). An outbreak of multidrug-resistant Pseudomonas aeruginosa infection associated with contamination of bronchoscopes and an endoscope washer-disinfector. Journal of Hospital Infection, 46, 23-30.

6.39. Nosocomial Transmission of *Pseudomonas aeruginosa* Following Bronchoscopy Associated with Improper Connection to the STERIS SYSTEM 1 Processor, New York, August - October 1998

This paper discusses the outbreak of Imipenem-Resistant *P. aeruginosa* (IRPA) after bronchoscopy procedures in the New York Hospital Medical Center of Queens in August, September, and October of 1998. IRPA was found in 18 patients total. Using traditional and molecular techniques, the investigators cultured multiple spots on bronchoscopes, cleaning equipment, and tubing. The results show that there was no direct patient-to-patient transmission. The likely cause of the infections was endoscopes used for the bronchoscopy procedure. The investigators linked the outbreak to poor training on new AERs for the

disinfection staff as well as the similar, yet different connectors found on the new AERs compared to the old AERs.

Sorin, M. (2001). Nosocomial Transmission of Imipenem-Resistant Pseudomonas aeruginosa Following Bronchoscopy Associated with Improper Connection to the STERIS SYSTEM 1 Processor. Infection Control and Hospital Epidemiology, 22(7), 409-413.

6.40. Pseudo-Outbreak of *Mycobacterium chelonae* and *Methylobacterium mesophilicum* caused by Contamination of an Automated Endoscope Washer, July – October 1998

Medical equipment pieces like fiber-optic scopes cannot withstand high temperatures; it then becomes hard to accomplish high-level disinfection or sterilization. Automated washers using 2% glutaraldehyde to reach high-level disinfection are commonly used to clean fiber-optic scopes. These washers can be contaminated with atypical mycobacteria, including *Mycobacterium chelonae*. In August of 1998, the microbiology laboratory reported an unusual number of acid-fast bacilli and pink bacteria identified as *M. chelonae* and *M. mesophilicum* during the cultures obtained during bronchoscopy. Between July 21st and October 2nd 1998, 26 of 131 fungal cultures obtained by bronchoscopy grew *M. chelonae*. The 26 cultures obtained came from 22 patients. Two of the 22 cases were not thought to be part of the outbreak. The automated washers were the result of the contaminations. The washers then contaminated the endoscopes and the bronchoscopes that were used to decontaminate. As a result, the medical center purchased new endoscopes and a new peracetic acid sterilization system.

Kressel, A. (2001). Pseudo-Outbreak of Mycobacterium chelonae and Methylobacterium mesophilicum Caused by Contamination of an Automated Endoscopy Washer. Infection Control and Hospital Epidemiology, 22(7), 414-418.