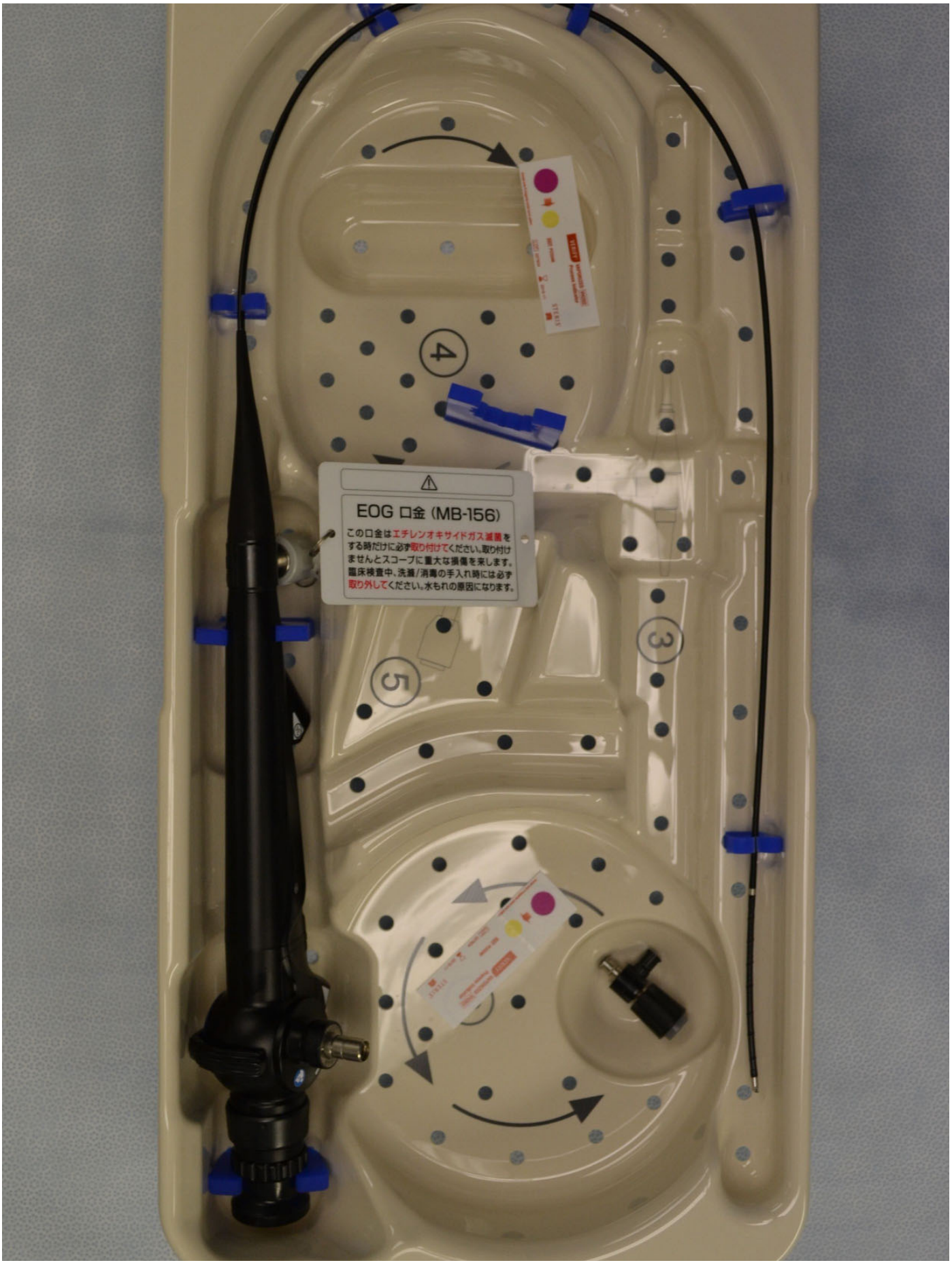
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Making a Case for Sterilization of Endoscopes:
Part Two

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LEARNING OBJECTIVES
1. Outline the workflow for sterilization of flexible endoscopes
2. Review the processes and types of sterilization systems available for endoscopes and their general compatibility information
3. Address considerations and concerns when transitioning to sterilization for flexible endoscopes

This is the second of a two-part lesson series that addresses transitioning flexible endoscopes from high-level disinfection (HLD) to sterilization as the terminal processing step. Part one, published in the March/April 2023 issue, addressed strategies for prioritizing and managing the sterilization process. This lesson outlines the workflow for sterilization, identifies the types of sterilization systems available for endoscopes, and highlights key considerations when transitioning endoscopes from HLD to sterilization.

Traditionally, healthcare facilities have performed HLD as the standard of care for processing flexible endoscopes. Recently, however, there has been an increased emphasis on transitioning endoscopes to sterilization and away from HLD due to the higher safety margin associated with terminal sterilization processes.[1,2] As noted in the previous lesson plan, ANSI/AAMI ST91:2021 states that sterilization is "a validated process used to render a product free from viable microorganisms." Shifting flexible endoscope processing from HLD to sterilization creates an opportunity to significantly reduce the risk of infection associated with the reuse of these devices.

Still, switching from HLD to sterilization for endoscopes is a challenging process that requires significant thought and planning. Creating and implementing a policy to transition flexible endoscopes to sterilization and including a logistics plan is a great first step, as is convening a multidisciplinary team to evaluate how to assess, oversee and elevate reprocessing to terminal sterilization.

Objective 1: Outline the workflow for sterilization of flexible endoscopes

Workflow for sterilized endoscopes begins with point-of-use treatment, followed by a) transport to the

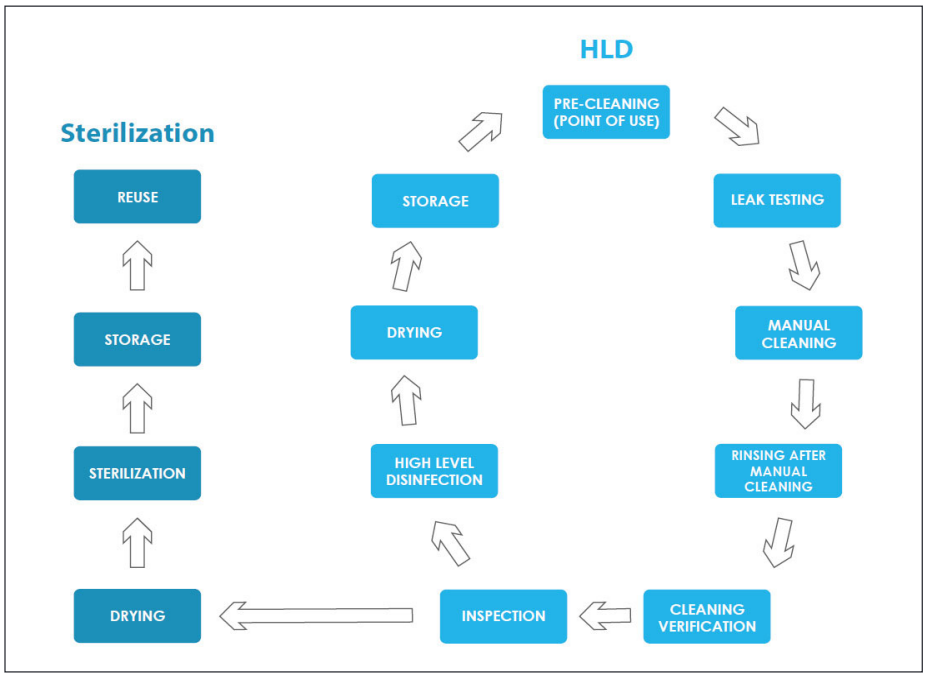

Figure 1: Workflow of high-level disinfection versus sterilization

processing area, b) leak testing, c) manual cleaning and rinsing, d) cleaning verification, and e) inspection, preferably with lighted magnification.

Instead of placing an endoscope in the automated endoscope reprocessor (AER) for HLD, the endoscope should be dried completely and prepared for sterilization. The device should be placed in a sterilization tray and wrapped or containerized and subjected to a sterilization process such as low-temperature vaporized hydrogen peroxide. After that, the device should be stored flat in its wrap/container per healthcare facility policy until it is reused or until the device needs to be reprocessed (see **Figure 1**).

Sterilized devices must still be prepared properly prior to sterilization. This means that devices require thorough cleaning, rinsing and drying before sterilization (remember, if a device isn't clean, it cannot be considered sterile). As shown in Figure 1, endoscopes also need to undergo cleaning verification and inspection prior to sterilization; a secondary inspection should occur prior to the device's reuse in the procedure room [in accordance with current standards, guidelines, endoscope manufacturers' instructions for use (IFU) and facility policy}.

Endoscopes do not need to undergo both HLD and subsequent sterilization. Some facilities perform this practice to render the instrument safe for handling and transport to sterilization; however, doing so is not necessary according to accepted workflow in IFU, standards and guidelines. In fact, this double processing scenario introduces additional exposure to chemicals for the endoscope and requires extra resources to be utilized for the department, including utilities and additional staff time.

An appropriate introductory step in the shift from HLD to sterilization is to prioritize which endoscopes will be transitioned first. Remember, according to ST91, high-risk endoscopes include bronchoscopes, duodenoscopes, linear ultrasound scopes, endobronchial ultrasound scopes, ureteroscopes, and any others as determined by one's facility, and those should be prioritized first. Next, consider endoscopes with safety alerts from the U.S. Food and Drug Administration (FDA), such as bronchoscopes, duodenoscopes and ureteroscopes.

Most facilities have sterilization systems available that are compatible with bronchoscopes, such as low-temperature vaporized hydrogen peroxide, but still choose to disinfect them in an AER—and often in the same basin where gastrointestinal (GI) endoscopes are placed. If sterilization is feasible (available), then the endoscope should be processed in that manner because of the greater 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 (SPD); however, this does not negate the need for sterilization. In this instance, endoscopes should be transported to the alternate department and a multidisciplinary team should be convened to determine the logistics for the new process.

Part 1 of this lesson stressed the importance of having endoscope IFU readily available to assist with sterilization method compatibility and other manufacturer requirements for inspection after cleaning and prior to reuse. It is helpful for processing professionals to carefully review sections pertaining to processing workflow and compatibility charts to determine material durability with

the sterilization modality. Also, it is vital to refer to customer statements/letters from the endoscope and/or sterilizer manufacturer to gain an even clearer understanding of sterilization compatibility and efficacy.

Objective 2: Review the processes and types of sterilization systems available for endoscopes and their general compatibility information

Sterilization systems are already available for many types of flexible and semi-rigid endoscopes. Although the equipment may not be available in all healthcare settings currently, through proper planning and budgeting, sterilization equipment can be acquired to complete the transition process.

In general, steam sterilization is not compatible with flexible endoscopes. Steam sterilization will cause severe damage to the devices. There are a few exceptions, however, such as one older model of autoclavable bronchoscope (BF-Q180AC) from Olympus and some flexible-tip laparoscopes. Refer to the endoscope manufacturer's IFU for more information about compatibility with different sterilization systems. Ideally, the market will see more steam-compatible endoscopes in the future.

Surgical flexible endoscopes (e.g., bronchoscopes and ureteroscopes) have better compatibility with sterilization modalities. Low-temperature vaporized hydrogen peroxide systems, such as specific cycles in some STERRAD® and V-PRO® units, are generally compatible with surgical flexible endoscopes. Again, it is essential to check the IFU for both the endoscope and sterilization system to ensure compatibility with a specific sterilizer unit and identify the correct processing cycle.

GI endoscopes are more complicated to sterilize than surgical flexible endoscopes. Currently, the only marketed and compatible sterilization system remains ethylene oxide (EO) gas sterilization, which is increasingly difficult to find in healthcare facilities due to its safety concerns. Processing professionals should remember that all instruments must be properly aerated following sterilization to remove toxic EO residuals, and this takes substantial time.

Regardless of which system is used, it is critical to follow the endoscope and sterilizer IFU to determine the proper parameters for sterilizing the endoscope (and to determine which accessories to use with the endoscope during the cycle). As an example, when performing low-temperature sterilization with certain bronchoscopes, the sterilization cap must be attached to the venting connector or significant damage will occur. For EO gas sterilization, the EO cap must be attached to the venting connector on the endoscope connector prior to EO gas sterilization. If the EO cap is not attached to the venting connector during the sterilization cycle, the air inside the endoscope will expand and can rupture the bending section. These are important details that must be clear in a facility's sterilization policies.

Additionally, processing professionals must consider what to do with their endoscope accessories. If the endoscope is being sterilized, it makes sense that the accessories would be sterilized, too. Generally, endoscope accessories marked with the word "AUTOCLAVE" or "AUTOCLAVABLE" or with green markings (i.e., a green component or label) are compatible with steam sterilization (autoclaving). This compatibility information will also be found in the endoscope's IFU. *Warning: Sterilization methods often use harsher chemicals than disinfection methods. Damage to endoscopes (e.g., deterioration of adhesives of the insertion section) may occur sooner than with HLD processes. Therefore, it is critical to perform diligent inspection to ensure that the endoscope is not damaged; this should occur after manual cleaning and again prior to use in the patient procedure room.*

Objective 3: Discuss cautions and considerations when transitioning to sterilization for flexible endoscopes

It is essential to thoroughly inspect each endoscope and its accessories for damage as outlined in the instructions (the reprocessing manual describes what to do during processing, and the operation manual outlines what to do in the procedure room before the endoscope is used on a patient). Inspection prior to reuse on the patient is a critical yet often-missed step. Again, significant damage can occur during sterilization, and damage would only be noted in the procedure room when setting up, so this secondary inspection is crucial to safety and positive outcomes.

The drying step is also vital when sterilizing an endoscope. With HLD, the drying step occurs after the endoscope is removed from the AER. Conversely, with sterilization, drying occurs after cleaning verification and inspection—prior to packaging for sterilization. *Note: Be sure to thoroughly dry the endoscope and accessories before sterilization. If the devices are not dried properly, the cycle could abort, or the process could be ineffective.* As is the case for any processing protocol, sterilization results depend on various factors, including how the equipment was packaged and the placement and

loading of the package in the sterilizer. As with any sterilized device, the sterilization process should be verified using biological indicators (BIs) and/or chemical indicators (CIs).

To maintain sterility of equipment following sterilization, sterilization pouches, wraps and containers should be used according to the IFU and national guidelines. Improper handling will recontaminate the device. Before use, confirm that the endoscope and accessories underwent proper processing after their previous use and that they have been stored properly. This can be done by checking the storage interval/expiration date, inspecting for surface contamination (e.g., dust), and checking for tears or other breaches in the sterile packaging.

For other devices, use only compatible sterilization wraps and pouches legally marketed in the U.S. Store the sterilized endoscope and accessories in a proper storage cabinet or rack following facility policies and applicable standards and guidelines. Sterilized endoscopes may be stored flat in their sterile wraps/containers in accordance with facility policy for storage of sterilized items. Therefore, concerns about length of storage (i.e., hang time) associated with disinfected endoscopes is not as great for sterilized devices. Moving to sterilization could reduce the number of processing cycles utilized.

Conclusion

Implementing a multidisciplinary team is a crucial starting point for transitioning endoscopes to sterilization because it helps prioritize high-risk endoscopes for sterilization and determine compatible and available methods. Creating an implementation strategy and outlining a plan of action with due dates and departmental responsibilities is also vital, as is keeping up with the latest technology, standards, guidelines, IFU, and FDA statements. With a detailed, comprehensive plan, healthcare organizations can focus on implementing best practices and improving processing quality and patient safety. P

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FOR FURTHER READING

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