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Container Packaging and Steam Sterilization

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LEARNING OBJECTIVES

1. Review basic packaging requirements
2. Identify how rigid containers react during the steam sterilization process
3. Explore characteristics of rigid containers

Maintaining sterility of items used in the Operating Room (OR) is essential for patient safety. Multiple types of packaging are available to help maintain sterility. This lesson addresses one type—rigid containers—and their sterilization process.

Objective 1: Review basic packaging requirements

There are multiple sterilization modalities available for Sterile Processing (SP), including steam, low-temperature methods and, occasionally, ethylene oxide (EO). Regardless of the sterilization method, the type of packaging material used must comply with key performance features. These include allowing penetration and evacuation of the sterilant; maintaining sterility of sterilized contents until they are opened; allowing for aseptic presentation; and having the ability to label the packaging.

Three primary packaging methods are offered today: paper/plastic peel pouches, flat wrappers, and rigid sterilization containers. When evaluating selecting packaging methods, it is important to ensure that the packaging/container:

- Offers protection during transport, storage and handling
- Is free of toxic ingredients or non-fast dyes
- Has minimal lint
- Can close securely (with a tamper-evident seal)
- Resists tears and punctures
- Is correctly sized to ensure even distribution of items to be sterilized
- Offers ease of use when preparing and opening the packaging
- Includes the manufacturer's instruction for use (IFU)
- Is cost effective

Paper/plastic peel pouches are designed for small, often individual, and

lightweight instruments. The sterilant enters the pouch, is removed on the paper side and is placed in the sterilizer to promote proper sterilant access. Labeling should be done on the plastic side of the pouch. Flat wrappers come in a wide range of sizes to cover the devices being sterilized. It is important to use properly sized packaging; too-large wrappers will have excess material that could cause steam to accumulate and pool, causing a wet pack. Proper wrapping technique ensures that the first fold completely covers the package and that the wrapper remains snug throughout the wrapping process. The packaging should be inspected each time it is handled to ensure no holes or tears are present.

Rigid sterilization containers are most commonly used when sterilizing multiple items (often, instrument sets). Containers come in a variety of sizes and feature filters or valves for sterilant penetration. Filters are often made of a cellulose or polypropylene material, both of which allow for penetration and evacuation of the sterilant and provide a long-term sterile barrier during storage. For sterilization containers, it is important to ensure the combined weight of the container and contents does not exceed 25 pounds (per Association for the Advancement of Medical Instrumentation standards and Association of periOperative Registered Nurses guidelines). They must also be easy to carry and handle; have prepping features such as loading, closing and locking; have stacking capabilities for transport and shelf storage (as well as stacking capability for internal baskets); feature effective filter retention mechanisms; come in a variety of sizes; and be compatible with various sterilization modalities.

For all types of packaging material, it is critical to understand the shelf life for sterilized items. Two considerations for shelf life are expiration date and event-related practice. Regardless of the shelf-life method a facility employs, it is crucial to always follow industry and manufacturer guidelines and IFU. Standards ANSI/AAMI ST77 and ST79 provide recommendations for rigid containers and steam sterility and assurance, respectively. Be sure to check with each packaging manufacturer to determine if there is an expiration date assigned to the packaging material.

Additionally, when ensuring effective packaging to maintain sterility, aseptic presentation must also be understood and performed properly. Aseptic presentation involves transferring sterile contents from their sterile barrier packaging to a sterile field using procedures that minimize the risk of microbial contamination. *Note: This is a critical step in the process to keep patients safe. Remember to always follow the packaging manufacturer's IFU, examine and inspect trays, baskets, liners, containers, etc., ensure labeling and indicators are easy to see and read, and check for packaging integrity after sterilization and before issuing the device.*

Objective 2: Learn how rigid containers react during the steam sterilization process

Prior to assembly and sterilization it is important to properly clean, rinse and dry the container following the manufacturer's IFU. Rigid containers must be cleaned after each use, even when they do not visibly appear soiled. During steam sterilization, items inside the containers are heated to the manufacturer's recommended appropriate temperature for the correct period amount of time. Rigid containers offer several advantages, including greater protection of contents, durability, cost-effectiveness, and increased staff efficiency and throughput.

Once loaded, sealed, locked and labeled, the rigid container is ready to be placed in the sterilizer. A pre-vacuum sterilizer goes through three phases in a cycle: conditioning, exposure and exhaust. During the conditioning phase, the dynamic air removal process removes air, and the chamber is heated. The chamber continues to heat until the set sterilization temperature is reached. During this time, steam penetrates the container filter, surrounding and warming the contents. In the exposure phase, the chamber holds the set temperature for the required amount of time to sterilize the chamber contents. In the final step, the exhaust phase, air is removed from the chamber and pressure is gradually reduced. Content drying also occurs during this phase. Upon completion of the three phases, the chamber can be opened, and the cooling process can begin. *Note: Do not touch the containers until the contents have cooled to room temperature.* The filter acts as a part of the sterile barrier, preventing contamination of the tray contents.

Figure 1: Placing filter in the container lid

Objective 3: Explore characteristics of rigid containers

The Association for the Advancement of Medical Instrumentation (AAMI) notes that rigid containers are "valuable tools in sterility maintenance and to prevent damage to surgical instruments and devices." Rigid sterilization container systems are durable and comprised of a rigid material such as anodized aluminum, stainless steel, or proprietary polymers.

These containers are validated by the U.S. Food and Drug Administration as Class II medical devices, which indicates the container has been designed, tested and validated to conform to industry standards in terms of specified sterilization modality, transport/shelf life, aseptic presentation, and labeling. The durable material used to make the containers ensures that the containers can endure multiple sterilization cycles, handling, storage, etc.

Figure 2: Outer container with inner trays

When properly maintained, many hospitals and ambulatory surgery centers can last 10 years or more, maximizing the return on investment. Proper care and handling that follows the manufacturer's IFU is paramount, along with inspection before and after each use.

Conclusion

Approved rigid containers have been FDA approved through the 510(k) process and have been on the market for more than 40 years, representing a lengthy history of use and efficacy in U.S. healthcare facilities. When properly handled and maintained, rigid containers can prevent damage to surgical devices, maintain the sterility of their contents until the processed devices are used in a procedure, and provide many years of use. P

RESOURCES

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