PENNSYLVANIA DEPARTMENT OF HEALTH
2021– PAHAN –580 – 07-15 - ADV
Recommendations for Reprocessing Flexible Bronchoscopes

DATE:	**07/15/2021**
TO:	Health Alert Network
FROM:	Allison Beam, JD, Acting Secretary of Health
SUBJECT:	**Recommendations for Reprocessing Flexible Bronchoscopes**
DISTRIBUTION:	Statewide
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This transmission is a "Health Advisory" provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL
EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE
FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE
LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE
PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

On June 25, 2021 the Food & Drug Administration (FDA) issued an update to their 2015 safety communication describing safety risks associated with flexible bronchoscopes.

The FDA provided two **new** recommendations:

- Consider using a single-use bronchoscope in situations where there is increased risk of spreading infection.
- When treating patients with Coronavirus Disease 2019 (COVID-19), refer to recent recommendations from the American Association for Bronchology & Interventional Pulmonology (AABIP).

This Advisory highlights key information about flexible bronchoscope safety and reprocessing and outlines action items for facilities using these devices. We request that facilities in Pennsylvania:

- Review FDA notices about flexible bronchoscope safety and reprocessing;
- Incorporate recommendations into the facility's written infection control plan and written policies;
- Ensure policies for reprocessing flexible bronchoscopes are followed by implementing observations of routine practices (auditing);
- Report failures in flexible bronchoscope reprocessing or clusters of disease associated with the devices to your local health jurisdiction and the Pennsylvania Patient Safety Reporting System.

If you have additional questions about this guidance, please contact **DOH at 1-877-PA- HEALTH (1-877-724-3258)** or your local health department.

On June 25, 2021 the Food & Drug Administration (FDA) provided updated information about medical device adverse event reports and recommendations for health care providers on bronchoscopes as a supplement to the 2015 safety communication on reprocessed flexible bronchoscopes. Relevant content from the updated notice from FDA is included in this Advisory in the Appendix.

The Department of Health requests that facilities and providers in Pennsylvania:

- Review FDA notices about flexible bronchoscope safety and reprocessing;
- Incorporate recommendations into the facility's written infection control plan and written policies;
- Ensure policies for reprocessing flexible bronchoscopes are followed by implementing observations of routine practices (auditing) as part of a comprehensive quality control program;
- Report failures in flexible bronchoscope reprocessing or clusters of disease associated with the devices to your local health jurisdiction and to the Pennsylvania Patient Safety Reporting System (PA-PSRS) as appropriate.

If you have questions about this guidance, please contact DOH at 1-877-PA-HEALTH (1- 877-724-3258) or your local health department. For technological questions or issues with the PA-PSRS system, contact PA-PSRS support at support_papsrs@pa.gov.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of July 15, 2021 but may be modified in the future.

APPENDIX

The relevant content from the FDA advisory for healthcare facilities and staff can be found below.

FDA RECOMMENDATIONS FOR HEALTH CARE FACILITIES AND STAFF

The FDA is reminding health care facilities and staff responsible for reprocessing bronchoscopes and their accessories about the importance of carefully following the manufacturer's reprocessing instructions.

Additionally, the FDA recommends the following:

- Consider using sterilization instead of high-level disinfection when feasible, because sterilization has a greater safety margin than high-level disinfection. Steps should include precleaning, leak testing, cleaning, and sterilization.
    - If sterilization is not available, then high-level disinfection steps should include precleaning, leak testing, cleaning, high-level disinfecting, rinsing with tap or utility water followed by alcohol flushing or with critical (filtered or sterile) water, and drying.
    - Use only manufacturer-specified cleaning accessories, high-level disinfectants, enzymatic cleaning agents, and detergents.
- You should not use damaged devices or those that have failed a leak test, as they could be a potential source of contamination. Examples of damage may include:
    - Loose parts
    - Damaged channel walls
    - Kinks or bends in tubing
    - Holes, cracks, or imperfections in the distal end
    - Other signs of wear or damage
- After reprocessing, you should store bronchoscopes in a manner that will minimize the likelihood of contamination or collection and retention of moisture, according to manufacturer's instructions.

- Follow the manufacturer's recommendations for preventive maintenance and repair of the device and accessories. For additional information, refer to the information provided with your bronchoscope or contact the manufacturer directly.
- Develop schedules for routine inspection and periodic maintenance in accordance with the manufacturer's instructions. This schedule should include written procedures for training and monitoring compliance with proper reprocessing procedures, and documentation of reprocessing procedures. Staff should be properly trained and wear appropriate personal protective equipment.
- Refer to the American College of Chest Physicians and American Association for Bronchology Consensus Statement, Prevention of Flexible Bronchoscopy-Associated Infection, for further recommendations regarding bronchoscope reprocessing.
- You should not reprocess or reuse single-use bronchoscopes.

FDA RECOMMENDATIONS FOR HEALTH CARE PROVIDERS

The FDA continues to recommend the following:

- Discuss the benefits and risks associated with procedures involving reprocessed bronchoscopes with your patients. Discuss signs of a potential infection after a bronchoscopy procedure and when patients should seek medical attention.

The FDA is providing the following new recommendations:

- Consider using a single-use bronchoscope in situations where there is increased risk of spreading infection (for example, multidrug resistant microorganisms, immunocompromised patients, or patients with prion disease) or when there is no support for immediate reprocessing of the bronchoscope.
- When treating patients with Coronavirus Disease 2019 (COVID-19), refer to recent recommendations from the American Association for Bronchology & Interventional Pulmonology (AABIP).

DEVICE DESCRIPTION AND BACKGROUND

A bronchoscope is a type of endoscope, and consists of a thin flexible lighted tube that is threaded through the nose, mouth, or other access point to the lower airways (for example, through a tracheostomy tube), to enable a doctor to examine a patient's throat, larynx, trachea, and lower airways.

A bronchoscope may be used to diagnose abnormalities in the airway, the lungs, or lymph nodes in the chest, or to treat issues such as an object or growth in the airway.

There are two types of bronchoscopes:

- Single-use (disposable) bronchoscopes are only intended to be used for one patient and do not require reprocessing.
- Reusable bronchoscopes can be used on multiple patients. These devices must undergo reprocessing in between uses, to clean the devices of soil and contaminants, and to inactivate microorganisms by sterilization or disinfection.

Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices including endoscopes. In FDA's March 2015 guidance document titled Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, bronchoscopes were identified 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. When performed according to manufacturer instructions, reprocessing a properly maintained reusable bronchoscope removes soil and microorganisms (including bacteria and viruses, such as SARS-CoV-2) and the bronchoscope is validated for safe reuse. If the reprocessing process is not followed meticulously by trained staff, the bronchoscope can remain contaminated, potentially resulting in infection transmission from one patient to the next. There is also a risk of spreading microorganisms through the air through aerosolization or from the surfaces of the bronchoscope when using and reprocessing a bronchoscope.

MEDICAL DEVICE REPORTS RECEIVED BY THE FDA

The FDA's analysis of Medical Device Reports (MDRs) related to infections or device contamination associated with reusable flexible bronchoscopes is ongoing.

- As reported in our 2015 safety communication, between January 2010 and June 2015, the FDA received 109 MDRs related to infections or device contamination associated with reusable flexible bronchoscopes.
- Between July 2015 and January 2021, the FDA received 867 additional MDR s related to infections or device contamination associated with reusable flexible bronchoscopes.
    - Similar to what was reported in 2015, factors contributing to infection included failure to follow manufacturer instructions, or continued use of devices despite integrity, maintenance, and mechanical issues.
    - Among the reports that included the name of specific microorganisms, the most frequently reported organisms were Mycobacterium, Pseudomonas, Serratia, and Klebsiella.
- Of the 867 reports received between July 2015 and January 2021, there were seven reports of deaths. Specifically:
    - Three reported that the bronchoscope tested positive for microorganisms.
    - One reported the cause of death was related to the patient's underlying pathology.
    - One reported the patient was involved in a multidrug resistant cluster in which a bronchoscope was identified as a commonality.
    - Two did not provide additional details.

It is unknown if the reported infections contributed to the patient deaths, and if patient comorbidities may have been a factor.

Since 2015, the number of MDRs relevant to infection or contamination submitted to the FDA has increased from under 100 per year to between 100-200 per year. There are approximately 500,000 bronchoscopy procedures performed annually in the United States alone, and the MDRs described above were received from all over the world. Although the MDR system is a valuable source of information, the limitations of a passive surveillance system mean that it should not be used to calculate the incidence of a specific event. It is often not possible to definitively determine the cause of the event based on the information submitted. MDRs are not, by themselves, definitive evidence of a faulty or defective medical device and cannot be used to establish or compare rates of event occurrence.

FDA ACTIONS

The FDA is committed to the continued evaluation of the safety, effectiveness, and availability of medical devices. The FDA takes the risk of infection with reusable endoscopes very seriously, as evidenced by recent evaluations and actions related to duodenoscopes and urological endoscopes.

The FDA continues to evaluate reprocessing issues for bronchoscopes and other types of endoscopes, including information about documented and potential infections. 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 has been a priority. The FDA continues to evaluate incoming medical device reports through follow up with health care facilities and manufacturers.

REPORTING PROBLEMS WITH YOUR DEVICE TO FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.