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FDA Issues Alert on Infections Associated with Reprocessed Flexible Bronchoscopes

September 18, 2015

- Sterile Processing, FDA, Healthcare Departments

The Food and Drug Administration (FDA) has issued a communication to healthcare professionals to share preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes.

A flexible bronchoscope is a thin, lighted tube that is threaded through the nose or the mouth to allow a physician to examine a patient's throat, larynx, trachea, and lower airways. Bronchoscopy may be done to diagnose problems with the airway, the lungs, or with the lymph nodes in the chest, or to treat problems such as an object or growth in the airway. Approximately 500,000 bronchoscopy procedures are performed in the United States each year.

Bronchoscopes must undergo reprocessing in between patient uses to clean the devices of soil and contaminants and to inactivate microorganisms by disinfection or sterilization. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable

devices. If the process is not followed meticulously, the flexible bronchoscope can remain contaminated, potentially resulting in infection transmission from one patient to the next.

The FDA has undertaken an ongoing, comprehensive investigation into infections associated with reprocessed reusable medical devices, working with federal partners, manufacturers, and other stakeholders to better understand the critical factors contributing to device-associated patient infection and how to best mitigate them. In the agency's March 2015 Reprocessing Final Guidance, wit identified bronchoscopes as being part of a subset of devices that pose a greater likelihood of microbial transmission and represent a high risk of infection if they are not adequately reprocessed, so we are proactively investigating these devices to determine if additional steps should be taken. As part of that investigation, the FDA has observed commonalities in some of the reports to the FDA regarding infections associated with flexible bronchoscopes. Based on current knowledge, the risk of infection transmission presented by reprocessed bronchoscopes appears to be lower than the risk of infection transmission presented by reprocessed duodenoscopes.

As part of the FDA's investigation, it analyzed Medical Device Reports (MDRs) submitted to FDA from manufacturers and healthcare facilities. Between January 2010 and June 2015, the FDA received 109 MDRs concerning infections or device contamination associated with flexible bronchoscopes. When compared to the number of bronchoscopy procedures performed in the U.S. each year, this is considered a small number of MDRs. However, in 2014, the FDA received 50 MDRs that mentioned infections or device contamination associated with reprocessed flexible bronchoscopes, which prompted additional investigation on this issue.

A small number of these reports indicate persistent device contamination despite following the manufacturer’s reprocessing instructions. The FDA continues to evaluate these reports through follow up with healthcare facilities and manufacturers to determine whether device contamination persisted despite meticulous adherence to the manufacturer’s reprocessing instructions and whether other factors may have contributed to these events.

While not every medical device report contains information sufficient to definitively identify the factors contributing to persistent device contamination or device-associated infection, the FDA's analysis to date has identified two recurrent themes:

•Failure to meticulously follow manufacturer instructions for reprocessing, including: Lack of pre-cleaning at point of use. Pre-cleaning typically includes surface wiping and channel flushing to prevent drying of blood, tissue and other biological debris;
Failure to perform thorough manual cleaning before high-level disinfection (HLD) or sterilization;
Failure to flush or brush channels;
Use of expired detergent or high-level disinfectant;
Insufficient flushing, rinsing and/or drying after HLD.

•Continued use of devices despite integrity, maintenance and mechanical issues, including:
Persistent device channel kinks or bends;
Channel wall scratches, divots, or crevices;
Holes, cracks, or other imperfections in the distal end;
Use of repaired or refurbished devices using out-of-specification parts;
Use of devices despite residual material in the instrument or suction channels.

Recommendations for Healthcare Facilities and Staff that Reprocess Flexible Bronchoscopes

The FDA recommends that facilities that reprocess flexible bronchoscopes take the following precautions:

•Strictly adhere to the manufacturer's reprocessing instructions. It is critical that staff responsible for reprocessing bronchoscopes have the manufacturer's instructions readily available to promote strict adherence to the reprocessing instructions in the device labeling. Do not skip steps. Be sure to follow all pre-cleaning, manual cleaning and HLD or sterilization steps.
Ensure that staff who reprocess soiled bronchoscopes understand the importance of manually cleaning the scope thoroughly before it is disinfected or sterilized. Meticulous cleaning is an essential part of endoscope reprocessing. Failure to perform adequate cleaning may result in failure of HLD or sterilization.
Use only bronchoscope manufacturer-specified cleaning accessories, high-level disinfectants, enzymatic cleaning agents and detergents and follow their directions for use.

•Immediately remove from service for assessment and repair or replace any bronchoscope that fails a leak test (performed to assess scope integrity after every procedure), or shows visible signs of damage. Examples of damage may include: loose parts, damaged channel walls, kinks or bends in tubing, holes in the distal end, or other signs of wear or damage.

•Follow the manufacturer's recommendations for preventive maintenance and repair of the device. For additional information on maintenance and repair services, refer to the manufacturer's information provided with your bronchoscope or directly contact the manufacturer.

•Implement a comprehensive reprocessing quality control program. 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.

•After reprocessing, store bronchoscopes in a manner that will minimize the likelihood of contamination or collection and retention of moisture, according to manufacturer's instructions.

•Refer to the American College of Chest Physicians and American Association for Bronchology Consensus Statement: Prevention of Flexible Bronchoscopy-Associated Infection: 2005 for recommendations regarding bronchoscope reprocessing.