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Flexible Endoscope Incident Report

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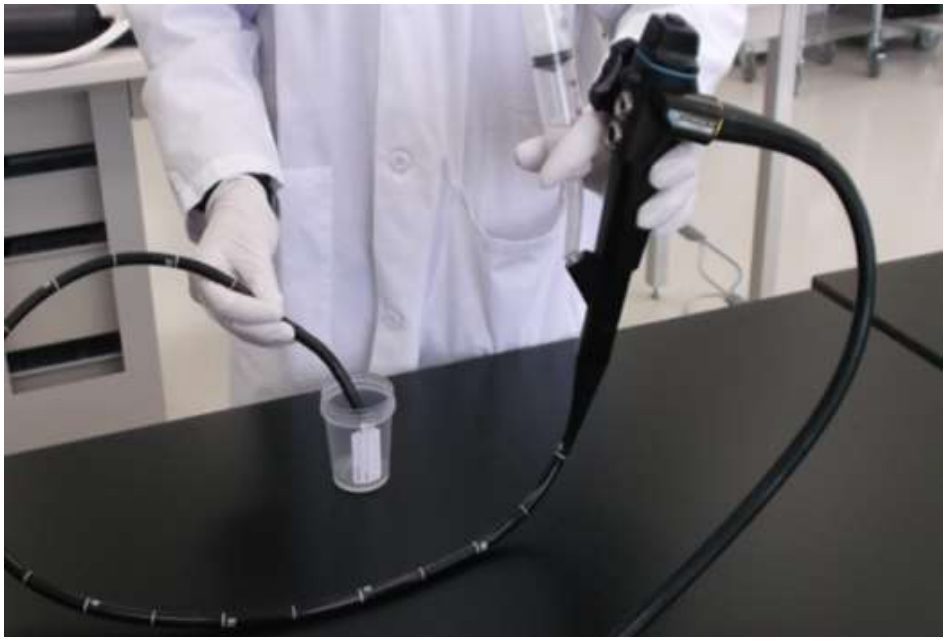

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The Flexible Endoscope Incident Report is created to be organized by topic that is related by different failure modes and is updated every quarter with new events and/or malfunctions that occur with endoscopes. The incidents in this document are found in the Manufacturer and User Facility Device Experience (MAUDE) data report. This database contains reports received by the U.S. Food and Drug Administration (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 Tissue fell into a patient that remained in the gastroscope from a previous procedure, February 2021

A report in the FDA's **MAUDE** database states the service center was informed of tissue remained in the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 from a previous patient and fell into another patient during an unspecified procedure. The facility verified there was no issue with the scope. The gastroscope was returned for evaluation due to verifying no issue with the scope after a piece of tissue remained in the scope after cleaning and was dislodged. Visual inspection was performed on the received condition inspected the biopsy, and suction channels for foreign material. An Olympus borescope was used to inspect both the biopsy and suction channels. The borescope was inserted through the distal end side of the channel and numerous scrape marks were found along the wall, which start from the distal end opening and proceed into the channel at approximately 80mm. The borescope was then inserted through the channel from the control body side and a stain was found upon entering the channel. The suction channel was also checked using the Olympus borescope (no damages or foreign material were noted). The functionality of the air/water function was also tested and verified the water flows consistently, with no stoppage, until release of the valve as intended. The videoscope passed the leak test. Olympus dispatched an Endoscopy Support Specialist (ESS) to the user facility to assess their reprocessing practices as part of the investigation. The ESS will also provide reprocessing training if necessary.

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1.2 Black ink like substance was leaking from the distal tip of the scope after reprocessing, February 2021

A report in the FDA's **MAUDE** database states, after the EVIS EXERA III Colonovideoscope PCF-H190L was reprocessed and hung, a black like substance was leaking from the scope's distal tip. The scope was returned to the service center/pending evaluation. No patient involvement occurred.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11285164&pc=FDF

1.3 A visual inspection was performed on the duodenovideoscope after it was sent back to the service center with findings of foreign residue and damage to the scope, February 2021

A report in the FDA's **MAUDE** database states the service center was informed the EVIS EXERA II Duodenovideoscope TJF-Q180V cultured positive twice for either non-pathogenic mold, or bacteria. The scope was cultured two times in 2020. The facility reported that all their scopes are cultured after every case. A visual inspection was performed on the scope and discovered foreign residue and stains inside the suction channel opening and biopsy channel opening. The biopsy channel was inspected with an Olympus Borescope and foreign residue was discovered at the distal end opening of the biopsy channel. Also, brownish stain was found on the backside of the forceps elevator, when fully manipulated in the up direction. The borescope was further inserted into the biopsy channel to find kinks located with the bending section portion as well as scrape marks found halfway into the biopsy channel. On the biopsy channel wall, a black streak was found near the control body side approximately at the 10cm marking. There were more findings with inspection within the biopsy and suction channels noted voids on the glue between the control body and forceps elevator. The glue had discoloration (with pinholes and wear around the edges) on both sides of the bending section causing small gaps. The glue surrounding the objective lens was also worn with pinholes and discoloration noted. The light guide lens has reddish brown (dried) foreign material within. The videoscope passed the leak test. The investigation of this event is ongoing.

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1.4 The bronchoscope was sent back to Olympus and found the bending section rubber was worn and peeled off with a deep cut on the surface of the insertion tube, February 2021

A report in the FDA's **MAUDE** database states the user facility forgot to reprocess the EVIS EXERA Bronchovideoscope Bronchofibervideoscope BF-3C160 after the procedure. The scope was not used on the patient. Microbiological testing by the user facility, no microbe was

detected from the sample collected from the suction channel and the instrument channel of the device. It was requested by the user facility to have Olympus to check for biofilm. No report on infection associated with this report. The scope was returned to Olympus and sent to a third-party lab for microbiological testing. The results found the following microbes were detected from the sample collected from the scope. All channels bacillus spp. Mesophilic (1cfu/endoscope), coagulase negative staphylococci (1cfu/endoscope). The testing cleared the French guidelines. The scope was checked and found the adhesive of the bending section rubber was worn out and peeled off, and there was a deep cut on the surface of the insertion tube. The exact cause could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11330892&pc=EOQ

1.5 During a Ureteroscopy using a Uretero-Reno Videoscope the surgeon had some resistance putting the 2.2Fr basket down and fibers fell out of the scope, February 2021

A report in the FDA's **MAUDE** database states that during a Ureteroscopy and laser Lithotripsy using a Uretero-Reno Videoscope URF-V2R the surgeon had resistance putting the 2.2Fr basket down. The physician repositioned the scope and managed to pass the basket, but no fibers came out. The physician was able to retrieve one of the fibers, then took the rest out of the patient and irrigated the ureter/kidney. No patient injury or infection related to this event. The scope was received by Olympus for physical evaluation and the investigation is ongoing. Upon inspection of the returned scope confirmed the scope is leaking from the instrument channel scrape marks found inside. IF also revealed cracks found in the bending section cover glue. The definitive cause of these issues is inconclusive. The report will be updated upon completion of the investigation or upon receipt of additional relevant information.

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1.6 Blood came out of the gastroscope the day after when it was used and reprocessed, January 2021

A report in the FDA's **MAUDE** database states the user informed Olympia Multi Specialty Clinic (OMSC) that blood came out of the EVIS EXERA III Gastrointestinal Videoscope GIS-HQ190 the day after it had been used and reprocessed with the cleaning brush and a Non-Olympus AER Soluscope and was then put in the drying cabinet. The scope was not returned to OMSC for evaluation. The exact cause of the reported event could not be concluded at this time. There was no patient injury associated with this report.

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1.7 A polyp tissue came out of the scope from a previous patient during a Colonoscopy, January 2021

A report in the FDA's **MAUDE** database states during a Colonoscopy the previous patient's polyp tissue came out of the EVIS EXERA LLL Colonovideoscope CF-HQ190L after a cold biopsy forceps was placed down the channel. The scope was properly cleaned (according to facility protocol) and ran through the scope cleaner DSD machine. No patient harm or injury reported due to the event. The scope nozzle channel was inspected, and no foreign material was noted. However, the distal end plastic cover of the unit was observed with deep dents and scratches. Based on evaluation findings, the issue was not confirmed. Possible causes could be due to (mis)handling and/or maintenance issue. To date, no patient infection reported.

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1.8 During a Cystoscopy using a Visera Cysto-NephroVideoscope, the doctor felt more friction than normal resulting in the patient to have some bleeding after the exam, January 2021

A report in the FDA's **MAUDE** database states the patient had some bleeding post-procedure after the Visera Cysto-Nephro VideoscopeCYF-V2 was removed. The doctor felt more friction than normal. The scope was examined by the customer after the procedure. It was noted on the tip of the flexible portion of the scope the outer covering is raised (formed a ring) and is not smooth. The procedure was completed as planned. No treatment was required as a result of this and the patient's current condition is stable with no continued bleeding. The physical evaluation of the scope was visual inspection of the condition of the scope was performed and found the bending section cover buckle/stretched. The inspector placed the bending section between two fingers and proceeded to moderately pull the bending section cover from the insertion tube side up to the distal end. After releasing the bending section cover it was noted that the cover became buckle/stretched, never returning to its original form. The inspector also tested the bending section, glue and cover, as stated in the inspection standards. The ring gauge was passed over the distal end and obstruction was found at the section of the bending cover, which had become buckled. A review of the scope history record was conducted and confirmed there were no abnormalities in manufacturing. The scope was 13 years and nine-months-old. The a-rubber had deteriorated, and the buoyancy occurred when the rubber was moving during procedure. External force: there is evidence that some external force was applied the a-rubber, damaging the a-rubber and contributing to the movement.

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1.9 After reprocessing, there was a black foreign material in the cleaning tank, December 2020

A report in the FDA's **MAUDE** database state after reprocessing, there was a black foreign material in the cleaning tank. No report of patient injury associated with this event. The user facility did not provide other detailed information. OMSC investigated the OER-5 100V Endoscope Reprocessor and the foreign material was a film-like green substance. As a result of the analysis, OMSC found that the main component of foreign material is alginic acid. Alginic acid is a type of dietary fiber and the main component of brown algae. In the medical field, it is used for surgical sutures, wound dressings, and hemostatic agents. OMSC surmised the following: a kind of brown algae was grown in the device; foreign material is derived from medical products. A device history record review indicates that the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. If additional information becomes available, this report will be supplemented.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10932617&pc=FEB

1.10 After reprocessing green sticky substances remained on a tray and the outside of the gastroscope, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed from the user that the green sticky substances remained on a tray and on the outside of the EVIS EXERA III Gastrointestinal Videoscope GIF-HQ190 after the scope was reprocessed. The following information was also shared by the user. Before the reprocessing, the gastroscope was used for the procedure in which there was an emergency case to retrieve two button batteries from a patient. Once retrieved, the scope was cleaned as per the usual procedure with a bed side cleaning with no evidence to indicate an unusual solution on or in the gastroscope. A disinfect and alcohol cycle in the Non-Olympus AER Medivators Advantage was completed. In the cycle Rapicide A and B, Matrix disinfectant and alcohol 70% was used to clean the scope. After the reprocessing procedure was completed, the scope was hung over night. Olympus Australia checked the scope and found the reported phenomenon could not be duplicated. No reported of infection associated with this report. The gastroscope has not been returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11064744&pc=FDS

1.11 It was observed after reprocessing that dirty water and black debris was coming from the gastroscope, December 2020

A report in the FDA's **MAUDE** database states the service center was informed that dirty water and black debris was observed coming from the auxiliary water supply after reprocessing. The EXIS Exera III Gastrointestinal Videoscope GIF-HQ190 was returned to the service center for evaluation. The customer's complaint of dirty water coming from the auxiliary water supply was not confirmed. The auxiliary water supply and water flow were found normal. A leak was observed at the scope's biopsy channel and tear marks noted in the gastroscopes forceps passage. The insertion tube was inspected, and its angulation appeared abnormal (snake-like) in shape when using the scope's control knob. The scope's id chip displayed a total usage count of 685. The investigation is ongoing and root cause currently unknown. If additional information becomes available this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11036083&pc=FDS

1.12 Six microbiological testing by the user, Olympia Multi Specialty Clinic (OMSC) found several malfunctions with the colonoscope, December 2020

A report in the FDA's **MAUDE** database states a user facility informed OMSC because of six microbiological testings. The sample collected from the instrument/suction channel of the EVIS EXERA LLL Colonovideoscope CF-HQ190L tested positive for unspecified microbes. On August 6, 2020, they detected P. aeruginosa (10-100CFU) microbes in the suction channel. Olympus checked the scope and found the suction cylinder cover port was leaking at the distal end, insulation test failed, the bending angle did not meet specification, the light guide lens was chipped/cracked, the rubber adhesive was detached, chipped, cracked, or had a burr. No report of infection associated with this report. The scope was not returned to OMSC for evaluation. The exact cause of the reported event is currently undetermined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11010250&pc=FDF

1.13 A clip came out of the instrument channel of the colonoscope during a procedure that did not require clips, December 2020

A report in the FDA's **MAUDE** database states the customer saw a clip coming out of the instrument channel of the EVIS EXERA LLL Colonovideoscope CF-HQ190I. The procedure did not require clips. The clip likely got stuck in the channel in the previous procedure using the same scope. The scope was not returned to OMSC for evaluation and no further details provided. No report of patient injury associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11044276&pc=FDF

1.14 The manufacturer of the duodenovideoscope inspected the scope and found multiple areas of damage on the scope, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed as a result of microbiological testing by the facility, the sample collected from the suction channel of the EVIS EXERA II duodenovideoscope TJF-Q180V tested positive for Klebsiella (60 cfu/20mL), Serratia (30 cfu/20mL), and E. coli (23 cfu/20mL0. The scope has been reprocessed with Olympus AER ETD3 plus using peracetic acid. No report of infection associated with this report. The scope was not returned to OMSC but returned to Olympus OEKG for evaluation. OEKG sent the scope to third-party lab for microbiological testing and the results showed no detection of microbes from the sample collected from the scope. The testing result cleared the German guideline. OEKG checked the scope and the following: signs of humidity under the light guide lens, bending section rubber was porous, insertion tube was kinked and buckled, the control section was worn out, the name plate on the control section was missing, air/water cylinder was worn out and had corrosion, suction cylinder was worn out, electrical connector was corroded, distal end corroded, and corrosion under the forceps elevator. The exact cause could not be conclusively determined.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11042579&pc=FDT

2.Malfunctions of Single-Use Scopes and Endcaps

2.1 The single-use cover moved as the duodenovideoscope was removed from the patient during the end of the procedure, February 2021

A report in the FDA's **MAUDE** database states OMSC was informed by the user that when EVIS EXERA III Duodenovideoscope TJF-Q190V was removed from the patient during the end of the procedure of a biliary catheterism. The user noticed that the single-use distal cover, which was attached the scope, moved. The user stated the single-use cover might have inappropriately

positioned to the scope before the procedure. The single-use distal cover remained in the patient's larynx. The user removed the single-use distal cover from the patient, which resulted in oxygen desaturation of the patient. There was no patient consequence and no problem to date. Olympus will train the user by request from the user. The scope has not been returned to OMSC for evaluation. The manufacturing history of the scope confirmed no irregularity. The exact cause of the reported event could not be conclusively determined. However, based on the reported information, the event may have occurred because of inappropriate attaching to the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11325980&pc=FDT

2.2 The disposable distal end cap dislodged and fell into the patient during an Endoscopic Retrograde Cholangio-Pancreatography (ERCP) procedure, January 2021

A report in the FDA's **MAUDE** database states Pentax Medical was made aware of an event in 2021 that the user reported. During the ERCP, the disposable distal endcap was dislodged and fell into the patient. The Pentax Medical accessory model OE-A63 lot 0011020 use with a medical video Duodenoscope ED34-I10T2. The Endoscopist attempted to find the lost cap, but was unable to locate it, and eventually withdraw. The facility responded to a good faith effort request via email on December 18, 2020, which stated the site is at a loss to explain why the scope tip (distal endocap) could come off. It was checked by both nursing and the physician before the procedure, and they claim they did hear audible click. A site meeting between Pentax Medical and the PLC clinical team is scheduled to discuss the complaint currently under investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11166914&pc=FDT

2.3 A piece of meat came out of the scope during an ERCP clinical demonstration, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed from the user that during and ERCP clinical demonstration, using with the TJF-Q290V, which the device was attached, the patient had severe stenosis and the physician could not continue the procedure. The physician replaced the TJF-Q290V to the JF-260V and completed the procedure. During the reprocessing, the TJF-Q1290V the device was detached from the TJF-Q290V, the unspecified tissue (a piece of meat) came out from the subject device. The facility stated that before the procedure the facility brushed the TJF-Q290V and reprocessed the scope with OER-4. No other detailed information was provided by the user facility. The scope was returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11011384&pc=FDT

2.4 During an ERCP procedure the disposable distal end cover came off the endoscope as the customer was withdrawing the endoscope from the patient, December 2020

A report in the FDA's **MAUDE** database states the user performed an ERCP with the disposable distal end cover MAJ-2315 and an endoscope TJF-Q290V. The disposable distal end cover came off the endoscope during the procedure at the timing the customer was withdrawing the endoscope from the patient. The disposable distal end cover was removed from the patient's mouth and the procedure was completed. No report of patient injury associated with this event. The device was returned to OMSC for evaluation. This product is supposed to be destroyed when it is detached from the endoscope for preventing unintended reuse. However, the device was not broken and suggests the device was attached to the distal end of the endoscope firmly. The device probably came off when the distal end of the endoscope hit the patient's mouth. The instruction manual provided preventive measures against the reported failure mode.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10933945&pc=FDT

2.5 The subject device fell off into the patient during the withdrawal of the endoscope after an ERCP procedure, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed by the user that the subject device fell off into the patient during the withdrawal of the endoscope after the completion of the ERCP procedure. The physician inserted another endoscope into the patient to find the subject device, but was unable to locate it. The physician stated the device did not fall off into the patient's lungs since the patient was intubated and general anesthetized. The physician did not retrieve the device from the patient, but they estimated that the subject device would be excreted naturally. The device was not returned to OMSC for evaluation and the exact cause of the reported event could not be conclusively determined at this time. No patient injury associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11027056&pc=FDT

3.Cleaning Verification Testing

3.1 Sample collected from the instrument channel of a gastroscope tested positive for Candida albicans after microbiological testing, December 2020

A report in the FDA's **MAUDE** database states OMCS was informed by the user facility that sample was collected from the instrument channel of a EXVIS Lucera Elite Gastrointestinal Videoscope GIF-H290 and tested positive for Candida Albicans (200 CFU/endoscope) after microbiological testing. The scope had been reprocessed with an Olympus AER OER-AW using peracetic acid. The gastroscope was not returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time. There was no report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11001085&pc=FDS

3.2 Sample collected from all channels on a colonoscope for microbiological testing resulted positive for microbes, December 2020

A report in the FDA's **MAUDE** database states microbiological testing by the user facility collected samples from all channels of the EVIS EXERA III Colonovideoscope CF-H190I tested positive for Enterococcus faecalis (>100 CFU) and Enterococcus faecium (>100 CFU). The scope had been reprocessed with an Olympus AER model ETD 3 Plus using peracetic acid. The scope was not returned to OMSC for evaluation. The exact cause of the reported event could not be conclusively determined at this time. There was no report of infection associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11071798&pc=FDF

3.3 Multiple microbiological testing for the duodenovideoscope microbes were detected from the sample collected, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed by the user facility the result of multiple microbiological testing. The following microbes were detected from the sample collected from the EVIS EXERA II duodenovideoscope TJF-Q180V: First time- Stenotrophomonas maltophilia; Second time- P. aeruginosa and Stenotrophomonas maltophilia. The scope has been reprocessed with Non-Olympus AER Wassenburg using peracetic acid. No infection was reported in association with this report. The scope was not

returned to OMSC but returned to Olympus. OFR sent the scope to a third-party lab for microbiological testing. The sample collected from all channels of the scope tested positive for Micrococcaceae (1 CFU/endoscope) and the sample collected form distal endo of the scope tested positive for gram positive bacteria (2 CFU/endoscope). The testing cleared the French guideline. 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=11052924&pc=FDT

4.Excessive Force with Equipment

4.1 During an unspecified procedure the Uretero-Reno Videoscope was found to have a broken tip, January 2021

A report in the FDA's **MAUDE** database states the Ureter-reno Videoscope URF-V2 was found with a broken tip during an unspecified procedure. The scope was evaluated by Olympus. The physical evaluation reveals: Leaks at the biopsy channel, bending section was broken with protrusion of the skeleton. A dent in the insertion tube, angulation was low. The manufacturers IFU provides the user information related to the reported event. The scope history record was reviewed and confirmed there were no abnormalities. The definitive cause of the reported event could not be established. Based on investigation results the probable cause may be the user inadvertently manipulated the scope with excessive force to bending section.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11215143&pc=FGB

5. Endoscope Malfunctions

5.1 Two endoscopes became hot at the distal tip of the Gastroscopes during preparation in November, December 2020

A report in the FDA's **MAUDE** database states OMSC was informed by the user that distal ends of two Olympus 1500 series endoscopes became hot. One hospitals Endoscopist experienced this issue during preparation on November 23 and at the beginning of procedures on November 24. The Endoscopist touched the distal tip of the Gastrointestinal Videoscope GIF-Z1500 with gloves on in order to protect the patient from the scope's light and noticed that the tip got hot. A nurse then touched the tip of the scope with gloves on for about 5 seconds and the scope made a mark on the gloves with its heat. There were no burns on the skin to the nurse's hands. The Endoscopist continued to use the scope to complete the procedure. The gastroscope was

being used in normal light mode at the timing the event occurred. The gastroscope has been used a total of eight times but has not been used thereafter because the washing cycle failed. The scope has been reprocessed with a Non-Olympus AER Getting Washer.

The scope was not returned to OMSC but was returned to Olympus service for evaluation. The scope was visually inspected and found no defects. Olympus services conducted scope surface temperature monitoring to reproduce the reported event. A significant increase in temperature was observed while activating the optical output of the video system center. The most significant increase in temperature was observed whilst activating the white light mode at maximum output. The highest temperature recorded was 72.5°C and the ambient temperature was 23°C. Olympus service did perform a surface contact test by pressing the distal end against the surface of nitrile inspection gloves and confirmed that direct contact with gloves burns them in white light imaging mode. Narrow band imaging mode and red dichromatic imaging mode did not burn the gloves but made marks on the gloves. The exact cause of the reported event could not be conclusively determined at this time. No report of patient injury associated with this event. There were no abnormalities that occurred on other endoscopes including the Olympus 290 series that the user facility owns. This is the second of two reports.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11070568&pc=FDS

6.Use Errors

6.1 An Endoscopy Support Specialist from Olympus did an in-service observation of the facility's reprocessing staff and found several reprocessing steps were being missed, February 2021

A report in the FDA's **MAUDE** database states an Olympus ESS did an in-service observation of repair reductions and facility summary. The ESS observed the reprocessing staff at the facility needed improvements due to missing steps on their manual cleaning procedure. Improper leak testing, improper manual cleaning and flushing syringe step was not performed. The sterile processing supervisor confirmed there were no patient injury, infection or harm associated with the urology and ENT flexible endoscopes. During the reprocessing steps, the ESS observed the following: A leak test was conducted without operating the far end. Detergent was used during the leak test. During manual cleaning, compatible detergents were not prepared as recommended by the manufacturer and water was not filled to the fill line. The diameter of the cleaning brush may not fit the channel because it did not use the sponge or the cloth without thread scraps. Flushing by syringe was not done. The ESS spoke with the nurse supervisor regarding the observation findings and sent an email with the observation summary including the forms, helpful literature, and the reprocessing manual for the Visera Cysto-Nephro Videoscope CYF-V2. The email included all the findings during repair reduction and the issues

found during reprocessing. A follow-up in-service has not been finalized. The legal manufacturer performed the device history records for the scope and all records indicated that the product was manufactured according to all applicable procedures and met final product release criteria. No abnormalities were found. The legal manufacturer confirmed the most probable cause of the incorrect/insufficient reprocessing was due to user error.

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6.2 Foreign matter was found adhering to the forceps/irrigation plug during a procedure, February 2021

A report in the FDA's **MAUDE** database states the user found foreign matter adhering to the Forceps/Irrigation Plug MAJ-891 during a procedure. After reprocessing, the user completed the procedure by using the device. Due to this problem the procedure did run longer than planned. No report of patient injury. The device was not returned to OMSC and could not be investigated. There was a possibility the incident reported was attributed to the insufficient reprocessing of the device by the user.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11357059&pc=FGB

6.3 A piece of the scope's sheathing came off and fell into the patient's lung, February 2021

A report in the FDA's **MAUDE** database states during a patient procedure with a Glidescope® BFlex 5.0 bronchoscope, that a piece of the scope's sheathing came off and fell into the patient's lung. The customer did state they believed they were able to suction the piece out. It was reported there was no delay in the procedure, use of a backup scope, or harm to the patient or user. The Glidescope® single-use bronchoscope was received by Verathon Inc. but was not yet analyzed. Verathon continues to investigate the reported event and a supplemental report will be submitted.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11304127&pc=EOQ

6.4 Patient coughed up piece of the light source from a bronchoscopy 12 days after procedure, January 2021

A report in the FDA's **MAUDE** database states that 12 days after the bedside Bronchoscopy in the CVICU. The patient was coughing and coughed up a piece of the scope which was the light

source. The scope that was used for the procedure was a Glidescope® Bronchoscope BFlex. Post procedural X-ray did show device but was not resulted by the radiologist.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11228833&pc=EOQ

6.5 A user facility did not change the disinfectant in their endoscope reprocessor for 84 days, December 2020

A report in the FDA's **MAUDE** database states a local service engineer checked the endoscope reprocessor, 84 days had passed since the last disinfectant change. No other detailed information was provided. OMCS could not investigate the device, because the endoscope reprocessor was not returned to OMSC. The device history record review indicates that the product was manufactured and tested in accordance with all applicable procedures and met all final product release criteria. Based on the report, OMSC surmised that the cause of this phenomenon was the following factor: Since the disinfectant solution concentration level is not checked each time, this event has occurred.

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6.6 The user facility utilized expired Acecide disinfectant in the endoscope reprocessor, December 2020

A report in the FDA's **MAUDE** database states the user facility reported to Olympus that they had utilized expired Acecide disinfectant in the endoscope reprocessor OER-PRO. The facility has a five-day limit on the usage of the disinfectant, but they utilized the reprocessor with the expired disinfectant on day six. Although the disinfectant was expired, the reprocessed scopes passed efficacy checks. One of the reprocessed scopes was used on a patient, which was reported on related MedWatch 8010047-2020-05979. The facility reported to Olympus, that to their knowledge, no patient injury or infection resulted from this event. The other scopes that were reprocessed with the expired disinfectant were reprocessed again with unexpired disinfectant.
An Olympus Endoscopy Support Specialist (ESS) had a meeting with the endoscopy nurse manager to provide staff training on proper reprocessing and changing Acecide on or before day five of the validation. The device history record was reviewed, and it was verified the device was manufactured in accordance with documented specifications. A Corrective and Preventative Action(s) (CAPA) has been opened to mane the actions related to remediation of this issue and any required Medical Device Reporting (MDR).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11030949&pc=FEB

6.7 The staff did not perform pre-cleaning for the elevation channel of a duodenovideosocpe in some time, December 2020

A report in the FDA's **Maude** database states a customer reported the inside of a EVIS Lucera duodenovideoscope JF-260V during pre-cleaning has not been performed in a long time. The scope was reprocessed in a Non-Olympus AER model Endoclens. The OMSC explained to the user facility the process method based on the instruction manual of the scope. The scope was not returned to OMSC for evaluation. The exact cause of the event could not be conclusively determined at this time. No report of injury or infection with associated with this report.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11044381&pc=FDT

7.Gram Negative Bacteria Outbreak

7.1 Seven patients were infected with Mycobacterium lentiflavum after Bronchoscopy procedure using the same bronchoscope, January 2021

A report in the FDA's **MAUDE** database states the user facility found that a total of seven patients were infected with Mycobacterium lentiflavum after a Bronchoscopy procedure where the same bronchoscope EVIS EXERA III Bronchovideoscope BF-H190 was used. Microbiological testing for only bacteria (not including Mycobacterium of the bronchoscope performed in the last few months) was not detected. In November and December 2020, the facility took samples of the water of the washer, bronchoscope, taps and drains for microbiological testing; and the results have not come back yet. The user did not operate additional treatments for the seven patients. One of the patients did die; however, it was due to the patient's underlying pathology. The conditions of the six remaining patients have no problem. Endoscope reprocessing method was not provided and OMSC is submitting seven medical device reports due to the number of infected patients. The scope was not returned to OMSC for evaluation and the exact cause of the event could not be conclusively determined at this time.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=11168659&pc=EOQ

7.2 Nine patients were examined by the same cystoscope with urine samples cultured showing positive for Extended Spectrum Beta-Lactamase (ESBL) and E. coli after the procedures, December 2020

A report in the FDA's **MAUDE** database reports the attending physician reported nine patients were examined by the same Cysto-nephro Fiberscope CYF-5. The patients' urine samples were cultured and an ESBL and E. coli had been recovered and the patients were treated with antibiotics. The physician stated some of the patients have had urine retention, hematuria, septic issues, and UTI after the procedures, which triggered him to have the urine cultured. The cystoscope was returned to Olympus for evaluation to see if there had been any damage on the scope. It was reported the scope has been manually reprocessed and soaked in Cidex® OPA. The user facility did report there had been no cultures performed prior to returning the scope to Olympus. The scope was sent to an off-site lab for microbiological testing. As part of the investigation, an ESS was sent out to visit the user facility to perform a scope reprocessing and infection control in-service for the staff. The ESS covered infection control information referenced in the manual and reprocessing manual. The ESS also requested the staff to show him each step in the use and reprocessing of the scope. The ESS observed the staff was not currently using correct transport bins, not pre-cleaning, not leak testing after each case, not currently reprocessing stopcock, not currently replacing saline bag or irrigation tubing between each case, not currently reprocessing reusable brushes, not soaking scope in detergent for recommended amount of time and not properly rinsing the scope. The ESS communicated the findings to the facility staff and proved a list recommended proper reprocessing techniques, proper handling, and storage of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=10934571&pc=FAJ