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Flexible Endoscope Incident Report

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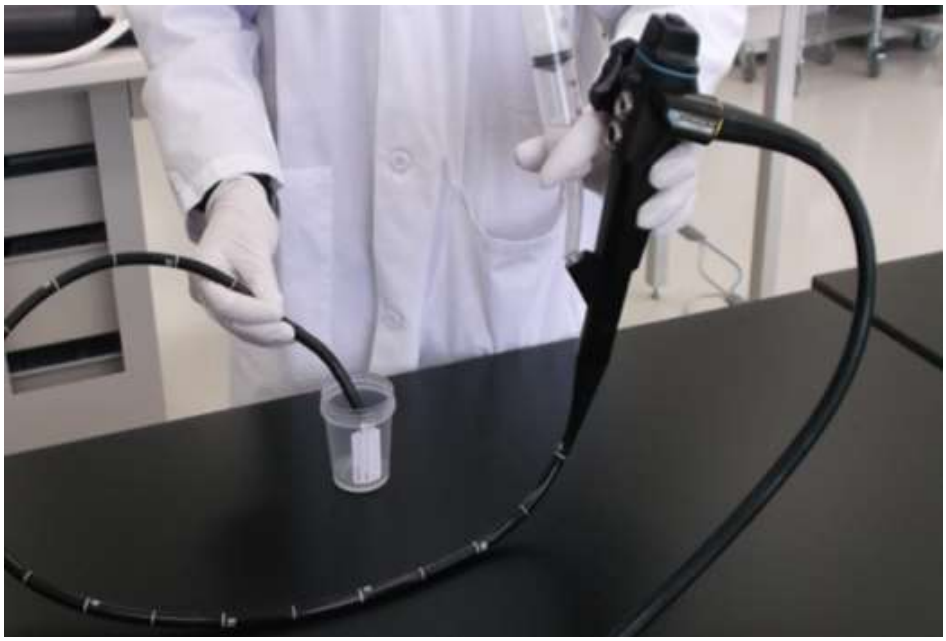

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The Flexible Endoscope Incident Report is created to be organized by topic that is related by different failure modes and is updated every quarter with new events and/or malfunctions that occur with endoscopes. The incidents in this document are found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

1.Failure of Visual Inspection

1.1 Mishandling of a Ureteroscope caused damage to the scope, April 2020

A report in the FDA's **MAUDE** database states that a Ureteroscope MR-6LA, 43CM was returned for evaluation and visual inspection determined the scopes distal end tip was damaged and bent. This was caused by a slight shadow and blur on the image. With further inspection, the outer tube of the scope was bent. The likely cause of damage, bent distal tip and outer tube is due to mishandling. There was no patient harm or injury reported due to the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10009441&pc=FGB

1.2 Foreign body fell into patient during surgery, April 2020

A report in the FDA's **MAUDE** database states a piece of foreign body fell off into a patient during a thoracic procedure. The KG Flex Intubation Endoscope 11301ABXK was use to check tube placement. An ENT surgeon was called in to remove the foreign body and prolonged to the procedure 2 hours. A return order was placed but the scope is not yet returned. The CRNA at the hospital said the patient is doing fine.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10038879&pc=CAL

1.3 The tip of an ERCP scope was found in the patient's mouth, March 2020

A report in the FDA's **MAUDE** database states upon removal of the ERCP scope, it was noticed the tip of the scope was missing. The missing piece was found in the patient's mouth and removed successfully. The tip was missing when scope was removed and patient was under anesthesia. The missing piece was found by finger sweep prior to extubation and there was no harm to the patient. The device was sent back to the company.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9792669&pc=FDT

1.4 A Ureteroscope became stuck in patient undergoing Bilateral Ureteroscoopies, March 2020

A report in the FDA's **MAUDE** database states that a patient was undergoing bilaterial ureterscopies due to ureteral stones. The physician tried to pull the Ueteroscope FLEX-X2S back. The physician met with resistance and felt like the scope was stuck. Retraction techniques untilized/attempted. A Rigid cyctoscope was utilized. Upon inspection, the outside lining of the flexible scope was very loose and was bunching.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9852990&pc=FGB

1.5 A metal clip was dislodged from a Gastroscope while a technician was trying to pass a brush through the scope, February 2020

A report in the FDA's **MAUDE** database states a nurse was asked to check the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 when the scope reprocessing technician could not pass a brush through the scope. While trying to pass the brush through a metal clip used in endoscopy procedures was dislodged from the scope. Earlier that day, the technician had the same experience on the same gastroscope when she could not pass the brush through. She suctioned fluid through the endoscope, trying to break up what was causing the blockage, and on the next attempt, the brush did pass through. The nurse was concerned that the endoscope was used with a retained clip in it did an investigation to determine when that scope was used to deploy clips. The scope was used in 07309 EGD procedure that same day where the physician reported clips being used, and "two clips did not deploy properly."

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9665429&pc=FAJ

1.6 An Esophagoscope was found to have biofilm and corrosion during a pre-inspectional check, January 2020

A report in the FDA's **MAUDE** database states a complaint was called into Pentax Medical customer service on December 19, 2019, and reported biofilm and corrosion found during pre-inspectional check of the endoscope and was documented as "potential endoscope contamination" involving a Pentax Medical Video Esophagoscope CC-1580K. The esophagoscope was received by Pentax Medical for evaluation on December 19, 2019, and inspected by Pentax Medical Service on December 26, 2019, and found the insertion tube severely crushed at stage 1, passed the dry leak test, distal body chipped, segment crushed, passed wet leak test, umbilical cable single buckled under PvE root brace. No patient injury or death of the patient or user. No delay in the procedure. This is the first time the esophagoscope has been returned for service at a Pentax facility since the scope was put into service on June 30, 2019. The scope is pending repair completion, resampling, and final quality control approval as of January 10, 2020.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9567402&pc=FDS

1.7 A piece of the flexible insertion tube of a Bronchoscope broke off and fell into the patient's airway, January 2020

A report in the FDA's **MAUDE** database states Pentax medical received a report for an event which occurred in the OR during use in Thailand. A piece of the flexible insertion tube of the Pentax Video Bronchoscope EB-1570K broke off and entered the patient's airway. The endoscope passed commissioning testing at the hospital before use on patients, also passed inspection at the Meditop workshop, which included leak testing, video test, and Icb check. The doctor performed a foreign particle removal procedure. The bronchoscope was not returned to Pentax medical for evaluation. Meditop has replaced the flexible insertion tube of the bronchoscope. The investigation is in process as of January 29, 2020.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mrfoi__id=9643211&pc=EOQ

1.8 A foreign body was noted in the patient's airway, January 2020

A report in the FDA's **MAUDE** database states the physician requested an intubation kit and paralytic because of "a foreign body was noted in the airway." The end of the Flexible Endoscope Bronchoscope 47700100 had broken off in ett. The retained end of the scope was retrieved.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9641665&p=EOQ

1.9 Possible contamination issues as three patients that had undergone Bronchoscopy with navigation procedures tested positive for a "light" growth of Serratia marcescens, December 2019

A report in the FDA's **MAUDE** database states the clinical nurse manager at the user facility reported there was a possible contamination issue as three different patients' that had undergone Bronchoscopy (with navigation) procedures were cultured via aerobic culture and gram stain broncho alveolar lavage positive and were positive for a "light" growth of Serratia marcesens. It is suspected that one scope is involved. The user facility did report the biopsy port at the proximal end of the EVIS ExeraII Bronchovideoscope BF-1T180 was noted to be loose. The biopsy port was reportedly taken apart, and foreign residue was present. The scope was not cultured by the user facility and was returned to the service center for evaluation. The clinical nurse believes the contamination of the scope was the cause of the patients' outcomes. The scope is immediately pre-cleaned after procedure, leak tested prior to manual cleaning, and the endoscope channel is brushed during manual cleaning. The cleaning/disinfectant solution's minimum effective concentration is checked every wash cycle. There has not been any problem noted with the AER machine. No manual air flushing as the AER machine flushes air at the end of the cycle. September 2018 was the last time a reprocessing in-service was provided. The scope is stored in a self-ventilated/clean scope cabinet. The scope was returned to the service center and forwarded to an independent lab for microbial testing with results pending. The scope was purchased in 2009 and received service via four repairs in the past three years with the last repair in 2018 for a biopsy port repair. An endoscopy support specialist visited the user facility in 2019 and performed a cleaning in-service with the staff. The ESS emphasize to the staff to always check that the biopsy port is intact and not loose. This report is for patient #2.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9469662&pc=EOQ

1.10 Patient ureter was perforated when the ureteroscope became stuck in the mid ureter upon withdrawal, December 2019

A report in the FDA's **MAUDE** database states a Medwatch report that was received on 11/25/2019; a patient was undergoing a Cystoscopy, right Retrograde Pyelogram, and Ureteroscopy with laser lithotripsy. A complication was encountered when the Flexible Ureteroscope, 7.5 Fr became stuck in the mid ureter upon withdrawal. The provider had difficulty withdrawing or advancing. The scope was successfully withdrawn after a very gentle

rotation of the scope and sheath. The patient's ureter suffered a perforation. The MD. Noted, "it appeared the sheathing came off the Ureteroscope causing the perforation." A sent was placed to treat the perforation, and the patient was admitted for observation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9438256&pc=FGB

1.11 During a Colonoscopy a clip misfired and became lodged within the channel of the Colonoscope, December 2019

A report in the FDA's **MAUDE** database states during a Colonoscopy clips were being used, and one misfired and became lodged within the channel of the Olympus GI Colonoscope PFC H190. This was not discovered until the clip was expelled with a large polyp that had been removed. After the investigation, during the original event, resistance was felt when trying to advance another clip. The Colonoscope was removed from the field, and the procedure was completed with another scope. The scope was sent for cleaning and disinfection per usual and brushes were run through the channel without resistance, but no clip was found and thought to have been removed during rinsing or while to advance the other device on the field. It was thought the clip was no longer in the channel since resistance was met previously but not longer. The scope was run through the Evotech per usual with no alarms engaged, and disinfection ran the normal course. The scope was put back in service and used on eleven more patients. During the procedure of the eighth patient, clips were used again; no resistance was felt, clips were deployed without incident. During the procedure in 2019, the clip was dislodged from the channel after the MD was trying to suction up a large polyp without success. When pushing the polyp out of the channel, the clip came out with the polyp. It was confirmed this clip did not belong to this patient, and the clip was removed. The scope was not sent for any testing since it had been used on numerous patients and successfully ran through the cleaning and disinfection process and passing the Resi-Test each time. Upon discovery, the scope was removed from service and sent to the manufacturer for inspection. The scope was a refurbished scope purchased from Olympus.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9444457&pc=FDF

1.12 Patient's pharynx was slightly injured by the gastroscope during an unspecified diagnostic procedure, December 2019

A report in the FDA's **MAUDE** database states that Olympus Medical Systems was informed that an unspecified diagnostic procedure the user facility noticed the patient's pharynx was slightly injured by the Gastrointestinal Videoscope GIF-Q150. The patient complained of nausea, and bloody saliva was observed. The facility alleged that the pharyngeal injury occurred due to the

rough surface of the insertion section of the aging scope. There was no report of further injury with the event. It was confirmed the scope was installed to the user facility in 2012. The service history of the scope and confirmed there was no maintenance performed until the event occurred. The scope was not returned to Olympus Medical Systems for evaluation. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9400675&pc=FDS

1.13 A patient's anal margin was burnt by the distal end of the gastroscope during an unspecified procedure, December 2019

A report in the FDA's **MAUDE** database states Olympus Medical Systems Corp. was informed that during an unspecified diagnostic procedure, the user facility noticed the patient's anal margin was burned when they were inserting the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 into the patient. It was reported the facility checked the scope and found that the distal endo the scope burnt the patient's anal margin. Another scope was used to complete the procedure, and there was no impact or patient hospitalization. The scope was returned to Olympus and evaluated the scope and confirmed the distal cover was damaged. The adhesive around the object lens had wear and tear and a slight scratch on the objective lens. OMSC reviewed the manufacturing history of the scope and confirmed no irregularity. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9409376&pc=FDS

2.Cleaning Verification Testing

2.1 Microbes were detected after multiple microbiological testing by the user facility, May 2020

A report in the FDA's **MAUDE** databases states multiple microbiolgical testing was done by the user facility and the following microbes in the EVIS Exera III Gasterointestinal Videoscope GIF-H190 were detected from the sample collected from the scope. Fist time: p. Aeruginosa (1cfu); Second time: the auxiliary water channel- p. Aeruginosa (1 cfu); The instrument channel: p. Aueruginosa (22 cfu); The suction channel: p. Aeruginosa (8 cfu). The scope had been reprocessed using peracetic acid. The scope has not been returned to OMSC but was returned to Olympus. The scope was sent to a third party lab for microbiological testing. No microbe was detected from the sample collected from all channels of the scope and testing result cleared the guideline. The exact cause could not be conclusively determined at this time. No report of infecton associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9845841&pc=FDS

2.2 Two patients acquired urinary tract infections and blood stream infection with same organism post procedure, April 2020

A report in the FDA's **MAUDE** database states two patients acquired urinary tract infections and blood stream infections with the same organism post cycstoscopy procedure for stent removal. Different scopes were used for each procedure. The facility has observed the procedure in the clinic setting and did not observe any practive or infection control concerns. The scope have been sent to the manufacturer's service center for evaluation. The scopes were forward to an independent laboratory for microbial testing. An Olympus EES was requested to be dispatched to the user facility to observe the facilitites reprocessing practice and to provide a reprocessing training. The visit has not been finalized as of date.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9975534&pc=FAJ

2.3 Gastroscope "may have failed strip test 3 times" with possible contamination issue, February 2020

A report in the FDA'a **MAUDE** database states a report on February 14, 2020 Pentax medical became aware of a Pentax Video Gastroscope EG29-I10 "may have failed strip test 3 times-possible contamination issue". Pentax medical received the gastroscope on February 21, 2020 for evaluation. The scope is pending inspection and biological sampling as of March 9, 2020. The scope has been routinely serviced at a Pentax facility since the scope was put into service on June 18, 2020.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9812389&pc=FDS

2.4 A patient developed Mycobacterium abscesses after undergoing a procedure using the facility's Duodenoscope, January 2020

A report in the FDA's **MAUDE** database states a patient developed Mycobacterium abscesses after undergoing a procedure using the facility's EVIS Exera II Duodenovideoscope TJF-Q180V. The infection was identified in the patient's blood culture. The patient had abdominal and back pain and was admitted. The user facility's nurse manager reported that to date, the scope was not cultured per the recommendation of the facility's infectious disease medical director to which the nurse believes the patient's infection is likely attributed to the injection tubing

and/or reusable tubing used during the procedure. The scope has been isolated until the issue is resolved. The scopes are reprocessed in a Steris 1e for ERCP and the Olympus OER Pro for all other endoscopes. The user facility participates in annual competencies, and the last in-service by Olympus was in 2018. The scope was returned to the service center for evaluation. A visual inspection was performed on the returned scope and found the bending section glue cracked. There were dents and kinks noted on the scope. The scope failed the leak test. The cause of the reported event could not be determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9553223&pc=FDT

2.5 Patient experiences an allergic reaction after undergoing repeat Cystoscopy procedures, December 2019

A report in the FDA's **MAUDE** database states the service center was informed by the user facility's performing doctor that the patient experiences an allergic reaction after undergoing repeat Cystoscopy procedures. Due to a pre-existing condition, the patient must undergo a Cystoscopy every three months. The patient experiences swelling of the penis and purple discoloration. The patient has no pre-existing allergies and was given topical cream to treat the reaction. The doctor reported the patient's condition last approximately two or three weeks, and that only KY lubricant is used. No other lubricants, creams, or soaps are used during the procedure. No other patients have been noted with this reaction; this patient is an isolated case. The doctor did not know the specific serial number for the referenced scope; therefore, it is unknown if the Visera Cysto-Nephro Videoscope CYF-V2 was returned to Olympus for evaluation/service and a review of the scope's history could not be performed. As part of the investigation, the content of this complaint has been escalated to the OEM for further investigation.

https://ww.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9507369&pc=FAJ

2.6 Three patients developed a fever after undergoing ERCP procedures, November 2019

A report in the FDA's **MAUDE** database states that three patients developed a fever after ERCP procedures from a loaner EVIS Exera II Duodenoscope TJF-Q180V. The first patient procedure was on October 8, 2019; The Second patient procedure was October 9, 2019; Third patient procedure was October 9, 2019. All three patients had already recovered when Olympus became aware of this event. The user facility did not conduct microbiological testing for the suspected scope and did not allege any failure of the scope. The Duodendoscope was manually reprocessed using a non-Olympus disinfectant. An annual inspection by Olympus was conducted for the subject endoscope on May 17, 2019, and no irregularity was found. A

representative of Olympus had conducted the reprocessing training for the user facility two years ago. The scope was returned and passed all functional tests. The scope was loaned to another hospital between October 6 and October 24, 2019. The scope was returned from the hospital on 24, 2019. The exact cause of the reported event could not be conclusively determined at this time. OMSC is submitting three medical device reports according to the number of potentially infected patients. This is three of three reports. A supplemental report was submitted to provide additional information. No blood results were provided to Olympus. Olympus contacted the user facility, and they would not disclose any further information. The subject device is quarantined. The scope was loaned to another facility after the incidents occurred. The other user facility, the Duodenoscope, was used for two patients. No report of patient infection. 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=9333954&pc=FDT

3.Leak Testing Failures

3.1 A Ureteroscope was found to have leakage at the biopsy channel and bending rubber, May 2020

A report in the FDA's **MAUDE** database states a patient was injured following a procedure involving a Uretero-Reno Videoscope URF-V in 2013 . The scope was returned to Olympus for evaluation for visual inspection to find leakage was found at that biopsy channel and bending rubber. The angulation wire was also found to be broken. The cause cannot be conclusively determined. Additional information was requested but not yet received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10081256&pc=FGB

3.2 Two incidents of endoscopes that passed leak testing were found to have residual fluid, January 2020

A report in the FDA's **MAUDE** database states that two recent incidents of endoscopes that passed automated leak testing, quality checks, and appropriate high-level disinfection that were found to have residual fluid. These two scopes were found to have leaks when inspected by the manufacturer. Flexible scopes were found to pass automated Veriscan leak test but failed when manually checked and contained leaks when inspected by OEM.

https://accessdata.fda.gov/scripts/cdrh/cfdocs/cfMADUE/detail.cfm?mdrfoi_id-9601618&pc=FCY

3.3 Scopes leave clinic in good condition and return damaged have failed leak testing, December 2019

A report in the FDA's **MAUDE** database states an Olympus Nasopharyngoscope ENF-V3 was used with no signs of damage. The scope was sent out and then returned two days later with a label that stated "scope failed the leak test". It was witnessed different carrier's handling the scopes in a very careles manner. This is a concern regarding the care, transportation, and possible sterileprocessing of equipment. Scopes leave in good condition and return damaged. The facility recently had another scope that was not used, and had not failed a leak test, go out to be cleaned and failed the leak test. The scope was sent in the afternoon but did not get processed by SPD until more than 24 hours later.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9805348&pc=EOB

4.Excessive Force with Equipment

4.1 Extensive damage to an Olympus Dur-8 Flexible Ureteroscope during a stent placement procedure, April 2020

A report in the FDA's **MAUDE** database states the doctor performed a right ureteroscopy, laser lithotripsy and stent placement procedure. The doctor inserted an Olympus dur-8 flexible ureteroscope DUR-8 ULTRA 007 to the level of the stone, which was then fragmented using a 365u laser fiber. While attempting to fragment the stone, the doctor fired the laser inside the scope multiple times causing extensive damage to the scope and its bending mechanism. The scope was so damaged it no longer functioned properly. The doctor inserted the scope further to evaluate the right kidney for possible stone fragments and after completion the doctor felt resistance as he attempted to withdrawn the ureteroscope from the patient's body. This was caused by the extensive damage by misfiring the laser inside the scope. The doctor pulled even harder on the ureteroscope attempting to withdraw it from the patient's body and could not be removed. The doctor however pulled even harder on the ureteroscope by applying ever increasing force and pressure to the scope to withdraw from the patient's body eventually causing the scope to disintegrate into multiple pieces while fragments of the scope were left behind in the right ureter. The doctor made several attempts to advance a different ureteroscope into the distal ureter and to grasp the largest fragment of the Olympus dur-8 flexible ureteroscope in order to extract it, but was unable to remove any significant portion of the scope. The doctor then place a resectoscope with a colin's knife and unroofed the intramual portion of the ureter, but was still unable to grasp the remaining fragments of the ureteroscope. The doctor lost access to the portion of the ureteroscope that was stuck in the ureter and could not further unroof the bladder. The doctor performed an exploratory laparotomy to attempt to remove the fragments of the ureteroscope that remained in the right

ureter. The doctor then used a scapel to open the ureter and remove the ureteroscope fragments, place a double j stent in the ureter before closing. The ureter became obstructed and infected which required the patient to have multiple surgeries and procedures to repair the damage caused. As of January 24, 2020, Olympus service center had completed a visual inspection of the scope, bus has failed to produce any evaluation or report, despite multiple requests. It is believed the scope remains in Olmpus possiession and control.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9947818&pc=FGB

4.2 During a Colonoscopy the scope bending rubber was ripped while inside the patient, February 2020

A report in the FDA's **MAUDE** database states a patient was injured while undergoing a Colonoscopy. The EVIS Exera III Colonovideoscope PCF-H190DL bending rubber was ripped while inside the patient, and the patient was injured. The scope was inside the patient when the customer noticed that the scope was caught on the tissue. The customer was able to pull the scope and retract it out from the patient and no reports of fragments falling into the patient. Customer notice the bending rubber was ripped, and metal mesh was visible where the rubber was ripped and could also see the wires and channels inside the scope. Patient tissue was found on the metal mesh and torn rubber to which the patient's colon was damaged by the scope. The scope was returned for evaluation, and visual inspection was performed and determined that the bending section was separated approximately 100mm from the distal end side. The bending section separation caused rough edges and the internal elements to be exposed (CCD, light guide bundle, angle wires, channels). Further evaluation determined the scope included non-Olympus bending section cover, bending section cover glue, insertion tube switch buttons, and bending section. It was observed there was heavy tension during angulation and play on the control knobs. The image was checked, and there was no picture being displayed on the monitor and no switch functionality. Based on the scope evaluation, the likely cause of the damaged section is due to mishandling and non-Olympus parts on the scopes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9699365&pc=FDF

5.Failures Due to Reprocessing Equipment (AERs)

5.1 A facility set the basin temperature below minimum requirement for an AER, March 2020

A report in the FDA's **MAUDE** database states Medivators Field Service Engineer reported a facility had their basin temperature set below the minimum requirement for a DSD 201 AER. The endoscopes may not have been adequately high level disinfected. The FSE reported the facility was using Cidex OPA HLD. The temperature was set below the minimm requirement and the heater on side A was turned off. The temperature was adjusted by the FSE and turned the side heater on. The FSE also found that an air filter on side B was installed backwards and lid cylinders needed urgent replacement, the adjustments were made and completed test cycles. The AER was installed in 2013 with no indication the AER malfunctioned. The AER was lasted serviced in 2018 by Medivators FSE and was found to be performing to specification. It is unknown at what point the incorrect temperature settings were made and the number of endoscope that were processed. There are no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9774454&pc=FEB

5.2 Facility reported using wrong high-level disinfectant in their AER, February 2020

A report in the FDA's **MAUDE** database states a facility reported that they used the wrong high-level-disinfectant in the AER. Employees were exposed to the Rapicide pa HLD fumes. The facility reported that the use of the incorrect chemistry was recognized right away, as the fumes were strong, and they needed to vent the room. Medivators field service engineer was dispatched to examine the AER for any damage and ensured that the unit was operating according to specifications. It was reported that the facility has two different models of AER's in the same room, a new operator put Rapicide pa part an HLD into the DSD-201 AER rather than into the Advantage AER. Medivators regulatory followed up with the facility in mid-January. At the time, they reported that three employees experienced exposure symptoms, and one of the three was treated in the emergency department. All three individuals were not wearing any PPE; all are reported to have no lasting symptoms. No endoscopes were processed in the AER with the incorrect HLD, therefore no patient procedural risk.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=9681269&pc=FEB

5.3 A facility was using Avantik Ultraclear Xylene substitute solution in the alcohol bottle in the AERs, January 2020

A report in the FDA's **MAUDE** database states the facility was using Avantik Ultraclear Xylene substitute solution in the alcohol bottle in the unit. Avantik is not validated for use it the AER. There is potential residual being left it the AER in the endoscopes being used inpatient procedures. Medivators FSE reported that all three of their facilities AERs had Avantik solution in the alcohol bottle. FSE observed that most rubber components within the AER were damaged. The FSE also found multiple other components showing signs of deterioration and was advised to stop using the AERs and endoscopes as there was too much damage and unsafe for use. It was reported that at least fourteen cycles had been run with this solution. It has not been confirmed if those scopes were used in patient procedures. The facility replaced all three AER units since Medivators FSE's initial visit and consulted with their Olympus representative and were advised to reprocess the endoscopes once more before continued use.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=9627170&pc=FEB

5.4 Two employees were sent to the ER due to exposure symptoms to peracetic acid from the DSD Edge AER, December 2019

A report in the FDA's **MAUDE** database states the facility reported a leak of Rapicide peracetic acid high-level disinfectant from their DSD Edge AER, causing two employees to be sent to the emergency room due to exposure symptoms. A Medivators Field Service Engineer was dispatched to the facility and inspected the AER. The FSE found that a manifold connector was not working properly and replaced the part. Test cycles were performed, and the unit was running according to specification. Medivators regularly followed up with the facility, and they confirmed one employee was wearing a mask at the time of the incident. One of the employees has asthma and was treated for symptoms in the ER. Both were provided with a doctor's note to be excused from work for three days. The employees' current condition is reported to be fine. There have been no reports of further incidents.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=9490209&pc=FEB

6.Sterilizer Malfunction

6.1 The facility's Sterrad® 100S sterilizer reported a cycle cancellation prior to completion, December 2019

A report in the FDA's **MAUDE** database states a customer reported a cycle cancellation with their Sterrad® 100S sterilizer, and the canceled cycle was released for use on patients prior to reprocessing. There was no harm, injury, or infections to patients associated with this issue. However, there is no report of patient injury or harm; Advanced Sterilization Products has determined in this situation sterility cannot be assured. ASP has decided to report all incidents of loads that are released from canceled cycles prior to reprocessing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cdMAUDE/detail.cfm?mdrfoi_id=9489644&pc=MLR

6.2 Customer reported a cycle cancellation with their Sterrad® 100S sterilizer, December 2019

A report in the FDA's **MAUDE** database states the customer's Sterrad® 100S sterilizer had a cycle cancellation and was released for use on patients prior to reprocessing. No report of infection, harm, or injury to patients. With no reports of patient injury or harm, ASP has determined sterility cannot be assured. ASP has decided to report all incidents of loads that are released from canceled cycles prior to reprocessing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=9511753&pc=MLR

7. Storage Cabinet Failures

7.1 Steris Endoscope storage cabinet was breaking down following sterilization, February 2020

A report in the FDA's MAUDE database states a user facility reported that the tubing sets for their Reliance 6000 Series endoscope storage cabinet was breaking following sterilization. A Steris account manager provided the customer with replacement tubing sets. The conditions of the event are under evaluation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9771597&pc=JRJ

8.Use Errors

8.1 Bronchoscope was reported broken during reprocessing, May 2020

A report in the FDA's **MAUDE** database states a during the reprocessing of a EVIS Exera Bronochovideoscope BF-3C160 was broke. The scope was returned and was evaluated. The user's complaint of broken was not confirmed. Visual inspection of the scope was completed and found not broken anomally with all parts still intact. However, three sections of the bending cover (rubber) were damaged with cuts, torn, and missing portion of the bending cover. The damaged bending cover exposed the bending mesh underneath. With further inspection, the bending section cover was removed; no physical damages on the bending skeleton and bending mesh were found, both in good condition. The servicing history showed the scope returned on January 29, 2020 for major repair due to deep buckles and leakes on the channel. It was noted the bending cover was over stretched during the estimation intake. Based on the evaluation and findings, the reported issue of "broke" could not be confirmed as there are no broken parts found on the scope during inspection. Damages found during inspection are likely what the user is referring to "broke".

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10040418&pc=EOQ

8.2 Suction buttons are getting stuck in the "suction" position and do not release, April 2020

A report in the FDA's **MAUDE** database states the suction buttons used in endoscopes in particular when pressed get stuck in the "suction" position and do not release as intended. Forceful/quick pressure is needed to release them. The issue started randomly but techs started sharing the issue among themselves not it was happening more consistently and involved different lot #'s. It did not happen in every kit but did happen numerous times in every box of kits. This was reported to Medivators. Not every lot had problems, random but consistent.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9977069&pc=ODC

8.3 Customer used Cidex OPA solution past the 14-day reuse date on instruments used on patients, March 2020

A report in the FDA's **MAUDE** database states a customer use Cidex OPA past the 14-day reuse date and on instruments that were released and used on patients. The customer stated the solution was tested prior to use and met the minimum effective concentration. No reports of injury, harm or infections reported. While no patient harm or injury reported, advanced

sterilization products has decided to report cases when the customer used expired product and releases the instruments for use since high-level disinfection cannot be assured.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9812390&pc=MED

8.4 A portion of an old stent was still in the Duodenoscope during an ERCP procedure, March 2020

A report in the FDA's **MAUDE** database states during an ERCP the spincterotome was passed through the EVIS Exera II Duodenovideoscope TJF-Q180V and thd MD felt resistance was met while trying to push the sphincterotome through the channel. A portion of an old stent was noted on the scope screen. The scope was immediately removed from the patient and was noted that an old stent from some previois pt/procedure was stuch in the scope and never came out during scope processing. The scope was sequestered and given to scope processing, evening shift supervisor.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9852970&pc=FDT

8.5 A snare and folded plastic piece of material came out of the Duodenoscope during an ERCP procedure, February 2020

A report in the FDA's **MAUDE** database states a patient was undergoing an ERCP procedure when the EVIS Exera II Duodenovideoscope TJF-Q180V was down in the patient's duodenm. The MD. attempted to traverse a extraction balloon through endoscope, the balloon would not pass. The physician pulled the scope out and examined it on the scope cart. The balloon was pushed strongly through the duodenoscope and what appeared to be a snare and a folded plastic piced of materials came out. The procedure was immediately stopped and changed all the equipment and alerted clinical operations manager, central sterile processing and supply, perioperative services, sterile processing department. Review of reprocessing protocols did not detect any resistance during brushing, scope passed dry and wet leak test. No decrease in pressurization via scope buddy and ultrasonic sink. No error messages or recorded fails from Medivator AER while high level disinfected via two required cycles. The scope was sent to Olympus service center for review after incident for possible damage to interior mechanisms in insertion tube.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9774014&pc=FDT

8.6 An ESS was requested by the facility doctor and head of Infection Control to review the site scopes reprocessing procedures, December 2019

A report in the FDA's **MAUDE** database states a facility doctor, and head of Infection Control requested an ESS to review the site scopes reprocessing procedure. Two scopes are in the facilities as reported by the ESS. It was found upon inspection and review that the facility is not compliant with Olympus and their scopes reprocessing steps. They do not have an air and water channel cleaning adaptor for pre-cleaning, no leak tester, no suction or suction tubing, no injection tubing for flushing channels, not using a 30cc syringe, no water rinse or alcohol rinse bins after the Cidex contact time. The facility ordered the necessary equipment and devices for the scope processing, and the ESS recommended the facility to have the G.I laboratory to clean the facility scopes. The infection control will be shutting down the scope reprocessing in the facility until they correct the reprocessing steps to be compliant. The ESS will perform a site visit once the facility is ready to continue to do scopes and review the setup, and in-service the staff before going live with patients again. There was no patient harm or injury reported due to the event. Supplemental reports have updates on the following: The ESS reported the facility is up and running, the facility worked closely with the ESS and infection control and sales representative to obtain everything the facility needed for the scope reprocessing. To date, the facility is operational, with no issue reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9513205&pc=FAM

9.Gram Negative Bacteria Outbreak

9.1 Two patients test positive for CRE from the same Duodenoscope after undergoing ERCP, April 2020

A report in the FDA's **MAUDE** database states an Olympus JF 140F Duodenoscope was used on a patient who was not know to have CRE tested positive post-procedure for cpcre e.Coli in urine after undergoing ERCP. The same scope was used another patient undergoing ERCP was also not known to have CRE. The patient tested positive of CPCRE. E.Coli in blod. The patient has had subsequent blood, urine, and pleural fluid cultures with not growth. The two patients were on the same inpatient unit 3 days apart and likely shared caregivers. The Duodenoscope was pulled from patient use upon notification of the index patient's positive CRE urine culture. The scope was sent for ETO sterilization per hospital protocol. The scope was used on an additional four patients, non of whom have exhibitied sign of CRE infection per medical record review. Following each ERCP the scope was reprocessed following manufacturer's IFU with the addition of double HLD per hospital protocol. Genome analysis of both CPCRE isolates reported to infection prevention on April 6, 2020 showed indistinguishable chromosomal patterns.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=9971644&pc=FDT