# Flexible Endoscopes: Terminal Sterilization and Impact to Patient Safety

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## Abstract

*Flexible endoscopes are implicated in deaths from healthcare-associated infections (HAIs), in particular antibiotic-resistant infections. This article analyzes whether terminal sterilization should be required as part of endoscope reprocessing to reduce or eliminate HAIs and thus improve patient safety. Reusable flexible endoscopes are processed to make them ready for clinical use by the processing department of the healthcare facility. Unlike most critical and semicritical medical devices, the final step of processing an endoscope is high-level disinfection and not terminal sterilization. This is because most flexible endoscopes come in contact with mucosal membranes (versus contact with direct blood stream) and cannot withstand sterilization. However, sterilization currently is performed by a small number of U.S. healthcare facilities on reusable flexible endoscopes with the belief that they are safer for use compared to flexible endoscopes that are high-level disinfected. Based on the analysis in this article, terminal sterilization is not a required or necessary step to eliminate HAIs.*

The processing department of a healthcare facility is responsible for cleaning, disinfection, and sterilization of applicable medical devices to ensure they are ready for use on the next patient. To perform these processes, the department follows the instructions for use (IFU) provided by the medical device manufacturer. Medical device manufacturers are required to validate each process listed in the IFU that will make an applicable medical device ready for clinical use. The design and clinical use of the reusable medical device determines which processes are required to be listed in the IFU to reduce the risk of infection.

To analyze the risk of infection, the Spaulding classification is used. This classification groups medical devices into three categories: critical, semicritical, and noncritical. Flexible endoscopes are categorized as semicritical devices, as they come into contact with mucosal membranes and do not penetrate tissue or enter sterile areas of the body cavity. However, the accessories that are used with flexible endoscopes (e.g., biopsy needles) are critical devices, as they enter blood streams and sterile areas of the body. Semicritical devices are required to be sterilized, unless the device cannot withstand sterilization. If the device cannot withstand sterilization, disinfection is required. Most flexible endoscopes cannot withstand multiple cycles of sterilization because of their unique design and materials. To reduce the risk of infection, flexible endoscopes are high-level disinfected, which is a process that kills viruses, mycobacteria, fungi, and vegetative bacteria, but not necessarily large numbers of resistant bacterial spores. High-level disinfection (HLD) is typically demonstrated through a log reduction of microorganisms that are used for the evaluation. For example, for HLD validation the process should be able to demonstrate at least a 6-log reduction of a Mycobacterium species.

For flexible endoscopes, reprocessing starts at the point of use. Once the endoscopes are cleaned at the point of use, they are transported to the processing department for further decontamination. Usually, the first step in the decontamination room is to leak test the endoscope. If the endoscope passes the leak test, it can then be decontaminated. The next phase is cleaning, which removes organic matter from the device to the extent necessary for further processing. Flexible endoscopes can be cleaned using automated or manual cleaning. Automated cleaning is done in an automated endoscope reprocessor (AER), which is designed to clean, high-level disinfect, and dry flexible

endoscopes. AERs are commonly used to reprocess flexible endoscopes and require Food and Drug Administration (FDA) approval before they are marketed. If the flexible endoscope is manually cleaned, it is then disinfected, rinsed with critical/treated water, and dried in drying cabinets.

Few healthcare facilities will then sterilize flexible endoscopes using liquid chemical sterilization. While liquid chemicals tend to be more compatible with the materials of the endoscope, the device cannot be packaged prior to sterilization. With no sterile barrier, the flexible endoscopes need to be used immediately or reprocessed again before use. Not only is reprocessing an unused medical device wasteful for a healthcare facility, it also degrades the materials of a flexible endoscope. Other sterilization methods available for flexible endoscopes include ethylene oxide (EO; either at the healthcare facility or an industrial sterilizer), vaporized hydrogen peroxide, or hydrogen peroxide gas plasma. These methods allow for packaging the device prior to sterilization. Therefore, these terminally sterilized flexible endoscopes can be stored without requiring reprocessing again before use.

## Analysis

Healthcare-associated infections (HAIs) related to contaminated flexible endoscopes are an increasing concern in recent years, not only because of the high volume of HAIs but also because of the death rate associated with antibiotic-resistant infections. A recent study from John Hopkins University reviewed more than 2.3 million patients in six states and reported that the infection risk is as follows[1]:

- Colonoscopy—about one patient per 1,000 surgeries
- Upper gastrointestinal endoscopy—about three patients per 1,000 surgeries
- Cystoscopy—about four patients per 1,000 surgeries
- Bronchoscopy—about 15.6 patients per 1,000 surgeries

Furthermore, a review of the FDA's Medical Device Reports shows that there were 79 deaths from January 2015 to July 2019 resulting from the use of contaminated duodenoscopes.[2]

The high HAIs associated with duodenoscopes, bronchoscopes, and colonoscopes relate to the challenges that these devices add to the decontamination process at a healthcare facility. These devices have difficult-to-clean areas and their complex design does not allow for visualization of these areas during decontamination. Furthermore, these difficult-to-clean areas are not always highlighted in the IFU as locations that require attention. As the devices are repeatedly used and reprocessed, there could be an impact to their service life: Wear and tear (e.g., scratches) on the devices make the device make more difficult to clean. Also, these flexible endoscopes are sometimes serviced at third-party vendors, who may add new materials or parts that make these devices more difficult to clean and bring the cleaning validation into question.

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The inherent design of flexible endoscopes is not the only reason they are difficult to reprocess. Other contributing factors are the healthcare facility's environment and the processing department: There is a lack of knowledge and sufficient training needed for those responsible for reprocessing endoscopes.[3] These devices require multiple decontamination steps that can be difficult to follow. Some of the processing departments do not have the appropriate equipment (e.g., brushes, water, light, AERs, connectors, inspection tools, containers, etc.) to perform processing. Malfunctioning AERs are an added challenge to the decontamination process of flexible endoscopes.[4] In the working group of ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities*, contaminated equipment was one of the items that was identified as a challenge to decontaminating flexible endoscopes (e.g., contaminated drying cabinets can contribute additional infection risk to the flexible endoscopes during storage). Damaged and compromised flexible endoscopes can harbor microorgan-

isms and be more difficult to clean. Furthermore, some healthcare facilities do not have the means to verify their decontamination process (e.g., inspection via a borescope or surveillance program) to determine whether the endoscope is contaminated prior to use.

Currently, no low-temperature sterilizers have been cleared with duodenoscopes claims except for EO sterilizers. However, it has been noted that low-temperature sterilizers reportedly reduce the use life of duodenoscopes because of damage to duodenoscope materials because of maintenance and monitoring requirements.[5]

Each task in the decontamination process requires adequate attention and awareness to ensure patient safety. While terminal sterilization would allow for storage and transportation of a sterile flexible endoscope, it is believed that the reduction in HAIs would be small. This is because terminal sterilization would only impact the microorganisms acquired after cleaning. If the design or cleanability of an endoscope and the processing department's environment are not changed, terminal sterilization will fail because dirty endoscopes cannot be sterilized effectively.[6]

A review of the microorganisms on the flexible endoscopes after clinical use was conducted to assess the bioburden load before and after cleaning. Rutala and Weber showed that the average bioburden levels on flexible gastrointestinal endoscopes after clinical use were estimated to be around $10^7$ CFU/mL, and after cleaning dropped to $10^2$ CFU/mL.[7] While the purpose of cleaning is not to reduce bioburden, it is understood that cleaning reduces bioburden and provides an additional benefit to the next step in the process.

Most of the microorganisms linked with infections through contaminated endoscopes (duodenoscopes) are high-concern organisms.[2] These are defined as organisms that are more often associated with diseases. Examples of high-concern organisms include gram-negative rods (e.g., *Escherichia coli*, *Klebsiella pneumoniae*, or other Enterobacteriaceae, as well as *Pseudomonas aeruginosa*); gram-positive organisms including *Staphylococcus aureus*, Beta-hemolytic Streptococcus, Enterococcus species; and yeasts. This definition is specified in the duodenoscope surveillance sampling and culturing protocol written by FDA and other affiliates.[8]

Opportunist organisms such as *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Escherichia coli* are common sources of HAIs; however, they easily can be destroyed through HLD. During the HLD validation process, endoscopes are inoculated with a Mycobacterium species at a concentration of $> 1.0 \times 10^6$ CFU per test site. A 6-log reduction for each test site shows the efficacy of the process. The challenge organism is considered to be a more resistant organism for HLD processes compared to the microorganisms most commonly seen with HAIs, thus demonstrating that HLD (if performed correctly) is sufficient to ensure patient safety and that terminal sterilization is not required.

## Discussion and Conclusion

Terminal sterilization is not required or necessary to eliminate HAIs associated with contaminated flexible endoscopes. These HAIs occur because flexible endoscopes place additional challenges on the decontamination process at healthcare facilities. Residual contamination from previous processing steps (cleaning, disinfection) can affect the efficacy of the sterilization process. Furthermore, the risk of infection will not be minimized by sterilization because of the clinical use of the flexible endoscope. Current guidelines continue to recommend thorough cleaning and HLD for endoscopes, in part because of the challenges (e.g., availability, incompatibility of materials) of sterilization methods. Continuous improvement efforts (e.g., emphasis on cleaning, HLD, drying, and surveillance programs) from the healthcare facilities and the medical device manufacturer will help reduce HAIs and thus improve patient safety.

## Further Reading

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