HEALTHCARE PURCHASING NEWS

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LEARNING OBJECTIVES

1. *List the standards and guidance documents for container care*
2. *Explain the importance of cleaning and decontaminating rigid containers after every use*
3. *Describe the rigid container quality inspection process*

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SELF-STUDY SERIES

Are you reprocessing your instrument containers correctly?

by Pamela Carter

While conducting a processing assessment at a healthcare facility, I noticed a steady flow of OR personnel arriving with used rigid containers. Instead of placing them in the queue for cleaning, they inverted the containers, smacked their sides, wiped them with a dry towel and placed new filters in them. After this process, the containers and their lids were stacked on a wire shelf in the assembly area. The SPD technician then retrieved these rigid containers to place newly cleaned instruments for sterilization in them.

When asked about the process, the technician stated, "If the container leaves the surgical suite before the patient comes into the suite, we don't send the containment devices back to the SPD decontamination area for cleaning. Instead, we bring the containers directly to the clean side for instrumentation assembly and packaging. We don't have the time or space to clean them and they're not dirty anyway. We have been handling our containers this way for years!"

Stunned, I turned to the sterile processing manager, who immediately recognized the problem and knew corrective action was required to achieve best practices. Not only were the containers' instructions for use (IFU) not being followed, but it was clear that staff didn't realize they were jeopardizing patients, colleagues and the facility.

Why clean all containers every time?

Container systems, which are medical devices, protect instrumentation during and after sterilization. In the course of their use, containers may be exposed to environmental and procedural contamination. Without proper cleaning and decontamination, those contaminants can be passed on to sterile processing staff who work with the containers, potentially causing injury or illness.

Those same residual contaminants could contact instruments and shield microbes from the disinfection or sterilization process. This could result in patient exposure in the OR, which could lead to an infection. In addition, residual procedural chemicals or disinfectants transferred to instruments can injure patient tissue during the procedure, which can complicate recovery and, in some cases, cause permanent disabilities like blindness.

Injuring patients and staff can have large ramifications for the facility. For example, in addition to the personal consequences to patients and staff, both the facility and the patient can incur increased costs due to required additional treatment. Facility reputations can also suffer, which can reduce the number of elective patients and ultimately reduce revenue. Ultimately, the failure to properly follow the IFU can lead to accreditation citings and the potential of losing reimbursement status.

Instrument containers serve a critical function in the surgical department. Staff must take the time needed to properly care for them.

Guidance for manufacturers

A number of organizations provide guidance to packaging manufacturers and to users. The sources most commonly used in the U.S. are the Association for the Advancement of Medical Instrumentation (AAMI), Association of peri-Operative Registered Nurses (AORN), and International Association of Healthcare Central Service Materiel Management (IAHCSMM).

There are several different types of packaging used to maintain the integrity of sterilized medical devices. These include peel pouches, woven fabric (muslin, which is rarely used now), non-woven disposable wrap, and rigid containers. Packaging manufacturers must validate that the packaging/containers they offer ensure sterilant penetration into the contained medical devices, and that they prevent ingress of microbial contaminants and maintain instrument sterility throughout handling, storage, transport and aseptic presentation in the OR.

Manufacturers of rigid container systems turn for guidance to ANSI/AAMI ST77 *Containment devices for reusable medical device sterilization*. ST77 covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument organizers. Rigid container manufacturers are responsible for providing thorough IFU that include safety and effective use, routine maintenance and inspections, generalized information on their medical device validation testing, weight limitations and design characteristics, and the proper cleaning and decontamination modalities to use. For example, *Section 4.3.2 – Decontamination* states that containment devices and their reusable accessories need to be properly cleaned and decontaminated after each use via manual or automated processes per the manufacturer's IFU. *Section 4.5.2 – Instructions for use* discusses several components needed by the end users to assist with the use of the manufacturer's containment devices.

Guidance for container users

Users of rigid sterilization container systems typically defer to the appropriate guidance document for each sterilization method used at the facility. These include:

- ANSI/AAMI ST79: 2017. Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.
- ANSI/AAMI ST41: 2008/(R)2012 Ethylene oxide sterilization in healthcare facilities: safety and effectiveness.
- ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in healthcare facilities
- AORN Guideline: Packaging Systems

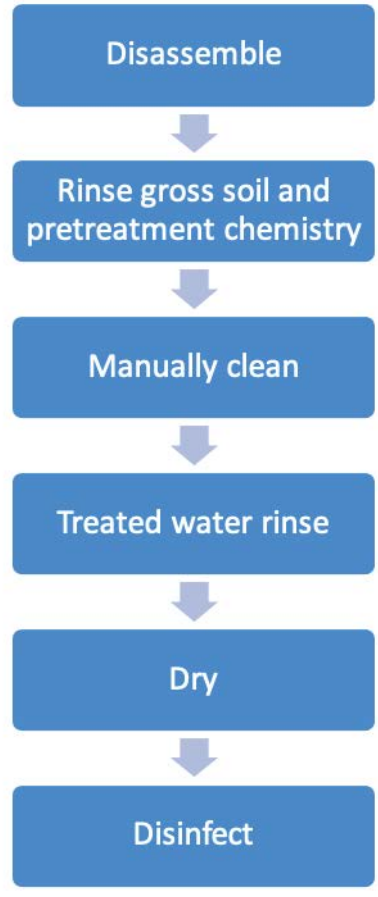
These guidance documents help SPD managers establish standard policies and procedures for workflow instructions in their departments. The container manufacturers' IFU also play a vital role in establishing care and use instructions. Before purchasing a new container system, sterile processing management should conduct a pre-purchase evaluation and request written manufacturer's IFU to ensure that their department can follow the validated cleaning and decontamination steps required for that containment system. The validated method of cleaning containers can be very detailed and can include the required cleaning agent, manual cleaning steps, mechanical cleaning steps, and disinfection process to use before loading instrument sets for sterilization.

Both AAMI and AORN state that containers should be cleaned and disinfected as soon as possible after each use. They also advise to:

a. Follow the manufacturer's written IFU
b. Include instructions for manual cleaning, mechanical cleaning or both
c. Use cleaning agents that don't damage the container or its components (seals, filter retention plates)
d. Follow accepted practices for decontamination and employee safety, including wearing of PPE

Cleaning and decontamination processes

Container systems follow the same cleaning and disinfection processes as other reusable medical devices. First, used containers must be disassembled, and all disposable components discarded. External process indicators and locks, single-use filters and retention plates, silicone mats and liners are removed, and accessory devices are disassembled per IFU.



Next, all surfaces and accessories must be thoroughly pre-cleaned using a proper brush or sponge as directed by the container manufacturer. Remove and rinse out any excess debris, soil, and pretreatment cleaning product with the sponge or brush before the manual or mechanical cleaning process.

Manual cleaning may involve several steps, and every step must be completed. The cleaning methods and chemistries must be compatible with the rigid container system. Abrasive cleaning agents can cause corrosion or damage external surfaces of the container, which could cause cracking or degradation. For aluminum and plastic containers, a neutral pH detergent is often recommended to avoid the adverse effects of harsher chemistries.

Following manual cleaning, all components of the container system must be rinsed with critical water to remove detergent and soil residuals. After rinsing, they are dried with a soft, clean, lint-free cloth. If any residual soils or cleaning chemistry are found during visual inspection, the cleaning process must be repeated.

The disinfection step is necessary to make the containers safe to handle. To assure an effective process, it's important to use compatible disinfectants formulated specifically for disinfecting medical devices and thoroughly removing cleaning chemistries.

Automated cleaning

Container cleaning can also be automated. Mechanical cleaning equipment cleans, rinses and thermally disinfects the containers. When using mechanical equipment to clean containers, end users must follow the system's IFU and must use the required washer accessories to avoid negative outcomes or a lapse in the processing cycle. It's also important to note that even if an automated process is being used, containers must still be disassembled and rinsed thoroughly per container IFU before they are placed in the automated system for processing. It may also be necessary to perform some manual pre-cleaning.

When loading containers into a washer-disinfector, it's important to use the racks and other accessories designed specifically for processing containers in that system. Special racks are often needed to assure thorough cleaning of container systems and their accessories. Some washer-disinfectors use a single rack or basket, while others can have multiple shelves or baskets. Knowing how to load a rack is essential. Detergent can only clean what it reaches. Shadowing, stacking and other improper loading techniques block proper distribution of water and cleaning chemistries within the equipment, which prevents cleaning and thorough rinsing.

Automated systems often have impingement technology that disperses water and cleaning chemistries to all surfaces of the containers. Spray arms and nozzles

Self-Study Test Answers: 1. C, 2. D, 3. A, 4. D, 5. A, 6. D, 7. B, 8. D, 9. D, 10. A

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increase the water pressure to apply force that dislodges residual soils. The programmed cycle used for containers is typically labeled "container" or "utensil," but may vary depending on the equipment's cycle names.

Cart washers come in an array of sizes to accommodate the needs of various sized facilities, from small ambulatory surgery centers to large hospitals. Using a cart washer to reprocess containers enables the department to improve its reprocessing workflows by not tying up smaller washer disinfectors with bulky containers. This frees up the washer disinfectors to be used for medical device sets and surgical accessories, which assures greater efficiency and throughput overall.

Quality inspections

Inspecting rigid containers after cleaning and disinfection is as important as the cleaning itself. Inspection checks for residual soils and cleaning chemistry, wear and tear, and mechanical disfunction that could potentially interfere with sterilization or could fail to maintain sterility of the contents. If inspection identifies damaged containers or accessories, they need to be repaired or replaced. Items to inspect include (but are not limited to) gaskets, valves, interior baskets, mating surfaces, reusable filters, filter retainers and latches. Damaged containers and accessories must be removed from the use inventory and the manufacturer needs to be consulted.

As part of a thorough quality system for containers, a routine preventive maintenance schedule should be established and documented; this assures that tools are in place to detect and/or avoid potential problems. Containers are not meant to last forever, so the container vendor can provide information about the expected useful life of each type of container. The department or purchasing manager should then budget accordingly for timely replacement of compromised or aging rigid containers.

Automated Equipment Items to Know

- **Maximum load weights**
- **Dissasembly and loading instructions**
- **Openings face down**
- **Place lids and retainer plates in loading slots**
- **Correct cycle choice**

Space constraints

Regulatory inspectors will not allow space constraints as an excuse for skipping reprocessing steps or not fully following manufacturers' IFU. They will expect departments to maximize the space they have by performing proper planning that includes workflow, case demands and calculated expected throughputs. It's worthwhile to consider automating the container cleaning process. Automation allows consistent proper practice while freeing staff to focus on case sets and other instrumentation.

Tight reprocessing spaces, like those in ambulatory surgical centers, require equipment with small footprints. In addition to the washer, it's important to have the correct number and types of racks needed to process the containers in use at the facility. Depending on the case load, it may also be wise to invest in a small cart washer, which would allow the washer disinfector to be dedicated to instrumentation and the larger cart washer to case carts. This would enable a better use of space and equipment, and would support a continuous, more efficient workflow and throughput for both instruments and container systems.

Avoid container woes

No one wants to be the person standing in front of the auditor explaining why containers are not being properly processed. Rigid sterilization container systems are Class II medical devices and are cleared by the U.S. Food and Drug Administration (FDA) for use. Per FDA and other regulatory guidance, facilities must adhere to the container manufacturers' IFU, which provide all the necessary information for correct use, care, cleaning, inspections, routine maintenance, sterilization methods, and storage. Facilities must develop policies and a standardized workflow that support these instructions, and confirm staff competency through training, education and regular evaluation of staff performance. Be the one who finds and corrects any problems in container processing, before the auditor does. HPN

Container System Inspection Item Examples	
GASKET	• No fraying, cuts or missing pieces
BASKET	• Broken or missing handles • Sharp edges or broken wires
MATING SURFACES	• No dents, chips, cracks • Filter retainer fits with no gaps
REUSABLE FILTERS	• Within its use limit
LATCHES	• No missing components • Securely attached • Lid secures with even latch pressure

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1. ANSI/AAMI ST41: 2008/(R)2012 Ethylene oxide sterilization in health care facilities: safety and effectiveness. Arlington, VA: Association for the Advancement of Medical Instrumentation

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6. Shaffer HL, Harnish DA, McDonald M., et al. Sterility maintenance study: Dynamic evaluation of sterilized rigid containers and wrapped instrument trays to prevent bacterial ingress. *American Journal Infection Control.* 2015; 43; 1336-41

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CONTINUING EDUCATION TEST • JANUARY 2021

Are you reprocessing your instrument containers correctly?

Circle the one correct answer:

1. **Which is a quality standard that provides guidance to manufacturers for rigid container systems?**
   A. ANSI/AAMI ST79
   B. ANSI/AAMI ST58
   C. ANSI/AAMI ST77
   D. SGNA
2. **Which is a quality standard that provides guidance for users of rigid container systems?**
   A. ANSI/AAMI ST91
   B. ANSI/AAMI TIR31
   C. ANSI/AAMI ST90
   D. ANSI/AAMI ST79
3. **Which is a method used to clean containers?**
   A. Mechanical cleaning equipment
   B. Paper towels
   C. Metal brush
   D. Detergent
4. **Why do all containers need to be cleaned?**
   A. Container manufacturer requirement
   B. Standards and guidance requirement
   C. Contamination can occur at any time
   D. All of the above
5. **What is removed from containers during the initial rinse?**
   A. Gross soil and residual pretreatment chemistry
   B. Bioburden and cleaning chemistries
   C. Saline and disinfectants
   D. Bone cement and sterilants
6. **Improper container loading techniques can:**
   A. Block proper distribution of water and cleaning chemistries
   B. Enhance cleaning
   C. Impede thorough rinsing
   D. a and c
7. **Cart washers cannot clean and thermally disinfect containers.**
   A. True
   B. False
8. **Using a cart washer to reprocess containers enables a department to:**
   A. Eliminate the need for thermal disinfection
   B. Allow smaller washer disinfectors to be used specifically for surgical instruments
   C. Help achieve greater efficiency and throughput for containers and instruments
   D. b and c
9. **Why is inspection important?**
   A. It finds residual soils
   B. It identifies containers needing repair or replacement
   C. It discovers mechanical disfunction that could potentially interfere with sterilization
   D. All of the above
10. **Rigid sterilization container systems are Class II medical devices cleared by the FDA for use, so facilities must adhere to the container manufacturers' IFU.**
    A. True
    B. False

CONTINUING EDUCATION TEST SCORING

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HSPA HEALTHCARE STERILE PROCESSING ASSOCIATION

The approval number for this lesson is **STERIS-HPN 200412.**

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