

U.S. Food and Drug Administration  
Protecting and Promoting Your Health

# Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication

Date Issued: September 17, 2015

## Audiences:

- Health care providers who use bronchoscopes
- Staff working in reprocessing units in health care facilities
- Infection Control Practitioners
- Patients considering bronchoscopy procedures

**Medical Specialties:** Pulmonology, Otolaryngology, Cardiothoracic Surgery, Infection Control

**Device:** All flexible bronchoscopes

## Purpose:

The purpose of this communication is to share preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes. Although this information is limited, health care providers may benefit from awareness of the issues we are seeing and of steps they can take to mitigate possible risks to patients.

## Summary of Problem and Scope:

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 our March 2015 [Reprocessing Final Guidance](#)

[\(/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf\)](#),

we 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, we have 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 our investigation, we analyzed Medical Device Reports (MDRs) submitted to FDA from manufacturers and health care 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 health care 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, our 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 Health Care 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](http://journal.publications.chestnet.org/data/Journals/CHEST/22030/1742.pdf) (<http://journal.publications.chestnet.org/data/Journals/CHEST/22030/1742.pdf>)  
 (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) for recommendations regarding bronchoscope reprocessing.

#### Recommendations for Patients:

- Discuss the benefits and risks of having a bronchoscopy procedure with your physician. For most patients, the benefits of undergoing bronchoscopy outweigh the risk of infection.
- Ask your doctor what to expect following your procedure and when to seek medical attention. You should call your doctor if, following your procedure, you have symptoms such as fever, pain, nausea and vomiting, that may be a sign of a more serious problem.

#### FDA Activities:

Advances in medical technology have generated more complex reusable medical device designs that are more difficult to reprocess. In addition, there has been a significant advance in knowledge and technology involved in reprocessing reusable medical devices. The FDA's March 2015 [Reprocessing Final Guidance](http://www.fda.gov/oc/ohrt/ReprocessingFinalGuidance.pdf) ([/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf](http://www.fda.gov/oc/ohrt/ReprocessingFinalGuidance.pdf)) reflects the scientific advances in these areas, and it identifies a subset of reusable devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed.

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 solutions to minimize patient exposure. Some of our ongoing activities include:

- Evaluating information about documented and potential infections from multiple sources, including [medical device adverse event reports](http://www.fda.gov/oc/ohrt/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm) ([/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm](http://www.fda.gov/oc/ohrt/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)) (MDRs) 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.
- Working with health care facilities and reprocessing personnel to understand their experiences implementing reprocessing protocols.
- Working with endoscope manufacturers prior to and during the development of their reprocessing validation protocols; conducting premarket review of their submitted reprocessing validation protocols; and evaluating the data resulting from validation testing.
- Taking other appropriate steps when significant problems with reprocessing and device design are reported through MDRs.
- Working with device manufacturers, federal partners, professional societies, the health care community, and other stakeholders to better address the issues that contribute to infections with reprocessed medical devices.

FDA continues to actively monitor this situation and will provide updates as appropriate.

#### Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations](http://www.fda.gov/oc/ohrt/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) ([/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm](http://www.fda.gov/oc/ohrt/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)).

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.

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 bronchoscope to the agency via the Medical Device Reporting (MDR) process. If a health care provider suspects bacterial contamination following use of a bronchoscope after a bronchoscopy procedure, we encourage the health care provider to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

**Additional Resources:**

AAMI Standard ST91: Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities. Published April 2015.

**Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling**

(/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf)  
(March 2015)

**Design of Endoscopic Retrograde Cholangiopancreatography (ERCP)**

**Duodenoscopes May Impede Effective Cleaning Safety Communication**

(/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm) (February 2015)

Association of Perioperative Registered Nurses (AORN) Recommended Practices for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories: 2009

**Preventing Cross-Contamination in Endoscope Processing: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm)**

(November 2009)


The Centers for Disease Control and Prevention/Healthcare Infection Control Practices Advisory Committee (HICPAC). **Guideline for Disinfection and**

**Sterilization in Healthcare Facilities: 2008**

(http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection\_Nov\_2008.pdf)

**American College of Chest Physicians and American Association for Bronchology Consensus Statement: Prevention of Flexible Bronchoscopy-**

**Associated Infection: 2005**

(http://journal.publications.chestnet.org/data/Journals/CHEST/22030/1742.pdf) 

(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

**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)

<mailto:DICE@FDA.HHS.GOV> 800-638-2041 or 301-796-7100.

**More in Safety Communications**

(/MedicalDevices/Safety/AlertsandNotices/default.htm)

**Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)**

**Preventing Tubing and Luer Misconnections**

(/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)

