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Sterile Barriers: Proper Use and Inspection

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LEARNING OBJECTIVES

1. Describe the three primary types of sterile barriers and their proper use
2. Explain key differences between packaging materials for different sterilization modalities
3. Understand the inspection process for rigid containers

Packaging and labeling of instruments and instrument sets for sterilization requires effective planning to ensure day-to-day and long-term process quality. This lesson addresses some of the many factors involved in selecting appropriate sterile barriers, inspecting the devices for sterilization, and labeling the packages for future identification.

Objective 1: Describe the three primary types of sterile barriers and their proper use

Three types of sterile barriers are most used in surgical instrument sterilization: peel pouches, sterilization wrap and rigid containers. Peel pouches feature clear plastic on one side that allows viewing of the instrument inside. The other side features either paper or high-density polyethylene (HDPE). HDPE is used in hydrogen peroxide (H_2O_2) sterilizers and will be described in objective 2.

Peel pouches may be purchased in a roll, such that each pouch must be cut to size and then heat-sealed, or in various pre-cut sizes that have a self-sealing strip. Peel pouches are used for lightweight single instruments. Heavy instruments are not compatible with peel pouches, as there is a high likelihood that the heavy item will compromise the seal of the pouch while in transport or storage.

Tip protectors are frequently required when placing items in peel pouches. Items that are sharp or that have a flat edge, even if the edge is not sharp, may poke through the pouch during transport or storage. The protectors should be used when pouching all items that could poke through or tear the pouch. Tip protectors may be made of plastic, or paper with a clear plastic window, depending on the type of instrument and the mode of sterilization. (See **Figure 1**) *Note: At times, Sterile Processing departments (SPDs) may desire to use pouches to keep small items together inside larger sets. It is important to consult the manufacturer's instructions for use (IFU) before introducing this practice.*

Figure 1

Peel pouches and paper tip protectors both commonly incorporate a Type 1 indicator. Type 1 indicators are the most basic type of indicator and show only that the item has been exposed to the sterilization process. Type 1 indicators provide a visual indication that the item has been processed but must be used in conjunction with higher types of indicators before being used in a procedure.

Before use, peel pouches should be inspected for pinholes, and the seal should be inspected for wrinkles or gaps. If pinholes are found in peel pouches, an assessment should be made of other pouches with the same lot number, as issue may stem from a manufacturing defect. Peel pouches should be stored in such a way to protect them from damage, debris and moisture before use. End users should also inspect sterilized pouches for tears, pinholes, wet spots and improper sealing (gaps and wrinkles in the sealed end).

Sterilization wrap is made from either linen (reusable woven fabric) or synthetic materials (non-woven, bonded and single use). Wrappers offer flexibility in protecting items of unusual shape, but they are subject to tears, closure malfunctions and holes, even with normal storage, transportation and handling practices. Wrappers come in pre-cut sizes, and sterilization personnel select the appropriate size wrapper for each specific application. Wrappers may be used for graphic trays, instrument sets in baskets or pans, and single instruments. For single instruments, wrappers are chosen when the instrument is too heavy to be placed in a peel pouch. Sterilization wrap may also be used for sets of instruments that are too small to warrant a rigid container. Wrappers are also used in many facilities for basin sets and linen packs. Tip protectors are recommended for use with wrapped items, just as with peel pouches. Commercially available corner protectors are also available to be used with sterilization wrap. Corner protectors can reduce the incidence of holes in wrappers; however, careful attention must be paid to the manufacturer's IFU for the wrap and the protector.

Wrapped items are typically secured with sterilization tape, and the tape is commonly also a Type 1 indicator. Sterilization tape may be made from paper for steam and ethylene oxide (EO) sterilization or from a plastic material to be used in H_2O_2sterilizers. It is important to recognize that sterilization tape may roll up if not stored properly. Sterilization tape that has rolled up may indicate a break in the sterile barrier, and a procedure should be in place to address the situation.

Before use, sterilization wraps should be inspected for pinholes or abrasions. As with peel pouches, if pinholes, abrasions or tears are found in wrappers, other wrap with the same lot number should be assessed to explore the possibility of a manufacturing defect. Sterilization wrappers should be stored in such a way as to protect them from damage dirt, debris and moisture before use. End users should inspect wrappers for pinholes, tears, compromised closure devices (tape), abrasions and wet spots.

Finally, woven reusable wrappers must be laundered according to the wrapper's IFU and then carefully inspected before use. Woven wraps may have sterilization cycle or washing limits that will be defined in the IFU and must be strictly adhered to by the facility.

Rigid containers are made of aluminum and have filters (similar to non-woven wrapping material) that must be placed properly to allow steam penetration, while maintaining a post-sterilization barrier. Rigid containers are the most robust type of sterile barrier, but they still must be inspected carefully before use. The containers do, however, consume more storage space and add weight to instrument sets that must be carefully considered according to the sterilizer IFU.

Rigid containers may be used for any instrument or instrument set, provided that the combined weight of the instruments and container are within the limits set by the sterilizer IFU. Rigid containers commonly have a place for a load card to be affixed to the outside of the case. Load cards can be written on to identify the container contents, sterilizer load details and other information. Containers are closed with sterilization locks, which are designed to provide proof that the container has not been opened. Load cards and sterilization locks usually feature a Type 1 indicator.

Before use, rigid containers must be inspected according to the container IFU. Inspection protocols for rigid containers will be discussed in objective 3. End users inspect rigid containers for a proper filter and filter holder placement, and for sterilization lock integrity.

Objective 2: Explain key differences between packaging materials for different sterilization modalities

Sterilizers of varying types use very different mechanisms to sterilize instruments and, as such, have unique requirements for the materials which may be used in packaging. Each type of sterilizer uses pouches, wrappers and rigid containers; however, it is essential to ensure the sterile barrier used is compatible with the sterilization modality. Each modality has specific types of these packages that can be used.

Steam sterilizers use high-temperature pressurized steam to sterilize instruments. Steam sterilization is typically compatible with:

- Paper/plastic pouches with either paper/plastic or plastic tip protectors
- Wrappers made from either linen (reusable woven fabric), or synthetic materials (single-use)
- Rigid containers with filters.

Due to the high temperature of steam sterilizers, HDPE pouches are not compatible and will shrink during the sterilization cycle.

EO sterilizers are low-temperature units that use a chemical to render instruments sterile. Packages for EO sterilizers are typically dual-use with steam sterilizers: paper/plastic pouches, woven or non-woven wrappers, and aluminum rigid containers with non-woven filters.

- H_2O_2 sterilizers are low-temperature sterilizers that use a chemical to sterilize instruments. The following may be used in H_2O_2 sterilizers:
- HDPE pouches
- Non-woven type wrappers (single-use). Tape must be selected specifically to the H_2O_2 modality to prevent absorbency.
- Rigid containers with filters.

Due to the small amount of sterilant injected into the chamber during sterilization, cellulose materials, such as paper pouches, and fabric materials, such as woven wrappers, are not compatible with H_2O_2 sterilizers; cellulose and fabrics are absorbent and may cause items in the load to be not sterile. These materials will also cause loads to fail due to low sterilant concentration. Tip protectors made from paper are also not compatible with H_2O_2 sterilizers; only plastic tip protectors may be used.

Objective 3: Understand the inspection process for rigid containers

Before sterilization, all rigid containers must be carefully inspected to ensure that sterility will be maintained. While it is important to consult the IFU for the specific brand and container being used, some general inspection principles apply to all rigid containers including:

- Check that there is noticeable spring when the latches are opened. The gasket must fit tightly when closed, and a spring action when the latches are opened indicates the gasket is in good condition.
- Inspect the filter retention pins in both the lid and base (if present). Filter pins secure the filter retention plate to the container lid and should provide a tight fit with no movement. (See **Figure 2**)

Lid inspection is also essential:

- Latch – Check that the latch and spring are intact, not bent or protruding. The latch should swing up and down freely.
- Gasket – Inspect the gasket for cuts, holes, shredding, visible degradation and color change. Check that the seams are intact (not separated) and that it is properly seated in its retaining groove.
- Dents – Inspect for dents, which could affect the gasket's sealing capabilities.

The container base should also be carefully inspected. Steps include:

- Checking that the handle sleeve is in good condition and not cracked or torn
- Diligently inspecting for dents on the upper lip of the container, which comes in contact with the gasket.
- Looking for a distorted shape and ensuring the filter plate rests flat on a flat surface
- Ensuring that the lever is not bent and secures the plate properly
- Checking for appropriate spring action or compression when the filter plate is secured.

Figure 2: Inspecting the filter retention plate

Most brands of rigid containers are repairable as medical devices. Check with the repair vendor about their program for repairing rigid containers.

Conclusion

Sterile barrier systems—peel pouches, single-use and reusable sterilization wraps, and rigid containers—are classified as medical devices by the FDA. Each must be carefully chosen with regard to instrument type, sterilization

modality, and storage conditions. Additionally, each must be carefully inspected according the manufacturer's IFU to ensure that the instruments it contains are properly sterilized and the barrier will be maintained during handling, transport and storage. P

RESOURCES

ANSI/AAMI ST79:2017/(R)2022 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

ANSI/AAMI ST77:2023 *Containment devices for reusable medical device sterilization.*

Healthcare Sterile Processing Association. (2025). "Chapter 7: Packaging for Sterilization" in the *Sterile Processing Instrument Manual*, second edition.

CIS Self-Study Lesson Plan Quiz
Sterile Barriers: Proper Use and Inspection

Lesson No. CIS 310 (Instrument Continuing Education – ICE) · Lesson expires June 2027

1. The three most commonly used types of barrier packaging are:
   a. Mesh trays, rigid containers and plastic pouches
   b. Reusable cloth, plastic bags and rigid containers
   c. Rigid containers, peel pouches, and wraps
   d. Plastic, wraps and peel pouches

2. The purpose of the clear side of peel packs is to:
   a. Visualize contents
   b. Keep the contents dry
   c. Enable low-temperature sterilization
   d. Protect the package from excess humidity

3. Type 1 indicators on peel pouches indicate that the:
   a. Package contents are sterile
   b. Package has been exposed to a sterilization process
   c. Contents are ready to use
   d. Contents are clean

4. Peel pouches should not be placed inside larger sets unless:
   a. Personnel from the Operating Room request it
   b. There is no other way to contain items
   c. The set will be used immediately
   d. The practice is specifically approved in the instructions for use (IFU)

5. Single instruments should be placed in wrappers when:
   a. The items are wet
   b. They are too heavy for a peel pouch
   c. There is a need for rapid turnaround
   d. They have small lumens

6. Corner protectors:
   a. Aid in drainage and drying during sterilization
   b. Come with large sterilization wrap
   c. Protect sets if they are dropped or stacked
   d. Reduce the incidence of holes in wrappers

7. Sterilization tape is:
   a. A Type 1 indicator
   b. A Type 2 indicator
   c. A Type 3 indicator
   d. Not recommended as an indicator

8. Wraps made with synthetic materials:
   a. Are not recommended for steam sterilization
   b. May only be used three times
   c. Are single use
   d. Are inexpensive

9. HDPE pouches:
   a. Will shrink in a steam sterilization cycle
   b. May be reused
   c. May be used in immediate use steam sterilization cycles
   d. Are not recommended for single instruments

10. Rigid containers:
   a. Must be inspected before each use
   b. Cannot be damaged due to their solid construction
   c. Should be used for all instruments
   d. Only require sterilization locks when they are going into storage

11. Which of the following is classified as a medical device by the U.S. Food and Drug Administration (FDA)?
   a. Rigid containers
   b. Sterilization wrap
   c. Peel pouches
   d. All of the above

12. Tip protectors containing paper:
   a. Are not conpatible with steam sterilization
   b. Are not compatible with H_2O_2 sterilization
   c. Are not compatible with EO sterilization
   d. May be used in any sterilization process

13. Before use, wrappers should be:
   a. Inspected for holes and tears
   b. Stored at 74° F
   c. Tested for barrier strength
   d. Sprayed with a chemical sealant

14. Most brands of rigid containers:
   a. Are non-repairable
   b. Are repairable as medical devices
   c. Feature lifetime warranties against damage
   d. Require their lids to be replaced every six months or as needed to maintain barrier integrity

15. Rigid containers are sealed with which of the following?
   a. Tape
   b. Heat
   c. Locks
   d. Specialty adhesive

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