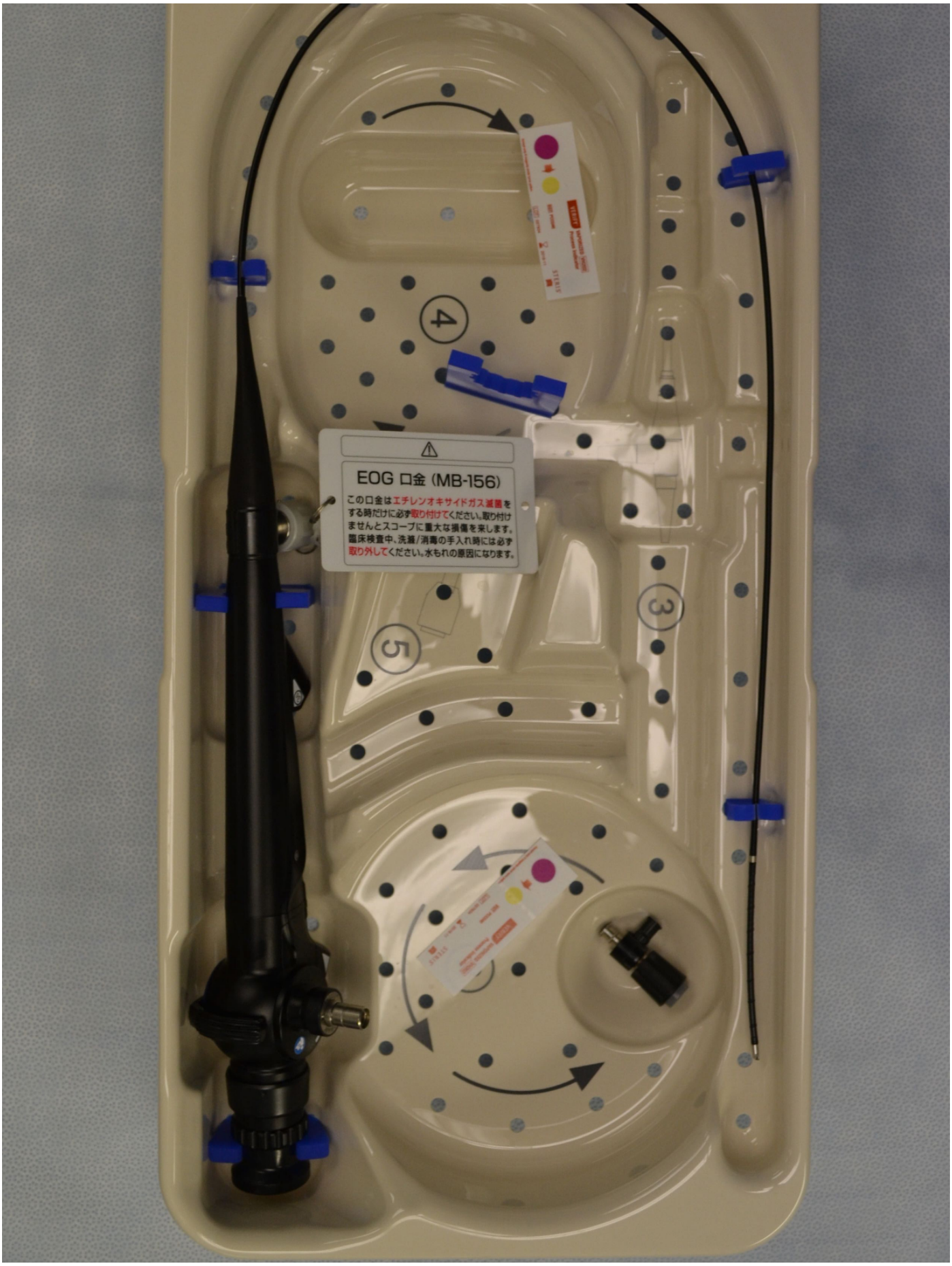
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Making a Case for Sterilization of Endoscopes:
Part One

BY MARY ANN DROSNOCK, DHSC, CIC, CFER, RM (NRCM), AAMIF, FAPIC, DIRECTOR, CLINICAL AFFAIRS—HEALTHMARK INDUSTRIES

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LEARNING OBJECTIVES
1. Understand the risks associated with certain types of endoscopes and inadequately processed endoscopes
2. Discuss recommendations in national standards and guidelines that relate to sterilization of endoscopes
3. Review strategies for prioritizing and managing the sterilization process

This lesson is the first of a two-part series that addresses the benefits of transitioning flexible endoscopes from high-level disinfection (HLD) to sterilization as the terminal process. This lesson shares how to make a case for the shift and provides strategies for prioritizing and managing the sterilization process. Part two, to be published in the May/June issue, will outline the types of sterilization systems available for endoscopes, the workflow for sterilization, and additional required steps such as cleaning verification and inspection.

Objective 1: Understand the risks associated with certain types of endoscopes and inadequately processed endoscopes

Infections after routine endoscopic procedures occur more frequently than previously reported, with estimates as high as 1.1 per 1,000 for colonoscopy screening.[1] There are numerous reported infections, outbreaks and deaths related to endoscopic procedures, such as gastroscopy, bronchoscopy, and duodenoscopy.[2] Pathogens, including drug-resistant organisms, can be introduced when there are improper processing techniques, breaches of host barriers, and person-to-person transmission.[3] More healthcare-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.[4] With an estimated 22.2 million endoscopic procedures performed annually throughout the U.S.,[5] there is considerable potential for high numbers of endoscopic-associated infections.

According to ANSI/AAMI ST91:2021, sterilization is "a validated process used to render a product free from viable microorganisms."[3] For terminal sterilization of endoscopes, ST91 states that sterilization is the preferred method of microbial inactivation and the only option for instruments to be

used in critical applications. Critical applications are when endoscopes enter sterile body cavities, tissues, or vascular spaces. Sterilization is recommended for all endoscopes, especially those that are high-risk. Sterilization is required for those that penetrate the mucosa. Sterile endoscopes provide increased safety over high-level disinfected ones, ST91 states. Therefore, a policy on transitioning to sterilization of flexible endoscopes will address the needs of patients and healthcare workers by making reprocessing these devices safer and more robust.

Objective 2: Discuss recommendations in national standards and guidelines that relate to sterilization of endoscopes

The Centers for Disease Control and Prevention (CDC) states that the reprocessing procedure for endoscopes includes cleaning, visual inspection, and either HLD or terminal sterilization per the manufacturer's IFU.[6] Traditionally, facilities have performed HLD instead of sterilization because of the ease of use, cost, turnaround time, and lack of compatibility with the sterilization cycle and sterilization chemicals. Recently, there has been heightened emphasis on sterilizing endoscopes instead of performing HLD due to the higher safety margin associated with terminal sterilization processes.[4] With the latest recommendations, facilities should implement a policy to transition flexible endoscopes to sterilization where feasible and create a plan to move all others to sterilization in the future.

A multisociety position paper on reprocessing flexible gastrointestinal (GI) endoscopes also notes that a critical device that enters the vascular system or sterile tissue should be sterilized to destroy all microbial life, including bacterial endospores.[7] Examples of critical devices include endoscopes used in sterile settings, such as laparoscopic endoscopy, endoscopic retrograde cholangiopancreatography (ERCP), and interventional endoscopic ultrasound (EUS).[7] A semi-critical device encounters intact mucous membranes or nonintact skin and does not penetrate sterile tissue. These devices should be sterilized, but at a minimum, HLD is acceptable if sterilization is not feasible.[7] Sterilization is feasible for many flexible and semi-rigid endoscopes; therefore, facilities should make this transition. Although the equipment may not be available in all healthcare settings initially, sterilization equipment can be acquired through proper planning and budgeting to complete the transition.

Additionally, the endoscope processing guidelines from the Association of periOperative Registered Nurses (AORN) state that a facility should sterilize reusable, flexible endoscopes that have been validated for sterilization by the manufacturer whenever possible.[8] The justification, according to the guideline, is that a greater margin of safety is associated with sterilization and that correctly sterilized items are rarely associated with patient infections.[8]

HSPA also emphasizes the importance of sterilization for flexible endoscopes. As the *Endoscope Reprocessing Manual* states, "there has been a movement aware from HLD to sterilization for all types of endoscopes" because of increased antimicrobial resistance of microorganisms and the availability of low-temperature sterilization modalities compatible with many flexible endoscopes.[9] *Remember: Devices must still be thoroughly cleaned, rinsed and dried before sterilization. They must also undergo cleaning verification and inspection before sterilization and then be re-inspected before their reuse in the procedure room.*

Endoscope reprocessors must also remember that instructions for use (IFU) for certain endoscopes, such as ureteroscopes, have already been updated to state that only sterilization is appropriate for those devices.

Objective 3: Review strategies for prioritizing and managing the sterilization process

A prudent first step toward shifting away from HLD is prioritizing the types of endoscopes that will be transitioned to sterilization. The healthcare organization should already have an inventory list of all endoscopes used in the facility. It is essential to review that list and identify high-risk endoscopes, which should be the first to transition to sterilization. Remember, according to ST91, high-risk endoscopes include bronchoscopes, duodenoscopes, linear ultrasound scopes, endobronchial ultrasound scopes, ureteroscopes, and any others determined by one's facility to be high risk.[3]

Next, it is recommended to prioritize endoscopes with additional recommendations or safety alerts from the U.S. Food and Drug Administration (FDA), such as bronchoscopes, duodenoscope, and ureteroscopes. Also, it is crucial to have the latest versions of endoscope manufacturers' IFU as well as the IFU for all processing equipment and supplies. *Note: It will be helpful to refer to their IFU while reading the second part of this lesson, which addresses the compatibility of various endoscope types and sterilization methods and IFU requirements for inspection after cleaning and before reuse.*

A 2021 safety alert by the FDA states that healthcare facilities should consider

using sterilization instead of HLD for bronchoscopes when feasible because sterilization has a greater safety margin than HLD.[10] If sterilization is not available, then HLD should be utilized.[10] Many facilities have sterilization systems compatible with their bronchoscopes but still choose to disinfect them. If sterilization is feasible (available), then the endoscopes should be processed in that manner because of the higher safety margin. *Keep in mind that the sterilization systems may be located outside the department where the endoscopes are used, such as the Sterile Processing department, but this does not negate the need for sterilization. In this instance, transport endoscopes to the alternate department and convene a multidisciplinary team to figure out the logistics of the new process.*

The FDA has received numerous medical device reports (MDRs) describing patient infections following an endoscopic procedure or other possible contamination issues associated with reprocessing the endoscopes. The agency further states that reprocessing steps should include one of the following options: cleaning and HLD or cleaning and sterilization.[10] In 2021, the agency sent a letter to healthcare providers about infections linked to reprocessed urological endoscopes. In 2022, the FDA issued another safety alert and recalled a type of urological endoscope, which the FDA stated had insufficient reprocessing instructions.[11, 12] The recall included the issuance of new IFU, which removed HLD as an option for the terminal process. These endoscopes now require sterilization. Similarly, in 2017, the FDA, combined with a different urological endoscope manufacturer, conducted a Class II recall for their ureteroscope, including a change to require sterilization as the terminal step of processing.[13]

The FDA also recommends the transition to sterilization for duodenoscopes, another type of high-risk endoscope, for those with innovative designs to enhance safety because of the increased risk associated with their use and reprocessing.[14,15] Innovative designs include those that are entirely disposable or have disposable components. They further state that for non-disposable duodenoscopes, consider reprocessing with supplemental measures such as sterilization or the use of a liquid chemical sterilant processing system consistent with the devices' labeling. Although sterilization, particularly terminal (e.g., gas) sterilization, provides a greater margin of safety than HLD, there currently is limited availability and compatibility of gas sterilizers with duodenoscopes.[14,15] There is a clear need for further development of sterilizer technologies for duodenoscopes.

With an estimated 22.2 million GI procedures performed annually in the U.S., healthcare facilities should immediately convene a multidisciplinary team to evaluate how the processing of flexible endoscopes can be elevated to terminal sterilization. Together, the team members can prioritize high-risk endoscopes for sterilization and identify other endoscope families that could transition from HLD to sterilization. It is also helpful to devise an implementation strategy and action plan with due dates and departmental/role responsibilities. With a detailed plan, facilities will be better focused and driven to institute best practices and drive quality and patient safety.

Conclusion

There is consensus in the current standards, guidelines, and endoscope manufacturers' IFU about the need to prepare facilities to transition from HDL to sterilization as the terminal processing step. Following ST91:2021, other applicable guidelines, and the most current IFU will help facilities transition to sterilization for endoscopes. Creating a multidisciplinary team to review endoscope inventories and prioritize endoscopes according to their level of risk serves as a great starting point for this transition. P

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