Flexible Endoscope Incident Report

Quarter 2

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Failure of Visual Inspection

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 The access sheath could be withdrawn but the device could not.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 A part of the ureter was retrieved and withdrawn with the subject device.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

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

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

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

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

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

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

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

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

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 lasted 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

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 a dvd 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

An unspecified number of patients Brochoalveolar Lavage (BAL) washings tested positive for mycobacterium porcinum. Marhc 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 precleaned after each procedure in the OR and manually cleaned and channels of the scopes are brushed with a non-Olympus Haylard 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

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. They 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

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

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

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

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

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. Patients 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

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

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

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

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 and Endoscopic Retrograde Cholangio-Pancreatography for primary sclerosing cholangitis with a Pentax Duodenoscope. Patient B returned to the emergency room two day 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 not prior history of this organism. Infection control was alerted to patient B by the infectious disease consult physician seeing the patient fourteen-day 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 know history. To determine if the infections were similar, the Pseuodomonas isolates where 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 Duoddenoscope 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

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

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

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 resistance 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

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 manufacturers 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 on 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

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 forecep 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

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

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 unknow 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

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

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-H190l 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

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=FDF

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

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 followd 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

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

A report in the FDA's **MAUDE** database states the facility reported blue reside remaining in Endoscopes and hookup tubing after reprocessing in their Advantage Plus Automated Endoscope Preprocessors. 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

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

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

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 afte 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

Flexible Endoscope Incident Reports

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*

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 Mycobaterium chelonae from bronahoalveolar 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

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

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 stenotrophomonaa 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

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 bronchoavelar 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

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 Mycobaterium 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

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

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

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

Foreign material was found present in a Colonoscope during a diagnostic Colonoscopy, December 2107

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=FDF

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 peracidic 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

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 unites 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

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 preformed to detect any leaks or tears in the endoscope which can allow fluid to accumulate and cause cross contamination. No harm to patients have been reported.

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

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

DSD-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

Gram Negative Bacteria Outbreaks

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

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

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

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

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

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

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

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 pneumonia,* 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 is 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

***Psuedomonas* 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

***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

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

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'.

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.

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, lead 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

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.

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, stops bacteria source.

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 election 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

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 Retreived May 16, 2016, from http://www.seattletimes.com/seattle-news/health/navy-vets-death-blamed-on-contaminated-medical-scopes/

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.

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

In June 2011 staff members at the Nation 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.

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.

Multidrug-resistant *Klebsiella pneumonia* outbreak after ERCP, France, December 2008 – August 2009

Gram negative bacteria*: Klebsiella pneumonia* 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 pneumonia* 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 pneumonia outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy, 42, 895-899.

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

***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.

Outbreak of *Pseudomonas aeruginosa* Infection Associated with Contamination of a Flexible Bronchoscope, Georgia, June – July 2007

There was a small outbreak of *Pseodomonas 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.

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.

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 were 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.

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.

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 bronchosopy 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).

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.

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.

Pseudo-Outbreak of *Mycobacterium chelonae* and *Methylobacterium mesophilicum* caused by Contamination of an Automated Endoscopy 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 paracetic 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.