Sterilization Container Systems

Learning Objectives:

1. Discuss rigid container systems and their advantages over other packaging options
2. Explain proper use, care, inspection, assembly, sterilizer loading/unloading, and point of use
3. Examine the criteria for the selection and evaluation of containers

Introduction

Containment devices for reusable sterilization are comprised of a number of different systems. They are intended to be used as packaging for medical devices before, during and after sterilization. Sterilization packaging systems are required to secure instrument sets, provide for sterilant penetration of contents and withstand multiple handling events during a prolonged period of storage and handling. There are two types of containment devices including rigid reusable sealed containers and case trays which are designed to be wrapped. Rigid, reusable container systems provide an efficient, cost-effective way to package and protect surgical devices for sterilization, transport, storage and aseptic presentation of contents. They are sealed systems and serve as an alternative to disposable and reusable sterilization wrap. A sterilization container's rigid sides protect fragile devices within and eliminate the tears associated with sterilization wrap. Some containers are cleared for steam sterilization only, others for low temperature sterilization. Only one is universal and corrosion resistant cleared by FDA for all current sterilization methods from steam to various low temperature methods.

Containers are most typically constructed from anodized aluminum and have a box-like structure with removal lids including a gasket to secure a tight seal. Sealed containers include tamper-proof locking mechanisms and handles for ease of transport. Sterilization containers have a filter mechanism designed to permit the sterilant to enter and exit as well as to act as a microbial barrier. Most sealed container systems are designed for terminal sterilization and extended storage, utilizing a disposable filter secured by a gasketed filter retention plate. Some containers have a filter-less system equipped with a pressure sensitive or thermostatic valve which opens and closes within the sterilizer. Such devices are cleared for pre-vacuum steam sterilization only, and few for sealed flash sterilization including gravity displacement steam.

Container contents

All sealed container systems require an inner basket or tray to secure the contents of the load. The basket may contain accessories including instrument brackets, partitions and posts to secure and to organize and protect contents. Some may include stackable trays to separate contents into levels and protect contents from damage during transport. Peel pouches may not be used within sealed or wrapped container systems as they are not able to stand on their sides for sterilization. Small perforated trays or insert boxes are recommended in lieu of pouches.

Rigid sterilization systems should be cleaned and inspected after each use. The disposable filter should be discarded and the components disassembled for cleaning. Valve type closures must be

decontaminated following manufacturer's written instructions. Particular attention should be given to type of the detergent used as alkaline cleaners and those followed by acid neutralizers can damage the passive layer of sealed systems. Inspection procedures should include verification that gaskets are intact and latches are properly functioning. If the hardware is riveted to the container such devices may become compromised over time as rivets loosen and create pathways for entry of microorganisms.

Aseptic presentation is important with all sterilization packaging systems. To properly remove the inner basket or tray from the container, the sides of the basket must not touch the edge of the container or the contents will be considered contaminated. Furthermore, the contents of the container system must be dry. Wet packs are considered non-sterile. The only exception being for flashed items, properly cleaned, decontaminated and sterilized for immediate use only. To manage wet packs, be sure that the contents are dry prior to sterilization. Pre-heat the load to reduce the formation of condensation during the cycle, evaluate the weight and density of the set and review manufacturer's recommendations for processing including proper cool down prior to transport to sterile storage. Plastic containers may require additional dry time as they do not have the thermal conductivity properties of aluminum and other metals. Metal materials used to construct containment devices must be corrosion resistant or treated to improve their corrosion resistance. Furthermore these materials must not affect the biocompatibility of the device.

Regulatory requirements

All containment devices whether sealed containers or wrapped trays are considered Class II medical devices and must be cleared by FDA for their intended use. According to AORN Recommended Practices, "Packaging systems should be evaluated before purchase and use to ensure that items to be packaged can be sterilized by the specific sterilizers and or sterilization methods to be used and should be compatible with the specific sterilization process for which it is designed." AAMI ST 77 provides guidelines for manufacturers of containment devices for reusable medical devices. Many international standards have been adopted in the U.S. document with the goal of providing minimal labeling, safety, performance, and validation requirements. Manufacturers are required to validate their containment devices and provide the data to FDA for clearance. However, health care personnel bear the ultimate responsibility for ensuring that the containment device or sterilization packaging is compatible with or can be effectively sterilized within the health care facility.

Verification and Inspection

According to AAMI ST79, health care personnel bear the ultimate responsibility to ensure that a packaging system, including a rigid sterilization containers system, is suitable for use in sterilization processing and sterility maintenance. The specific design of the rigid sterilization container system needs to be compatible with the design and performance of the sterilizer as well as the devices to be sterilized. Manufacturers cannot possibly test all combinations of sterilizer sizes, cycles, and instrument configuration.

Health care personnel need to perform testing to verify that there are no problems or to identify technical problems to be resolved in consultation with the container system manufacturer as well as sterilizers' manufacturer and the device manufacturer.

Users are responsible for routine maintenance and inspection of containment devices to verify that the gaskets in the lid, and filter retention plates are in good working order and that the plates properly seal over the vented area of the container lid and base. Furthermore, the gasket should be intact and the edge of the container base nest properly within the container lid. Dents and deformations can affect the seal of the container compromising the integrity of the containment device.

Container Selection

When selecting a container system, it is important to identify the needs of the facility and to assess what the container system is capable of and for which sterilizers it is compatible. Not all container systems are compatible with low temperature sterilization or with lumened devices. For example, a container cleared for steam sterilization may not be suitable for use in a different modality.

There are numerous factors to consider when selecting a container system. Among these are factors such as container size, estimated life of the container system, aseptic presentation of contents, protective accessories for tray customization, ease of use, as well as maximum weight. It is important to review any special instructions for decontamination and handling. Although manufacturers are required to validate for efficacy and safety, verification of the packaging system within the hospital is important. When verifying containers at healthcare facilities, BIs must be placed within the containers in areas that will provide the greatest challenge. This may include areas such as the opposing corners of the instrument basket and the underside of the lid away from the filter.

Manufacturers' Instruction for Use

The written recommendations of the device manufacturer should always be followed. The device manufacturer is responsible for ensuring that the device can be effectively cleaned and sterilized. It is important that all rigid containers be completely disassembled, washed, and dried after each use. Most sterilization container systems are manufactured from an anodized aluminum alloy which requires cleaning with a pH neutral detergent to maintain the passive layer and the durability of the device. Thorough rinsing is essential for the removal of all soil and for removal of cleaning agents. A thoroughly dry container and contents is critical for sterilization. Some low temperature sterilization systems will abort if the container and its contents are not properly dried. Moisture within containers can create wet packs.

When processing container systems in gravity displacement steam, an extended reprocessing time may be required. In addition, the materials of construction and the design of the containment device itself may increase either processing time or drying time. Internal chemical indicators or integrators should be placed in the corner of each inner basket for routine monitoring. Biological indicators should be utilized for verification of an instrument set and for weekly or daily monitoring of the load. In addition, an external indicator and tamper evident seal which serves as a security lock should be assembled to the

container prior to sterilization. Such indicators demonstrate that the set has been processed when a color change is confirmed.

Containment devices must be placed flat on the sterilizer cart. If wrapped items are included in the sterilizer load, they must be placed on the shelf above the containment device to avoid moisture in the load. To minimize a potential for condensate formation within the seal container system a gradual cool down is required. The door of the sterilizer may be cracked after processing and the cart with containers placed in cool down. Wet packs are unacceptable for use. The only exception is when flash sterilization or immediate use sterilization is required on an emergency basis.

In summary, rigid reusable container systems provide an excellent barrier to microorganisms. They are easy to use and provide the utmost for instrument protection and organization. They save time over wrap and avoid the added expense of wrapping and the disposal costs associated with the removal of the wrap. In addition, sterilization containers may be stacked for transport and storage and some are cleared for stacking within the autoclave and within the container itself. These features maximize storage space and increase productivity and efficiency.

References:

ANSI/AAMI ST77: 2006

ANSI/AAMI ST79: 2008

AORN Recommended Practice for Selection and Use of Packaging Systems for Sterilization: 2010

Central Service Technical Manual Seventh Edition IAHCSMM 2008