# ADVERSE EVENT REPORTS IN **ENDOSCOPE REPROCESSING**

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## ABSTRACT

Failures in endoscope reprocessing continue to be a high-risk for healthcare facilities. Missed steps, cross contamination, positive cultures, use error, and serious adverse patient events continue to be routinely reported. Many types of events can occur in facilities leading to adverse events and are classified as follows:

- Missed/abbreviated steps or not following the IFU or national standards (ST91)
- Use error
- AER malfunction
- Failure to visually inspect after cleaning and before use
- Failure to perform cleaning verification testing
- Microbial surveillance cultures positive
- Cross-contamination/Outbreaks


**EXAMPLES OF REPORTED REPROCESSING EVENTS WILL BE DISCUSSED TO DEMONSTRATE HOW TO RESEARCH AND FIND THESE TYPES OF TOPICS:**

## 1: FAILURE OF VISUAL INSPECTION

Endoscopes should be inspected after manual cleaning prior to disinfection or sterilization for residual debris and repair condition. If residual debris is found upon inspection, the endoscope should be completely manually cleaned again. If the endoscope is found to have repair issue, then it should not be used and should be sent out for inspection.

*Visual inspection using a borescope*

### A. EVENT – SEVERE PATIENT INJURY RESULTS FROM A FAILURE TO INSPECT PRIOR TO USE

Patient's ureter stuck to the scope and was avulsed during procedure, a Nephrectomy was performed, January 2019.

A report in the FDA's MAUDE database states that during a procedure the ureteroscope was placed into the ureter and advanced toward the kidney. During removal the ureter stuck to the scope and was avulsed. The ureter could not be repaired, and a Nephrectomy was performed. The scope's shaft was bent with approximately 60% broken light fibers.

*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8379098&pc=FGB*

**Implementing a step of Visual inspection with lighted magnification should have identified damage to the endoscope prior to use on the next patient.**

## 2: FAILURE TO FOLLOW NATIONAL STANDARDS AND PROFESSIONAL SOCIETY GUIDELINES FOR BEST PRACTICES IN ENDOSCOPE REPROCESSING

National Standards provide recommendations for endoscope reprocessing that are applicable to all healthcare settings. Professional society guidelines help to establish best practices for reprocessing flexible endoscopes. Manufacturer's IFUs outline the set of steps that at minimum must be followed with each reprocessing cycle. By not following the IFU, standards and recommendations outlined in these documents, the facility is put at risk for reprocessing failures.

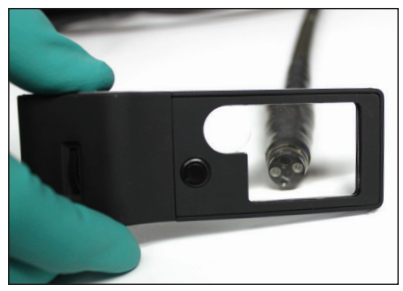
### A. EVENT - A FOREIGN MATERIAL FELL OUT OF THE SCOPE INTO THE PATIENT DURING A THERAPEUTIC COLONOSCOPY PROCEDURE, FEBRUARY 2019

A report in the FDA's MAUDE database states that during a colonoscopy procedure, foreign material fell out of the colonoscope. The material was retrieved with suction through the endoscope's channel and no unusual bleeding was observed with no additional intervention was required.

The device was returned to the manufacturer for evaluation. A borescope was used to perform a visual inspection on the scope and found a yellow discoloration inside the instrument channel. Kinks and scratch marks were found inside. The scope was leak tested and failed.

*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8313579&pc=FDF*

**Performing an inspection step and thorough leak testing per the IFU helps to prevent issues like this. Standards and professional guidelines recommend a visual inspection step with lighted magnification.**



*Above:* Handheld lighted magnification of the distal end of an endoscope

*Right:* Examples of endoscope leak testers

## 3: NOT PERFORMING ROUTINE MICROBIOLOGICAL SURVEILLANCE, PATIENT FOLLOW-UP AND INSPECTION

Routine microbiological surveillance of endoscopes is an important step to prevent infections. Culturing is recommended as a risk mitigation strategy for duodenoscopes by the FDA and the protocol has been established and validated by the FDA. Follow-up with patients after procedures helps to identify potential issues such as infections. Establishing an inspection steps helps to identify residual debris and damage to an endoscope. Retained debris and damaged scopes can harbor infectious microorganisms.

### A. EVENT – PATIENT INFECTION OCCURRED

Patient died due to an infection caused by the remained stones after an ERCP procedure of bile duct stone extraction, January 2019.

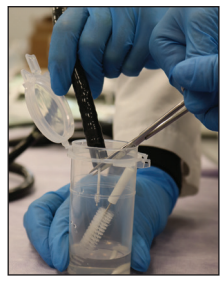
A report in the FDA MAUDE database states that a patient developed a fever and sepsis after an ERCP procedure using a duodenoscope. Once a month cultures were performed for the scope. It was reported that bacteria were detected. The manufacturer determined that the device was not likely the cause of the reported event. Results of sampling showed that P. aeruginosa was detected from the forceps elevator and Candidia parapsilosis was detected from the air/water channel.

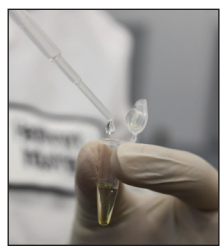
*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8201799&pc=FDT*

### B. EVENT – ANTIBIOTIC RESISTANT INFECTIONS

Report of an outbreak involving 20 patients with 19 patients that developed an infection of unspecified drug resistant organisms and 1 patient expiring after and ERCP, January 2019

A patient is found to have a fever and cholangitis. An ERCP procedure retrieves a sample, which cultures positive for Enterococcus faecium, Vancomycin resistant (VRE). Patient had a stroke and expired. The facility reported 8 more patient infections and 1 patient death after ERCP procedures due to drug-resistant organisms like Enterobacter, VRE and CRE.





*Above & Below:* Steps taken during microbial surveillance testing

A delay in the precleaning of the facility's ERCP scopes may have been a contributing factor. An audit found that 3 endoscopes sat for at least 30 minutes for leak testing & manual cleaning.

*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=8207609&pc=FEB*

**By implementing microbial surveillance, following up with patients and adding in quality steps, an outbreak may be avoided. These steps can identify clusters of infections, pseudo-infections and endoscope reprocessing issues.**

## CONCLUSION

Improper reprocessing of endoscopes results in adverse events and patient infections. These reports are due to:

- missed reprocessing steps,
- use error,
- no inspection steps
- no cleaning verification
- no microbiological sampling

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