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Flexible Endoscope Incident Report

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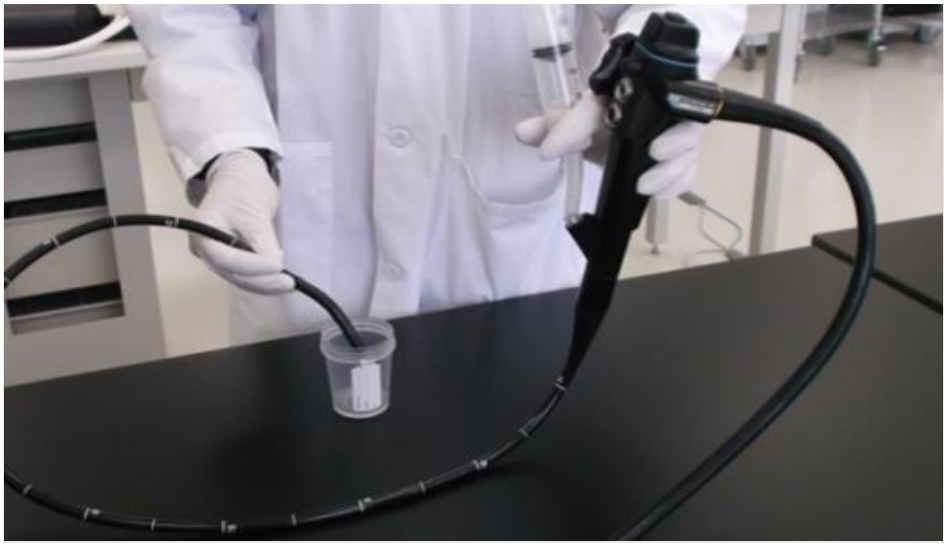

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9.28 Three (3) patients were infected with *P. aeruginosa* by the same bronchovideoscope for which the facility was unable to decontaminate using standardized scope cleaning processes, December 2022

The Flexible Endoscope Incident Report is created to be organized by topic, 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 A clip used from the previous case was inhaled and came out inside the patient's body in the next case, November 2023

A report in the FDA **MAUDE** database states an Olympus representative reported on behalf of the customer that the clip used in a previous case was inhaled and came out inside the patient's body during the next case.

Brushing and washing were performed on the EVIS Lucera Elite Colonovideoscope PCF-H290TI after each case. It is unclear whether the paper clip was recovered or left inside the patient's body. No patient harmed was reported.

Additional procedural details were requested but unknown/not provided.

The scope was not returned for evaluation.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18194641&pc=FDF

1.2 Tissue-like substance came out of the tip of the gastrointestinal videoscope and pushed into the patient during a procedure, November 2023

A report in the FDA **MAUDE** database states the customer reported that after pushing down the biopsy forceps into the EVIS Exera Lucera Elite Gastrointestinal Videoscope GIF-H290, they

noticed a tissue-like substance came out of the tip and were worried it was tissue left behind [from a prior procedure].

The issue was observed during a gastroscopy procedure. A misdiagnosis and retrieval of broken parts from the patient were also reported. The procedure was completed using the same scope after an unknown delay. There was no further harm or injury reported due to the event.

The customer indicated the scope went through the washer before and was also inspected prior to the procedure without any [known] issues. Additional information was requested to clarify event details, but no further information was received at this time.

The scope referenced in this report has not been returned to Olympus. A comprehensive leakage check was completed prior to technical evaluation and no leaks were found. The scope was inspected immediately upon arrival from the customer.

- Technical evaluation revealed an uneven edge at the distal end's adhesive.
- Brushed channel with no evidence of tissue-like substance.
- Leak tested and all channels were flushed with water with no evidence of tissue-like substance.

Technical evidence has not confirmed the fault, nor the tissue-like substance evident during the investigation. The suggested root cause is most likely due to user handling and the cleaning process.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18107676&pc=FDS

1.3 The cystonephrofiberscope was found to have damage in several areas when sent to Olympus for an annual inspection, November 2023

A report in the FDA **MAUDE** database states a user facility returned the (cystonephrofiberscope CYF-5) to Olympus for annual inspection. Upon inspection and testing, Olympus found dirt in the biopsy channel and on the distal tip (possible blood deposits). No patient involvement.

Additional issues were identified during the evaluation:

- Cementing defects found on the bending section cover.
- Peeled off connecting tube coating.
- Broken up/down button.
- Spider webs on the image guide bundle

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18234454&pc=FAJ

1.4 A loaner unit was twice processed before use, forceps were advanced from the working channel causing biological material to be pushed out into the patient, October 2023

A report in the FDA **MAUDE** database states a loaner unit Pentax® Video Upper G.I scope EG29-I10 underwent prewash and had been found satisfactory (for this purpose it is sampled and sent through the RDGE twice in total).

During the first examination, biological material was pushed out of the working channel when forceps were advanced. According to the UKE, this material should have come from the previous patient and not from the UKE. A photo of the biological material [was] attached to the submitted report. The material could not be removed, and the patient did not suffer any harm. This event occurred at the time of during use.

This event meets the requirements for FDA reportability. The scope passed several reprocessing's without any findings before use at the customer's side. We also checked the endoscope reprocessing procedures at UKE and found that they were carried out using standardized procedures. According to the process, this loaner scope has been reprocessed at least twice before use. Investigation is in-process.

If additional information becomes available, a supplemental report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18001436&pc=FDS

1.5 During a procedure with a gastrointestinal videoscope, a broken piece of the cleaning brush popped out of the suction port, September 2023

A report in the FDA **MAUDE** database states the customer reported that during an unspecified diagnostic procedure using the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190, a piece of the broken cleaning brush popped out of the scope's suction port. This report is being submitted for the procedure performed in 2023, whereby the same scope may have been used and the brush may have been in the suction channel at the time of the procedure. There have been no reports of patient or user harm due to the event.

Additional information from the report shows the endoscope passed reprocessing before the first procedure without any errors from the Evotech™ cleaner/reprocessor. Immediately after the 2023 procedure with the "broken brush", it was cleaned with a new cleaning brush, which passed through all channels and effectively completed the Evotech™ cycle without any errors. The scope was taken to the washroom where it was soaked in high-level disinfectant and a cleaning brush was inserted through and ran through all the channels, and then ran through the Evotech™

for the final step of disinfectant. All accessories were without abnormality. The endoscope was then hung in the scope cabinet after the disinfection cycle. There did not appear to be any disruptions in the flow and/or suction prior to the start of the case in 2023, and there were no interruptions or visualization of debris during the procedure. Biopsies were also taken without any issues. Disposable buttons used in the procedure had no issues intra-operatively.

The scope was returned to Olympus for evaluation. Inspection and testing found the following:

- Dented and scratched plastic distal end cover insulation.
- Cut on switch button one.
- Low and out of specification angulation in the up direction/.
- Loose play on the control knob of the up/down right/left movement.
- Scratched distal end plastic cover.
- Chipped objective lens.
- Chipped and cracked light guide lens x1.
- Cut in the bending section cover.
- Cracks of the bending section on both sides.
- Cut on the boot of the insertion tube.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17723544&pc=FDS

1.6 During an unspecified procedure, the tip of the bronchovideoscope fell into the patient and retrieved with minimal impact to the patient, September 2023

A report in the FDA **MAUDE** database states an Olympus representative reported on behalf of the customer the tip of the EVIS Exera III Bronchovideoscope broke inside the patient during an unspecified procedure. The piece was retrieved with minimal impact on the patient. The company representative did not know exactly what caused the damage or how bad the damage was at the time of the report. There was no further harm or user injury reported due to the event.

The scope was returned to Olympus. Evaluation revealed:

- Peeling glue causing failed testing on the distal end cover insulation
- Chipped distal end plastic cover
- Removed adhesive and stretched bending section cover
- Peeled glue of the distal cover
- No reading on electrical continuity on the bending section
- Distal end cover:
    - Detached distal end cover
    - Dried adhesive
    - No broken stands

    - Cut, charged coupled device unit shrink tube
- Boot:
    - Chipped, worn labels, and cut (for the scope connector).
    - Multiple dents on the insertion tube
    - Failed ring gauge and chip on the boot

The scope was repaired as required and restored to its original factory specifications.

Additional information has been requested. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation. This report has been submitted by the importer under this MDR report number 2429304-2023-00281.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17685602&pc=EOQ

1.7 Cystoscope was sent back to Pentax™ due to fluid damage in the CCD module along with multiple findings of fluid damage in other areas of the endoscope, August 2023

A report in the FDA **MAUDE** database states the Video Cystoscope ECY-150S was returned to Pentax Medical™ for repair. The technician checked the returned unit and confirmed that the distal end with CCD module fluid damage. Based on the result, we concluded that it was caused due to the fluid damage from the distal end with CCD module.

In addition, our technician confirmed:

- Fluid damage in the:
    - Control body
    - Large connector
    - Shield cover
    - Glass rod
- Damage to the coating of the insertion flexible tube
- Perforated light guide cable
- Dirty biopsy inlet-T-piece.

However, these defects are not the main cause of and/or irrelevant to the alleged complaint. Based on the technical report "HR-RPT-0586 (image failure) and/or the risk analysis results, it was evaluated to submit an MDR. The time of the event is unknown. There was no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17593265&pc=FAJ

1.8 The end of the Glidescope broke off in the bronchus of the patient during a procedure, August 2023

A report in the FDA **MAUDE** database states during use of a Fiber Optic Glidescope 3.8 (Model 0570-0380) for dual lumen intubation, the end of the scope broke off in the patient's bronchus. Another scope was used to retrieve the broken piece, which was hollow plastic approximately 4–5 mm in diameter and 1.5–2 cm in length.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17624522&pc=EOQ

1.9 The gastroscope was left in Cidex® too long, the forceps in the biopsy channel caused a cloudy silver-tinged liquid to come out of the scope into the patient's duodenum, July 2023

A report in the FDA **MAUDE** database states Pentax™ was made aware of a complaint that occurred in the United States. The customer reported that they used a Video Upper G.I Gastroscope EG-2990I that went into the patient. Biopsy forceps were inserted through the channel and some "cloudy silver-tinged liquid" came out of the endoscope into the patient's duodenum. This endoscope was cleaned in high-level disinfectant (HDL) Cidex® solution. The user is questioning if there is any risk to the patient. If so, what type of precautions do they need to take?

This event occurred at the time of during use. This event meets the requirements for FDA reportability; however, submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event.

The user facility responded to a good faith effort request via email on June 22, 2023, that the scope was soaked in Cidex® for too long causing breakdown. Two (2) drops of black fluid dropped from the scope into the patient's duodenum during the procedure, while a biopsy forceps was being inserted through the channel. The procedure was for diagnostic purposes. There wasn't a delay in the procedure, which would require medical intervention (i.e., additional anesthesia or a prolonged hospital stay). Patient discharged after procedure.

The patient was notified by the MD about drops of cleaning solution from the scope having leaked into the patient's duodenum. The safety data sheet (SDS) was consulted for Cidex® that states to flush with water or milk if accidentally ingested and to only treat if any allergic reactions occur, do not induce vomiting. The patient was given water to drink to flush. She was also observed for any reactions, educated on reactions, and to call for help if any occur. Patient verbalized understanding of signs to look for and felt comfortable for discharge.

Investigation is in-process. If additional information becomes available, a supplemental report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17263023&pc=FDS

1.10 After a diagnostic procedure was complete, the user removed the balloon off the scope and the white part broke off the distal end, July 2023

A report in the FDA **MAUDE** database states Olympus was notified by the customer that while using the EVIS Exera II Ultrasonic Bronchofibervideoscope BF-UC180F, a piece of the white part broke off the end of the scope after the diagnostic procedure was complete. The user was taking the balloon off the scope.

The scope was returned to Olympus for evaluation and the customer's reported issue was confirmed. Evaluation determined:

- Broken probe unit tip
- Cracked adhesive on the image guide bundle part
- Dented insertion tube
- Short scope connector wire length.

No reports of patient harm or impact associated with this event. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17371635&pc=PSV

1.11 A chip broke off from the bronchovideoscope during a procedure and was found in the patient's airway, July 2023

A report in the FDA **MAUDE** database states the customer reported the chip broke off from the EVIS Exera II Bronchovideoscope BF-1T180 during an unspecified diagnostic procedure. The broken piece was found in the patient's airway. The scope was immediately removed along with the whole broken piece accounted for. The scope was replaced, and the airway was reinspected, finding no additional fragments. The procedure was prolonged for 30 minutes and completed without further incident using a similar device.

The scope was returned to Olympus for evaluation and confirmed:

- Missing glue joint between the insertion tube and bending section cover
- Cut/leak and peeling from the insertion tube
- Corrosion on the electrical connector
- Failed electrical continuity test
- Out of specification angulation.

The scope was repaired and restored to its original factory specifications.

No harm or injury to the patient was reported due to the event. The investigation is ongoing, and a supplemental report will be submitted up0on completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17378754&pc=EOQ

1.12 The colonovideoscope was not inspected before use and foreign material came out of the scope and into the patient during the procedure, June 2023

A report in the FDA **MAUDE** database states a field service engineer (FSE) reported to Olympus that during a colonoscopy procedure, a foreign material came out from the EVIS Exera II Colonovideoscope PCF-Q180AL and into the patient. The procedure was completed with the same scope. As reported, the scope was not inspected before use.

The technician used suction to remove the foreign material with no additional treatment, and the patient was discharged from the hospital.

An FSE visited onsite and found a leak in the channel. There were no reports of further patient or user harm associated with this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17131881&pc=FDF

1.13 Mucosal tissue was left behind on the albaran lever of the endoscope during an unspecified procedure causing a mucosal injury, June 2023

A report in the FDA **MAUDE** database states the head nurse reported to Olympus that a mucosal injury occurred when the single-use distal cover MAJ-2315 was used in an unspecified procedure and a small piece of mucosal tissue was left behind on the Albarran lever of the endoscope. There were no reports of patient(s) harm.

Two complaints (single use distal cover-MAJ-2315 and EVIS Exera III Duodenovideoscope TJG-Q190V) have been created for reporting this event.

The device was not returned to Olympus for evaluation. A supplemental report will be submitted if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17093174&pc=FDT

1.14 The patient had to undergo an additional surgery to have a distal ring removed that fell into them during the initial procedure, June 2023

A report in the FDA **MAUDE** database states there was an event with a Video-Uretero-Renoscope 11278V—the loss of the distal ring in the patient's body. The patient must be re-operated to recover this part. No further information has been provided.

Belated evaluation and reporting of this complaint were done during retrospective review as part of CAPA 20-0074 corrective action 6. The following were found during the investigation:

- Lifted wall in the channel with no leak
- Thermal damage on the distal tip

- Missing ceramic sleeve on the distal tip.

The defects on the scope are due to erroneous maintenance and reprocessing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17118496&pc=FGB

1.15 A gastrointestinal scope had a balloon catheter stuck in the biopsy channel, May 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 has a balloon catheter stuck in the biopsy channel during an unknown diagnostic procedure and was completed using the same set of equipment. There was no report of patient harm or user injury associated with this event. The scope was returned to Olympus for inspection, and the customer's allegation was not confirmed. In addition, the following non-reportable malfunctions were found during the scope evaluation:

- Leak on the instrument channel (brush passage).
- Cuts found on switch button 1.
- Forceps passage (no pass)
- Low angulation: low tension and play of control knob.
- Dents and scratches on plastic distal end cover.
- Worn objective and light guide lenses with glue and peeling adhesive.
- Nozzle not drying.
- Cracked glue at bending section.
- Buckles and scratches in insertion tube.
- Clog in suction flow.
- Scratches (minor) in light guide tube

This investigation is pending. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16874360&pc=FDS

1.16 The auxiliary water channel of the gastrointestinal videoscope had a blackish liquid coming out of it during a therapeutic endoscopic submucosal dissection procedure, May 2023

A report in the FDA **MAUDE** database states the Olympus employee reported on behalf of the customer that the gastrointestinal videoscope GIF-XZ1200 (when used along with HX-110LR rotatable clip fixing device) had a blackish liquid seen exiting from the auxiliary water channel during the therapeutic endoscopic submucosal dissection (ESD) procedure. The procedure was completed using the same set of equipment.

The facility has requested an investigation of the composition of the liquid. No patient harm was reported.

The scope was returned to Olympus for evaluation, and the customer's allegation was confirmed. The scope evaluation identified a gauze with black liquid on it that was included with the scope. Inspection of the scope revealed no abnormality related to the black liquid. A foreign material related questionnaire found the product was not cleaned, disinfected, and sterilized before it was sent to Olympus. It is unknown when the foreign material was adhered to the endoscope. There was no delay in the start of the pre-cleaning (no lag time between the end of clinical use and the start of pre-cleaning). The customer aspirated water through the instrument/suction channel. There were abnormalities found in the accessories used for pre-processing. The customer wiped/brushed the instrument channel outlet with clean lint-free cloths, brushes, or sponges. The customer brushed the instrument channel, instrument channel port, and suction cylinder.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16924664&pc=FDS

1.17 It was discovered that a stent was still lodged in the duodenovideoscope channel after it was used in four (4) additional procedures, May 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that a stent device was found lodged in the EVIS Exera III Duodenovideoscope TJF-Q190V from a previous therapeutic procedure that took place in 2023. The stent-lodged in the duodenovidoescope's channel was finally discovered after being reprocessed for the fourth time and identified the scope as having been used in four (4) additional procedures) There were no reports of patient harm associated with this event.

An Olympus endoscopy support specialist (ESS) has been scheduled for an on-site visit to observe reprocessing techniques. The scope was decontaminated and reprocessed per manufacturer instructions, and the channel was tested prior to going into the Olympus Automated Endoscope Reprocessor (OER) with Healthmark's ChannelCheck™ for carbohydrates, proteins, and blood, which all tested negative.

Olympus received further information that the issue was during therapeutic Endoscopic Retrograde Cholangiopancreatography. The stent fell into the patient and was retrieved with a snare. The procedure was prolonged for 15 minutes. Additionally, the nurse reported the scope was new to the facility and that a crimp/wrinkle at the distal end of the scope may have caused the stent to become stuck in the scope. No further information was provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16979119&pc=FDT

1.18 Suction was used to remove particulates from the patient's bladder during a cystoscope, May 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that there were three small black particulates observed in the bladder after the physician introduced the Cycsto-Nephro Videoscope CYF-VH and flushed it with water during a cystoscopy. The particulates were removed via suction and no further particulates were noted on cleaning. The procedure was completed using the same scope. There was no impact to the outcome of the procedure nor was there any harm or user injury due to the event.

The scope was returned to Olympus for evaluation. Inspection revealed:

- Separation of the distal end from the bending section
- Cracked and peeled adhesive on the bending section
- Worn insertion tube
- Failed insulation.

The scope was refurbished with new parts and restored to original factory specifications.

Additional information is being requested with the investigation ongoing. If additional information is received a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16542448&pc=FAJ

1.19 A metal like foreign body was found in the patient during the flushing process during a Cystoscopy, May 2023

A report in the FDA **MAUDE** database states it was reported to Boston Scientific Corporation that a Lithovue Flexscope was used during a Cystoscopy, left Ureteroscopy with laser lithotripsy and basket stone removal procedure performed in 2023. During the procedure, there was a left ureteral stent exchange, right ureteral stent removal and left retrograde pyelogram. While performing laser lithotripsy on the left ureter/kidney a thin metal like foreign body was found during the flushing process. It was reported the Lithovue Flexscope had the tip sheared off. In the physician's assessment the metal piece came from either the retrieval basket (unknown manufacturer) or the scope but did occur during the procedure.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16878380&pc=FGB

1.20 The colonovideoscope was found to have white crystallized contamination in the air/water channels during the scope evaluation at Olympus, April 2023

A report in the FDA **MAUDE** database states the control body of the EVIS Exera Lucera Elite Colonovideoscope CF-HQ290L was leaking. The issue was found during reprocessing. There

was no reported patient harm or impact due to this event. During the scope evaluation at Olympus, the air/water channel was contaminated with foreign material. A white crystallized contamination believed to be simethicone type product was evident in the air/water channels. The report is being submitted due to foreign material in the scope found during the evaluation.

The scope was returned and evaluated by Olympus and found the complaint was confirmed:

- Leaking control body.
- Chipped objective guide lenses.
- Worn:
    - Lens glue
    - Bending section cover glue
    - Switch.
- Delaminated light guide tube.
- Water ingress of scope connector.
- Reduced angulation (knobs had play).
- Failed air/water flow.

This event is under investigation, and a supplemental report will be submitted upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16699876&pc=FDF

1.21 The duodenoscope had an objective lens that was cloudy caused by moisture condensation, April 2023

A report in the FDA **MAUDE** database states that the PENTAX DEC HD Video Duodenoscope ED34-I10T2 was returned to PENTAX Medical for repair. Their technician checked the returned unit and confirmed that the objective lens was cloudy (not clear view). Based on the results, we concluded that it was caused due to the moisture condensation in the objective lens.

In addition, while these defects are not the main cause, and/or irrelevant to the alleged complaint, their technician confirmed:

- Cracked:
    - objective lens
    - led cover glass
- Leaking bending rubber
- Cut:
    - operation channel (primary)
    - insertion flexible tube
    - O-ring
- Hard to move:
    - r/l lock knob

    - u/d lock lever
- Chipped air/water socket.

Based on the technical report "HR-RPT-0586 (image failure) and/or the risk analysis results, it was evaluated to submit a Medical Device Report (MDR). The time of the event is unknown. There was no report of patient harm, Video image failure (cloudy).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16730336&pc=FDT

1.22 Foreign material was in the forceps channel causing the breakage of the instrument of the duodenovidoescope, April 2023

A report in the FDA **MAUDE** database states that a review of the EVIS Exera II Duodenovideoscope TJF-Q180V history record found no deviations that could have caused or contributed to the reported issue. This is being submitted for the malfunction found during the scope evaluation.

Based on the results of the investigation, a definitive root cause could not be determined. However, the following are the potential causes of why the event occurred:

- Deformation of the forceps channel.
- Breakage of the instrument.
- Foreign material in the Forceps channel.

Other damages include:

- Dented scope connector
- Scratched:
    - scope cover unit
    - objective lens
    - universal cord
- Worn adhesive around objective lens and light guide lens
- Shaved distal end was
- Corrosion around the lever arm.

Per the legal manufacturer, these other scope issues identified by service have no potential to cause or contribute to death or serious injury if the malfunctions were to recur. Olympus will continue to monitor field performance for this scope.

The scope was received at an Olympus Service Center for evaluation with a report that a clip was stuck in the working channel (instrument channel). There were no patients or user injuries reported. During inspection and testing, the OSC found that due to clogging of the instrument channel the forceps could not be inserted or removed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16700527&pc=FDT

1.23 The bending section came off the bronchoscope during inspection, causing a 30-minute delay in the procedure, April 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that the bending cover of the EVIS Exera Lucera Bronchovideoscope BF-1T260 came off during inspection before use for an unknown diagnostic procedure. The procedure was delayed for 30 minutes, increasing the patient's waiting time. The Patient, as reported, was not under sedation when issue was found. The procedure was completed with a similar scope. There were no reports of patient or user harm associated with this event.

E1 complete state/province: this scope was returned for evaluation. During the inspection, it was found that the adhesive at the bending cover was aging and fell off, the insertion section had serious scratches, and the protector was aging.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16792292&pc=EOQ

1.24 The colonovideoscope air/water nozzle glue peeled off due to physical damage to the nozzle, March 2023

A report in the FDA **MAUDE** database states the air/water nozzle peeled off (black glue). The PENTAX Video Colonoscope-I10 SLIM EC34-I10L was returned and confirmed the nozzle [black] glue was missing. It was confirmed it was caused due to the physical damage applied to the nozzle gluing.

In addition, PENTAX confirmed the bending rubber leak and bending rubber cut; however, they are not the main cause and/or irrelevant to the alleged complaint. In terms of glue missing, the possibility of it dropping into the human body could not be denied. Moreover, based on the technical report HR-RPT-0585 (nozzle) and/or the risk analysis results, it was evaluated to submit an MDR. The time of the event is unknown and no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16484842&pc=FDF

1.25 During a ERCP detergent was leaking into the patient from the duodenovideoscope, March 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that during high-risk therapeutic endoscopic retrograde cholangiopancreatography, the EVIS Exera II Duodenovideoscope TJF-Q190Ve started leaking blue fluid, which was later discovered to be detergent from cleaning. The scope failed the leak test, but when manually tested, there were no bubbles or any physical manifestation of a leak. When blue fluid was discovered in the patient

after an Rx sphincterotome was inserted down the biopsy channel. The user immediately took the scope out of the patient, retested the scope manually, and still no leak was discovered. The scope was in the patient for 2 minutes when it was discovered. The procedure was completed by switching to another scope. There were no reports of patient or user harm associated with this event.

The suspect scope was returned to Olympus and evaluated. Olympus performed a visual inspection during a water dunk test on the scope in the received condition. The scope was connected to regulated airline of 7 psi and submerged into a tub of water. As the scope was fully immersed, the air/water, suction, and biopsy channels were flushed with water to remove the remaining trapped air. Once the channels were flushed, there were no signs of the bubbles exiting the scope when manipulating the a) control knobs, b) insertion tube, c) light guide tube, and d) bending section.

In addition, a secondary leak test was performed as the scope was connected to Cosmo—an electronic leakage detector that reads pass or fail. The scope passed the leakage tester at a reading of +0.02. Surface scratches and kinks were found on the wall of the biopsy channel and in the opening of the suction channel. Additional evaluation findings are as follows:

1. Play at the up/down knob.
2. Loose tension at the up/down knob.
3. Dents and scratches noted on the hold ring.
4. Flabby bending section cover
5. Cracked adhesive.
6. The insertion tube boot was noted torn.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16508665&pc=FDT

1.26 During a Cystoscopy procedure, small black particulates were in the patient's bladder and removed via suction, March 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus there were three small black particulates observed in the bladder after the physician introduced the Cysto-Nephro Videoscope CYF-VH and flushed it with water during a Cystoscopy. The particulates were removed via suction and no further particulates were noted on cleaning. The procedure was completed using the same scope. There was no impact on the outcome of the procedure nor was there any harm or user injury due to the event.

The suspect scope was returned to Olympus for evaluation. Inspection revealed that the distal end was separated from the bending section and the adhesive on the bending section was cracked and peeled. Additional findings included a worn insertion tube and failed inspection. The scope

was refurbished with new parts and restored to original factory specifications. Additional information is requested.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16542448&pc=FAJ

1.27 Old laser fibers from a Uretero-Reno Fiberscope were removed from a patient's ureter that were pushed out of the scope from a previous procedure, March 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the Uretero-Reno Fiberscope URF-P7R had laser fibers left in it from a previous case. The current laser fiber was inserted and reportedly pushed out the old laser fiber pieces into the patient's ureter during an unspecified therapeutic procedure. The procedure was prolonged by a couple of minutes with the patient under sedation since the old fiber pieces had to be retrieved with a grasper and the scope had to be replaced. The procedure was completed using a similar scope. The scope was sent back to be reprocessed and then an error message occurred. There was no harm, injury, or infection reported due to the event.

This report has been submitted to importer MedWatch #2429304-2023-00031. The scope referenced in this post has not been returned to Olympus at this time.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16483191&pc=FGB

1.28 A bronochvideoscope had green foreign substance attached to the distal part of scope and connector after reprocessing in the OER-4, March 2023

A report in the FDA **MAUDE** database states the customer provided response to the questionnaire regarding the presence of foreign material.

- The product was cleaned, disinfected, and sterilized before repair.
- Customer does not know when the foreign material adhered to the scope.
- There was no delay in the start of precleaning.
- There were no problems with accessories used for reprocessing.
- The external surface of the EVIS Lucera Elite Bronchovideoscope BF-P290 was wiped with clean lint-free cloth, brush, or sponge.

The scope was returned. The investigation is ongoing.

The customer reported to Olympus (after reprocessing the bronchovideoscope with OER-4 Reprocessor) that the scope had a green foreign substance attached to the distal part of the scope and connector. When other scopes were reprocessed, there was no adherence of foreign matter. The customer determined that the issue was with the scope. The cleaning, disinfection and sterilization process followed onsite included primary cleaning followed by high-level disinfection with OER-4 Reprocessor. The same event has occurred once in the past, and it is the second occurrence with no patient involvement.

A supplemental report will be submitted on completion of the investigation or if any additional information is available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16521519&pc=EOQ

1.29 During reprocessing of the uretero-reno videoscope it was discovered there was an image problem, February 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the Uretero-Reno Videoscope URF-V3R had an image problem. The reported issue was discovered during reprocessing of the scope. There was no patient/user harm or injury reported due to the event. Upon scope return and evaluation, it was observed that foreign material was falling out from the channel which is a reportable event. This medical report (MDR) is being submitted to capture the reportable malfunction found during evaluation.
The scope was returned to Olympus for evaluation and the customer's allegation was able to be confirmed.

- Blurry image
- Found white powder on scope's end
- Stained distal end plastic cover metal
- Leaking channel and unable to be sealed
- Dent in light guide tube
- No angulation in the Up and Down direction
- Non-movable control knob

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16300188&pc=FGB

1.30 During a therapeutic right percutaneous nephrolithotomy procedure, foreign material fell from the channel and into the patient, February 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the Uretero-Reno Videoscope URF-V2 had foreign material falling off from the channel. The reported issue occurred during a therapeutic right percutaneous nephrolithotomy procedure. The procedure was

subsequently completed with the same scope. It was indicated that the foreign piece was discovered and vacuumed or removed from the patient with no adverse effects. It was confirmed that the procedure was not delayed due to the reported issue. In addition, an X-ray was taken at the end of the procedure to confirm the absence of any additional foreign bodies. No patient/user harm or injury was reported due to the event.
The scope was returned to Olympus for evaluation. During the scope evaluation, it was observed the scope did not pass the water dunk test due to a leak found in the channel caused by physical damage.
The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16401499&pc=FGB

1.31 During an endoscopic submucosal dissection, the gastroscope hood separated and fell off into the patient and retrieved without harm or injury, January 2023

A report in the FDA **MAUDE** database states on January 13, 2022, Fujifilm corporation was informed of an event involving Fujifilm Hood Model DH-40GR Gastroscope. It was reported that the hood separated and fell off during an endoscopic submucosal dissection of the sigmoid colon. The piece was retrieved, and the procedure was completed successfully without harm or injury. There was no death or serious injury associated with the event.
A supplemental report will be submitted pending investigation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16253620&pc=FDS

1.32 The air/water channel on the Pentax colonoscope was clogged due to insufficient reprocessing, January 2023

A report in the FDA **MAUDE** database states the Pentax Video Colonoscope 3.8c 2.8C 13.2T FWJ EC-3890FK2 was returned to Pentax and confirmed that the air/water channel clogged. Based on the result, we concluded that it was caused by insufficient reprocessing at the facility. In addition, we confirmed that the a) light guide cable buckled, b) nozzle gluing was missing, c) bending rubber leaked, and d) right and left lock knobs were hard to move. However, those are not the main cause, and/or irrelevant to the alleged complaint.
The time of the event is unknown, and there is no report of patient harm. Air/water tube clogged.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16155832&pc=FDF

1.33 Moisture condensation caused the video image in the colonoscope to be cloudy, January 2023

A report in the FDA **MAUDE** database states Pentax Video Colonoscope EC38-I10NL-US was returned to Pentax, checked, and confirmed the image shadow was caused due to the moisture condensation in the image. In addition, we confirmed the a) distal body cracked, b) operation channel leaked, c) bending rubber leaked, d) operation channel resistance, and e) the insertion flexible tube was dented; however, these are not the main cause, and/or irrelevant to the alleged complaint. The time of the event is unknown.
There is no report of patient harm. Video image failure (cloudy).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16156176&pc=FDF

1.34 A similar uretero-reno videoscope was used to complete a therapeutic transurethral lithotripsy procedure when black liquid came out of the previous scope channel during pre-use inspection, January 2023

A report in the FDA **MAUDE** database states the customer reported the Uretero-Reno Videoscope URF-V2 had black liquid come out when the channel was flushed during pre-use inspection prior to a therapeutic transurethral lithotripsy procedure. The procedure was completed with a similar scope. There was no reported patient harm or impact due to this event. Attempts to retrieve additional information from the customer are in progress. The cleaning, disinfection, and sterilization involved bedside cleaning after each use. The scope was then transported to the cleaning room and hand washed by brushing the inside of the channel. The endoscope was then sterilized using a Stella automatic endoscope reprocessor. This event is under investigation. A supplemental report will be submitted upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16239375&pc=FGB

1.35 During a procedure the bending section of the bronchofibervideoscope was detached from the distal end hanging by a thread, January 2023

A report in the FDA **MAUDE** database states a nurse reported to Olympus, the entire end of the EVIS Exera II Ultrasonic Bronchofibervideoscope was hanging by a thread during an unspecified procedure. It appeared as if a needle went through it. There was no report of patient harm associated with this event.
The scope was returned to Olympus for evaluation. During inspection and testing, the allegation was confirmed, due to the bending section being detached from the distal end of the scope.

- Leakage from the bending section cover due to a cut.
- Soft pink rubber bubble of the scope's distal end.
- Cracked adhesive of the bending section cover.
- Excessive image guide breakage.

- Stained (white) around edge of Evis image.

The investigation is ongoing and follow-up with the user facility is currently being performed. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16099973&pc=PSV#

1.36 The distal end fell off the Bronchofibervideoscope when preparing the scope for a procedure, January 2023

A report in the FDA **MAUDE** database states the customer reported the plastic tip of the EVIS Exera II Ultrasonic Bronchofibervideoscope BF-UC180F fell off the distal end. The issue was found when preparing the scope for use. There was no reported patient harm or impact due to this event.
During the scope evaluation at Olympus, the complaint was confirmed, and the tip was broken at the probe unit. In addition, evaluation found the bending section cover adhesive was cracked. This event is under investigation. A supplemental report will be submitted upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16202158&pc=PSV

1.37 The tip of the bronchoscope broke inside of the intubation tube in the patient after positioning and prepping of the patient, January 2023

A report in the FDA **MAUDE** database states disposable bronchoscope 0570-0396 broke inside of the intubation tube in the patient. Anesthesia stated the tip of the bronchoscope broke after positioning and prepping of the patient. The patient was placed back into the supine position to address the issue and reintubate. The bronchoscope was examined by anesthesia and the doctor. The tip of the bronchoscope was still lodged inside of the intubation tube that was removed. It was questioned whether all the fragments were removed from the patient. An X-ray was performed as well as a bronchoscopy with Bronchoalveolar lavage (BAL).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16350814&pc=EOQ

1.38 During a colonoscopy procedure, the forceps did not pass into the biopsy channel nor could a pipe cleaner pass through the channel during reprocessing, December 2022

A report in the FDA **MAUDE** database states the customer reported to Olympus the EVIS Exera III Colonovideoscope CF-H185I did not suction and does not pass the pipe cleaner into the biopsy channel. The reported issue occurred during a diagnostic colonoscopy procedure. While attempting the procedure, the forceps did not pass into the biopsy instrument channel. During

reprocessing post procedure, it was observed that the pipe cleaner could not pass through the channel. There was no patient/user harm injury reported due to the event.
Upon scope return and evaluation, it was observed that the channel mount had foreign objects, which is a reportable event. This medical scope report (MDR) is being submitted to capture the reportable malfunction found during evaluation.
The scope was returned to Olympus for evaluation and the customer's allegation was confirmed. During the scope evaluation it was observed that there was no passage in the biopsy channel due to a disposable cleaning brush clogging the channel. Upon further inspection it was observed that the channel mount unit had foreign objects due to insufficient reprocessing of the scope.
Additionally, there were:

- Damaged air and water nozzles caused water removability to not meet the standard value.
- Discolored grip and suction cylinder.
- Discoloration on the circuit board and plug unit due to water leakage.
- Dirty scope connecter case unit due to water leakage.
- Compromised internal elements due to water invasion.
- Buckling and wrinkled connecting tube.
- Buckling and deformed universal cord.
- Scratched scope connector cover, which caused a loss in water tightness.
- Cracked scope body, which caused a loss in water tightness.
- Pinhole on the bending section cover, which caused a loss in water tightness.
- Damaged image guide protector.
- Dented plastic distal end cover.
- Discolored adhesive around the objective lens and light guide lens.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15974100&pc=FDF

1.39 The operator's eye had a splash injury during the process of exchanging an empty water bottle for a new one during a colonoscopy, December 2022

A report in the FDA **MAUDE** database states the customer reports during a colonoscopy procedure using an EVIS Exera III Gastrointestinal Videoscope and an EVIS Exera III Colonovideoscope CF-HQ190L, a user experienced a splash injury (eye). The provider was wearing a face shield, and in the process of exchanging an empty water bottle for a new one, sustained a splash exposure from the valves which were well placed. We commonly notice that the change in pressure during the bottle exchange can cause a blow back, which may have happened in this case. Immediate action was taken to rinse the operator's eye. The patient was HIV+. The operator had to be on anti-retroviral therapy for months after the exposure. The scope was inspected prior to use. There were no issues completing the procedure. The patient did fine and was not impacted by the event.
The scope was not returned to Olympus for evaluation. The definitive cause of the user's experience cannot be determined at this time. The investigation is ongoing, and the report will be updated upon completion of the investigation or upon receipt of additional relevant information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16060258&pc=FDF

1.40 The bending section of the uretero-Reno Fiberscope had broken in the patient's ureter for treatment to remove a two (2) cm stone, December 2022

A report in the FDA **MAUDE** database states a company representative reported to Olympus on behalf of a user facility that the bending section of the uretero-reno fiberscope URF-P7 had broken in the patient's ureter. The indication for initial surgical treatment was a two (2) cm stone. A fiber laser was used to spray the stone without difficulty. Upon removal of the uretero-renoscope, it blocked the iliac ureter and was impossible to remove. After multiple attempts, the scope was removed but 10 cm of the distal end of the uretero-renoscope remained in the upper-left ureter next to the iliac vessels. A catheter was placed parallel to the foreign body to drain the kidney. The lower ureter was explored and scratched mucosa was found with a mucous flap. The surgeon decided not to attempt to remove the foreign body to avoid further damage and a bladder catheter was placed.
Three days later, the patient underwent a two (2)-hour intervention for extraction of the foreign body in the left ureter. A transperitoneal laparoscopic approach was utilized to access and dissect the left-ureter. The foreign body was located in the ureter just above the iliac vessels and was removed. A "jj loop" (a double pigtail ureteral stent) was placed; the position was checked by pyelography through their ureteral probe and was found to be well looped into the kidney. The catheter was removed and jj loop was left in place. No blood loss occurred. Post-procedurally, the patient was transferred to another unit. Their hospital stay was extended by six (6) days. The plan of care for the patient was to keep the jj loop in place for three (3) months with regular monitoring. Additional information has been requested, and if received, a follow-up report will be sent.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16032876&pc=FGB

1.41 Image failure in a bronchoscope due to fluid damage to the CCD driver PCB, December 2022

A report in the FDA **MAUDE** database states the Pentax Video Bronchoscope EB15-J10 was returned and confirmed the CCD driver PCB had fluid damage. It was also confirmed that the a) electrical connector had fluid damage, b) LG cable connector had fluid damage, light guide fiber bundle was broken, and c) the insertion flexible tube was worn out. However, they are not the main cause, and/or relevant to the alleged complaint.
Based on the technical report "HR-RPT-0586 (image failure) and/or the risk analysis results, it was evaluated to submit MDR. The time of the event is unknown. There was no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15903421&pc=EOQ

2. Malfunction of Single-Use Scopes and Endcaps

2.1 The single use duodenoscope used for an ERCP caused a perforation of the patient's stomach due to the rigidity of the scope, September 2023

A report in the FDA **MAUDE** database states it was reported to Boston Scientific Corporation that an Exalt D model Duodenoscope M00542420 was used during an endoscope retrograde cholangiopancreatography (ERCP), under general anesthesia and in the prone position, to treat stones in 2023.

During the procedure, a perforation in the patient's stomach was observed. It was noted that there was food in the patient's stomach. Therefore, an immediate cessation of the procedure was required. In the physician's assessment, the perforation may be attributed to the rigidity of the scope during its passage into the duodenum. Surgical intervention was required to address the perforation.

At the time of this report, the patient's status remains unknown despite good faith efforts. The complainant was unable to provide the scope lot number—the lot expiration and device manufacturer dates are unknown.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17793976&pc=FDT#

2.2 Single-use distal cover was missing after the ERCP procedure and the patient coughed out the cap, September 2023

A report in the FDA **MAUDE** database states Olympus received a voluntary MedWatch report that the single-use distal cover MAJ-2315 was missing after the therapeutic Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure. Initially, the staff were unable to locate the cap. The patient was alert and stated it felt like something was running in their throat, and they started vomiting thick, greenish secretions and eventually coughed out the cap.

The scope was being used with the EVIS Exera III Duodenovideoscope. The procedure lasted 56 minutes and 36 seconds and was not prolonged. The patient's condition was not impacted by the failure; the cover was coughed up by the patient. The outcome of the procedure was not affected. No medical intervention was required, and the procedure was completed with the same scope. No patient harm was reported.

The scope was not returned for evaluation. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17790078&pc=FDT

2.3 The single use distal cover fell into the patient's throat after an ERCP and went into respiratory arrest in the post anesthesia care unit, August 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that unbeknownst to the health care provider, the single-use distal cover MAJ-2315 had apparently come off the EVIS Exera III Duodenovideoscope and into the patient's throat after an endoscopic retrograde pancreatography (ERCP) procedure, which caused the patient to go into respiratory distress in the post anesthesia care unit (PACU). The distal cover was suctioned out from the patient's throat and the patient's respiratory status went back to normal. The procedure took about 1 hour and was completed using the same scope without delay.

The outcome of the procedure was not impacted. The customer indicated that the scope was functioning properly and that an Olympus representative had advised that the distal cover came off probably due to not being put on correctly. An in-service was pending on how to properly attach the distal cover.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17646149&pc=FDT

2.4 The duodenoscope was inserted into the endotracheal tube causing the endcap to fall in the patient, June 2023

A report in the FDA **MAUDE** database states Fujifilm corporation was informed of an event involving a Fujifilm Duodenoscope ED-580XT. During an ERCP, the distal cap (DC-07D) detached from the distal end of a duodenoscope and fell into the patient's oral cavity. An ENT intervention was required to extract the cap. The procedure was completed successfully without harm or injury.

As the result of investigation, Fujifilm believes the facility may have made a user error when assembling the caps. It was thought that since the endotracheal tube was inserted at the same time as the duodenoscope, the diameter of the insertion path became narrow, thus possible the DC-07D easily caught on the edge of the mouthpiece when the duodenoscope was removed.

There were several previously reported issues in 2019 and 2020 related to the DC-07D distal end cap falling off the ED-580XT during a procedure. In response to those incidents, Fujifilm revised the scope labeling to provide clearer and more detailed directions for proper attachment of the disposable DC-07D. The revised labeling was distributed with a safety notification to all existing customers in April 2020. This user facility was not a customer at the time of that notification. Since the lot that the customer purchased did not accompany the revised labeling, this facility received training on the proper attachment of DC-07D as part of the installation of the device.

After the occurrence of this incident, our local distributor sent a letter to the facility again to inform them of the proper attachment procedure of DC-07D.

There is no death reported with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17162364&pc=FDT

2.5 The disposable elevator cap dislodged during the procedure into the patient and was not able to be retrieved, April 2023

A report in the FDA **MAUDE** database states per the initial report, a disposable elevator cap OE-A63 became dislodged from the scope during the procedure and was lost inside the patient. Description of any actions taken:

- ED34-I10T2 was removed from the patient and a gastroscope was inserted to attempt retrieval of the cap.
- The retrieval was unsuccessful. The cap was not visible to the eye but was present on fluoroscopy imaging.
- The nurse contacted PENTAX Medical to report the event and request advice on how to proceed with the patient.
- PENTAX medical territory manager advised her that he was unable to provide medical advice, but that she should follow hospital protocol for patients who present with foreign body and that she would contact PENTAX to have someone from our regulatory team or medical officer contact them to advise. Furthermore, he explained to her that he would need to open a complaint and request all relevant information regarding model and serial numbers, lot numbers, details about the procedure, and that we may need to have the scope and remaining cap sent in for evaluation.

This event meets the requirements for FDA reportability.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16671040&pc=FDT

2.6 An abrasion to the patient's esophagus was caused by a crack in the single-use distal cover, April 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the single-use distal cover MAJ-2315 was slightly cracked and caused an abrasion on the patient's esophagus. The issue was found during an endoscopic retrograde cholangiopancreatography procedure, which was completed using the same scope. The patient was discharged in good health with no additional treatment. There were no additional reports of patient impact.

The device was not returned to Olympus for evaluation, so the customer's allegation could not be confirmed. The reported event is a non-serious injury, procedure was completed without incident, and patient was discharged as planned.

The investigation is ongoing. A supplemental report be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16827496&pc=FDT

2.7 A single use biopsy valve was being reprocessed and became stuck in the biopsy channel, March 2023

A report in the FDA **MAUDE** database states an Olympus representative reported to Olympus (on behalf of the customer) that during reprocessing the single-use biopsy valve MAJ-1555 became stuck in the biopsy channel. It was identified that the staff was reusing the valves, which is affecting the integrity of the scope. The staff, doctors, biomedical and ward manager(s) were considering starting using reusable valves. There were no reports of patient or user harm associated with this event. To date, this device has not been returned for evaluation.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16624414&pc=FDS

2.8 The duodenoscope had a cloudy image due to moisture condensation in the CCD module, January 2023

A report in the FDA **MAUDE** database states the Pentax Video Duodenoscope ED34-I10T2 is classified as import for export; therefore, 510k is not applicable. The scope is available in the USA with a 510k number K192245. We checked the returned unit and confirmed the foggy image. Based on the result, we concluded it was caused due to the moisture condensation in the CCD module. In addition, we confirmed that the LCB distal cover glass was broken and the IFT cut. They are not the main cause, and/or irrelevant to the alleged complaint.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16200690&pc=FDT

2.9 The single-use distal end cap became detached from duodenoscope after it was mistakenly inserted in the patient's trachea and remained in the patient's lungs, January 2023

A report in the FDA **MAUDE** database states Pentax medical was made aware of a complaint in 2023 that occurred in the operating room during use in the EMEA region involving Pentax Video Duodenoscope ED34-I10T2, serial number A110393 that was used with Pentax medical sterile distal end cap accessory, Model OE-A63, lot number 0011012.
The reported complaint was that the sterile single-use distal end cap detached from the distal end of the duodenoscope and remained in the lungs. This issue happened after the duodenoscope, model ED34-I0T2, was mistakenly inserted in the trachea.

According to an email received on January 27, 2023, this circumstance led to a necessary transfer to another hospital (Sanaklinikum Offenbach) department of pulmonology. After several bronchoscopic interventions, it was then possible to remove the distal end cap. Patient had to be ventilated for several days. Afterwards, the patient left the hospital. Despite all of this, there was no report of patient harm. This event meets the requirements of FDA reportability; however, submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused/contributed to the event.
Post-procedurally a colleague from Bu-Germany confirmed that it was impossible to attach a new sterile distal end cap (OE-A63) securely to the ED34-I10T2. We investigated the returned ED34-I10T2 and found the following errors:

1. Light guide cover glass damaged.
2. Instrument channel severely kinked distally.

Otherwise, there are no abnormalities on the distal end body and also not on the rest of the endoscope. At 12.5 mm, the distal bounding of the bending cuff is 0.2 mm smaller than specified and is therefore within the tolerance range. There is a clearly audible click when putting on our test distal end cap. The cap sits firmly on the end body and can only be loosened by pressing it in from the side.
The investigation is in-process. If additional information becomes available, a supplemental report will be filed with the new information. Due to this event, Pentax medical filed the following MDR reports MFR report number 2518897-2023-00001 with the FDA for Pentax medical video duodenoscope model ed34-i10t2, serial number a110393 MFR report number 2518897-2023-00002 with the FDA for Pentax medical sterile distal end cap accessory, model oe-a63, lot number 0011012.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16308873&pc=FDT

2.10 During an ERCP procedure, patient tissue was found on the cap when removed from the distal end of the Duodenovideoscope, **eight (8) similar events were reported over a twenty-day period**, January 2023

A report in the FDA **MAUDE** database states Olympus was informed that after a therapeutic ERCP procedure, the customer found patient tissue on the cap when it was removed from the distal end of the EVIS Exera III Duodenovideoscope TJF-Q190V. The intended procedure was completed with the same scope. There was no delay in the procedure and no other devices replaced during the procedure. The patient was discharged home post-procedure, as planned. The patient sustained non-specified gastrointestinal mucosal trauma but required no medical or surgical intervention as a result. Additionally, Olympus was informed that over a twenty-day period, the customer reported a cluster of eight (8) similar events occurring during ERCP procedures using the scope with a single-use distal cover. These events involved gastrointestinal tissue trauma and/or tissue found in the distal cover following the procedure. The customer attributes these similar events to cracked caps (MAJ-2315). Customer reports speaking with the team, and they did report having difficulty in the beginning with cracking the caps. The caps were changed out if they were found to be cracked. The customer also reported discovering a few caps were cracked when coming out of the packaging.

The scope was not returned to Olympus for revaluation. A device history review for performed and confirmed that the scope meets all manufacturing specifications and final product release criteria. Replication test has been conducted using a test scope with a distal cover attached and pig organ. Removal of the test scope from the pig organ was experimented under two (2) parameters "distal cover with/without slight crack" and "suction activated/not activated to remove the scope." The test results show tissue is embedded in the distal cover after the scope is removed with suction activated, which is observed regardless of "distal cover with/without slight crack." More tissue is embedded when a small crack is present on the distal cover and suction is activated during removal. This could cause more severe damage to tissue. When there is no crack on the distal cover and suction is not activated, no tissue is embedded in the distal cover. In addition, we tested a new distal cover in our stock and verified that it conforms to the product specification. Therefore, it is unlikely that the reported issue was caused by manufacturing defect. The definitive cause of the reported events could not be established. Based on investigation findings, the following are presumed to be the likely causes:

- User operates suction while distal end opening space was near the surface of mucosa, which causes the mucosa sucked into distal cover.
- When the user tried to remove scope in this situation, the mucosa is damaged by the edge of the distal cover.
- Distal cover cracks at tear-offline due to inappropriate attachment of distal cover to scope.
- When pressing distal end to surface of mucosa in this situation, the mucosa gets caught in the cracked cover and damaged even though suction is not operated.

Investigation activities have been opened to manage the actions related to this report and any required MDR reporting.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16251176&pc=FDT

2.11 A plastic stent came out of the duodenovideoscope and fell into the patient, the patient was not harmed, January 2023

A report in the FDA **MAUDE** database states the customer reported the EVIS Exera III Duodenovideoscope TJF-Q190V was being used in an ERCP procedure to put a metal stent in the patient. A plastic stent came out of the scope and fell into the patient. The plastic stent was removed and there was no harm or adverse impact to the patient. The procedure was completed with the same scope without any delay and the patient did not need additional anesthesia. Patient is being monitored for infection by the facility. The current status of the patient is unknown; however, there is no report of the infection as of yet, and the duration of the procedure is unknown.

The scope had been reprocessed as usual in the automatic endoscopy reprocessor (AER) after the procedure the previous day in which the plastic stent had been used. No abnormality had been noticed during the reprocessing, nor was it observed that the cook 5FR plastic pigtail stent that was used in that procedure was still in the scope. The AER had not given an alarm to warn of the retained stent in the scope and therefore considered cleared to be used in a procedure. There are two (2) associated scopes in this event—the scope with the stent used in a procedure and the AER in which the scope was reprocessed to use after a procedure on the previous day.

Due diligence was performed for this event. The customer considers that this event is a singular case and that the issue is resolved. The scope will not be returned for repair nor is it available for evaluation. As such, a definitive root cause of the reported complaint cannot be determined at this time. This event is under investigation. A supplemental report will be submitted upon completion of the investigation or upon receiving additional information. Olympus ESS suggested since the pancreatic stent is very small, the precleaning should be performed immediately after the procedure with a reusable brush to make sure the stent is removed from the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16255461&pc=FDT

2.12 A patient had a five (5) cm perforation in the duodenum, the physician stated stiffness and lack of tactile feedback with the scope contributed to the perforation, January 2023

A report in the FDA **MAUDE** database states Boston Scientific Corporation was made aware of an Exalt Model D Single-Use Duodenoscope M000542421 was introduced for use in an Endoscopic retrograde cholangiopancreatography (ERCP) in 2022 for treatment of stones. The patient was placed under local anesthesia in the prone position. During insertion of the scope, the doctor was maneuvering the scope to get past the pylorus and saw free air on the X-ray. The physician asked for an esophagogastroduodenoscopy (EGD) scope and saw a five (5) cm perforation in the duodenum. The physician removed the scope and discontinued the procedure. In the physician's assessment, stiffness of the scope and lack of tactile feedback contributed to the perforation. The patient was sent to surgery and admitted to the hospital. They are reported to be in stable condition and recovering well.
The complainant was unable to provide the suspect-scope lot number. The lot expiration and scope manufacture dates are unknown. The complainant indicated the scope is not available for return; therefore, a failure of analysis of the suspect-scope could not be completed. If any further relevant information is identified, a supplemental MedWatch will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16094487&pc=FDT

2.13 The distal end cap detached while it was inserted into the patient during and ERCP, which was retrieved from the side of the patient's mouth, December 2022

A report in the FDA **MAUDE** database states Pentax medical was made aware of a complaint in 2022 that occurred in the operating room during use in the United States involving Pentax medical sterile distal end cap accessory with Elevator OE-A63, lot number 0011041 was used with Pentax medical video duodenoscope model ED34-I10T2. The reported complaint that the sterile single-use distal end cap detached while inserted in the patient during an ERCP procedure. The physician stopped the procedure immediately and requested an EGD (esophagogastroduodenoscopy) endoscope for retrieval of the foreign body. The physician was unable to visualize the elevator cap with the EGD endoscope or X-ray. The manager was notified. The ERCP procedure was resumed by the physician and upon extubation, the distal end

cap was observed and retrieved from the side of the patient's mouth. The distal end cap was removed intact with no reported harm to the patient. Although no harm was reported to the patient, since the distal end cap detached inside the patient and the physician needed to retrieve the patient the distal end cap, we will be reporting this event as FDA-reportable.
This event meets the requirements for FDA reportability; however, submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event. Investigation is in-process. If additional information becomes available, a supplemental report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15945714&pc=FDT#

2.14 After the diagnostic ERCP the doctor did not notice the tip cover fell off into the patient's body causing the patient discomfort in the pharynx, December 2022

A report in the FDA **MAUDE** database states the customer reported the doctor attached the tip cover MAJ-2315 to the TJF-Q290V and carried out the examination, which was a diagnostic ERCP procedure. When the endoscope was removed from the patient's body at the end of the examination, the tip cover fell off; though, the doctor did not notice and ended the examination as it was.
In the ward, the patient complained of discomfort in the pharynx, proceeded to vomit, and the tip cover was collected from the vomit. It was discarded by the user. There was no change in the patient's planned hospitalization period, and there was no problem with the patient's prognosis because of the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15977808&pc=FDT

2.15 Staff notified an Olympus endoscopy account manager tissue was on the seam on the back of the single-use distal cover after an unspecified procedure, December 2022

A report in the FDA **MAUDE** database states An Olympus endoscopy account manager reported on behalf of the customer (physician) that following an unspecified procedure, one of the hospital staff notified him that there was tissue on the seam that is on the back of the Single Use Distal Cover MAJ-2315. The physician went back in with a scope and found that there was a tear just below the gastroesophageal junction. The physician used a couple of clips to close the tear and the patient seemed to be doing fine.
The customer was not sure of the serial number of the TJF-Q190V scope that was in-use at the time of the event, but with some assistance from the hospital staff, the lot number associated with MAJ-2315 was determined to be H2126. No additional information has been provided. This report is being submitted for MAJ-2315.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15982518&pc=FDT

3. Cleaning Verification Testing

3.1 The bronchovideoscope tested positive for 3 CFUs of filamentous fungus during reprocessing, September 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that during reprocessing the EVIS Exera III Bronchovideoscope BF-Q190 tested positive for three (3) CFUs of filamentous fungus. All channels of the scope were sampled. The user did not report any contamination or any other serious deterioration in the state of health of any person to which the scope could have been a contributory cause.

The scope was first sent to an independent laboratory for culture testing and the evaluation is pending. The customer provided the cleaning, disinfection, and sterilization (CDS) process. There was no deviation, deficiencies, or concerns in reprocessing. Precleaning was performed immediately after the patient procedure, and water was aspirated through the instrument/suction channel with a suction pump. The forceps elevator was not moved to raised and lower three times in the water during aspiration. The scope was dried with filtered compressed air and the storage method was listed as "other." There were no patient infections.

The hygiene microbiological investigation report indicated the channels of the scope were cultured and less than one (1)-CFU of viable microorganisms resulted–in compliance with the target level for an endoscope subject to high-level disinfection and rinsed with sterile water.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17755825&pc=EOQ

3.2 After bedside and pre-cleaning, the colonovideoscope failed the ChannelCheck™ soil test three times, May 2023

A report in the FDA **MAUDE** database states the EVIS Exera III Colonovideoscope PCF-H190DL failed the ChannelCheck™ soil test (internal residual carbohydrate, protein, and blood) three times after bedside and precleaning. The failed test occurred prior to the endoscope reprocessor OER-Pro scope's use. During reprocessing, the customer used STERIS Prolystica® detergent per the instructions for one (1)-gallon of water to a 30-cc solution. The scope channel was brushed with Olympus brushes during manual cleaning: first at the bedside, then tested for leaks before cleaning using the Olympus OER-Pro Reprocessor device. The devices are up to date with their preventative maintenance, and the Olympus representative was out within the last 2 weeks for an in-service. The customer has 3 certified technicians and two that are not certified. However, they are trained and follow instructions. The customer does not have any new personnel. There were no reports of patient harm associated with this event.

The scope was evaluated by Olympus, and it was reported that after borescoping, the technician found tears and stains inside the channel. No foreign material was found inside channel cells 1 through 5. Additional issues were identified during the scope evaluation:

- Scratched:
  - Labeling with worn edges
  - Insertion tube (dented)
  - Switch
- Failed leak test from the auxiliary water channel at the distal end
- Low angulation.
- Control knobs had play.
- Cracked:
  - Distal end plastic cover
  - Light guide lens
  - Distal sheath glue.
- The investigation is ongoing. Follow-up with the user facility is currently being performed. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16862335&pc=FDF

3.3 During reprocessing before use, a routine culture of a uretero-reno videoscope tested positive, May 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, the Uretero-Reno Videoscope URF-V3 tested positive for *Staphylococcus aureus*. The issue was found during a routine culture of the scope. Sampling occurred at reprocessing (before use). The user did not report any contamination or any other serious deterioration in the state of health of any person to which the scope could have been a contributory cause.

The Olympus scope was sent to an independent laboratory for culture testing, and the results are currently pending.

The scope was returned to Olympus where scope evaluation is currently in process. Additional information has been requested regarding this event.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17007757&pc=FGB

3.4 The gastrointestinal videoscope was tested three times and tested positive for microbial growth, April 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, the EVIS Exera III Gastrointestinal Videoscope GIF-XP 190N tested positive for microbial growth when it was sampled three times during reprocessing and as part of an annual culturing of the scope.

Sampling	**# of CFUs**	**Microbial Species Found**
1	Unknown	*Stenotrophomonas maltophilia*
2	Unknown	*Enterococcus avium*
3	Unknown	Gram-positive bacilli *Nesterenkonia*

There was no patient/user harm or injury reported due to the event.

As of this report, Olympus has not received third-party test results to confirm this allegation. The customer has not provided the cleaning sterilization and disinfection (CDS) processes performed at the user facility; however, this information has been requested.

The scope was returned to Olympus for evaluation. During the evaluation, it was uncovered that the a) insertion tube had a buckle and dent, b) light guide tube had scratches, c) glue of the bending section cover was cracked, and d) upon a leak check, the forceps passage was leaking.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16710204&pc=FDS

3.5 All channels were sampled on a colonovideoscope which tested positive for 1–10 CFU of mold species, April 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, the EVIS Exera III Colonovideoscope tested positive for 1–10 colony forming unit (CFU) of mold species. The issue was found during a routine culture of the scope. Sampling of all channels were taken at reprocessing. This scope was a loaner from Olympus and was not in use. The user did not report any contamination/serious deterioration in the state of health of any person to which the scope could have been a contributory cause.

The customer's scope was returned for investigation. Upon evaluation, the control unit was damaged and scope case unit deformed. The faulty parts will be replaced.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16702056&pc=FDF

3.6 The distal end of the duodenovideoscope tested positive for *Klebsiella pneumoniae*, April 2023

A report in the FDA **MAUDE** database states a visual inspection of the EVIS Exera III Duodenovideoscope Flexible Video Duodenovideoscope TJF-Q190V for clinical sampling was performed by the facility. The forceps elevator and body surface around the elevator had no visible debris. The objective lens and light guide lens at the distal end of the insertion section had no residue or stains and no scratches or cracks. The glue around the lenses and the ring were neither discolored nor pitted and the glue was not peeling or chipping. Both the white isolation block and air water nozzle at the distal end of the insertion section had no cracks or dents (on the ring). The surface of the distal body at the distal end of the insertion section had no corrosion and no debris. The glue condition around the left side surface of the distal end was not discolored nor pitted, had no cracks, and had no peeling or chipping glue.

The facility reprocessed the scope in an Olympus OER-elite automatic endoscope reprocessor (AER). Sampling of the scope for culture testing was performed by the facility. All personal protective equipment was worn. The sampling was pre-disinfected using provided disinfectant. All the necessary supplies were aseptically placed in the sterile field. No defects were in the sample collection container and solution. No other person other than Olympus staff entered the sampling area. The distal end was inspected, and no visible debris was observed. The correct surfaces of the distal tip were swabbed. The correct areas of the elevator recess were brushed and flushed. The instrument channel was brushed and flushed. No significant deviations were observed regarding aseptic or sterile techniques during sampling that could have contaminated the sample. All the correct sterile components and materials were used. No sampling instruments touched any non-sterile areas or surfaces besides the scope. No gloved hands made any contact with non-sterile surfaces. The scope was properly dried using filtered compressed air after sampling was completed.

An Olympus endoscopy support specialist (ESS) visited the customer in 2023 to perform an observation of the reprocessing techniques. The facility technician performed all manual cleaning steps per the instructions for use (IFU). The technician used a VERISCAN™ LT Leak Detection System leak tester for evaluation but was sent to an independent laboratory for destructive sampling.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

As part of the Olympus 522 post-market surveillance study, the distal end of the scope microbiologically cultured and tested positive for 1- CFU of *Klebsiella pneumoniae*. After a therapeutic endoscopic retrograde cholangiopancreatography (ERCP) procedure, and post

reprocessing, samples were collected and sent to an independent laboratory for testing. No patient injury reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16706736&pc=FDT

4. Leak Testing Failure

4.1 An air leak was discovered in the uretero-reno videoscope and sent out for repair with multiple findings of damage to the scope, November 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the Uretero-Reno Videoscope URF-V3 had an air leak. The scope was returned for evaluation.

During evaluation, a foreign object came out from the forceps channel: a reportable malfunction. No reports of any patient harm. This medical device report (MDE) is being submitted to capture the reportable malfunction found during evaluation.

The scope was returned to Olympus for evaluation and the customer's allegation was confirmed. There was residual liquid/foreign material coming out of channel-tube and the bending section cover Additional findings were as follows:

- Water tightness lost due to a pinhole on channel/tube.
- Scratched bending section cover.
- Chipped and foreign objects of the adhesive on the bending section.
- Sticky up/down plate and universal cord.
- Loose venting connector of the light guide connector.
- Deformed video connector case.
- Worn angle wire caused the bending angle in up direction and does not meet the standard value.
- Unsmooth movement of the angulation lever due to damage.
- Slippage downward of the light guide-bundle.
- Sticky control unit is due to water leakage.

Follow-up regarding the cleaning sterilization and disinfection (CDS) processes performed at the user facility was requested. The customer provided the following information: "It is unknown if the scope was cleaned, sanitized, and disinfected prior to being sent for repair." The facility stated, "The cleaning process was completed, sterilization unknown, and the foreign objects were unknown." It is unknown if there was a lag between the end of clinical use and the start of prewashing. Precleaning: the facility wiped the insertion section. Brushed points for air/water channel performed with clean lint-free cloths, brushes, sponges. The facility noted there were no abnormalities on the accessories used for reprocessing. Facility did not note any comments or concerns regarding reprocessing.

The investigation is ongoing. A supplemental report will be submitted if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18074921&pc=FGB

4.2 The cysto-nephro videoscope had water leakage from the tip causing it to fail the air leak test, May 2023

A report in the FDA **MAUDE** database states the Olympus representative reported on behalf of the customer that an air leak was confirmed from the tip when water leakage was detected on the Cysto-Nephro Videoscope CYF-VHA. The issue was detected by the Olympus endoscope reprocessor. After checking a second time, no air leak was confirmed. Therefore, the scope was cleaned, and a brown or green liquid came out of the tip of the endoscope. The scope was not used on a patient after cleaning, and there were no reports of patient harm associated with this event.

The scope was returned to Olympus for inspection, and the customer's complaint was partially confirmed. When the scope was checked for air leaks: bubbles were generated from the tip, but no brown or green liquid came out.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16963946&pc=FAJ

5. Excessive Force with Equipment

5.1 During maintenance of the colonovideoscope, white crystalized contamination (simethicone) was present in the air and water channels along with additional findings to the scope, August 2023

A report in the FDA **MAUDE** database states an Olympus representative reported that the EVIS Exera Lucera Elite Colonovideoscope CF-HQ290L had white crystalized contamination believed to be an infacol (simethicone) type product that was evident within the air and water channels during maintenance. Scope evaluation found:

- Chipped light cover glasses
- Worn Glasses' adhesive.
- Chipped optical cover glass
- Damaged distal end cap
- Worn Distal end adhesive
- Aspiration housing colored ring worm

- Leaking plug body and damaged production labels
- Low angle, knobs play.
- Failed electrical safety test.

There was no report of patient harm or injury associated with this event. The investigation is ongoing, and a supplemental report will be submitted upon completion or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17538149&pc=FDF

5.2 Olympus found multiple damaged areas during the evaluation of the colonovideoscope including a chipped lens which was initially reported by the customer, July 2023

A report in the FDA **MAUDE** database states Olympus was made aware by the customer the EVIS Exera Lucera Colonovideoscope PCF-H290I had a chipped lens.

The scope was returned to Olympus for evaluation and the customer's allegation was confirmed as well as found additional issues:

- Foreign material in the scope*
- Peeling of objective lens adhesion
- Peeling of the light guide lens adhesion
- Broken distal cover
- Cracks and cloudiness of rubber adhesion
- Scratches and wearing of hoses
- Peeling paint of the suction cylinder.

*This medical device report (MDR) is being submitted to capture the reportable malfunction of foreign material in the scope found during evaluation. There were no reports of patient harm, and the investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17325936&pc=FDF

5.3 The technician confirmed the colonoscope had glue missing from the air/water nozzle due to physical damage, June 2023

A report in the FDA **MAUDE** database states the Pentax™ Video Colonoscope EC38-I10L was returned to Pentax Medical™ for repair. Our technician checked the returned unit and confirmed that the nozzle gluing was missing.

Based on the result, we concluded that it was caused due to the physical damage applied on the nozzle gluing. In addition, our technician confirmed that the bending rubber was cut and leaked, and the nozzle gluing was dirty. However, these defects are not the main cause and/or irrelevant

to the alleged complaint. In terms of gluing missing, the possibility of dropping into the human body could not be denied.

The time of the event is unknown. There was no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17095752&pc=FDF

5.4 The cysto-nephro videoscope was returned to for annual inspection and several defects were found, June 2023

A report in the FDA **MAUDE** database states the company representative reported that the Cysto-Nephro Videoscope CYF-VH was returned for annual inspection of the scope. Upon evaluation, free space was found underneath the cementing of the scope and debris could be seen. The foreign debris was found after the scope underwent two complete cleanings, disinfection, and sterilization (CDS) cycles: one at the hospital and one at the repair center. The debris could infect patients. The was no complaints from the customer and no patient involvement.

The scope was evaluated and there were additional findings:

- Scratched lens cover glass
- Damaged distal end cap
- Separated adhesive
- Dents in the insertion section
- Scratched light guide
- Damaged coating of the cable unit
- Cracked housing of the connector
- Less than specified value of the angulation.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if any additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17059921&pc=FAJ

5.5 The gastroscope was cleaned abrasively after it was removed from the patient, April 2023

A report in the FDA **MAUDE** database states on March 22, 2023, Fujifilm healthcare Americas Corporation was informed on an event involving Gastroscope DH-28GR. During an Endoscopic Submucosal Dissection of the GI tract, the user removed the scope to clean residue that had adhered to the scope. The user abrasively cleaned the gastroscope causing damage to the tip of t and making it unstable. The user continued to use the gastroscope throughout the procedure. When the scope was removed, the tip of the product became caught in the anal sphincter muscle

and fell off. The piece was retrieved, and the procedure was completed successfully without harm or injury.

There was no death reported with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16667977&pc=FDS

5.6 A Bronchoscope was removed from the patient with excessive force because of non-compatible ETT and DLT causing distal tip to detach from the bronchoscope, February 2023

A report in the FDA **MAUDE** database states the distal tip detached from the bronchoscope during procedure. The scope was removed from the patient immediately. Patient outcome was not affected. The AScope™ 4 Broncho Regular 477001000 was not received for investigation. A picture of the scope was provided, and fault verified from the picture. The scope was retrieved for investigation from retention sample. The tip of the retention sample was verified to be in good condition. A simulation test was conducted on the retention sample to replicate the reported failure. An ETT size six (6) mm and a DLT size 41 FR. was used-(the minimum compatible sizes). The retention sample was lubricated and passed through the tubes smoothly. The test was then repeated with smaller sized tubes (ETT 5.0 mm and DLT 37 FR.). The scope was stuck in the entry of the EET and could not pass. In the DLT, the scope became stuck during the insertion and after removal the top was observed to be broken. No feedback was received from the customer on the size of tube being used. Compatible sizes ETT and DLT are indicated in the IFU.
Based on available information and the performed simulation test, it is suspected the scope got stuck in a tube with a non-compatible size (being too small) and removed with excessive force, thereby causing the tip of the scope to break. According to the IFU, the user shall not apply excessive force when removing the endoscope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16395800&pc=EOQ

6. Failures Due to Reprocessing Equipment (AERs)

6.1 The Scope Buddy™ Plus one way valve was defective causing contaminated detergent water to suction back into the clean detergent reservoir, November 2023

A report in the FDA **MAUDE** database states the Scope Buddy™ Plus detergent dosing/endoscope flushing system one way valve defective causing contaminated detergent water to suction back into the clean detergent reservoir. Medicators/STERIS® are aware of the issue—no recall in place—and informed users would just need to call in a work order for repair (if identified). This was escalated to the company in October, and there has been no communication since.

We have significant concerns regarding potential contamination and the spread of infectious materials as it is not obviously apparent when this is happening. Two areas in our organization reported this after an awareness document was sent out. Concerned about other health systems that may be using this product and may be unaware of this issue.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18239861&pc=FEB

6.2 Expired Cidex™ OPA test strips were used by the customer to verify the minimum effective concentration for the Cidex™ OPA solution, October 2023

A report in the FDA **MAUDE** database states a customer reported an expired Cidex™ OPA test strip was used to verify the minimum effective concentration (MEC) for the Cidex™ OPA solution. No performance issues were reported. The customer stated the result was as expected, and the affected load was released for patient use. There was no report of infection, injury, or harm to patients associated with this event.

Although no prior incidents have resulted in serious injury, ASP decided to report all incidents where high-level disinfection cannot be assured, and the scope was released and used on a patient without reprocessing. The customer has been retrained that the product should not be used after the expiration date. Per the Cidex™ OPA test strips IFU, "Always note the date the bottle was opened and the do not use after date in the space provided on the bottle." Additional event information was requested; however, the customer did not provide further details.

This report may be based on information not investigated or verified before the required reporting date. This report does not reflect a conclusion by advanced sterilization products or their employees that the report constitutes an admission that the product, advanced sterilization products, or its employees caused or contributed to the potential event described in the report. If new information is obtained, a follow-up report will be filed as appropriate.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17905623&pc=JOJ

6.3 The ICG usage indicator warning light on the AER showed the Acecide®-C disinfectant should have been changed 23 days prior, October 2023

A report in the FDA **MAUDE** database states the endoscopy support specialist (ESS) visited the site to provide a reprocessing in-service for the OER-Pro and scopes. All endoscope staff at the site were advised of the proper way to care for and reprocess the scopes in accordance with the IFUs to avoid acquired infections to the patients. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

The Olympus field service engineer, prior to performing preventative maintenance, noted the ICG usage indicator warning light on the front of the AER indicative the Acecide®-C disinfectant should have been changed 23 days prior—in accordance with the IFU. During that timeframe, the AER was used to reprocess multiple scopes which were then used in various diagnostic esophagogastroduodenoscopy procedures (averaging 10-minute durations) and diagnostic colonoscopies (averaging 20-minute durations). The customer reported the disinfectant has since been changed, and all the scopes were properly reprocessed. The customer noted that all of the times the AER's were used previously, the minimum effective disinfectant concentration check was performed and passed as positive (indicating the chemical was intact for reprocessing of the scopes). All the scopes passed the adenosine triphosphate (ATP) test performed after coming out of the AER. There were no traces of biofilm found as part of the customer's routine quality control.

The customer reported the endoscopy staff revised the scope reprocessing protocol (the proper way to care and reprocess the scope):

- Using the manufacturer's recommendations and the hospital process protocol to ensure compliance with all the steps and regulations for infection control.
- Established a new log to indicate:
    - Mandatory change of the disinfectant every 5 days ensure
    - Enough supply of the scope washer is on hand.

All patients involved were followed by the customer site's infection control practitioner, and there were no reports of infections, symptoms, medical interventions, procedure delays, or procedure cancelations. Reports are being submitted on the scopes that were reprocessed using the OER-Pros.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18024313&pc=FDS

6.4 An AER had expired Acecide®-C, which was used for 51 days, and the facility was continuing to process scopes, October 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, the OES Cystonephrofiberscope CYF-5A was reprocessed in an endoscope reprocessor used with expired Acecide®-C. The concentration had not been checked, even though the facility had Acecide®-C and concentration checkers in stock. The Acecide®-C was used for 51 days before changing. This was done intentionally under the direction of the hospital director due to the cost of the Acecide®-C. There were no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17993386&pc=FAJ

6.5 Foreign matter was found in the OER-4 after reprocessing process failed, September 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that foreign matter (black scum) was found in the endoscope Reprocessor OER-4 after the reprocessing process failed. The black scum accumulated in the circulation port mesh filter in the cleaning layer. There were no reports of patient harm. The Endoscope reprocessor was not returned to Olympus for evaluation.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17734450&pc=FEB

6.6 Two endoscope reprocessor OER-4s water flow was weak, and both the water filters had not been changed since August 7, 2019, August 2023

A report in the FDA MAUDE database states the field service engineer reported to Olympus the water flow in the endoscope reprocessor was weak for reprocessing. The endoscope reprocessor OER-4 was not returned to Olympus for evaluation as the field service engineer (FSE) was on site.

The OER-4 evaluation found that there were two endoscope reprocessors with the same issue, and the FSE found both reprocessors did not have their filters changed since August 7, 2019.

There were no reports of patient harm. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17568937&pc=FEB

6.7 Endoscopes have been insufficiently reprocessing some of the Olympus scopes, which did lead to a thin-red object to come out of the tip of air/water valve, August 2023

A report in the FDA **MAUDE** database states that the customer reported that while his medical staff was washing after an EUS-FNA test, a thin-red object came out from the tip of his Olympus air/water value. Reportedly, after that, a red-brown object appeared also. As this was discovered following the completion of the procedure, this event had no impact on the patient of this case.

While performing diligence concerning this event, it became clear that the user facility had been insufficiently reprocessing some of their Olympus scopes. This report is the eighth of 11 being submitted to capture the series of insufficiently reprocessed scopes by the same user. While in discussions with the customer, he noted about 50 cc of a red liquid and a brown linear object came out from the tip. The customer did confirm that the most recent patient had no signs of

infection. According to the physician who used this product most often, he felt it had been difficult to send water through for a long time. Reportedly, there were times when the condition was good and times when bad. Further inquiry revealed after the case, the air/water channel cleaning adapter had not been used, and the solution was immediately brought to the sink and delivered with the injection tube. The customer went on to note that since it was troublesome to remove the balloon, the balloon channel may not be aspirated during the process. No cleaning brush was used during this process. No water or air supply inspection was performed after the case, and it is unclear whether the button had been replaced during the inspection or not.

The device had not been returned for evaluation. If additional information becomes available prior to the conclusion of the investigation, a supplemental report will be filed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17623467&pc=FEB

6.8 The facility used functional water instead of Acecide®-C to clean the OER-4 causing mold to grow in the disinfectant tank, June 2023

A report in the FDA **MAUDE** database states an Olympus representative reported on behalf of the customer that during an onsite visit, the user facility staff was using their own functional water instead of Acecide®-C to clean the endoscope reprocessor OER-4. Therefore, mold developed in the disinfectant tank, and error "e75" (water supply irregularity during preparation of the disinfectant solution) was displayed. No patient infections or injuries reported.

The OER-4 was not returned to Olympus for evaluation. A review of the device history record (DHR) of the AER found it was free from non-conformity in manufacturing, and it was shipped in accordance with specifications. The root cause of the remaining foreign material in the AER is unable to be specified.

The facility operates the disinfection process in OER-4 using functional water (not Acecide®-C), which was chosen depending on the decision of the facility. The reprocessor was used in the unrecommended procedure:

1. Endoscope was cleaned with cleaning detergent
2. Rinsed in OER-4, then
3. Disinfected in functional water, followed by being
4. Rinsed after disinfection in OER-4.

Olympus had announced that Acecide®-C was a high-level disinfectant … inappropriate usage of the OER-4 … [follow the OER-4 IFU] section 4.13 setup of the disinfectant solution, use Acecide®-C 6% disinfectant solution (800 ml cassette bottles) specified by Olympus as the disinfectant solution. Disinfectant solutions not specified by Olympus are not guaranteed for the combination of endoscope and equipment. Endoscope reprocessing may be insufficient, or the equipment may not operate normally.

Olympus will continue to monitor field performance for this OER-4.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17083945&pc=FEB

6.9 The water filter of the OER-4 was not replaced regularly causing algae to grow in the disinfectant tank which tested positive for bacteria, June 2023

A report in the FDA **MAUDE** database states the customer reported that algae had grown in the disinfectant tank of the OER-4 automatic endoscope reprocessor (AER) and an "e75" message was displayed.

The issue was found during pre-use inspection. The algae were cultured and tested. Bacteria was detected in the AER and water filter used with the AER. The type of bacteria culture was unknown. The algae were removed, and the AER was cleaned. The customer noted the water filter was not replaced regularly according to the IFU. Reports are being submitted on the OER-4, water filter, and the scope that was reprocessed using the AER.

The cleaning disinfection and sterilization (CDS) was performed by the customer. There was no patient infection. An OER-4 AER was used. The water quality of the rinse water was controlled, but the water filter was not replaced according to the IFU. The customer noted that water was used as disinfectant. The scope was dried using the AER.

There was no reported patient harm or impact due to this event. This event is under investigation and a supplemental report will be submitted upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17124957&pc=FEB

6.10 An employee felt their lips, tongue and throat become numb and tingling after they ingested Rapicide OPA/28 high-level disinfectant of an instrument was not properly rinsed, May 2023

A report in the FDA **MAUDE** database states the user facility reported via CHEMTREC® report that an employee ingested Rapicide OPA/28 high-level disinfectant (HLD) ML02-0127 that was present on an instrument that had not been properly rinsed. The employee reported a numbing and tingling sensation on their lips, tongue, and throat in addition to a poor taste in their mouth. The employee was advised to visit the emergency room.

The lot number of Rapicide OPA/28 HLD was not provided. The reported event is attributed to improper rinsing practices by user facility personnel as stated in the Instructions for Use (IFU). STERIS has offered in-service training on the proper use of the Rapicide OPA/28 HDL (specifically proper rinsing instructions); however, we are awaiting a response from the user facility. A follow-up report will be supplemented when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16875487&pc=MED

6.11 After the videoscope was cleaned in the OER-6, white deposits appeared on the insertion tube, April 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus states after cleaning a videoscope with the Olympus Endoscope Reprocessor OER-6, disinfecting alcohol, flushing, and wiping off, white deposits will appear on the insertion site after a while. It was also noted that the user attempted to change detergent; however, the issue was not resolved. There was no harm or user injury reported due to the event. The OER-6 has not been returned for evaluation.

The investigation is ongoing, and a definitive root cause of the reported event cannot be determined at this time. If additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16777809&pc=FEB

6.12 Staff washed unapproved dilators in the OER-Pro Endoscope Reprocessor, April 2023

A report in the FDA **MAUDE** database states Olympus was informed that during an onsite visit, the user facility staff had washed unapproved dilators in the OER-Pro Endoscope Reprocessor. No patient infections or injuries reported.

Based on the observation summary report from an Endoscopic Support Specialist (ESS), there were some reprocessing deviations observed during the onsite visits:

- Unapproved dilators were washed in the Olympus OER-Pro because the customer had previously washed them using the automatic endoscope reprocessor (AER).
- ESS informed the customer that the connector and the Cook Savary dilators are not approved to be reprocessed in the OER-Pro.

The ESS provided reprocessing in-service/reprocessing training to the user facility staff and provided the user facility staff with reprocessing training materials for their reference.

The scope is not expected to be returned for evaluation.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16727378&pc=FEB

6.13 During reprocessing, it was noticed the OER-4 water filter was suspected of poor reprocessing due to not being replaced since October 2019, January 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus customer information center (CIC) the Endoscope Reprocessor OER-4 received an E01 error code. Filling the basin with water took too long. It was reported that the device filter had been used for too long without being replaced—last replaced October 2019.
The issue was found during reprocessing. It was also reported that there were other endoscopes/accessories that were suspected of poor reprocessing due to inadequate water filter handling or inadequate water supply piping disinfection. There were no reports of patient involvement.
The device was not returned to Olympus for evaluation. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16084145&pc=FEB

6.14 White residue was found on the scope that was being used on the patient and also in the patient's colon, January 2023

A report in the FDA **MAUDE** database states the facility reported that white residue was observed on a scope that was used during a patient procedure. The scope was processed in their Advantage Plus Endoscope Reprocessing system (AER 1-2-5110.003) prior to use. No report on injury or procedure delay. Through follow-up with use facility personnel, it was noted that the white residue was also observed in the patient's colon. No medical intervention was required. Facility personnel informed the technician that Rapicide PA high-level disinfectant was used to disinfect the scope subject of the reported event and that a strong smell was noted. The technician was also informed that an employee's hands "turned white," as she was not wearing proper PPE when handling the scope. No injury was reported.
A Steris technician arrived onsite to inspect the Advantage Plus Endoscope Reprocessing System, ran four (4) test cycles, and could not duplicate the reported issue. No issues were noted with the function or operation of the reprocessing system, and it was returned to service. The reported event may be attributed to user error, as user facility personnel should have ensured that all hookup connections were properly made in addition to ensuring that the scope was properly disinfected prior to procedural use. Steris has offered in-service training on the proper use and operation of the AER; however, a date is in the process of being scheduled.
The AER user manual states:

- *Warning*: avoid possible chemical burns. Always wear personal protective equipment (e.g., gloves, goggles) when handling disinfectant and/or detergent.
- Before closing the basin lid, inspect the hookup to ensure that all connections are made properly, and the tubing does not interfere with the sprayer.
- Before removing the endoscope, verify all connections to the endoscope are secure.
- If an adapter is loose or disconnected, the disinfection is not complete and must be repeated. Failure to do so could result in an endoscope which is not disinfected and therefore should not be used on a patient.

- The efficacy of a disinfection procedure is directly related to the disinfectant solution used and the amount of time the endoscope is exposed to that solution.
- Rapicide PA high-level disinfectant (HLD) must be monitored for potency in every cycle.
- Use the Rapicide PA test strips to test the potency of the solution.
    - If the potency of the solution is below minimum recommended concentration, discard and replace it with fresh solution.
    - Never use disinfectant with unacceptable potency levels.

A three (3) year complaint review indicates this to be an isolated event. A follow-up MDR will be submitted when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16026080&pc=FEB

7. Endoscope Malfunction

7.1 The cystoscope was returned to Pentax® for repair due to fluid damage along with several other damaged areas to the scope, October 2023

A report in the FDA **MAUDE** database states the time of event was not during the procedure. The Video Cystoscope 2.0C 5.5TP 400L (ECY-1575K) was returned to Pentax® medical for repair.

Pentax's® technician checked the returned unit and confirmed the CCD module with drive PCB had fluid damage. Based on this result, they concluded it was caused due to fluid damage from the CCD module with drive PCB. In addition, the technician confirmed, a) the control body had fluid damage, b) CCD drive PCB had damage, c) electrical pin connector had fluid damage, d) objective lens had fluid damage, e) objective lens was cloudy (not clear view), f) light guide cable was buckled, g) remote control buttons were cracked, and h) the remote-control buttons were cut. However, these defects are not the main cause and/or irrelevant to the alleged complaint.

Based on the technical report HR-RPT-0586 (image failure) and/or risk analysis results, it was evaluated to submit an MDR.

There was no report of patient harm. Video image failure (fluid damage).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18027376&pc=FAJ

7.2 During a routine transvaginal exam, the Philips transvaginal probe broke in half as the sonographer was removing the probe from the patient, November 2023

A report in the FDA **MAUDE** database states that when the exam was complete, the Philips transvaginal probe broke off in half during a routine transvaginal exam, as the sonographer was

removing the probe from the patient. The sonographer notified Philips of the issue. The issue is the exact same as the defects described in a large recall for similar devices. However, this device model is not listed in the recall, so Philips will not cover a replacement. Manufacturer response is for transducer, ultrasonic, diagnostic, transducer 3D9-3V.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18064221&pc=ITX

7.3 Moisture condensation caused the colonoscope to have a cloudy image and was sent in for repair, September 2023

A report in the FDA **MAUDE** database states the product was returned to Pentax® Medical for repair. Their technician checked the returned Imagnina Colonoscope EC38-I10CL and confirmed the CMOS module with drive PCB was cloudy (not clear view). Based on the result, they concluded it was caused due to the moisture condensation inside. The technician confirmed the objective lens cracked; however, this defect is not the main cause, and/or irrelevant to the alleged complaint.

Based on the technical report "HR-RPT-0586 (image failure)" and/or the risk analysis results, it was evaluated to submit an MDR.

The time of the event is unknown and there is no report of patient harm. Video image failure.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17709006&pc=FDF

7.4 The bronchovideoscope was returned to Olympus because of an air/water leak discovered during reprocessing, September 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the EVIS Lucera Elite Bronchovideoscope BF-1TQ290 had an air/water leak that was observed during reprocessing. No patient or procedure was involved. This medical device report (MDR) is being submitted to capture the reportable malfunction found during evaluation.

The scope was returned to Olympus for evaluation and found the customer's allegation that the scope had insufficient angle and the channel tube was leaking. There was also tissue glue attached in the distal end that caused clogging and a blackout screen occurred due to damage on the charged coupled device unit.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17687274&pc=EOQ

7.5 The colonoscope had a cloudy image in the objective lens and was sent back to Pentax™ for repair, August 2023

A report in the FDA **MAUDE** database states the Pentax™ HD Video Colonoscope 3.8C EC-3890FI was returned to Pentax Medical™ for repair.

The technician checked the returned unit and confirmed that the objective lens was cloudy (not a clear view). Based on the result, they concluded that it was caused due to the moisture condensation in the objective lens. In addition, the technician confirmed that the electrical pin connector was deformed; however, this defect is not the main cause, and/or irrelevant to the alleged complaint.

Based on the technical report "HR-RPT-0586 (image failure)" and/or the risk analysis results, it was evaluated to submit MDR.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17507373&pc=FDF#

7.6 The scope had a cloudy image due to moisture condensation in the objective prism and was returned to Pentax™ for repair, June 2023

A report in the FDA **MAUDE** database states the Ultrasound Video EB19-J10U was returned to Pentax Medical™ for repair.

The technician checked the returned unit and confirmed that the objective prism was cloudy (not clear view). Based on the result, we concluded that it was caused due to the moisture condensation in the objective prism. In addition, the technician confirmed the insertion flexible tube buckled and the operation channel (primary) leaked; however, these defects are not the main cause and/or irrelevant to the alleged complaint. There was no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17214203&pc=EOQ

7.7 A blank image appeared when the bronchovideoscope was connected to the imaging software, June 2023

A report in the FDA **MAUDE** database states the customer notified Olympus that the image was not stable, and when plugged in with the EXIS Exera III Bronchovideoscope BF-P190 the screen was blank when connected to the imaging software. Otherwise, the screen would be blue. The issue was found during preparation for use.

The scope was returned to Olympus for evaluation, and it was confirmed there was a blank display. However, after aeration, it was okay. In addition, the scope evaluation found:

- Leaking from the small instrument channel.

- Dents were found at the insertion tube and the scope connector boot.
- Fluid invasion at the opening to the body control unit and the scope connector (using advanced diagnostics).
- Failed electrical continuity test.

No patient was harmed. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17206710&pc=EOQ#

7.8 The colonovideoscope felt stiff and "strange" with a crack in the wheel and angulation snapped while inside the patient's sigmoid colon, April 2023

A report in the FDA **MAUDE** database states an Olympus representative reported to Olympus on behalf of the customer that the EVIS Lucera Elite Colonovideoscope PCF-H290DL felt stiff and "strange". The scope had a crack in the wheel, exhibited loss of tip contact, and the angulation snapped. Reportedly, it was in the sigmoid when the angulation snapped loudly. The angulation wheel became less responsive from that point. The scope was replaced, and during withdrawal in the sigmoid, the endoscopist noticed a tear. There was minimal bleeding with about 10 milliliter blood loss. Six (6) clips were subsequently applied to the tear site. A 3-minute delay was reported but was deemed to be clinically irrelevant. The procedure was completed with a new scope. The patient subsequently underwent a computed tomography (CT) scan, which was negative for perforation. The patient was placed on antibiotics as a precaution due to the tear and discharged home after 2 hours. The patient is currently well.

The scope has been returned to Olympus and the allegation was confirmed. Initial evaluation showed lifting of the distal end adhesive. The up, down, left, and right angles did not meet specification with evidence of straining. The scope failed the electrical safety test.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16697171&pc=FDF

7.9 During the evaluation the bending section cover was broken, dirty with foreign material from previous procedures, April 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, the EVIS Exera II Duodenovideoscope TJF-Q180V was returned as part of the annual inspection. The scope was returned, and an evaluation revealed the bending section cover was broken, dirty and had foreign materials (determined to be accumulated residues left over from previous procedures). This report is being submitted to capture the reportable malfunction found during evaluation. There was no complaint from the customer and no patient involvement.

An evaluation of the returned scope revealed the a) key top of the switch button 1 had a pinhole, b) electrical connector was corroded c) connecting tube had a cut, d) light guide lens and objective lens were dirty, and e) left arm was corroded.

The investigation is ongoing. A supplemental report will be submitted on completion of the investigation or if any additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16808091&pc=FDT

7.10 PENTAX bronchovideoscope had video image failure due to fluid damage, April 2023

A report in the FDA **MAUDE** database states the PENTAX Video Bronchoscope EB15-J10 was returned to PENTAX Medical for repair. Our technician checked the returned unit and confirmed the CCD drive PCB had fluid damage. In addition, our technician confirmed the electrical pin connector and large connector were fluid damaged from the CCD drive PCB. It was also found that the insertion flexible tube buckled, and the operation channel (primary) leaked. However, these defects are not the main cause, and/or irrelevant to the alleged complaint. The time of the event was not during the procedure.

There was no report of patient harm. The video image failure is from fluid damage. Based on the technical report "Hr-RPT-0586 (image failure)" and/or the risk analysis results, it was evaluated to submit MDR.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16821220&pc=EOQ

7.11 A bronchovideoscope had excessive curvature of the distal end that became stuck in the patient's main bronchial tube, January 2023

A report in the FDA **MAUDE** database states a facility submitted a repair request to the Olympus service center indicating, during the procedure, an instrument got stuck into the main bronchial tube of the patient due to excessive curvature of the distal end. It was noted the EVIS Exera III Bronchovideoscope BF-Q190 was extracted from the patient by the doctor with some difficulty, and it was subsequently noticed that the distal sheath appeared to have collapsed and was not responding to lever commands. Additionally, the doctor noticed resistance from the bronchoscope toward the end of the procedure. The doctor carefully proceeded to remove the scope, then used a similar scope to finish the procedure and check that no damage had been caused. There was no harm to the patient or user injury reported due to the event. The procedure was finished with a 10-minute-delay—no clinically relevant delay occurred. After the extraction, the doctor noticed the probe was bent beyond the angled section while the tie rods functioned correctly.
The scope has been returned to Olympus for evaluation, and it was observed the a) insertion part of the distal end was damaged, b) the bending section cover (a-rubber glue) was separated, c) the

connection tube of the insertion part had dent, d) the grip unit of the control unit had a scratch, and e) the distal sheath appeared to have collapsed.
The investigation is ongoing, and a definitive root cause of the reported event cannot be determined at this time. If additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16208850&pc=EOQ

7.12 The distal end bent and would not go back straight after becoming stuck in the patient, causing stomach discomfort symptoms after the procedure, December 2022

A report in the FDA **MAUDE** database states Pentax Medical was informed of an event that occurred in China (within the APAC region) in the operating room during use of the Pentax Video Gastroscope EG29-I10. The user reported that the distal end rotated and bent, then it would not go back straight and was difficult to remove. Lt was useless to rotate the angle knob repeatedly. The user rotated with both hands and slowly adjusted the bending part, then removed the endoscope successfully. Afterwards, the patient had stomach discomfort symptoms without bleeding, but symptoms were relieved after medication (medical information not provided). During reprocessing, the nurse found that the angle knob was out of order due to the angle wire fracture. She contacted the equipment department for repair.
This event meets the requirements for FDA reportability. Note, the submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event. The investigation is in progress, and a supplemental report will be added when available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15918777&pc=FDS

8. Use Errors

8.1 A facility failed to follow the instructions for use (IFU) for reprocessing a fiberscope, which an Olympus Endoscope Support Specialist (ESS) provided on-site reprocessing training materials, November 2023

A report in the FDA **MAUDE** database states that Olympus was informed by an endoscopy support specialist (ESS) (based on their observation summary report) that during an on-site visit , there were some reprocessing deviations as follows:

- The user facility staff did not use brushes to clean channels.
- They only wiped down the scope and used a 30-cc syringe to flush the suction valve.
- They did not flush suction connector with 30-cc of detergent or let the scope soak for recommended time.

The ESS provided the user facility staff with reprocessing training materials for their reference. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available. No patient infections or injuries reported.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18178953&pc=EOQ

8.2 The duodenovideoscope was returned for a standard inspection where foreign material was discovered in the air/water cylinder and tube, October 2023

A report in the FDA **MAUDE** database states user facility returned an EVIS Exera II Duodenovideoscope to the service center for an annual inspection. The customer did not report any problems associated with the scope and there was no patient user injury or harm reported to Olympus. This medical device report (MDR) is being submitted to capture the reportable malfunctions found during evaluation.

Evaluation of the scope uncovered foreign material in the air/water cylinder and tube. This occurrence was likely due to remains from a previous procedure. This finding was due to insufficient cleaning or handling of the scope. Additionally, it was observed that the:

- Distal end had a crack.
- Air/water cylinder had no color
- Label on the scope connector was damaged.
- Play of the up and down knob was out of the standard value due to wear of the angle wire.

The faulty parts were replaced. The scope was inspected and passed Olympus functional standards.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17936113&pc=FDT

8.3 After an endoscopic ultrasound, the remnant of a balloon was left behind on a scope and went through high-level disinfection process, September 2023

A report in the FDA **MAUDE** database states a customer submitted a MedSun report to the FDA stating, the remnant of a balloon was left behind on a scope after an endoscopic ultrasound and went through the high-level disinfection (HDL) process.

It is not clear if the balloon3 MAJ-233 was not fully removed prior to reprocessing or it broke, leaving the elastic band behind. This went unnoticed due to the color of the balloon being a

similar color to that of the scope. A new balloon was then applied over the remnant and utilized on a second patient. This placed the patient at risk of potentially being exposed to a bloodborne pathogen. The patient was offered lab monitoring for communicable agents such as a human immunodeficiency virus (HIV) and hepatitis (Hep-B). The Hep-B lab monitoring was negative. There was no report of patient harm associated with this event.

(NOTE: There is a request to consider manufacturing balloons in a different color other than off-white, to ensure the balloon is easily identifiable. There were no alerts when Balloon3 was going through the HDL process. The remnant was not identified until after the procedure was completed. The intended procedure was a diagnostic endoscopic ultrasound with biopsy.)

To date, Balloon3 has not been returned to Olympus for evaluation.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17822222&pc=FDF

8.4 It was discovered by the ESS during an on-site visit that the facility was reusing the same water and detergent after each scope for reprocessing, September 2023

A report in the FDA **MAUDE** database states: during an on-site visit for annual reprocessing maintenance, it was discovered that the facility used the same water and detergent after each scope for reprocessing. There was no report of patient harm or user injury associated with this event.

There was no scope returned. Olympus Endoscopy Support Specialist (ESS) performed reprocessing in-service with the staff that included demonstration. The customer does not clean scopes with Ethylene Oxide. The ESS recommended the customer follow all Olympus reprocessing procedures (as documented in the reprocessing manual) and explained the importance of each, which was acknowledged by all staff in attendance. The staff then completed the checklist, were asked to refer to the endoscope reprocessing manual for instruction on how to reprocess and/or sterilize the scope accessories and were reminded that the Olympus connect website provides copies of the endoscope instruction manuals and reprocessing manuals as well as visual reprocessing guides for some scopes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17726033&pc=FDS

8.5 Pre-cleaning was not performed on upper GI scopes after procedures before being sent to the reprocessing room, September 2023

A report in the FDA **MAUDE** database states the endoscopy support specialist (ESS) reported that during the bedside pre-cleaning in-service, it was found that pre-cleaning was not being

done to upper GI scopes before being sent to the reprocessing room. There is no patient infection associated with this reported event. No harm reported, no user injury reported due to the event. The EVIS Exera II Colonovideoscope PCF-H180AL was not returned for evaluation as there is no reported issue against the scope.

During the on-site visit, the ESS performed a scope reprocessing in-service for the staff and covered infection control information referenced in the user manual and reprocessing manual. All products are listed in the product section of the service. All attendees are listed on the attendance sheet.

In addition, ESS informed the team that per the IFU every scope *must* have a bedside pre-clean before being sent to the reprocessing room, and advised the reprocessing staff that per the IFU every scope needs 30 seconds of aspiration (after brushing), to ensure all lose debris is removed from the scope. ESS recommended that the customer follow all Olympus reprocessing procedures as documented in the reprocessing manual and explained the importance of each, which was acknowledged by all staff in attendance.

This investigation is ongoing. This report will be supplemented accordingly following investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17751051&pc=FDF

8.6 Empower enzymatic solution was put into the Medivator DSD washer instead of OPA by an inexperienced scope tech, September 2023

A report in the FDA **MAUDE** database states that on August 8, 2023, Fujifilm Healthcare Americas Corporation was informed of an event involving Fujifilm Video Endoscope EC-760R-V/L. It was reported that the customer requested advice on a potential infection control issue.

An inexperienced scope tech put 1/4 to 1/2 cup of empower enzymatic solution into one of their Medivators DSD washers where the OPA was supposed to go, and two of the scopes that were run through there were used on patients before they caught them mistake.

There is no serious injury or death associated with the event. Therefore, this report is being submitted with abundance of caution.

A supplemental report will be submitted pending investigation results.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17701856&pc=FDF

8.7 The Endoscope Support Specialist (ESS) learned during an in-service that the staff is not leak-testing the scopes or brushing the scope appropriately, September 2023

A report in the FDA **MAUDE** database states during a scheduled in-service, Olympus learned the staff is not leak testing the scopes, not testing the Aldahol® disinfection and is not brushing the scope appropriately (no channel opening brush). There was no report of patient harm.

The Cystonephrofiberscope CYF-5R was not returned to Olympus for evaluation. However, as part of the investigation into this report, an Olympus endoscopy support specialist (ESS) was dispatched on-site to assess the reprocessing practices at the user facility:

- Completed a reprocessing in-service with staff.
- Attendance sign in sheet and ontrack forms were completed.
- Information provided to staff regarding ordering:
    - scopes reprocessing manuals
    - test strips for the Aldahol®
    - leak tester
    - cleaning brushes.
- Staff members did have a reprocessing cleaning guide available.

The investigation is ongoing, and a definitive root cause of the reported event cannot be determined at this time. If additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17712838&pc=FAJ

8.8 Bedside pre-cleaning was not being performed on the fiberscope after procedures when the ESS was at the facility for an annual training, September 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the Uretero-Reno Fiberscope URF-P6 was not undergoing bedside precleaning. The scope was sent to the reprocessing team after use. The issue was found after an annual training with an endoscopy support specialist (ESS). There were no reports of any patient harm.

The scope was not returned to Olympus for evaluation. The Olympus endoscopy support specialist performed a scope reprocessing in-service which covered infection control information that is referenced in the user manual and reprocessing manual. The customer used an automatic endoscope reprocessor (AER), and it was recommended that the customer contact the AER's manufacturer for proper use.

The investigation is ongoing. A supplemental report will be submitted if any additional information is provided by the user facility

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17746042&pc=FGB

8.9 Unidentified solid black material was clogging the air/water nozzle causing the duodenovideoscope to malfunction, August 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the EVIS Exera III Duodenovideoscope TJF-Q190V does not pass inspection with errors "e101-118". The issue occurred after the diagnostic procedure which was completed with the same scope.

The scope was returned for evaluation and found the reportable malfunction that the air/water nozzle is clogged by unidentified foreign solid black material.

The scope was returned to Olympus for evaluation and confirmed the customer's allegations. The following was found during evaluation:

- Clogged air/water nozzle by unidentified foreign solid black material.
- Annual preventive maintenance on the biopsy channel and keytop 1 and forceps elevator system were done.
- Worn out distal sheath rubber glues
- Worn out lens's glues
- Deformed insertion tube
- Peeled off coating of the insertion tube
- Out of spectrum bending angulations.

No reports of patient harm. This medical device report (MDR) is being submitted to capture the reportable malfunction found during evaluation.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17590653&pc=FDT

8.10 The rhino-laryngo videoscope leaked after washing while being dried causing green water to come of the forceps mouth when preparing for a therapeutic procedure, July 2023

A report in the FDA **MAUDE** database states the customer reported the Rhino-Laryngo Videoscope ENF-VT3 had green water coming out of the forceps mouth. The customer noted the scope leaked when being dried after washing. The issue was found when preparing the scope for use in a therapeutic procedure.

During scope evaluation at Olympus, it was found the complaint was confirmed:

- Water tightness was lost due to a pinhole on the instrument tube
- Corrosion of the distal end caused no electrical continuity
- Chipped adhesive at the bending section cover
- Dented connecting tube. Worn angle wire caused an unmet standard value of the bending angle in an up direction

- Leak caused the control unit to become sticky
- Scratched in multiple parts of the scope.

There was no harm to the patient due to this event. This event is under investigation and a supplemental report will be submitted upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17171033&pc=EOB

8.11 Seven suction valves were contaminated with *Stenotrophomona maltophilia* due to reprocessing procedures not being followed, July 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that the seven (7) suction valves MD-493 were contaminated with *Stenotrophomonas maltophilia* bacteria that occurred during reprocessing. There was no report of patient infection.

According to the report, contamination occurred because of inadequate reprocessing (not following appropriate procedures). No patient was harmed, nor user injury reported due to this event. The suction valve will not be returned to Olympus for evaluation. Additionally, contamination or culture results of the involved suction valves were not provided including the lot number of valves were also not provided. The report noted the valves are autoclaved and the manufacturer's IFU on reprocessing and precleaning was requested by the customer.

In a follow-up communication, the customer company representative clarified and confirmed that there was no patient infection. In addition, per the follow-up report, the customer contacted the Olympus representative for support regarding reprocessing, as the customer has problems with reprocessing of the valves/endoscopes that are currently urgent assistance/clarifications on side of Olympus to provide the IFUs the customer requested and support the customer with the device portfolio.

Supplemental report(s) will be submitted should any relevant new information is available and or received. The investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17385621&pc=FDS

8.12 The ESS noted improper reprocessing steps when cleaning endoscopes and provided education and in-services to the staff, July 2023

A report in the FDA **MAUDE** database states a (clean, disinfect, sterilize) CDS in-service was being provided to staff on an Olympus Endoscopy System (OES) cystonephrofiberscope CYF-5R. Endoscopy support staff (ESS) noted improper reprocessing steps being performed. It was observed that there were rusty scopes, a disposable brush being used multiple times on scopes, and the staff were using the same detergent (not changing the detergent between cases). There were other instruments sitting in the high-level disinfectant (HDL) solution with the scopes.

The scope was rusted on the biopsy channel and venting cap. It was hard to put the leak tester on the venting cap due to the rust. The staff did not have a drying cabinet and the scopes sat on the counter in-between cases. No patient or procedural involvement with the event.

The scope is not expected to be returned. However, ESS demonstrated and educated the staff on the proper reprocessing steps, which is stated in the Olympus reprocessing manual, beginning with bedside precleaning through manual HDL. Multiple in-services were provided to staff. The ESS advised the staff should not be using the same disposable cleaning brush for each scope, and they need to leak test every scope after use. The staff must change the detergent after each wash and check the MEC. The ESS advised staff to place the scope in the proper drying cabinet or area.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17311538&pc=FAJ

8.13 The ESS reported the facility did not properly reprocess their scopes and provided training to the staff, July 2023

A report in the FDA **MAUDE** database states the endoscopy support specialist (ESS) reported to Olympus, the Uretero-Reno Videoscope URF-V3R was reprocessed with a different procedure from the instruction manual during reprocessing. The user did not preclean, perform a leakage test, nor properly a) brush, b) flush, c) wipe with an appropriate cloth, or d) transport the scope. The customer was provided with the IFU on how to correctly clean the scope.

The scope was not returned to Olympus for evaluation. A review of the device history record (DHR) found no deviations that could have caused or contributed to the reported issue. It has been over 4 years since the subject scope was manufactured.

There were no reports of patient harm. A definitive root cause cannot be identified. It is considered that the user's understanding differed from Olympus recommendation in scope handling and/or reprocessing steps. Olympus specialized staff already provided training in the correct handling. Olympus will continue to monitor the filed performance of the scope.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17270385&pc=FGB

8.14 The balloon channel for any EBUS scopes were not being brushed by the user facility because they did not have the BW-400B brush to use to clean the channel properly, July 2023

A report in the FDA **MAUDE** database states the user facility staff asked questions concerning reprocessing of the EVIS EUS Ultrasound Bronchofibervideoscope BF-UC190F, BF-UC180F,

when an Olympus endoscope support specialist (ESS) was visiting the user facility. During this conversation, it was discovered that the user facility staff was not brushing the balloon channel with any of the EBUS scopes and had not ordered the BW-400B channel brush. Based on the observation summary report from an Olympus ESS, there were some reprocessing deviations observed (as noted above).

The ESS provided the client with the reprocessing wall chart for the BF-UC180F, BF-UC190F, and provided the client with the brush model BW-400B. ESS also recommended the facility to order the BW-400B brush and inform the ESS when it is delivered so that the ESS can return to provide an in-service on proper use.

No patient infections or injuries reported. The investigation is ongoing, and a definitive root cause of the reported event cannot be determined at this time. If additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17367874&pc=PSV

8.15 The bronchovideoscope had black liquid coming out after cleaning and the procedure was completed using the same scope, July 2023

A report in the FDA **MAUDE** database states that Olympus was made aware that black liquid came out of the EVIS Lucera Elite Bronchovideoscope BF-P290 after washing was completed. The issue was found after cleaning, and the procedure was completed with the same scope.

The scope was returned for evaluation and the customer's allegation was not confirmed. It was noted

- Water tightness was lost due to a pinhole on the bending section rubber
- Scratched universal cord
- Worn angle wire caused unmet standard value of the bending angle in the up direction

No reports of harm associated with the event. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17298857&pc=EOQ

8.16 During inspection for a therapeutic procedure, tissue was found in the gastrointestinal endoscope and was completed with another endoscope, June 2023

A report in the FDA **MAUDE** database states Olympus was made aware that the EVIS Exera III Gastrointestinal Videoscope GIFH190 had tissue in the scope after it was reprocessed. The issue

was found during inspection for a therapeutic procedure, and it was completed with another scope. There were no reports of harm associated with the event.

The scope was returned for evaluation and the customer's allegation was confirmed. It was noted:

- Insulation values:
  - Plastic distal end: 0.50 ohms
  - Insertion tube: 4 ohms.
- Up and down angulation was out of customer standard
- Dented plastic distal end cover
- Peeling cement on the charge couple scope lens
- Chipped light guide lens.
- Cracked rubber glue of the bending section
- Insertion tube was:
  - Wrinkled at1 meter and 20 cm (120 cm)
  - Crushed between 30 cm and 40 cm.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17217959&pc=FDS

8.17 The facility cleaned the loaner colonovideoscope twice after using the scope on patients, and the third time cleaning it, a two-inch section of a cleaning brush came out of the scope, June 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that upon receiving their loaner EVIS Exera III Colonovideoscope PCF-H190DL, they cleaned it by passing a cleaning brush through the channels. They then used the scope on a patient, and afterwards cleaned it again. After a second patient's procedure, they cleaned the scope a third time.

Upon cleaning the scope, the third time, a two (2)-inch section of a cleaning brush came out of the scope. The customer noted that the brush part that came out was not one of their own. They used a Steris brush with a white sheath and white bristles, while the brush that came out of the loaner scope had a clear sheath with a yellow tip.

The customer is no longer using the scope and there was no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17126190&pc=FDF

8.18 An ESS noted that the facility technician skipped multiple steps in the manufacture's IFU when reprocessing the duodenoscope which tested positive for *Shigella dysenteriae*, June 2023

A report in the FDA **MAUDE** database states as part of the Olympus 522 post market surveillance study, the distal end of the EVIS Exera III Duodenovidoescope TJF-Q190V was microbiologically cultured and tested positive for 2 CFU of *Shigella dysenteriae*. After a therapeutic ERCP procedure, and post reprocessing, samples were collected and sent to an independent laboratory for testing.

A visual inspection of the scope for clinical sampling was performed. A) The forceps elevator and body surface around the elevator had no visible debris. B) The objective lens and light guide lens at the distal end of the insertion section had no residue or stains and no scratches or cracks. C) The glue around the lenses was not discolored or pitted and the glue was not peeling or chipping. D) The air water nozzle at the distal end of the insertion section did not appear damaged and there was no visible debris. E) The distal ring at the distal end of the insertion section had no cracks or dents on the ring. The glue around the ring was not discolored or pitted and the glue was not peeling or chipping. F) The white isolation block at the distal end of the insertion section did not have any cracks or dents. G) The surface of the distal body at the distal end of the insertion section had no corrosion and no debris. H) The glue condition around the left side surface of the distal end was not discolored nor pitted, had no cracks, and had no peeling or chipping glue.

The facility reprocessed the scope in (equipment/steps and timestamps):

- Medivator DSD edge automatic endoscope reprocessor (AER) after the ERCP in 2023, which was completed at 1:36pm.
- Manual cleaning of the scope commenced at 1:37pm.
- AER reprocessing commenced at 2:01pm and was completed at 2:32pm.
- Sampling of the scope for the culture testing was performed.
    - All personal protective equipment was worn.
    - The sampling was pre-disinfected using provided disinfectant.
    - All the necessary supplies were aseptically placed in the sterile field.
        - No defects were in this sample collection container and solution.
        - No other person other than Olympus staff entered the sampling area.
    - The distal end was inspected.
        - No visible debris was observed.
        - The correct surfaces of the distal tip were swabbed.
- The correct areas of the elevator recess were brushed and flushed.
- The instrument was brushed and flushed.

No significant deviations were observed regarding aseptic or sterile techniques during sampling that could have contaminated the sample. All the correct sterile components and materials were used. No sampling instruments touched any non-sterile areas or surfaces besides the scope. No gloved hands made any contact with non-sterile surfaces. The scope was properly dried using filtered compressed air after sampling was completed.

An Olympus Endoscopy Support Specialist (ESS) visited the customer in 2023, to perform an observation of the reprocessing techniques. The ESS noted the facility technician did not check the condition of the distal end flushing adapter, did not perform flushing of the distal end flushing adapter, and did not dry the connector cap and venting connector. The facility technician moved the angulation knobs for the entire time while leak testing and did not observe the scope but instead looked at the clock the entire time. The facility technician a) did not know where to look for bubbles, b) performed improper leak testing, c) did not dissemble the distal end flushing adapter in water, d) did not open and close the instrument outlet three times, and e) did not check the disinfectant concentration. The ESS educated the facility technician on the proper reprocessed steps.

No patient injuries were reported. The scope referenced in this report was not returned for evaluation but was sent to an independent laboratory for destructive sampling. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17219263&pc=FDT

8.19 The user facility was reprocessing scopes without using a leak tester and did not have the correct cleaning brush, June 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that they do not have a working leak tester to reprocess the EVIS Exera II Ultrasonic Bronchofibervideoscope BF-UC180F. They do not have a BW-400B brush cleaning brush. A Medivator Advantage was being used for AER reprocessing. The customer continued to reprocess scopes without using a leak tester or completing the leak testing steps.

The scope is not expected to be returned for evaluation. It was recommended to the customer not to use the scope unless all reprocessing steps are followed by the Olympus IFU. An in-service was conducted for the staff, which included cleaning, disinfection, and sterilization information contained in the Olympus manual.

No patient or procedural impact associated with the event. The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17218137&pc=PSV

8.20 A bronchofibervideoscope was being improperly reprocessed by the staff and not completing the precleaning steps properly, June 2023

A report in the FDA **MAUDE** database states the Olympus endoscope support specialist (ESS) was informed by the user facility staff that the EVIS Exera II Ultrasonic Bronchofibervideoscope

BF-UC180F was being improperly reprocessed, the user facility staff was not completing the precleaning steps properly.

An Olympus ESS was dispatched on-site to assess the reprocessing practices at the user facility. Based on the information provided by the user facility staff, there were some reprocessing deviations, the staff were not completing the precleaning steps properly. The ESS provided a precleaning reprocessing in-service to the user facility staff, which included the information contained in the Olympus service manual. All models reviewed during the in-service were listed in the on-track form. There were no reports of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17213509&pc=PSV

8.21 The Pentax™ bronchoscope had an accessory or object stuck in the operation channel due to inadequate reprocessing at the facility, June 2023

A report in the FDA **MAUDE** database states the Pentax™ Video Bronchoscope 1.2C 3.8TP 600L EB-1170K was returned to Pentax Medical™ Center for repair.

The technician checked the scope and confirmed the operation channel was stuck with an accessory/object. It was concluded that it was caused due to the inadequate/insufficient reprocessing at the facility on the operation channel. In addition, the technician confirmed:

- Broken ICB (light carrying bundle)
- Perforated insertion flexible tube
- Leaking insertion flexible tube
- Twisted insertion flexible tube.

However, these defects are not the main cause, and/or irrelevant to the alleged complaint.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17223164&pc=EOQ

8.22 Insufficient cleaning was the cause of foreign material to be found in the nozzle of the colonovideoscope, May 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the EVIS Exera Elite Colonovideoscope PCF-H290I had a cloudy image. There was no patient harm associated with the event. The scope was found with the nozzle having foreign objects. This medical device report is being submitted to capture the reportable malfunction found during the scope evaluation.

The scope was returned to Olympus for evaluation and the cloudy image was not confirmed. In addition, there were foreign objects found in the nozzle due to insufficient cleaning. The root cause of foreign matter remaining in the equipment could not be identified. Due to clogging of

the nozzle, water removal ability did not meet the standard value. The scope was cleaned, disinfected, and sterilized before it was sent back to Olympus. It was unknown what the foreign material was. The air/water nozzle was flushed with water and air and there were no abnormalities in the accessories used for reprocessing. The air/water nozzle was wiped/brushed with clean lint-free cloths, brushes, or sponges.

Additional evaluation findings were as follows:

- Deformation of up/down knob caused water and air leakage.
- Wear of angle wire.
- Bending angle in up direction did not meet the standard value.
- Cracked light guide lens and the adhesives around large lens had a white-clouded area.
- Peeling adhesive around objective lens.
- Scraped suction cylinder and the paint was peeling.
- Scratched image guide connecting tube.
- Chipped, cracked, and cloudy adhesive of the bending section cover.
- Scratched Switch 1
- Scratched image guide protector.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16899382&pc=FDF

8.23 A single-use cleaning brush was being used as a reusable cleaning brush, April 2023

A report in the FDA **MAUDE** database states during a reprocessing in-service conducted onsite by Olympus, the customer informed Olympus that the BW-400B single-use cleaning brush was being used as a reusable brush. The customer was advised they should not be reusing it. No patient involvement.

The Uretero-Reno Videoscope URF-V3R will not be returned. This report is being submitted to capture the complaint on scope reprocessed following incorrect procedure. The investigation is ongoing and will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16683781&pc=FGB

8.24 Due to insufficient cleaning of the cystoscope, foreign material was coming out of the forceps channel, March 2023

A report in the FDA **MAUDE** database states the customer returned the Cysto-Nephro Videoscope CYF-VA2 for evaluation and repair of a no image issue. There is no reported harm

to any patient. This MedWatch is being submitted for the reportable issue of foreign material coming out of the forceps channel as observed during device evaluation.

Upon evaluation of the returned scope, foreign material was observed coming out of the forceps channel. This is attributed to failure to clean adequately.

Other observations for the scope:

- Image is not displayed due to damage of the charge couple device (CCD).
- Lost water tightness due to the pinhole on forceps channel.
- Dented universal cord.
- Sticky up/down plate and grip.
- Sticky control unit due to water leakage.
- Wearing of angle wire caused bending the angle in up direction to not meet the standard value.
- Dented forceps channel prevents a channel cleaning brush from being inserted smoothly.
- Poor illumination due to light guide bundle slipping down.
- Corrosion of suction cylinder stops the expected insulation capacity from being obtained.
- Corrosion stops switch (SW) SW1 from working.
- Snaking connecting tube.
- Scratched protector of universal cord.

Customer provided information on reprocessing of the scope. The scope was cleaned, disinfected, and sterilized before requesting repair. When the foreign material adhered to the scope is not known. No delay in the start of pre-cleaning, which was done properly. The water was aspirated through the instrument/suction channel. Information on manual cleaning: there were no abnormalities in the accessories used for reprocessing. The instrument channel outlet was wiped/brushed with clean lint-free gauze, brush, or sponge.

The user's complaint of no image is confirmed, and the evaluation is ongoing. Supplemental report(s) will be submitted when any relevant new information is available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16463649&pc=FAJ

8.25 Endoscope Support Specialist (ESS) observed during an in-service staff were not conducting pre-cleaning steps at the end of the case, March 2023

A report in the FDA **MAUDE** database states the endoscope specialist (ESS) completed a repair reduction observation at the site along with facility summary review. In-service included repair reduction information, tips, techniques, and cost. During observation, facility staff were found not performing any of the pre-cleaning steps at the end of the case using Uretero-Reno Fiberscope URF-P7R. Staff were observed doing leak testing steps out of sequence in the sterile processing department.

This report is being submitted because of an incorrect reprocessing procedure performed by the site. There was no patient involvement. Staff were in-serviced on proper pre-cleaning and leak testing steps (found in the Olympus manual). The scope will not be returned.

The investigation is ongoing. A supplemental report will be submitted on completion of investigation or if any additional information is available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16577055&pc=FGB

8.26 Red staining/bioburden found in the biopsy channel of the bronchovideoscope, a chipped distal end plastic cover, and a failed insulation test discovered during reprocessing, March 2023

A report in the FDA **MAUDE** database states that the customer reported to Olympus, there was red staining/bioburden found in the biopsy channel of the EVIS Exera II Bronchovideoscope BF-1T180 during reprocessing. There were no reports of patient harm associated with this event.

The scope was returned to Olympus for evaluation and the customer's allegation was confirmed.

- There was a stain at the bending section of the forceps passage/channel.
- The distal end plastic cover was chipped.
- There was a hold in the insertion tube that caused the insertion tube insulation test to fail.

The investigation is ongoing and follow-up with the user facility is currently being performed. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16616199&pc=EOQ

8.27 The operation channel was clogged on the gastroscope due to insufficient reprocessing, January 2023

A report in the FDA **MAUDE** database states that the returned Pentax Video Gastroscope EG29-I10 confirmed the operation channel was stuck/clogged with accessory/object. MDR was submitted based on evaluation. We concluded that it was caused due to insufficient reprocessing at the facility on the operation channel. In addition, we confirmed that the a) light guide cable buckled, b) suction channel buckled, c) bending rubber was cut, d) light guide fiber bundle was defective, and e) segment was hard to move. Those are not the main causes, and/or irrelevant to the alleged complaint. The time of the event is unknown. There is no report of patient harm.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16135561&pc=FDS

8.28 Foreign material was found on the forceps elevator during an inspection and testing, January 2023

A report in the FDA **MAUDE** database states during inspection and testing, foreign material was found on the forceps elevator of the EVIS Exera II Duodenovideoscope TJF-Q180V due to insufficient cleaning. Also found:

- A leak due to a scratch on the distal end.
- The distal end was shaved due to handling.
- There was corrosion around the lever arm.

The scope was sent to an Olympus service center for annual inspection with no complaint. During the inspection and testing, foreign material was found on the forceps elevator. This report is being submitted for the malfunction found during evaluation (foreign material). There was no harm or user injury reported due to the event.
The investigation is ongoing, the root cause cannot be determined at this time. If additional information becomes available this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16264084&pc=FDT

8.29 An ESS identified reprocessing steps for the OER cysto-nephro fiberscope were not being followed based on the reprocessing manual, January 2023

A report in the FDA **MAUDE** database states an Endoscopy support specialist (ESS) identified that the reprocessing steps for the OES Cysto-nephro fiberscope Flexible Fiberoptic Cysto-nephroscope CYF-5R were not followed based on the reprocessing manual. The customer was not performing a wet leak and failed to manually clean using a detergent solution prior to manual high-level disinfection (HLD). Furthermore, the customer was not storing scopes in a bin or sterile area before or after the patient procedure. The ESS demonstrated proper reprocessing step from precleaning at bedside through manual HLD. In addition, the ESS recommended for the customer to perform a wet leak test in a bin or sink large enough for the scope to be completely immersed in water.
The investigation is ongoing; therefore, the root cause of the reported event cannot be determined at this time. If additional information becomes available, this report will be supplemented accordingly. An ESS reported incorrect reprocessing of the OES Cystonephrofiberscope during a facility summary review observation. There was no patient involvement, no harm or user injury reported due to the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16124811&pc=FAJ

9. Endoscope contamination/outbreaks

9.1 The same gastrointestinal videoscope was used on six patients, which they all developed CRE after their procedures due to a scratch on the scope harboring bacteria, September 2023

A report in the FDA **MAUDE** database states a customer reported that multiple patients developed carbapenem-resistance enterobacterial (*Enterobacteriaceae*) infections which may have been related to the use of an EVIS Lucera Gastrointestinal Videoscope GIF-XP260NS. The customer initially reported that the scope was not tested for bacteria: however, the user thinks that bacteria entered the scope via a scratch on the scope. The therapeutic ileus tube procedures were completed with the same scope. The scope is usually cleaned and disinfected with ENDOCLENS™ Neo-S Advanced™.

The patients with the confirmed infections were initially reported to have had surgery on the same day, were placed in ICU beds next to each other, and were examined with the same endoscope.

Olympus received further information clarifying that there were six (6) patients who were suspected of to be infected by the scope.

- Patient 1 underwent an in-patient procedure using the scope in 2023
- Patient 2 in 2023, it was unknown if it was an inpatient or outpatient procedure
- Patient 3 as inpatient
- Patients 4, 5, and 6, it was unknown if they were inpatient or outpatient procedures.

The customer also indicated that the endoscope/accessories were cultured; however, the results have not been provided at this time. The scope was reportedly quarantined after the infection was confirmed. There have been no deviations/deficiencies/concerns in reprocessing. Additional information has been requested but no further information was provided at this time. This event requires 7 reports.

The scope referenced in this report has been returned to Olympus for evaluation. The physical evaluation has not been completed. The customer provided the cleaning, disinfection, and sterilization process stating:

1. Precleaning was performed immediately after the procedure
2. Water was aspirated through the instrument/suction channel with a suction pump. The air/water and balloon channels were flushed with water and air by using MH-948: air/water channel cleaning adapter.
3. The scope passed the leak test.
4. During manual cleaning, the detergent used was Power Quick Enzyme Cleaner.
5. The instrument/suction channel, suction cylinder, and instrument channel port were brushed.
6. The AER used was ENDOCLENS™ Neo-S Advanced™ with Endot EndoPure® detergent and disOPA™ disinfectant.
    a. Expiration date of the disinfectant was controlled.

b. Disinfectant met the minimum effective concentration.

7. All water channels were connected with cleaning tubes when the endoscope was setting up into the AER.
8. The water quality was controlled. (Note: It was not known if the filter was replaced periodically in accordance with the IFU.
9. The scope was dried by drying process of AER and stored in a drying cabinet.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18188353&pc=FDS

9.2 The same cysto-nephro videoscope was used in several patient diagnostic procedures--afterward, patients had burning with urination, November 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus that several patients had burning with urination after the Cysto-Nephro Videoscope CYF-V2 was used in diagnostic cystoscopy procedures. Results from urine cultures were not available at the time of this report. Aldahol® was used to clean the scope. The customer performed extensive cleaning and reported seeing pink fluid come out of the scope and forceps irrigation plug.

Additional details have been requested regarding the reported event. No more information has been provided. This event is under investigation. A supplemental report will be submitted upon receiving additional information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18098780&pc=FAJ

9.3 Two patients developed an infection from EBUS procedures with the same scope and were hospitalized for 10 days after, November 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus the EVIS Exera II Ultrasonic Bronchofibervideoscope BF-UC180F results were positive to microbiological testing. Additionally, Olympus received information from the customer indicating that two (2) patients had developed an infection after this scope was used in 2023.

Procedure?	**Symptom(s)?**	**Treated With?**	being **Discharged?**
Outpatient endobronchial ultrasound (EBUS) procedure,	Fever for ≈ 10 days post-procedure.	Bactrim, linezolid, tazobactam, and piperacillin.	After 10 days.

The scope was reportedly quarantined without being used after the patient infection was confirmed. The physician performed some bibliographic analysis regarding this tissue and found that the cause may be in small lesions of the biopsy channel or the instrument terminal. There was no further harm or user injury reported due to the event.

The scope has not yet been returned to Olympus for evaluation for physical evaluation. Before the evaluation, the scope was sent out for more microbiological testing and the microbiological analysis results are pending.

The investigation is ongoing and follow-up with the user facility is currently performed. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18165341&pc=PSV

9.4 The same duodenovideoscope was used on two (2) patients that immediately developed an *Enterobacter* bacterial infection after their procedures, October 2023

1. A report in the FDA **MAUDE** database states the customer reported two (2) patients were infected with an *Enterobacter* bacterial infection in their facility.

This report is for the first patient. (report 1 of 2).

The nurse manager reported a 25-year-old male patient was infected with *Enterobacter* bacterial infection after a procedure with an EVIS Exera III Duodenovideoscope TJF-Q190V.

- Height: 5 feet 9 inches (1.752 m)
- Weight: 190.98 lb (86.63 kg)
- History of gallstones (choledocholithiasis)

It was originally reported that the scope was due for annual preventive maintenance/inspection. Reportedly the patient had a fever starting one day after the procedure, was put on antibiotics, and blood cultures were collected. The patient was discharged to home post-hospital stay.

The reprocessor has not been cultured for a possible source of infection. The Resi-Tests™ were completed, and the results were negative. Reportedly no endoscopes were reprocessed incorrectly.

The scope was returned to Olympus for evaluation. Upon inspection, it was found that a) The rubber glue had a crack, b) adhesive on the control body was dry, c) objective lens glue was peeling, d) light guide lens glue was peeling, e) control knob movement-angle play was low, and f) the biopsy channel was leaking near the distal end. The scope was repaired and returned to the customer.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation. (report 1 of 2).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18021776&pc=FDT

2. This report is for the second patient. (report 2 of 2). The nurse manager reported that a patient developed *Enterobacter* bacterial infection after using a scope for Choledocholithiasis. The facility first requested preventive maintenance and later stated an infection was discovered after the procedure. The procedure itself was unremarkable and no complications occurred.

The patient presented with a fever the same day as the procedure. Blood cultures were drawn that day, as well. The patient was treated with antibiotics and was "eventually," discharged home.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=18021564&pc=FDT

9.5 During the reprocessing of the fiberscope, the scope tested positive for *Moraxella osloensis* and *Micrococcus luteus*, October 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, during reprocessing, the Uretero-Reno Fiberscope URF-P6 tested positive in 2023 for two (2) CFUs of *Moraxella osloensis* and Micrococcus luteus, all channels were sampled.

The scope tested positive once more on September 13, 2023, for 1-CFU of *Micrococcus luteus*, all channels were sampled. The user did not report any contamination or any other serious deterioration in the state of health of any person to which the scope could have been a contributory cause.

The scope has not yet been returned to Olympus for evaluation; therefore, the physical evaluation has not been completed. (Prior to the evaluation,) the scope was sent out for additional microbiological testing and the microbiological analysis results are pending.

The investigation is ongoing and follow-up with user facility is currently being performed. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17932850&pc=FGB

9.6 The same bronchofibervideoscope was used on all four patients, and three patients tested positive for *Klebsiella oxytoca*, October 2023

A report in the FDA **MAUDE** database states an Olympus representative reported on behalf of the customer that the EVIS Lucera Ultrasonic Bronchofibrevideoscope BF-UC260FW was used on a patient (patient 1), who was subsequently found to be positive for *Klebsiella oxytoca* infection (through samples of flushed fluid from the patient). The scope was reprocessed as usual and used on a second patient (patient 2) the following day. Patient two was also found to be

positive for *Klebsiella oxytoca* infection. The scope was used on a third patient (patient 3) seven days after patient two, who then became positive for *Streptococcus*. The patient did not have *Klebsiella oxytoca*. The following day, the scope was then used on a fourth patient (patient 4), who was also found to be positive for *Klebsiella oxytoca* infection.

The staff then liaised with infection prevention and a microbiologist and took the scope out of use. The customer indicated that although the scope was working, they are concerned that there was something with the scope leading it to be susceptible to harboring *Klebsiella oxytoca* despite reprocessing. The customer was advised to send the scope for repair to Olympus and the incident will be investigated.

The customer has also reviewed patients on whom that scope was used prior to patient one, and none where positive for *Klebsiella oxytoca*, so it was later received from the customer. Patients one, two and four all had an endobronchial ultrasound (EBUS) to check for malignancy.

Patient	Infection?	Hospitalized?	Treatment?
1	*Klebsiella oxytoca*	No	• EBUS to check for malignancy. • No symptoms. • Received antibiotics.
2	*Klebsiella oxytoca*	No	• EBUS to check for malignancy • No symptoms. • Received antibiotics.
3	*Streptococcus* (did not have *Klebsiella oxytoca)*	Unknown	• EBUS under general anesthesia. • Referred by another facility with query of sarcoid after finding enlarged lymph nodes on imaging: (patient has severe asthma on biologics). • Referrer was informed of the growth and sensitivities, so it was presumed antibodies were sorted locally. • No further clinical information available.
4	*Klebsiella oxytoca*	No	• EBUS to check for malignancy. No symptoms. • Received antibiotics

(*Note: One of the three patients with Klebsiella was being managed by another facility, and the other two were progressing from a malignancy symptom point-of-view and are under palliative care and oncology*.)

The customer also reported that the samples that were sent from the scope came back negative—no fault was found on the scope after service. The customer would be happy to put the scope back into circulation after risk assessment. There was no further patient impact reported.

The scope has not yet been returned to Olympus for evaluation and the investigation is ongoing. The user facility confirmed that samples sent from the scope came back negative. The user facility provided their cleaning, disinfection, and sterilization process stating that precleaning was performed immediately after patient procedure.

1. Water was aspirated through the instrument/suction channel with a suction pump and the air/water channel was flushed with water and air by using an Olympus® MH-948.
2. Revital-Ox® beside side complete:
    a. 215 mL enzymatic detergent was used in preclean 'beside clean'.
    b. If manual cleaning was not performed within one-hour, presoaking was performed. (Note: The detergent used for manual cleaning was Serchem Neutra-Scope-A.F.)
3. The scope passed the leak test.
4. The following instrument/suction channel, suction cylinder, instrument channel port, and balloon channel were brushed.
5. The AER used is Getinge Ed-Flow with Getinge DLC/Poka Yoke DLC detergent and Getinge Aperlan Poka Yoke Agent A and Agent B disinfectant.
6. All channels were connected with tubes when the endoscope was set up, not the AER.

The concentration and expiration of the disinfectant was controlled. The water quality was filtered water, and the filter was replaced periodically in accordance with the instructions for use (IFU).

One scope was used straight to the patient and dried with sterile gauze while others were placed in a drying cabinet. The scope was stored in a drying cabinet.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17936811&pc=PSV

9.7 Mold was found in the Bronchofibervideoscope causing two patients to develop the same type of fungal infection after their procedures, October 2023

A report in the FDA **MAUDE** database states two (2) patients developed a fungal infection, and their specimens grew the same type of mold. The same EVIS Exer III Bronchofibervideoscope BF-MP190F was used on both patients, and the customer sent in the scope for testing to see if it was the scope that was causing this. The scope was not sampled and cultured.

The customer provided their facility's cleaning, disinfection, and sterilization process.

- The cleaning disinfectant solutions used with the endoscope are STERIS® Prolystica. The minimum effective concentration is being checked with every use of disinfection of the scope.
- The AER being used to reprocess the scope is an ASP Sterrad® 100nx.

- The scope is being brushed with an Olympus single-use brush during manual cleaning. (Note: The model numbers of the brushes being used are BW41D, BW18V.)
- Pre-cleaning is performed by the endo staff immediately after the procedure.
- The endoscope is being leak tested prior to manual cleaning. (Note: The model and manufacturer of the leak tester is an Olympus® MU-1.

There have not been any problems noted with the AER. The date of the last reprocessing in-service conducted by an Olympus endoscopy support specialist (ESS) was on May 18, 2023. There has been a change in the facility's reprocessing personnel since the last on-site visit by an Olympus ESS. All reprocessing personnel are trained in how to properly reprocess an endoscope. The endoscope is being stored in a cabinet.

The scope was returned to Olympus; however, evaluation has not yet begun.

The investigation is ongoing. Additional information is requested. A supplemental report will be submitted upon completion of the investigation. This report has been submitted by the importer under this MDR report number 2429304-2023-00318.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17876790&pc=EOQ

9.8 After bronchoscopy cases, multiple patients' specimens tested positive for *penicillium* species due to deviations with reprocessing bronchoscopes, September 2023

A report in the FDA **MAUDE** database states the customer requested reprocessing in-service due to issues with the EVIS Exera III Bronchovideoscope BF-H190 reprocessing and stated they have had multiple instances where patient specimens tested positive for *penicillium* species after bronchoscopy cases. The endoscopy support specialist (ESS) performed reprocessing observations at the facility and noted deviations to instructions for use (IFU) reprocessing instructions.

During manual cleaning, it was noted that the scopes were flushed with detergent solution instead of aspirating. After manual cleaning and rinsing, the scopes were placed in OER-Pro reprocessor for reprocessing.

The ESS was on-site for observation of bedside cleaning with respiratory staff. During observations, the ESS noticed that endobronchial ultrasound (EBUS) 180 scopes were not having the irrigation channel flushed with detergent, and the same pre-cleaning sponge and detergent mixture was being used on bronchoscope and EBUS 180 scope used during procedure of the same patient.

The ESS completed a reprocessing in-service to correct deviations and provided the customer with scope cleaning wall charts. The customer stated that they will send in all bronchovidescopes and EBUS 180 scopes to Olympus service center for scope evaluations for damage.

The scope was not returned.

Based on the results of the investigation, the root cause of the incorrect reprocessing was that the user's understanding differed from Olympus recommendation in device handling and/or reprocessing steps. Retraining for the correct handling was completed. Olympus will continue to monitor field performance for this scope.

This report is being submitted to capture the incorrect reprocessing procedure followed by the site.

There were no reports of patient harm associated with the event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17669848&pc=EOQ

9.9 It is unknown if the gastrointestinal videoscopes were used for a procedure after testing positive for microbial contamination when an unknown number of patients exhibited fever and chill after an endoscopy exam, August 2023

A report in the FDA **MAUDE** database states the Olympus representative reported on behalf of the customer that an unknown number of patients exhibited fever and chills after undergoing an endoscopy exam. Although no patient infections were reported or confirmed, Gastrointestinal Videoscopes GIF-H170 had tested positive for unspecified microbial contamination. It is unknown if the scopes were used for a procedure after testing positive.

This medical device report (MDR) is being submitted to capture the reportable malfunction of microbial contamination on the scope. Related patient identifiers—this event requires six (6) MedWatches to reflect the unknown number of patients associated with the microbial contamination of the scopes (three patients per affected scope).

The scope is not expected to be returned to Olympus for evaluation and analysis. The customer provided the cleaning, disinfection, and sterilization (CDS) processes performed onsite at the user facility. According to the customer, all precleaning and disinfection were performed step by step and correctly. The scope underwent ETO sterilization. The scopes were last reprocessed the day before the exam. Precleaning was performed immediately at the end of the exam. Water was aspirated through the instrument/suction channel with a suction pump. There were no abnormalities with the reprocessing accessories. Manual cleaning was performed after precleaning. The leak test was performed on the AER and detergent enzymatic Indazyme 6 St. Renylab was used. Any area of the scope that can be brushed is brushed, and those areas that it is not possible to brush are injected with enzyme solution, water, and then dried.

The user facility underwent a reprocessing in-service a couple of months ago, which had been conducted by Olympus. There have been no changes in the facilities reprocessing personnel since the last reprocessing in-service. It was reported that one of the technicians did not continue with the training.

The scopes are stored in their own air-conditioned cabinet, in an upright position with the connectors facing up. It is unknown if all the channels were connected to tubes when connected

to the automated processing machine. The field service engineer (FSE) verified that in the clinic (there was no contact with the enzymatic) the cleaning valve was not used. This is the equipment they already had.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation or if additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17511155&pc=FDS

9.10 *P. aeruginosa* was detected in three patients' bile after testing the duodenovideoscope, the same scope was used on all three patients, July 2023

A report in the FDA **MAUDE** database states Olympus employee reported on behalf on the customer that *Pseudomonas aeruginosa* was detected in the bile of three (3) patients after testing the EVIS Lucera Elite Duodenovideoscope TJF-Q290V.

Reportedly, similar events happened in the past. It is unknown if the same scope had a causal relationship for the infection that occurred in the past since the endoscope equipment culture test has not been performed. Reportedly, bedside washing was not performed according to the procedure. All 3 patients are reported to be stable. Additional follow-up has been requested for and the number of similar events in the past; however, no information has been received as of this report.

The scope referenced in this report was not returned to Olympus for evaluation. The root cause cannot be determined at this time and the investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17346979&pc=FDT

9.11 Post-cystoscopy procedures, four (4) patients developed urinary tract infections, the customer was leaving the scopes overnight in a container before reprocessing, July 2023

A report in the FDA **MAUDE** database states in the customer report to Olympus that four (4) patients had urinary tract infections post-cystoscopy cases using Cystonephrofiberscope CYF-5. The provider was concerned that the scopes were not being reprocessed correctly before patient use.

As reported, the customer had been leaving scopes overnight in a container before reprocessing. A leak had been identified in one scope that was used on 3 out of 4 infected patients. The scopes have not been tested for microbial contamination. The patients had body fluid cultured and presented symptoms of fever, nausea, and pain.

There were no reports of further patient or user harm associated with this event.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17414378&pc=FAJ

9.12 Three (3) patients may have been exposed during an endoscopy procedure with a gastrointestinal endoscope that was confirmed to test positive for *Enterobacter cloacae*, June 2023

A report in the FDA **MAUDE** database states Olympus received information that this Gastrointestinal Videoscope GIF-H190 had processing defects and confirmed *Enterobacter cloacae* (*E.cloacae*) contamination. The customer did viral analysis for patients having undergone endoscopy procedures between the last conform sample and the date of sequestration.

As reported, three (3) patients have undergone endoscopy procedures with this non-conform scope and a patient recall is in progress. The customer's opinion about the cause of the issue is processing fault and the age of the scope.

Additional information has been requested. To date, the scope has not been returned for evaluation. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17224414&pc=FDS

9.13 The same gastrointestinal videoscope was used on four (4) patients and they tested positive for bacteria (*E. coli*) after colonoscopy procedures, and one (1)-patient died of general decline, June 2023

A report in the FDA **MAUDE** database states the customer initially reported the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190 tested positive for bacteria and is requesting all channels to be replaced and that four (4) patients tested positive for *Escherichia coli (E. coli)* extended spectrum beta-lactamase (ESBL). It was reported that the customer was using a gastroscope for colonoscopy.

Patient 1 of 4 had an endoscopy procedure with the scope in 2023. The patient's urine sample was cultured in 2023 and tested positive for microbial contamination. The patient's blood and urine were cultured and tested positive for microbial contamination. The patient had urinary tract infection followed by sepsis, with a working diagnosis of urosepsis, and was treated with *ceftriaxone* in 2023, switched first to *tobramycin* and then to *meropenem* in 2023. The customer reported there was no hospitalization. The patient was discharged to a nursing in 2023 where he recovered from the infection, but delirium continued. It is unknown if the patient had delirium prior to the procedure. The patient dies a few days later and the facility believes it was a result of general decline. The facility reported the patient had multiple cultures of his throat, rectum, and urine in 2022 and the results were negative. The customer reported there was no epidemiological relationship with the other three (3) patients and the only connection was the same endoscope.

The customer stated a contact investigation was started for GIF-HQ190 due to patient 1's urine and blood testing positive for *E. Coli* ESBL, and which emerged from the urine and blood cultures approximately one and a half weeks following the procedure with the scope in 2023. The customer reported the DNA profile of the bacteria looked very much ("very close relationship") to three (3) other patient's DNA profiles from 2022. Epidemiological research showed that the only common factor in these four (4) patients is this endoscope.

After consulting with physicians, the facility sent culture kits to 10 patients who had procedures with the same endoscope in 2023 to find out whether more patients are positive. The facility determined to test eight (8) in two weeks prior in 2023 and two (2) patients after in 2023. The results are pending. The endoscope was used twice after patient 1 and the patients are being tested. After being used twice and identifying a link between the four (4) patients, the endoscope was quarantined.

In 2023, the endoscope was viewed with a "SpyScope", and the last part of the canal was identified as damaged. The canal was cultured with negative findings. The customer clarified that there was no culture result but that it concerns a patient with an invasive infection with an *E. coli* ESBL (ST131, CTX-M27 with a co-resistance to *ciprofloxacin* and *cotrimoxazole*). The facility takes samples of every patient after every treatment in the hospital as well as doing DNA tests of all samples; hence, this data was found. Additional information is being requested on the details surrounding patient 1's death as well as the status and any treatment given for patients 2, 3 and 4.

The event date is estimated to be in 2022 since the three other patients with similar isolates were also scoped in 2022. The endoscope has not been returned to Olympus. The customer provided the cleaning, disinfection, and sterilization process. Precleaning was performed immediately after the patient procedure. Water was aspirated through the instrument/suction channel with a suction pump. The endoscope passed the leak test. The instrument/suction channel port were brushed. The AER used was WASSENBURG®. There were no defects noted on the AER. The AER detergent was Neodisher® Mediclean Forte, and the AER disinfectant was Neodisher® Septo. All the channels were connected with tubes when the endoscope was set up into the AER. It was unknown if the concentration of and expiration date of the disinfectant was controlled. The water quality of the rinse water was controlled. The water filter was replaced periodically in accordance with the IFU. The endoscope was dried using a drying cabinet or used wet on a patient within 4 hours. It was stored in a drying cabinet.

The endoscope was sent out for additional microbiological testing. The hygiene microbiological investigation report indicated the channels of the scope were cultured with negative results. In addition, there was damage at the distal end of the suction channel, which was also cultured and was negative.

The investigation is ongoing, and a supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=17044116&pc=FDS

9.14 Two gastrointestinal scopes were used on multiple patients and confirmed to have *NDM E. coli*, May 2023

A report in the FDA **MAUDE** database states Olympus received a voluntary MedWatch report regarding the EVIS Exera III Gastrointestinal Videoscope GIF-HQ190, stating the user facility had been notified by the state of an *E. coli* patient that was housed inpatient.

Upon notification, the user facility began a chart review to determine possible causes. During said chart review, it was found that two scopes confirmed to have *NDM E. coli* were used on multiple patients. Both scopes have been sequestered for examinations.

The facility has been contacted multiple times to clarify the event and patients, but no response has been received. Six (6) MDRs are required for this event, as multiple scopes and multiple patients were involved.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16964300&pc=FDS

9.15 A duodenoscope was the cause of eleven (11) patients becoming infected with *Pseudomonas aeruginosa* 4-MRGN VIM positive, May 2023

A report in the FDA **MAUDE** database states a user facility reported to Olympus that there was a concern for infection on the repair request. Upon follow-up, it was stated that 11 patients at the facility were infected with *Pseudomonas aeruginosa* 4-MRGN VIM positive. The facility did not have any specifics regarding the patient's and when the procedures occurred, or any other infection details. It was only stated that all 11 patients had procedures in 2022 with the last detection of the microorganism in March 2023. It was stated that it became clear to the facility in 2023 the EVIS Exera II Duodenovideoscope TJF-Q180V was the cause of infection.

The entire cleaning process had been reviewed by local regulatory authorities, including the cleaning machines, and it was found that the reprocessing was adequate. The following outcomes were reported:

- Three (3) of the 11 patients have since died. (The facility has clearly communicated that the infection was not the cause of death, but rather their pre-existing conditions.)
- Eight (8) of the 11 patients are "doing well."
- One of these 8 patients was placed on the liver transplant list after the infection. (The facility refused to clarify if it was directly due to the infection or not.)

D1. The customer was unable to provide the model and serial number for the scope involved. A representative product code and legal manufacturer was selected based on related complaints. The scope referenced in this report was not returned to Olympus for evaluation. The root cause cannot be determined at this time.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16996540&pc=FDT

9.16 Eighteen (18) children were exposed to the bronchoscope and twelve (12) children tested positive for *Pseudomonas aeruginosa* infection in 2023, May 2023

A report in the FDA **MAUDE** database states PENTAX Medical received a report from the French national agency for medications and health products safety (ANSM) about patient risk through a contaminated PENTAX Medical bronchoscope EB11-J10 during use within the EMEA region. Event description from the complaint notification form: "transmission of *Pseudomonas aeruginosa* to patients from the endoscope. Endoscope contaminated during fibroscopy in a child with cysticovicidosis." It is clearly stated out in the ANSM report that the death of the patient is not related to the infectious complication The date of the reported death has not been provided and remains unknown. This event occurred at the time of during use. This event meets the requirement for FDA reportability; however, submission of this report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event.

In 2023 the affected bronchoscope was sent for repair to the PENTAX medical service center. The bronchoscope was returned from repair. It was sampled and microbiologically examined—there was zero (0) CFU and returned to the user facility.

- There was a total of 18 child patients exposed to the PENTAX medical bronchoscope since that last monitoring in 2023.
- There was a total of 12 children who tested positive for *Pseudomonas aeruginosa* infection in 2023.
    - Antibiotics were given to the patients who tested positive following the results, and none of the patients returned for infections complications.
    - The patients will be seen by a pulmonologist with a control ECBC.
- There was one (1)-patient unrelated death and was clearly stated the death was not related to the infectious complication, and there is no causal relationship between the scope and death of the patient.

After receiving the notification of these cases from the ANSM, the bronchoscope was requested by PENTAX Medical from the hospital to carry out further examinations in our service center. The sampling for *Pseudomonas aeruginosa* outcome after receiving the endoscope back from the hospital in 2023 was:

Bronchoscope Location	**# of CFUs per 100 mL**
Endoscope	> 80
Instrument Channel	5
Suction Channel	> 200

(Note: 80 CFU is an alert level.)

We contacted the hospital to provide us with information about how they perform their re-processing of the bronchoscope EB11-J10.

- Used cleaning brush: we found that the hospital uses another cleaning brush, EBI-1215 (manufactured by LTA Medical), instead of the recommended cleaning brush CS-C11A. EBI-1215 does not completely fill the whole diameter of the suction channel; thus, parts of the inside channel wall can be missed resulting in not completely removing debris.
- Drying the bronchoscope after re-processing: we were informed that the hospital manually dries the endoscope (with pressurized medical air), neither using a drying cabinet nor a drying/storage cabinet. By this means it cannot be assured that all channels are dry before entering the bronchoscope into the Surestore System. If channels of the bronchoscope are not completely dry, biofilm can form and grow.
- In the hospital, the reprocessing of bronchoscope is almost systematically done in AER (after cleaning and rinsing step) at the centralized endoscope disinfection service or at the endoscope disinfection room located in the operating room. Manual maintenance of bronchoscopes can be done very punctually in the hospital when there is an AER failure, for example.
- Use of detergent and disinfectant: although the used detergent and disinfectant are not listed on our material compatibility list for chemicals and our endoscopes, this is only related to material compatibility and not microbiological compatibility.

Investigation is in-process. If additional information becomes available, a supplementary report will be filed with the new information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16981873&pc=EOQ

9.17 Sixteen (16) patients tested positive after several bronchoscopes tested positive for *Sarocladium* during routine culture testing, May 2023

A report in the FDA **MAUDE** database states the customer reported to Olympus, the EVIS Exera Bronchovideoscope Bronch BF-UC180F wash tested positive for *Sarocladium* during a routine culture of the scope. The sampling was taken at reprocessing, before use. Additional information received indicated there were 16 patients with positive culture results between March 20, 2018, and February 25, 2022. None of the patients were treated for this organism.

The events were discovered with the culture results as identified for the patient. The user facility provided additional information regarding the cleaning, disinfection, and the sterilization processes performed onsite for the endoscopes.

According to the customer, the scope was reprocessed after every use with no delay, and water was aspirated through the instrument/suction channel with a suction pump. No abnormalities were found with the reprocessing accessories and the scope passed leak testing.

Manual cleaning was also performed 1-hour after the procedure and the scope instrument/suction/balloon channel, air/water/suction/biopsy valve were brushed, and pure (Boston Scientific) detergent solution was used.

For automated endoscope reprocessor (AER) treatment, the Medivators reprocessor (along with Intercept™ PLUS detergent and Rapacide™ PA disinfectant) were used. The reprocessor and the scope were not tested.

As part of their own investigation, the facility invited state surveyors to come and investigate their processes, which did not draw any definitive conclusions as to the cause of these positive cultures. The customer decided to send one scope to Olympus BF-Q190. Depending on the findings, the facility will discuss and decide on the need to send the additional scopes in for investigation. The scope was sent to Nelson Lab by Olympus for independent culture testing. The customer reported that the last reprocessing in-service conducted by an Olympus endoscopy support specialist (ESS) was 2022. An Olympus ESS visit was scheduled for a future date to observe the user facility's reprocessing practices from start to finish and provide reprocessing in-service training.

The investigation is ongoing. If additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16970212&pc=PSV

9.18 *Providencia Rettgeri bacterium* was detected in thirteen (13) patients from a bronchoscope used for bronchoscopy procedures, March 2023

A report in the FDA **MAUDE** database states that the customer reported to Olympus that the *Providencia Rettgeti bacterium* had been detected in 13 patients that this EVIS Exera II Bronchovideoscope BF-1T180 had been used from October 2022 to January 2023. The only link between these patients was the use of the bronchoscope for a bronchoscopy procedure.

Samples were collected from the patients through bronchoaspiration. Biosafety samples performed on the endoscope were negative. However, the customer suspected that the bacterium must be lurking inside, probably in the form of biofilm. Hence, a thorough study of the endoscope was requested to assess whether there were microtears inside it where it could have been deposited. The patients did not have any signs or symptoms of infection, did not require treatment or hospitalization, and are currently in a good state of health.

The scope was returned to Olympus and an initial scope inspection was performed. The device evaluation indicated that foreign material was flushed out when the channels were flushed. Additional findings included a) a gap between the distal end cap and distal end in the biopsy channel outlet, b) deposits between the distal end cap and distal end, c) deformed universal cord, d) broken inner mechanics, e) corroded guide pins and contacts on the plug unit, f)

deformed/scratched/damaged handle shell, and g) a biopsy channel that was damaged several times over the entire length (chip formation).

Prior to the scope evaluation, the scope was sent out for additional microbiological testing. The hygiene microbiological investigation report indicated the channels of the scope were cultured and the following bacteria were **not** detected: *E. coli* and other *Enterobacteriaceae*, *Enterococci*, *Pseudomonas aeruginosa* and other non-fermenter, *Staphylococcus aureus* and other hygiene-relevant bacteria, "greening" *Streptococci (viridans)*, and germ differentiation.

The customer provided the cleaning, disinfection, and sterilization process. A pre-cleaning to manual cleaning took less than 30 minutes. The manual detergent was Neodisher® MultiZym and the manual disinfectant was peracetic acid. There was no defect noted in the reprocessing accessories.

The scope was leak tested and performed in accordance with the instructions for use (IFU). The instrument/suction channel and instrument channel port were brushed. The detergent was aspirated through the instrument/suction channel. The air/water channel, instrument/suction channel, and auxiliary channel were flushed according to the IFU. The scope was appropriately rinsed before manual disinfection and dried after rinsing.

The AER used was Soluscope Serie 4 PA. The AER detergent was Soluscope CLN, and the AER disinfectant was Soluscope PAA.

A simple cabinet is used for storage with a clear system established to avoid any mix up/cross contamination of contaminated and reprocessed endoscopes and accessories. The scope is stored 24 hours before the next procedure.

Olympus is the maintenance company. The cleaning, disinfection, and sterilization (CDS) was performed by the customer.

The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16535234&pc=EOQ

9.19 Several patients were infected after the same cysto-nephro videoscope was used, February 2023

A report in the FDA **MAUDE** database states a customer reported to Olympus that there were several [unspecified number of] patients who were infected after scoping with a Cysto-Nephro Videoscope CYF-VHR. One patient was reported to have been admitted.
Additional information was requested regarding this event. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or if additional information is received.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16437805&pc=FAJ

9.20 The hospital is unsure where or when two (2) patients were infected with a multi-drug resistant bacterium from the same bronchoscope from a bronchoscopy procedure, February 2023

A report in the FDA **MAUDE** database states a user facility reported to Olympus that there were two (2) patients that had undergone bronchoscopy with an OES Bronchofiberscope BF-P60 that was infected with a multi-drug resistant bacterium. The hospital was unsure where or when they were infected. The hospital was exploring all possible sources of infection; however, the hospital did not have a traceability system, there were no records of disinfections, and did not perform microbiological tests on the scope.
Olympus sent the scope for microbiological testing. The distal end unit was swabbed, and sampling solution was obtained from the biopsy/suction channel. There were no organisms detected in either sample. The scope was returned and evaluated.
The investigation is ongoing, and follow-up with the user facility is currently being performed. A supplemental report will be submitted upon completion of the investigation or if any additional information is provided by the user facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16400583&pc=EOQ

9.21 A routine culture of the colonovideoscope tested positive of *Enterobacter cloacae* with all channels sampled at reprocessing, January 2023

A report in the FDA **MAUDE** database states the EVIS Exera III Colonovideoscope CF-H190I tested positive for 36 colony forming units (CFUs) of *Enterobacter cloacae*. The issue was found during a routine culture of the scope. Sampling occurred at reprocessing and all channels were sampled. The user did not report any contamination or any other deterioration in the state of health of any person to which the scope could have been a contributory cause.
The Olympus scope was sent to an independent laboratory for culture testing. All channels were sampled. The scope tested positive for less than one (1)-CFU of unspecified microorganisms. The results obtained are in conformance with the requirements. The scope was evaluated by Olympus and found the bending section cover glue was worn out and separated.
Additional information has been requested regarding this event. The investigation is ongoing. A supplemental report will be submitted upon completion of the investigation or when additional information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16188890&pc=FDF

9.22 Dirt and string of blood was observed coming out of the tip of the scope and was immediately discontinued, January 2023

A report in the FDA **MAUDE** database states dirt was observed coming out from the tip of the scope GF-UCT260, string of blood was also observed. The use of the scope was immediately discontinued and was not used on another patient. According to the report, the scope was cleaned using an OER-5 (scope reprocessor machine) after its use on December 2, 2022. On the morning of December 6, 2022, the reported event occurred. There was no harm reported: No patient harm (no patient infection associated with this reported event) and no user injury reported as the result of the event.
The reported scope was used in combination with MAJ-1444 device (air/water valve unit). The MAJ-1444 was not returned for evaluation. In communication with the facility, it was conveyed that "… reprocessing properly implements brushing. . .." The scope was returned for evaluation and (a) supplemental report(s) will be submitted should any relevant new information is available. Investigation is ongoing.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16100704&pc=ODG

9.23 A potential exposure to patients of Hepatitis B and HIV at a facility where Olympus equipment was potentially used—where neither the chemical nor testing minimum concentration with two (2) OER-Pro machines were being changed, January 2023

A report in the FDA **MAUDE** database states an Olympus representative reported to Olympus that he saw a news report on TV of a potential exposure of Hepatitis B and HIV to patients at a facility where Olympus equipment was potentially used. A second Olympus representative reported an updated news report, which stated three (3) patients tested positive for infectious diseases at the same facility. There was one (1) patient tested positive for Hepatitis B and two (2) patients for HIV. It was also reported the customer was neither changing the chemical, testing minimum recommended concentration, nor using alcohol with two (2) OER-Pro machines. The Olympus representative for the facility reported they were reprocessing CYF-VH urology scopes in the OER.
There are no patient incidents reported. The hospital notice sent to patients was precautionary. To date, no patient harm has been reported to Olympus personnel. This medical device report (MDR) is being submitted to capture the potential infections that may have been caused by Olympus endoscopes reprocessed with either of the two (2) OER-Pros used at this facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=16142730&pc=FAJ

9.24 Patient's blood culture was identified with *Candida auris* after an upper GI endoscopy, December 2022

A report in the FDA **MAUDE** database states six (6) days after an upper GI endoscopy with per-tube placement (for nutritional support) using an EVIS Exera II Gastrointestinal Videoscope GIF-HQ190, *Candida auris* was identified in the patient's blood culture. The customer could not report how the infection was treated, as the patient had already been discharged home with hospice care due to underlying pathology/co-morbidities. The patient's current condition was

reported as “assumed death,” although this could not be verified by the customer and no date of death could be provided. The patient was not diagnosed with urosepsis on admission. It is unknown if the patient was colonized with an organism prior to the procedure. Routine testing for Candida is not currently being conducted at the facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15950831&pc=FDS

9.25 Patients that have undergone a procedure with a gastrointestinal videoscope were exposed to an outbreak of extended spectrum *Beta-lactamase*-resistant bacteria at the hospital, December 2022

A report in the FDA **MAUDE** database states the customer reports there was an outbreak of extended spectrum *Beta-lactamase*-resistant (ESBL) bacteria at the hospital in patients who underwent a procedure with a Gastrointestinal Videoscope GIF-XZ1200 (reprocessed with an AER)~~,~~ per the physician in the infectious diseases department of the facility. The physician requested information regarding endoscope reprocessing methods and culture test methods to investigate the cause of the outbreak. It is unknown at this time if the outbreak is related to the scope. The field safety engineer staff has explained the culture method and reprocessing method to the facility.
Currently (as of the time of this submitted report):

- No scope culture results are available.
- It is unknown how many patients are involved.
- It is unknown what treatment/intervention has been provided to the patients.
    - The patient’s current condition is unknown.
    - This information has been requested and not yet provided.

The scope was not returned to Olympus for evaluation. The definitive cause of the user’s experience cannot be determined at this time. The investigation is ongoing and will be updated upon completion or upon receipt of additional relevant information.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15998698&pc=FDS

9.26 A multi-resistant gram-negative *K. pneumoniae* was detected in the gastroscope causing an outbreak in four patients, December 2022

A report in the FDA **MAUDE** database states Olympus was informed about a hygiene issue and a multi-resistant germ found in an unidentified Olympus Gastroscope GIF-1100. The clinic has recently converted the entire endoscope park to Olympus. Reprocessing is done in a Getinge-RDG-E, which was newly purchased last year.
Currently, the clinic reportedly had an outbreak of four (4) multi-resistant gram negative (MRGN) *Klebsiella pneumoniae* with OXA 181 (emerging carbapenem-hydrolyzing oxacillinase). The customer had detected 80 CFU/10 ML of *K. pneumoniae* in the water channel of a new gastroscope as part of their endoscope check. The *carbapenemase* rapid test was positive for OXA 48. However, it may still turn out to be OXA 181 in the nitrate reductase

(NRZ). The customer further reported that they had this several times in the outbreak and this gastroscope was used on a patient, who was part of the outbreak. According to the clinic, there are frequent error messages in the RDG-E in which the gastroscope is prepared.
Since there was no specific model and serial number provided, it is unknown if the scope has already been returned to Olympus for evaluation or not. However, Olympus is communicating with the customer to obtain more clarifying information regarding the reported event. The cause of the report event cannot be conclusively determined at this time. This report will be updated accordingly when new and relevant information becomes available.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15925590&pc=FDS

9.27 After a bronchoscopy procedure two (2) patients tested positive with *Stenotrophmonas maltaphilia* from the same bronchoscope, December 2022

A report in the FDA **MAUDE** database states an Olympus Support Specialist (ESS) reported on behalf of the customer, that two exhibited an infection of the same organism after a bronchoscopy procedure. The customer was looking to test the EVIS Exera III Bronchovideoscope BF-1TH190 to ensure it was not transmitted by the scope.
This report is for the second patient. The bronchoscopy was performed in 2022. Prior to the procedure, the patient was presented to the emergency department in 2022, with shortness of breath and was diagnosed with pneumonia and chronic-obstructive pulmonary disease (COPD). After the bronchoscopy, the patient tested positive for *Stenotrophmonas maltaphilia*. The facility reviewed all bronchoscope procedures performed in 2022 and found 30 bronchoscopies were performed in that timeframe (with the scope in question, as well as all other scopes, were used), and no other patients had the reported organism.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15976325&pc=EOQ

9.28 Three (3) patients were infected with *P. aeruginosa* by the same bronchovideoscope for which the facility was unable to decontaminate using standardized scope cleaning processes, December 2022
A report in the FDA **MAUDE** database states the customer reported to Olympus, the EXIV Lucera Bronchovideoscope BF-260 used during bronchoalveolar lavage (BAL) procedures had been linked to infection status in multiple patients. Three (3) patients placed in the respiratory intermediate care unit (RICU) who had right ventricular hypertrophy (RVH) were identified to have isolated *P. aeruginosa*. The patient samples were all determined to be the same type and an outbreak was declared in 2022. It was confirmed that none of the 3 patients were nursed in the unit at the same time, however, all 3 patients had undergone bronchoscopy procedures, using the same bronchoscope. It was further reported, the bronchoscope contained material for which the facility was allegedly unable to decontaminate using the standardized scope cleaning processes. The bronchoscope had been quarantined by the critical care scientist staff and remains out of service. The bronchoscope was sent for 3rd party investigation to determine possible sources of continued contamination.

The bronchoscope was not returned to Olympus for evaluation. The customer provided their cleaning, disinfection, and sterilization process. It was reported in most cases they try and manually clean every scope within Three (3) hours of the procedure but in some cases, this is not possible. If this is the case, then nursing staff must place a damp cloth over the scope to keep damp until processing. The nursing staff preclean directly after patient use (bedside clean).
The customer has two (2) different AERs. At the Royal Victoria Hospital, they have three (3) ISIS machines manufactured by Cantel. In the City Hospital, they have eight (8) Wassenburg® machines manufactured by Wassenburg®. The endoscope is dried by using a non-lint cloth. After processing, the scope is either stored or hung in a drying cabinet.
The investigation is ongoing. If additional information becomes available, this report will be supplemented accordingly.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15988276&pc=EOQ