

INFECTION CONTROL hotline

“Sterilization packaging is the critical first factor that contributes to maintaining sterility until the package is intentionally opened...”

source notes



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care professionals for sterilization container systems and medical device cleaning solutions for seven years. She answers questions relevant to sterilization packaging and cleaning agents, as well as the processes used for sterilization and cleaning in the health care setting. She has 25 years of experience as a registered nurse and in central service management and has served on the national board of directors of the American Society for Healthcare Central Service Professionals (ASHCSP) for two terms. Carlo achieved ASHCSP fellow status and was the 2002 recipient of the Leonard A. Leibus Award. Carlo also is a member of IAHCSSM, AORN and AAMI.

about this column

This column presents answers and practical guidance to some of the most commonly asked questions of suppliers and educators in the infection control and sterile processing communities. To submit a question to the column, e-mail Bob Kehoe, executive editor, at rkehoe@healthforum.com.



Photo courtesy Case Medical

Sterilization cues for containers

Questions often arise regarding safe practices relevant to sterilization containers—from cleaning these holding devices to the maximum weight for containerized instrument sets to shelf life and sterility maintenance. Following nationally established, recommended practices can help ensure optimal container effectiveness, infection control and patient safety. This month's column addresses these subjects and related issues.

Q: Is it necessary to clean sterilization containers after each use?

Sterilization containers are reusable medical devices and should be cleaned after each use based on the infection control principle that all medical devices and equipment are considered to be dirty/contaminated after use.

The newly revised Association for the Advancement of Medical Instrumentation's (AAMI) Recommended Practices:

Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2006 Section 7.5.9 states: “Rigid sterilization systems should be cleaned carefully before sterilization even if they are to be returned immediately to use.”

Adequate cleaning is the first and most important step in the decontamination and reuse process. The purpose of cleaning is to remove visible soil and reduce microbial contamination that cannot be

seen with the naked eye.

Container users should consult and follow the manufacturer's instructions for disassembly, cleaning, cleaning methods and use of compatible cleaning agents for their containers.

Generally, containers can be cleaned by either mechanical or manual methods. Prior to cleaning containers, all single-use items such as filters, load cards and locks should be removed and discarded. Interior baskets should be removed from the container for cleaning and removable filter plates or valve plates should be removed to allow for thorough cleaning of the container and the components. Most container manufacturers recommend a neutral pH detergent for cleaning containers to avoid damage to the containers' construction material.

For example, detergents that do not have a neutral or near neutral pH can damage the protective surface of anodized aluminum containers, causing discoloration, pitting and corrosion, and certain detergent additives can adversely affect some plastic containers. After cleaning containers, they should be rinsed thoroughly to remove any detergent residue and dried before they are placed in the clean prep/pack area and reused to house cleaned and decontaminated instruments for sterilization.

Q: Can we use peel pouches inside our sealed containers?

Peel pouches are not recommended for use inside sterilization containers. The recommended practice in ANSI/AAMI ST79:2006, Section 8.3.4 states: "It is inadvisable to use paper-plastic pouches within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, steam contact and drying."

In addition, peel pouches placed inside containers could block the vents in the container and cause it to implode, rendering the container unusable. Small

reusable insert cases (e.g., perforated boxes with covers/lids) are specially designed to contain small items and protect delicate instruments, and are recommended for use in sets inside sterilization containers. Single-use products such as an absorbent, single-layer flat wrap or an autoclavable medical grade paper bag also may be used to contain small items.

Q: Is there a weight limit for containerized instrument sets ?

Container users should consult the container manufacturer's documentation regarding the weight limit of instruments validated for their specific container sizes.

A maximum weight limit of 25 pounds for containerized instrument sets has been recommended in the new ANSI/AAMI ST77:2006 standard, "Containment devices for reusable medical device sterilization." ST77, the first U.S. performance standard for rigid sterilization container systems, Section 4.3.5 states: "The combined weight of the containment device, the instruments, and any accessories or wrappers shall not exceed 25 pounds when a containment device load is configured according to the manufacturer's instructions."

According to the new standard, the weight limitation is intended to help ensure that the contents of a container can be reliably sterilized and dried.

The weight limitation also addresses the ergonomic aspects of protecting health care workers from lifting-related injuries.

Heavier instrument sets may have to be divided into more than one set. The design and density comprising the set are important factors. Multiple layers and insert devices can help organize the instruments within sets.

A note included in the standard states: "If a health care facility requests an instrument set heavier than 25 pounds or chooses to place an instrument set inside a containment device that takes the combined weight above 25 pounds, the health care

facility is responsible for verifying that the set can be sterilized and dried using hospital sterilizer settings."

Q: Can containers be placed in a mixed load with wrap and peel pouches in the sterilizer?

The recommended practice in ANSI/AAMI ST79:2006, Section 8.5.6 states: "Rigid sterilization containers can be sterilized safely and economically in the same load as other supplies that require a common exposure cycle."

When combining loads for sterilization, containers should be placed on shelves below absorbent packs to prevent condensation from the containers from dripping onto the packs.

Containers should be placed flat on the shelf to help ensure adequate air evacuation, adequate sterilant penetration and efficient drying or aeration.

Before stacking containers for sterilization, users should consult the container manufacturer's documentation to determine if stacking is recommended and if any restrictions apply regarding the number of containers that can be stacked and/or the height.

The user should also conduct verification testing in the sterilizer to be used. Stacking container systems of different manufacturers is not advisable because the configurations might not be compatible.

Q: What is the shelf life of sterilization containers?

According to ANSI/AAMI ST79:2006, Section 8.9.3: "Shelf life of a packaged sterile item is event-related and depends on the quality of the packaging material, the conditions during storage and transport, and the amount of handling. Shelf life is not simply a matter of sterility maintenance, but also is a function of device degradation and inventory control."

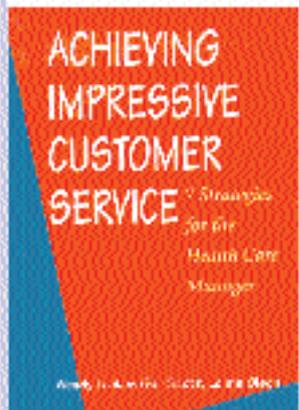
Event-related shelf life is based on the

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principle that specific events, not time, are responsible for sterile products becoming contaminated.

Sterilization packaging is the critical first factor that contributes to maintaining sterility until the package is intentionally opened and the sterile contents used.

A sterilization container's material com-

The sterile storage area is best located in a separate enclosed area with limited access. Temperature, humidity and air exchanges should be controlled: temperature at approximately 75 degrees F, humidity not to exceed 70 percent and a minimum of four air exchanges per hour.

Containers may be stacked in the ster-



Photo courtesy Case Medical

Sterilization containers should be cleaned after each use. Most container manufacturers recommend a neutral pH detergent for cleaning containers to avoid damage to the containers' construction material.

position, rigid construction and design features combine to provide a high degree of sterility assurance and a reliable barrier to protect the sterilized contents until they are used.

Container manufacturers should be contacted to obtain test documentation of the shelf-life studies that were performed for their sterilization container systems.

This will verify that the containers can be used in an event-related, shelf-life system after terminal sterilization.

Storage and transport conditions and the number of times containers are handled after sterilization also are important factors in maintaining sterility.

After sterilization, containers should be stored in an area where they will be protected from the environment, i.e., dust, dirt, moisture and insects.

ile storage area and should be stored 8-to-10 inches off the floor, 18 inches below the ceiling or level of sprinkler heads and at least two inches from an outside wall. Rotating the containers using the first in/first out practice will help minimize the number of times the container is handled while stored.

When transporting containers to the point of use, they should be in case carts or covered supply carts to provide protection from contaminated sources during transport. The end-user ultimately bears the responsibility to visually inspect and assess the integrity of the container before the container is opened and the contents are used. **MMHC**

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