Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

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Updated Information for Healthcare Providers Regarding Duodenoscopes (/downloads/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/UCM436588.pdf)

Audience:

- Gastroenterologists
- Gastrointestinal surgeons
- Endoscopy nurses
- Staff working in endoscopy reprocessing units in health care facilities
- Infection control practitioners
- Patients considering endoscopic retrograde cholangiopancreatography (ERCP) procedures

Medical Specialties: Gastroenterology, Infection Control

Device: All ERCP endoscopes (side-viewing duodenoscopes)

Figure 1: Close-up view of an ERCP endoscope tip.

Purpose:

The FDA wants to raise awareness among health care professionals, including those working in reprocessing units in health care facilities, that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection, but may not entirely eliminate it.

Summary of Problem and Scope:

More than 500,000 ERCP procedures using duodenoscopes are performed in the United States annually. The procedure is the least invasive way of draining fluids from pancreatic and biliary ducts blocked by cancerous tumors, gallstones, or other conditions. Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, stomach, and into the top of the small intestine (the duodenum). They contain a hollow channel that allows the injection of contrast dye or the insertion of other instruments to obtain tissue samples for biopsy or treat certain abnormalities. Unlike most other endoscopes, duodenoscopes also have a movable “elevator” mechanism at the tip. The elevator mechanism changes the angle of the accessory exiting the accessory channel, which allows the instrument to access the ducts to treat problems with fluid drainage.

Although the complex design of duodenoscopes improves the efficiency and effectiveness of ERCP, it causes challenges for cleaning and high-level disinfection. Some parts of the scopes may be extremely difficult to access and effective cleaning of all areas of the duodenoscope may not be possible. In addition, a recent FDA engineering assessment and a growing body of literature have identified design issues in duodenoscopes that complicate reprocessing of these devices. For example, one step of the manual cleaning instructions in device labeling is to brush the elevator area. However, the moving parts of the elevator mechanism contain microscopic crevices that may

not be reached with a brush. Residual body fluids and organic debris may remain in these crevices after cleaning and disinfection. If these fluids contain microbial contamination, subsequent patients may be exposed to serious infections.

The FDA is closely monitoring the association between reprocessed duodenoscopes and the transmission of infectious agents, including multidrug-resistant bacterial infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE) such as Klebsiella species and Escherichia coli. In total, from January 2013 through December 2014, the FDA received 75 MDRs encompassing approximately 135 patients in the United States relating to possible microbial transmission from reprocessed duodenoscopes. It is possible that not all cases have been reported to the FDA. The agency is continuing to evaluate information about documented and potential infections from multiple sources, including Medical Device Reports (MDRs) submitted to the FDA, the medical literature, the health care community, professional medical societies, and the Centers for Disease Control and Prevention (CDC).

Recommendations for Facilities and Staff that Reprocess ERCP Duodenoscopes:

- **Follow closely all manufacturer instructions for cleaning and processing.**
  - The FDA recommends adherence to general endoscope reprocessing guidelines and practices established by the infection control community and endoscopy professionals, as described in the Additional Resources section, below. In addition, it is important to follow specific reprocessing instructions in the manufacturer's labeling for each device.
  - Even though duodenoscopes are inherently difficult to reprocess, strict adherence to the manufacturer's reprocessing instructions will minimize the risk of infection. Deviations from the manufacturer's instructions for reprocessing may contribute to contamination. The benefit of using cleaning accessories not specified in the manufacturer's instructions, such as channel flushing aids, brushes, and cleaning agents, is not known.
- **Report problems with reprocessing the device to the manufacturer and to the FDA, as described below.**
- **Follow these additional general best practices:**
  - Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessor (AER). Raise and lower the elevator throughout the manual cleaning process to allow brushing of both sides.
  - Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality

monitors used during the reprocessing procedure.

- Refer to the **Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011 (http://www.asge.org/uploadedFiles/Public_E-Blast_PDFs/ReprocessingEndoscopes.pdf)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** consensus document for evidence-based recommendations for endoscope reprocessing.

Recommendations for Health Care Providers:

- Inform patients of the benefits and risks associated with ERCP procedures.
- Discuss with your patients what they should expect following the ERCP procedure and what symptoms (such as fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools) should prompt additional follow-up.
- Thoroughly disinfect duodenoscopes between uses and have in place a comprehensive quality program for reprocessing.
- Take a duodenoscope suspected of being associated with a patient infection following ERCP out of service and meticulously disinfect it until it is verified to be free of pathogens.
- Submit a report to the manufacturer and to the FDA **via MedWatch (/Safety/MedWatch/HowToReport/ucm2007306.htm)**, as described below, if you suspect that problems with reprocessing a duodenoscope have led to patient infections.

Recommendations for Patients:

- Discuss the benefits and risks of procedures using duodenoscopes with your physician. For most patients, the benefits of ERCP outweigh the risks of infection. ERCP often treats life-threatening conditions that can lead to serious health consequences if not addressed.
- Ask your doctor what to expect following the procedure and when to seek medical attention. Following ERCP, many patients may experience mild symptoms such as a sore throat or mild abdominal discomfort. Call your doctor if, following your procedure, you have a fever or chills, or other symptoms that may be a sign of a more serious problem (such as chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools).

FDA Activities:

The FDA is actively engaged with other government agencies, including CDC, and the manufacturers of duodenoscopes used in the United States to identify the causes and risk factors for transmission of infectious agents and develop solutions to minimize patient exposure. Recent

FDA activities include:

- Collaboration with CDC and the Environmental Protection Agency (EPA) to test the antibiotic-resistant organisms to assess their susceptibility to high-level disinfectants.
- Exploration, with CDC, of additional potential strategies to reduce the risk of infections, such as microbiological surveillance testing of duodenoscopes.
- Communication with international public health agencies to study the extent of the problem and identify possible solutions being considered outside the United States.
- Reviews of reprocessing validation data from each of the three manufacturers marketing duodenoscopes in the United States (FUJIFILM, Olympus, and Pentax).

The FDA continues to actively monitor this situation and will provide updates as appropriate.

Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. Health care providers should submit voluntary reports of the transmission of an infection due to an inadequately cleaned duodenoscope to the agency via the **Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** process.

If, after following the manufacturer’s reprocessing instructions, a health care provider suspects bacterial contamination—either because of an increase in infections after ERCP, or because of the results of bacterial surveillance culturing of duodenoscopes—we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Additional Resources:

- **American Society for Gastrointestinal Endoscopy: Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011 (http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety guideline on reprocessing flexible gastrointestinal.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Society of Gastroenterology Nurses and Associates: Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (http://www.sgna.org/Portals/0/sgna_stand_of_infection_control_0712_FINAL.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **FDA: Reprocessing of Reusable Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm2025268.htm)**
- **FDA: Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm)**

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Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

Preventing Tubing and Luer Misconnections (/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)