Division of Public and Behavioral Health
Technical Bulletin

Date: December 14, 2018
Topic: The U.S. Food and Drug Administration (FDA) Issued Updated Safety Communication Regarding Duodenoscope Medical Devices
Section/Program: Division of Public and Behavioral Health/Office of Public Health Informatics and Epidemiology
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To: All State-Licensed Health Care Providers and Facilities

Current Situation:
Interim results from recent FDA studies indicate higher-than-expected contamination rates after reprocessing duodenoscopes. Inadequately reprocessed reusable medical devices used on patients can result in avoidable exposures to biological agents and probable transmission of serious infections.

Recommendations for Facilities and Staff that Reprocess Duodenoscopes:

The FDA recommends facilities and staff strictly adhere to the manufacturer's reprocessing and maintenance instructions and follow these best practices:

- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessors (AERs). 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 for monitoring 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.
- Be aware that FDA has previously issued a Safety Communication 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.

To review the FDA's updated safety communication:
https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm628020.htm

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