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Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication

Date Issued: August 4, 2015

Audiences:

- 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)
- Patients considering Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures

Medical Specialties: Gastroenterology, Infection Control

Device: All ERCP endoscopes (side-viewing duodenoscopes)

Purpose:

FDA is providing a detailed list of supplemental duodenoscope reprocessing measures that emerged from an agency-led expert panel meeting earlier this year. 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.

We recognize that not all health care facilities can implement one or more of these measures, which require specific resources, training, and expertise. Therefore, it is critical that staff responsible for reprocessing duodenoscopes have the manufacturer's instructions readily available to promote strict adherence to the reprocessing instructions in the device labeling, understand the importance of their role in reprocessing the device, and maintain proficiency in performing these reprocessing tasks. While the risk of infection transmission cannot be completely eliminated, the benefits of these devices continue to outweigh the risks in appropriately selected patients.

Summary of Problem and Scope:

Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices, and can result in infection transmission if reprocessing instructions are not followed in every step of the process. While there will always be a risk of infection transmission with devices used internally, it is important to take all possible steps to minimize that risk so that patients may realize the benefits of these devices.

For duodenoscopes, their unique and complex design improves the efficiency and effectiveness of ERCP, it also presents challenges for effective reprocessing, notably:

- Duodenoscopes are complex instruments that contain many small working parts. Proper cleaning and disinfection of the elevator mechanism is of particular concern. The moving parts of the elevator mechanism contain microscopic, hard-to-reach crevices. If not thoroughly cleaned and disinfected, tissue or fluid and residual bacteria from one patient may remain in device crevices of a duodenoscope, exposing subsequent patients to risk of infection.
- Meticulous adherence to the manufacturer's reprocessing instructions is labor intensive and prone to human error. It is critical that staff responsible for reprocessing duodenoscopes have the manufacturer's instructions readily available to promote strict adherence to the reprocessing instructions in the device labeling, understand the importance of their role in reprocessing the device, and maintain proficiency in performing these reprocessing tasks.
- The FDA is aware of instances of persistent bacterial contamination even following strict adherence to manufacturer reprocessing instructions. Because of this, FDA recommends that facilities and staff that reprocess ERCP duodenoscopes establish and implement a comprehensive quality control program for reprocessing duodenoscopes.

At an expert panel meeting, representatives from several health care facilities and the panel discussed additional strategies that have been implemented to reduce the risk of infection transmission. In each case, staff applied these supplemental methods in addition to meticulous cleaning as part of strict adherence to the manufacturer's reprocessing instructions, as recommended in previous FDA Safety Communications. Furthermore, these measures may not be feasible in all health care facilities and each of these options comes with its own benefits and limitations.

Supplemental Measures for Facilities and Staff that Reprocess Duodenoscopes to Consider:

Among the variety of infection mitigation strategies discussed at the Advisory Committee meeting, several specific supplemental measures have been implemented in individual health care facilities. Combined with strict adherence to the duodenoscope manufacturer's reprocessing instructions, the following supplemental measures may further help reduce the risk of infection transmission associated with the use of duodenoscopes.

- Microbiological Culturing
- Ethylene Oxide Sterilization
- Use of a Liquid Chemical Sterilant Processing System
- Repeat High-Level Disinfection

The FDA recommends health care facilities performing ERCP evaluate whether they have the expertise, training and resources to implement one or more of these options:

- **Microbiological culturing of duodenoscopes**

Microbiological culturing involves sampling duodenoscope channels and the distal end of the scope and culturing those samples to identify any bacterial contamination that may be present on the scope after reprocessing. Some facilities have successfully implemented routine or periodic surveillance culturing to assess the adequacy of duodenoscope reprocessing and to identify duodenoscopes with persistent contamination despite reprocessing.

In March 2015, the CDC released an [Interim Duodenoscope Surveillance Protocol \(http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html\)](http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html) that includes duodenoscope [sampling \(http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-sampling.html\)](http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-sampling.html) and [culturing \(http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html\)](http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html) protocols, which may be used as a guide for health care facilities to assess the adequacy of their duodenoscope reprocessing. This interim protocol includes several options for duodenoscope culturing based on the resources and requirements of each healthcare facility. One option is to culture duodenoscopes after every reprocessing cycle and to quarantine the duodenoscope until culture results are known. Another option is to culture at intervals defined by the health care facility, i.e. weekly, monthly or after a fixed number of procedures.

The CDC's interim duodenoscope surveillance protocol is a good tool; however, the false positive rate, the false negative rate and the limits of detection for microbial surveillance have not yet been established for this method. Nevertheless, persistent duodenoscope contamination as defined in the interim surveillance protocol should lead to action by the health care facility, such as taking the scope out of circulation until negative culture results can be demonstrated following repeat reprocessing.

Health care facilities evaluating the potential implementation of duodenoscope microbiological culturing following duodenoscope reprocessing should consider the following:

- Any duodenoscope found to be contaminated should not be returned to use until the contamination has been eliminated from the device. The CDC has provided an [interim protocol \(http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html\)](http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html) to assist in interpretation of culture results.
- Microbiological culturing is resource-intensive and includes added costs of microbiological testing and staff time needed to collect and process samples.
- Some health care facilities have "outsourced" duodenoscope culturing to environmental or contract laboratories due to lack of on-site experience with culturing, uncertainty in interpretation of results and workflow considerations.
- Surveillance culture results take time to produce. When duodenoscopes are cultured after every reprocessing cycle, the duodenoscope is typically quarantined and not available for use until culture results are known.
- Health care facilities should assess their supply and clinical demand for duodenoscopes when considering microbiological culturing implementation.

- **Ethylene oxide (EtO) sterilization following cleaning and high-level disinfection**

At a minimum, as per the manufacturer's instructions, duodenoscopes should be subjected to high-level disinfection following manual cleaning after each use. When possible and practical, duodenoscopes should be sterilized due to the greater margin of safety provided by sterilization. Sterilization is a validated process used to render a product free from all viable microorganisms.

An ethylene oxide gas (EtO) sterilizer is a non-portable device that uses ethylene oxide gas to sterilize medical products. Since it does not rely on heat, EtO gas sterilization may be an effective method for heat-sensitive instruments, like duodenoscopes, that can be damaged by high temperatures. Following cleaning and high-level disinfection, EtO is an additional measure that may eliminate the presence of micro-organisms on a device through the introduction of EtO gas.

Health care facilities evaluating potential use of EtO sterilization following cleaning and high-level disinfection should consider the following:

- It is critical that devices are meticulously cleaned and disinfected prior to EtO sterilization. Gas sterilization with ethylene oxide may fail in the presence of viable microorganisms after inadequate cleaning and disinfection.
- Implementing EtO gas sterilization is costly and the process may not be readily available in or accessible to all health care facilities.
- EtO may affect the material and mechanical properties of the duodenoscope.
- EtO may be toxic to reprocessing personnel, and to patients if residual EtO remains on the device after sterilization.
- Health care facilities should assess their supply and clinical demand for duodenoscopes when considering EtO sterilization.
- Users should follow duodenoscope manufacturer reprocessing instructions pertaining to EtO concentration, sterilization temperature, exposure time, and relative humidity.

- **Use of a liquid chemical sterilant processing system following cleaning and high-level disinfection**

A liquid chemical sterilant (LCS) processing system is a device that uses a chemical solution (liquid chemical sterilant) to destroy all viable forms of microbial life. Notably, because this process requires rinsing with highly purified (but not sterile) water following device sterilization, the device does not remain completely free of all viable microbes. The concentration, exposure time and temperature of a liquid chemical sterilant are crucial because inappropriate dilution, insufficient exposure, or inadequate temperature may result in ineffective reprocessing outcomes.

Health care facilities evaluating potential use of a LCS processing system following cleaning and high-level disinfection should consider the following:

- Meticulous cleaning is an essential part of duodenoscope reprocessing and should precede any liquid chemical sterilization and high-level disinfection of these instruments. Failure to perform adequate cleaning may result in failure of the sterilization or high-level disinfection.
- Use only LCS processing systems that have been FDA-cleared and indicated for liquid chemical sterilization of endoscopes, including duodenoscopes, and adhere to the LCS processing system manufacturer's instructions for use.

- **Repeat high-level disinfection**

Because a small number of duodenoscopes may have persistent microbial contamination despite reprocessing, some health care facilities have implemented repeat high-level disinfection (HLD) after the first HLD cycle in their duodenoscope reprocessing procedures, either manually or through the use of Automated Endoscope Reprocessors (AERs). HLD involves immersing the device with a disinfectant and is expected to inactivate all microorganisms except for large numbers of bacterial

endospores. AERs are devices that wash and high-level disinfect endoscopes and scope accessories to decontaminate them between uses. AERs are designed to expose outside surfaces and interior channels of endoscopes to chemical solutions in order to kill microorganisms.

Health care facilities evaluating the use of repeat HLD following cleaning and high-level disinfection should consider the following:

- Repeat HLD, either manually or using AERs, does not eliminate the need for meticulous manual cleaning prior to HLD. Failure to perform adequate cleaning may result in reprocessing failure.
- Users should refer to the AER manufacturer's instructions in the labeling to determine whether a specific duodenoscope model and high-level disinfectant are compatible with the AER.

Additional Recommendations for Facilities and Staff that Reprocess Duodenoscopes

FDA recommends facilities and staff that reprocess duodenoscopes review the recent FDA [Safety Communication \(7993/20170722150658/https://www.fda.gov/medical-devices/safety/alerts-and-notices/ucm434871.htm\)](https://www.fda.gov/medical-devices/safety/alerts-and-notices/ucm434871.htm) for important additional information and recommendations. In addition to consideration of the supplemental measures described above, the FDA continues to recommend strictly adhering to the manufacturer's reprocessing instructions and following these best practices:

- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using 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 \(http://wayback.archive-it.org/7993/20170722150658/http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety%20guideline%20on%20reprocessing%20flexible%20gastrointestinal.pdf\)](http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety%20guideline%20on%20reprocessing%20flexible%20gastrointestinal.pdf) [\(http://wayback.archive-it.org/7993/20170722150658/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm\)](http://wayback.archive-it.org/7993/20170722150658/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) consensus document for evidence-based recommendations for endoscope reprocessing.

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).

Background and FDA Activities:

FDA has been working with federal partners, manufacturers, and other stakeholders to better understand the critical factors contributing to bacterial infections associated with duodenoscopes and how to best mitigate them.

On May 14-15, 2015, the FDA convened the [Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee \(7993/20170722150658/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm\)](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm) to seek expert scientific and clinical opinion related to reprocessing of duodenoscopes based on available scientific information. The supplemental reprocessing measures outlined in this safety communication reflect discussions held at the advisory panel.

Ensuring the safety of reprocessed medical devices is a shared responsibility among the FDA and other federal agencies, state and local health departments, medical device manufacturers, health care facilities, professional societies and others. The FDA is actively engaged with many of these stakeholder groups to better understand the causes and risk factors for transmission of infectious agents associated with these devices and to develop strategies to minimize patient exposure.

The FDA continues to actively monitor this situation and is currently:

- Evaluating information from multiple sources, including [medical device adverse event reports \(7993/20170722150658/https://www.fda.gov/medical-devices/safety/report-a-problem/ucm2005291.htm\)](https://www.fda.gov/medical-devices/safety/report-a-problem/ucm2005291.htm) submitted to the FDA, the medical literature, the health care community, professional medical societies, international public health agencies, federal partners and state and local governments.
- Collaborating with the CDC, the American Society for Microbiology (ASM) and other endoscope culturing experts to develop a validated culturing protocol that facilities can adopt as a best practice to reduce the risk of infections associated with duodenoscopes.
- Collaborating with the Centers for Medicaid and Medicare Services (CMS) and The Joint Commission to strengthen health care facility adherence to duodenoscope reprocessing instructions.
- Working with health care facilities and reprocessing personnel to understand their experiences implementing reprocessing protocols.
- Working with industry as they modify and validate their reprocessing instructions to enhance the safety margin of the methods used to clean, disinfect and sterilize duodenoscopes. The FDA will alert users when updated and validated reprocessing instructions become available.

The FDA is committed to providing updates as we continue our investigation.

Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations \(7993/20170722150658/https://www.fda.gov/medical-devices/device-regulation-and-guidance/postmarket-requirements/reporting-adverse-events/ucm2005737.htm\)](https://www.fda.gov/medical-devices/device-regulation-and-guidance/postmarket-requirements/reporting-adverse-events/ucm2005737.htm).

Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements \(7993/20170722150658/https://www.fda.gov/medical-devices/device-regulation-and-guidance/postmarket-requirements/reporting-adverse-events/ucm2005737.htm\)](https://www.fda.gov/medical-devices/device-regulation-and-guidance/postmarket-requirements/reporting-adverse-events/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 \(MDR\) \(7993/20170722150658/https://www.fda.gov/medical-devices/safety/report-a-problem/ucm2005291.htm\)](https://www.fda.gov/medical-devices/safety/report-a-problem/ucm2005291.htm) process.

If a health care provider suspects persistent bacterial contamination of a duodenoscope following reprocessing—either because of an increase in infections after ERCP, or because of the results of microbiological 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 \(7993/20170722150658/https://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm\)](https://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm).

As required by 21 CFR 803.32, user facility MDR reports must include:

- the brand name of the device
- the type of the device
- the manufacturer’s name and address
- a description of the adverse event or problem
- outcomes attributed to the adverse event (e.g., death or serious injury)

Although not required, it would also be helpful to the Agency for user facilities to submit device evaluation results, if available.

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.

Additional Resources

- [Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes Safety Communication \(March 2015\)](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm) (7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm)
- [Design of Endoscopic Retrograde Cholangiopancreatography \(ERCP\) Duodenoscopes May Impede Effective Cleaning Safety Communication \(February 2015\)](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm) (7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm)
- [CDC: Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing](http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html) (<http://wayback.archive-it.org/7993/20170722150658/http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html>)
- [American Society for Gastrointestinal Endoscopy: Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes: 2011](http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety%20guideline%20on%20reprocessing%20flexible%20gastro) (http://wayback.archive-it.org/7993/20170722150658/http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Multisociety%20guideline%20on%20reprocessing%20flexible%20gastro) (<https://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)
- [Reprocessing of Reusable Medical Devices website](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/default.htm) (7993/20170722150658/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/default.htm)
- [Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication \(November 2009\)](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm) (7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm) [ARCHIVED]

More in Safety Communications

(7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm)

[2017 Safety Communications](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm) (7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)

[2016 Safety Communications](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553855.htm) (7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553855.htm)