SELF-STUDY SERIES

Sterilization of flexible endoscopes

Does current evidence support a change?

by Janet Prust, Director, Standards and Scientific Affairs/3M Medical Solutions Division

Flexible endoscopes are complex medical devices and important tools for the diagnosis and/or treatment of a wide variety of patient health problems. These types of devices enter the patient typically through an existing opening or orifice and are used for both diagnostic (colonoscopy) and therapeutic (endoscopic retrograde cholangiopancreatography or ERCP, bowel resection, tumor excision using endoscopic ultrasound or EUS, etc.) procedures. Flexible endoscopes are complex devices constructed with multiple materials and components including optics, electronics, and multiple polymers and are designed with complex geometries and mechanical functions that are typically not compatible with steam sterilization but require low temperature chemical disinfection or sterilization processes. Endoscopes can be quite costly, and many health care facilities strive for maximum utilization of these devices necessitating fast turnaround time for reprocessing.

Historically, it was believed that the risk for endoscopy-associated patient infection was very rare, but it is now known to be much higher based on evidence of multiple outbreaks.1,2,3 A recent, very large, epidemiological study of U.S. based ambulatory procedures show the risk ranges between common and uncommon (based on World Health Organization definitions). In this study, upper gastroscopy, cystoscopy and bronchoscopy procedures represented the highest risk.4 This study also showed that when an endoscopy-related infection occurs, the outcome for the patient is poor often requiring multi-day hospital stays and a negative impact on quality of life.

Flexible endoscopes are highly contaminated during procedures — much more so than typical surgical instruments and the complex design can make them difficult to effectively and repeatedly safely reprocess.5,6 Documented infections have occurred with every type of endoscope and in general, current clinical practices are often far below existing recommended professional standards.7-9 Because flexible endoscopes are classified as medical devices and regulated by the Food and Drug Administration (FDA), endoscope manufacturers are required to develop and test or validate reprocessing instructions including the requirements for cleaning, high-level disinfection and/or sterilization processes. Users must rely on the manufacturers to develop methods that can be performed in the health care facility. FDA can and has required flexible endoscope manufacturers to revalidate reprocessing instructions and has more recently implemented post-market surveillance requirements to ensure the endoscope manufacturer’s instructions for use can be effectively performed in healthcare facilities.10

Evidence

Beginning in 2013, alarming outbreaks with multi-drug resistant organisms (MDROs) were associated with duodenoscopes, and some of the outbreaks were widely publicized. While much of the focus was on duodenoscopes, there have been documented transmission and continuing reports of patient ready endoscope contamination for other endoscope types as well. An increasing number of publications, safety alerts, updated reprocessing guidelines, patient injury reports, and continuing calls to improve the process have been issued.1,2,10,11

Several of the facilities with MDRO and duodeneroscope-related outbreaks changed their process and moved from high-level disinfection to terminal sterilization with ethylene oxide. This change was in addition to assessing the complete reprocessing practice and ensuring it met both the manufacturers’ IFUs and recognized guidelines. The move to ethylene oxide was attributed to halting the endoscope-related transmission.12,13,14,15,16,17,18

All the relevant U.S. organizations have issued updated guidelines related to reprocessing flexible endoscopes.11,12,18,19 While the guidelines vary on the specific recommendations, all focus on improving training and competency assessments, more thorough cleaning procedures and using or
assessing the use of cleaning verification indicators, implementing good quality control practices, performing risk assessment and periodically testing the entire reprocessing procedure with microbial testing of patient-ready endoscopes. The open question in the guideline discussion is if flexible endoscopes should be classified as critical devices and terminal sterilization mandated. AORN 2016 Guideline for reprocessing flexible endoscopes states: Package and sterilize endoscopes that enter sterile tissues or the vascular system. The Spaulding system classifies items as critical, semi-critical, or noncritical. Items such as flexible endoscopes that come in contact with nonintact skin or mucous membranes are semi-critical and should be processed by sterilization or, at a minimum, by high-level disinfection.

Clinical challenges
Minimally invasive surgical techniques (MIS) represent a significant advancement in medical technology in the 20th and 21st centuries. The most common types of MIS procedures are performed through a very small incision using rigid endoscopes that are commonly terminally sterilized with steam sterilization. MIS procedures are also increasingly performed with flexible endoscopes that enter the body through existing orifices (e.g., mouth to esophagus or lungs, urinary tract to bladder or kidneys, rectum to large intestine, mouth to duodenum and other upper GI structures). MIS procedures can greatly benefit the patient with lower risk of infection, faster recovery and overall less cost to the healthcare system. A more recent technological evolution of MIS includes the use of robotics with flexible endoscopes which conceivably could present additional challenges for reprocessing.

While the endoscopes themselves have evolved to perform complex procedures, the reprocessing standard of care has not evolved significantly. Even though flexible endoscopes are used in these critical MIS procedures, the standard of care in the gastroenterology community for reprocessing these devices continues to be high-level disinfection.

The Spaulding classification scheme is a widely referenced basis for determining how a medical device should be reprocessed based on how the device is used on the patient and the subsequent risk of infection to the patient. Most references citing Spaulding include examples of various types of devices that fit into the three categories: Critical, Semi-critical and Non-critical devices. Typically, the semi-critical category lists flexible endoscopes but if that endoscope is used that dictates the risk to the patient, but rather how that endoscope is used that dictates the risk to the patient. FDA recommends sterilization for all critical and semi-critical devices. If a semi-critical device cannot be sterilized, it should be at a minimum high-level disinfected.

Additional requirements for successful reprocessing
Effective cleaning procedures:
It is critical to reduce the amount of clinical soil on flexible endoscopes so that the subsequent lethal processes of high-level disinfection or sterilization can be effective. Precleaning should be performed according to IFUs and guidelines and full manual cleaning initiated within one hour of the procedure.

Inspection for damage:
Careful inspection using lighted magnification is needed to assess damage to the endoscopes. Damage can impact the functionality of the endoscope and can also increase the risk of biofilm formation.

Satisfactory leak testing:
Performed prior to manual cleaning, leak testing ensures the endoscope is not damaged so that fluids cannot invade the portions of the endoscope that are not designed for fluid contact. The appropriate procedure is described in the endoscope manufacturer’s IFU.

Effective drying:
Complete drying is required for effective sterilization and effective storage of a high-level disinfected endoscope. Current data shows that a 10-minute forced air drying can be effective.

Compatible packaging for sterilized endoscopes:
A terminally sterilized endoscope provides a sterile barrier and retains a sterile state until used or compromised. Some types of sterilization processes may require specific packaging compatible with that system.

Sterilization and high-level disinfection comparison
According to ANSI/AAMI ST58: 2013 — Chemical Sterilization and high-level disinfection in healthcare facilities — Annex A, physical sterilization processes (including steam and chemical sterilization processes) are defined based on how effective they are at killing microorganisms, including bacterial spores. Spores are the standard as spores have the greatest resistance to the lethality of the process. The effectiveness of the chemical sterilant or high-level disinfectant is determined by how effective it is at killing spores under the defined conditions or parameters of the process. The methods used to validate or prove it works for steam and gaseous chemical sterilization processes are different than the methods used to validate liquid, high-level disinfection. High-level disinfection provides microbial kill under defined conditions but does not kill all spores.

Terminal sterilization is a linear process. This means the process is predictable in how it delivers the lethality and can provide a probability calculation of surviving microorganisms, also known as a sterility assurance level (SAL). The survival kinetics (or profile) for steam, dry heat, and for chemical sterilization with ethylene oxide
endoscope material compatibility with the chemical process
- length of the cycle
- quality control system that is or is not available for the process
- cost of the process
- evidence that the process is effective at halting endoscope related outbreaks

**Summary**

Effective flexible endoscope reprocessing is a challenging task with many complexities and considerations. Patient outbreaks and evidence of patient-ready contaminated endoscopes have been well documented in the literature and standards. Users should understand that satisfactory cleaning, inspection and drying is always required and critically important for successful disinfection, liquid sterilization or terminal sterilization. Terminal sterilization processes are designed and validated with an overkill or ‘safety’ factor and provide a significantly higher level of lethality compared to liquid processes. The type of process used for sterilization of a flexible endoscope should be based on the endoscope manufacturer’s IFU as the manufacturer has validated the reprocessing recommendations. Evidence shows that several of the duodenoscope-related outbreaks were effectively halted when the facility switched from high-level disinfection to a terminal sterilization process using EO. HPN

**Table 1 — Comparison of flexible endoscope reprocessing methods**

<table>
<thead>
<tr>
<th>High-Level Disinfection</th>
<th>Liquid Chemical Sterilization</th>
<th>Low-Temperature Terminal sterilization</th>
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<tbody>
<tr>
<td>Kills mycobacterium and all less-resistant organisms but not all spores.</td>
<td>Kills all organisms, including spores.</td>
<td>Kills all living organisms, including spores.</td>
</tr>
<tr>
<td>Various test organisms used for validation.</td>
<td>Various test organisms used for validation.</td>
<td>Specific spore type defined in standards used for validation.</td>
</tr>
<tr>
<td>Designed to kill up to 6 logs of mycobacterium.</td>
<td>Designed to kill up to 6 logs of mycobacterium, including spores.</td>
<td>Designed to kill 12 logs of most resistant to the process spores as defined in standards.</td>
</tr>
</tbody>
</table>

- 6 logs = $10^6 (10x10x10x10x10x10) = 1,000,000
- 12 logs = $10^{12} (10x10x10x10x10x10x10x10x10x10x10x10x10) = 1,000,000,000,000

SAL not applicable

**Quality control monitoring tools:**

- Physical parameters
- HLD minimum effectiveness indicator

**Quality control monitoring tools:**

- Physical parameters
- HLD minimum effectiveness concentration indicator

**Quality control monitoring tools:**

- Physical parameters
- External and internal chemical indicators
- Biological indicators used in a process challenge device

- Provides a wet, high-level disinfected item.
- Effectiveness dependent on effective cleaning and complete drying of device prior to storage.
- Provides a steril, packaged item that maintains sterile barrier until used or packaging is compromised.
- Effectiveness dependent on effective cleaning and complete drying of device prior to packaging.

**Quality control monitoring tools:**

- Provides a wet, liquid sterilized item to be used immediately. If stored, must be reprocessed directly before use.
- Provides a sterile, packaged item that maintains sterile barrier until used or packaging is compromised.
- Provides a wet, high-level disinfected item.

- Effectiveness dependent on effective cleaning. Device wet when used on patient. Complete drying required prior to storage as an HLD device.
- Effectiveness dependent on effective cleaning and complete drying of device prior to packaging.
- Provides a wet, high-level disinfected item.

| Performance with manual soak method or automated reprocessor | Performed in automated liquid chemical sterilant reprocessing system. | Performed in a sterilizer. |

**References:**

Sterilization of flexible endoscopes

Circle the one correct answer:

1. Only duodenoscopes have been associated with post-endoscopy related patient infection.
   A. True  B. False

2. Spaulding Classifications designate the infection risk to the patient based on how the device is used.
   A. True  B. False

3. False Both rigid and flexible endoscopes are used with minimally invasive surgery.
   A. True  B. False

4. A recent epidemiological study provides new evidence of the risk of endoscopy associated infection and reveals that the risk is much higher than previously cited.
   A. True  B. False

5. Sterilization of endoscopes is not recommended by FDA.
   A. True  B. False

6. Only terminal sterilization processes performed in a sterilizer provide an overkill process and a 'safety' factor.
   A. True  B. False

7. Published evidence shows that terminal sterilization with ethylene oxide has contributed to halting duodenoscope related outbreaks.
   A. True  B. False

8. Liquid chemical processes produce a packaged, sterilized endoscope.
   A. True  B. False

9. High-level disinfection processes show linear, predictable lethality.
   A. True  B. False

10. Effective cleaning, inspection and drying are required for proper repro-cessing of flexible endoscopes.
    A. True  B. False

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Janet Prust is with 3M Medical Solutions Division as Director of Standards and Global Scientific Affairs. She has over thirty years of healthcare industry experience including surgical services, occupational health, industrial and healthcare sterilization and prior to 3M, twelve years of clinical practice experience as researcher, surgical assistant and administrator. She has held other technical and business positions within 3M and is a nationally and internationally recognized educator.

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