ICT INFECTION CONTROL TODAY

Supplemental Measures to Enhance Duodenoscope Reprocessing

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

The Food and Drug Administration (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 healthcare 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.

The FDA says it recognizes that not all healthcare 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, multi-step 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.

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• 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 healthcare 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. Furthermore, these measures may not be feasible in all healthcare 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 healthcare 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 healthcare 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 that includes duodenoscope sampling and culturing protocols, which may be used as a guide for healthcare 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 healthcare 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 healthcare facility, such as taking the scope out of circulation until negative culture results can be demonstrated following repeat reprocessing.

Healthcare 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 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.

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- Some healthcare 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.
- Healthcare 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.

Healthcare 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 healthcare 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.
- Healthcare 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.

Healthcare 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.

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- 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 healthcare 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.

Healthcare 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 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 consensus document for evidence-based recommendations for endoscope reprocessing.