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Flexible Endoscope Incident Report

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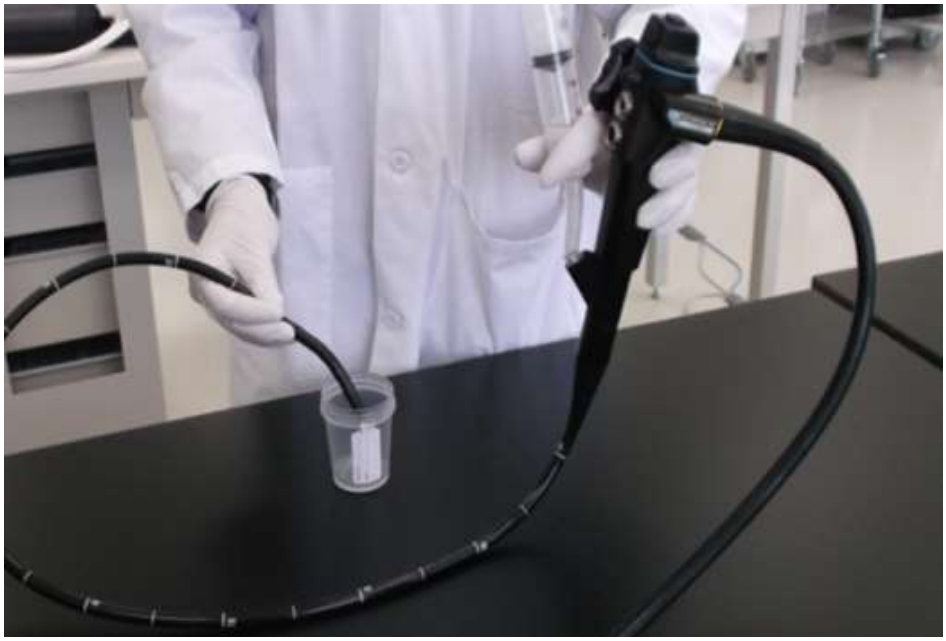

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The Flexible Endoscope Incident Report is created to be organized by topic that is related by different failure modes and is updated every quarter with new events and/or malfunctions that occur with endoscopes. The incidents in this document are found 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 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, 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."

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

A report in the FDA's **MAUDE** database, 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.

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1.3 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.

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1.4 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.

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1.5 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.

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1.6 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.

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1.7 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.

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1.8 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.

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1.9 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 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

2.2 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.

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2.3 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

Leak Testing Failures

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

A report in the FDA's **MAUDE** database 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.

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Excessive Force with Equipment

4.1 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.

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Failures Due to Reprocessing Equipment (AERs)

5.1 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.

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5.2 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

5.3 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

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.

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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

Use Errors

7.1 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