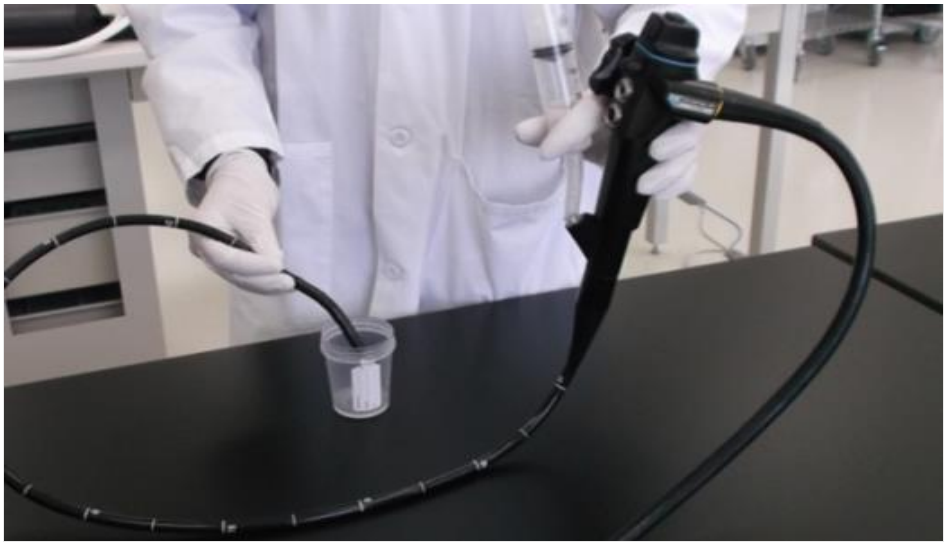
# Flexible Endoscope Incident Report

# April 2023

# Volume VI



# Table of Contents

7.8 A multi-resistant gram-negative *K. pneumoniae* was detected in the gastroscope causing an outbreak in four patients, December 2022

7.9 After a bronchoscopy procedure two (2) patients tested positive with *Stenotrophmonas maltaphilia* from the same bronchoscope, December 2022

7.10 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 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.

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**1.2 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.

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**1.3 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.

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**1.4 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.

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**1.5 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).

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**1.6 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.

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**1.7 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.

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**1.8 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.

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**1.9 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).

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**1.10 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

**1.11 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

**1.12 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.

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**1.13 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.

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## 2. Malfunction of Single-Use Scopes and Endcaps

**2.1 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.

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**2.2 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

**2.3 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

**2.4 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.

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**2.5 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

**2.6 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.

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**2.7 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

**2.8 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.

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## 3. Excessive Force with Equipment

**3.1 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

## 4. Failures Due to Reprocessing Equipment (AERs)

**4.1 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

**4.2 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

## 5. Endoscope Malfunction

**5.1 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

**5.2 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

## 6. Use Errors

**6.1 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 and 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

**6.2 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

**6.3 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

## 7. Endoscope contamination/outbreaks

**7.1 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

**7.2 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

**7.3 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

**7.4 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

**7.5 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

**7.6 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 conducted at the facility.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=15950831&pc=FDS

**7.7 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

**7.8 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

**7.9 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

**7.10 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