The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing Instructions: FDA Safety Communication

Date Issued:

April 12, 2019

Audience:

- Users and reprocessors of duodenoscopes including:
  - Gastroenterologists
  - Gastrointestinal surgeons
  - Endoscopy nurses
  - Staff working in endoscopy reprocessing units in health care facilities
  - Infection control practitioners
  - Personnel conducting endoscope culturing (e.g., clinical diagnostic and laboratory staff)
  - Facility risk managers
- Patients considering Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures

Medical Specialties:

Gastroenterology, Infection Control

Purpose

The U.S. Food and Drug Administration (FDA) is issuing this communication to update the **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm628020.htm)** issued December 2018 regarding results from **postmarket surveillance studies mandated under Section 522 of the Federal Food, Drug, and Cosmetic Act ("522 studies") for duodenoscopes (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm)** used in Endoscopic Retrograde Cholangiopancreatography procedures (ERCP). The FDA is also reminding facilities about the importance of strictly adhering to the manufacturer's reprocessing and maintenance instructions, following best practices, and reporting adverse event information to the FDA.

Device:

All endoscopes used in Endoscopic Retrograde Cholangiopancreatography procedures (ERCP) (side-viewing duodenoscopes).

Duodenoscopes (/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm) are complex instruments that contain many small working parts. If reprocessing instructions are not followed in every step of the process, tissue or fluid from one patient can remain in a duodenoscope when it is used on a subsequent patient. In rare cases, this can lead to patient-to-patient transmission of infection.

Summary of Problem and Scope

Update: Information on the Duodenoscope Contamination Rate from the Postmarket Surveillance Studies

On October 5, 2015, the FDA ordered all three manufacturers (Fujifilm Medical Systems USA, Inc, Olympus Medical Systems Corporation, Pentax of America) who make duodenoscopes sold in the U.S. to conduct **postmarket surveillance studies (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm)** so the FDA can better understand how duodenoscopes are reprocessed in real-world settings.

As of March 2019, the manufacturers continue to collect samples for the Sampling and Culturing Study.

The study was designed to evaluate the percentage of clinically used duodenoscopes which remain contaminated with viable microorganisms after use of labeled reprocessing instructions. The studies were designed assuming less than a 0.4% contamination rate. The preliminary results as of March 2019 indicate higher than expected levels of contamination:

- For low to moderate concern organisms with >100 CFU, updated culturing results continue to indicate a higher-than-expected contamination rate after reprocessing, with up to 3.6% of properly collected samples testing positive.
- For high concern organisms, defined as organisms that are more often associated with disease, such as *E. coli*, and *Pseudomonas aeruginosa*, updated culturing results appear to show that up to 5.4% of properly collected samples test positive, which is an increase from the 3% contamination rate that was previously reported.

Root cause analyses are currently underway to better understand these culturing results. Some factors that may contribute to device contamination after reprocessing include device damage and errors in reprocessing. These results remain preliminary because they are based on the collection of only a portion of the samples that the FDA has mandated be collected and tested. Each manufacturer must still submit to the FDA culturing results for the total number of samples required in each approved study plan.

The numbers of samples collected and the contamination results to date, along with summary descriptions of the FDA-approved study plans, are available on the respective FDA 522 Postmarket Surveillance Studies webpage for each manufacturer: **Fujifilm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=353&c_id=3725)**, **Pentax (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=355&c_id=3727)**, and **Olympus (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3726)**.

Update: Medical Device Reporting for Duodenoscopes

As announced in **December 2018 (/NewsEvents/Newsroom/PressAnnouncements/ucm628096.htm)**, the FDA has observed a decline in the number of medical device reports associated with patient infections after **safety measures (/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454641.htm)** to improve reprocessing techniques were implemented, beginning in 2015. Our analysis of medical device reports associated with patient infections for duodenoscope indicates that the number of medical device reports peaked in 2015 at 250 reports and declined 62% to fewer than 100 reports per year in 2017.

However, late in 2018 we received additional medical device reports of patient infections and device contamination. Our analysis of 205 medical device reports received from October 15, 2018 through March 31, 2019 includes 45 reports of patient infection, one (1) report of patient exposure, and 159 reports of device contamination. In 2018, 3 deaths were reported in the US related to duodenoscopes. These reports indicate that although the number of reports has declined, there continues to be a need for improvement of the safety of reprocessed duodenoscopes.

Recommendations for Facilities and Staff that Reprocess Duodenoscopes

The FDA recommendations have not changed. Facilities and staff are reminded of the importance of strictly adhering to the manufacturer's reprocessing and maintenance instructions and following these best practices:

- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an **automated endoscope reprocessor (AER). (/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm483896.htm)** Raise and lower the elevator throughout the manual cleaning process to allow brushing and flushing of both sides. After cleaning, carefully inspect the elevator recess and repeat cleaning if any soil or debris is visible.
- Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures to monitor training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.
- Follow the duodenoscope manufacturer's recommendations for inspection, leak testing, and maintenance of the duodenoscope.
  - Prior to each use, closely inspect and remove from service for assessment, and repair or replace any duodenoscope that shows visible signs of damage, as recommended in the duodenoscope instruction manuals. Examples of damage may include: loose parts, protrusions or abnormal bulging from the endoscope, kinks or bends in tubing, cracks and gaps in the adhesive that seals the device's distal cap, or other signs of wear or damage.
  - During each reprocessing cycle, conduct leak testing and remove from service for assessment, and repair and replace any duodenoscope that shows signs of leakage. Follow the duodenoscope manufacturer's leak testing instructions for angulating the bending section and elevator during leak testing.
  - As recommended in the duodenoscope instruction manuals, return the duodenoscope to the duodenoscope manufacturer for inspection, servicing, and maintenance of the device at least once per year.
- Be aware that FDA has previously issued a **Safety Communication (http://wayback.archive-it.org/7993/20170722150658/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm)** and provided a detailed list of supplemental duodenoscope reprocessing measures that can be implemented to reduce the risk of infection transmission, such as: microbiological culturing, sterilization, use of a liquid chemical sterilant processing system and repeat high-level disinfection. Hospitals and health care facilities that utilize duodenoscopes can, in addition to meticulously following manufacturer reprocessing instructions, take one or more of these additional steps to further reduce the risk of infection and increase the safety of these medical devices.

Information for Patients

You may be aware of incidents where inadequately reprocessed reusable medical devices were used on patients. The risk of infection from inadequate reprocessing is relatively low, and the FDA recommends that you do not cancel or delay any planned procedure without first discussing the benefits and risks with your health care professional.

Before you have a medical procedure, it is always a good idea to learn more about the procedure and steps the health care facility takes to keep patients safe.

Your health care provider is one resource for information about your medical care. Many organizations, including **The American Academy of Family Physicians (http://familydoctor.org/online/famdocen/home/pat-advocacy/healthcare/837.html)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** provide tips for talking to your doctor.

Recent FDA Activities:

The FDA is actively working with reprocessing experts, medical device manufacturers, and other government agencies to advance innovative ways to decrease infection related to duodenoscopes.

In May 2019, the FDA plans to engage the infection control community at the **Healthcare Infection Control Practices Advisory Committee (HICPAC) (https://www.cdc.gov/hicpac/)** meeting to update the public on the FDA's work and engagement and seek input on improving the safety of reprocessed devices.

On March 9, 2018, the FDA issued **Warning Letters (/NewsEvents/Newsroom/PressAnnouncements/ucm600388.htm)** to all three manufacturers who make duodenoscopes sold in the U.S. for failure to provide sufficient data to address the postmarket surveillance studies requirements under Section 522 of the Federal Food, Drug, and Cosmetic Act. All three manufacturers responded to the warning letters and submitted plans that outlines how study milestones will be achieved including enrolling new sites and collecting samples.

The FDA continues to:

- Analyze monthly sampling and culturing results submitted by all three manufacturers who make duodenoscopes sold in the U.S.
- Carefully track cases of infection with multi-drug resistant bacteria and the use of duodenoscopes through review of **medical device reports (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** submitted to the FDA, literature and stakeholders feedback.
- Work with health care facilities and reprocessing personnel to understand their experiences implementing reprocessing protocols.
- Work with the companies to modify the reprocessing instructions to enhance the safety margin of methods used to clean and disinfect duodenoscopes.
- Encourage the development of new technology and design features, such as disposable components, to enhance patient safety

The FDA will continue to provide additional information to the health care community and the public as new information becomes available.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products. If you suspect or experience a problem with a duodenoscope, we encourage you to file a voluntary report through **MedWatch (/Safety/MedWatch/ucm2005699.htm)**, the FDA Safety Information and Adverse Event Reporting program. 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.

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)

2019 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm630141.htm)

2018 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)