Rigid sterilization containers were first used in the late 1970’s in the U.S., and since then their use for reprocessing instruments in healthcare facilities has become commonplace. Some facilities have a large inventory of containers from a variety of manufacturers. Although containers are a common daily tool in SPDs, there is a surprising amount to know in order to make good container purchasing decisions and ensure proper handling and use. The better informed a sterile processing department is, the more benefits they can gain from these helpful systems.

Thoughtful and thorough evaluation
The selection of rigid sterilization containers should be a detailed, thoughtful process. It should include an assessment of each system’s features, benefits, and practical applications for a specific facility, and of how containers can be best utilized in that facility’s complete perioperative sterile processing workflow cycle. In order to do this, the needs of the facility must be defined, the quality and track record of each container system should be considered, and the ease of use of each system should be investigated.

A thorough product evaluation should always be conducted for new products being considered. It is also useful to contact current and former customers of each container system to collect actual-use feedback. Another important consideration is the anticipated time and cost required for repairs from normal wear and tear, improper handling, and for routine maintenance activities such as manufacturer recommended replacement of gaskets.

Containers for transport
Some rigid sterilization containers may meet AAMI recommendations for the containment of contaminated items during transport from the point of use to the decontamination area. Some containers with solid bottoms may allow transport of contaminated items soaking in a pre-cleaning solution, while other containers with filtered bottoms may allow the transport of contaminated items if the filter is in place and the items are not soaking in a solution. According to AAMI, containment may be accomplished by any means that adequately prevents personnel contact with the contaminated items during transport. Although some rigid sterilization containers may satisfy this criterion, the container manufacturer’s instructions for use should be consulted to confirm appropriate use.

Safe container practices
There are physical elements related to safe use of container systems that users should be aware of. Containers processed in automated cleaning equipment should be placed on washer racks or carts in a manner that promotes drainage and avoids water accumulation. Improperly placed containers may contain very hot water at the end of a cycle that could be a burn hazard for staff members removing the containers from the washer. Water spilling from containers after they are removed from washing equipment may also result in wet floors and slip hazards. Baskets of instruments must be loaded into washers correctly to prevent instrument damage. And, as with all decontamination activities, appropriate personal protective equipment must be worn when cleaning rigid containers.
In addition, departmental cleaning policies should be aligned with AAMI guidelines. Some facilities have adopted a policy that allows a container to be reused without cleaning if a set is removed from a rigid container at the point of use and the container is removed from the procedure room prior to the patient entering the room. This is a poor practice because it results in many fewer container cleaning cycles. According to AAMI, reusable sterilization containers should be cleaned carefully prior to sterilization even if they are to be immediately reused. Removable, reusable filters should be disassembled, cleaned, and replaced according to the manufacturer’s instructions.

**Detailed regular inspection**

As with any packaging material, rigid sterilization containers must be thoroughly inspected before each use. Containers should be inspected for changes in the composition of the container due to denting, chipping or warping. Dents are a frequent problem with metal container systems if the container or lid is accidentally dropped or handled improperly. The dent in the lid could interfere with the contact between the container bottom and the gasket in the lid, which could compromise sterility.

Dents in container components are often overlooked by technicians unless the lid does not fit into place on the container bottom. This is not any more acceptable for patient use than a hole in a sterilization wrap or other type of packaging material. Devices that hold filter media in place should also be inspected for proper operation. Pop-in type filter retainers are susceptible to weakening of the spring mechanism over time and may come loose during sterilization or transport. If inspection is not performed, a loose filter may not be discovered until the container is opened at the point of use. Latches, fasteners, rivets and screws should be checked to ensure that they are tight, and both reusable and disposable filter media should be inspected for damage.

Containers must also be inspected before each use to ensure that gaskets are intact and in good working condition. If gasket integrity has been compromised, it is impossible to maintain a good seal and assure sterility of the container contents. Some gaskets are hollow and require scheduled replacement; some gaskets are solid and have a lifetime warranty from the manufacturer. Hollow gaskets may also become compressed over time, causing latches to become loose and possibly pop open unexpectedly. For all container systems, department personnel should review and follow the manufacturer’s instructions for maintenance and replacement of gaskets. If the containers have valves, the valves should work freely and should have no breaks, cuts, chips, or dents.

In order to ensure a thorough understanding of the process for inspecting containers and container components, an in-service should be conducted by the appropriate container manufacturers.

**Container loading and placement**

According to ANSI/AAMI ST77 (reference AAMI ST792010, 8.4.2, page 76), a maximum weight limit of 25 pounds for containerized sets is recommended. However, a container may be validated for less weight. It’s important to read each container’s instructions for use to confirm the maximum weight limit for that container type and size.

The weight of instrument sets, whether packaged in rigid containers or not, should be based on whether personnel can use proper body mechanics when carrying the set.

Each instrument set should be laid out so that individual instruments comprising the set and the overall mass (density) is evenly distributed. The mass of the sterilizer load should also be evenly distributed within the chamber. Users should consult the container manufacturer for recommended weight limits, but it is each facility’s responsibility to determine if each set processed in a container can be sterilized and dried effectively.

In addition to the even distribution of the metal mass within the sets, it is always important to ensure that instruments are properly disassembled if necessary, and all jointed instruments are in the open position. If small basins or glass containers are components of an instrument set, they must be positioned in a manner that promotes drainage, and glass items should be protected against breakage.

Most rigid sterilization containers can be used for a variety of sterilization methods. When steam sterilization is used for lumened instruments, the internal lumen surfaces should be moistened with treated water before sterilization. This ensures that steam can be generated from within the lumen, which is an area that is challenging to contact directly with steam during the sterilization process.

In contrast, if ethylene oxide or gas plasma sterilization is used, the container and all set components must be completely dry before sterilization.

In addition, heavier instruments should be placed below lighter, more delicate instruments to prevent damage to the lighter instruments. Complex instruments (e.g., air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the device manufacturer’s written instructions. When combining complex instruments in a set, users will need to test and evaluate the effectiveness of their sterilization and drying processes.

**Self-Study Test Answers**

- 1. A
- 2. F
- 3. A
- 4. E
- 5. B
- 6. F
- 7. C
- 8. B
- 9. D
- 10. C

Please note: paper/plastic peel pouches have sometimes been used to package small parts and pieces of an instrument or to organize groups of instruments within a container; however, this is not a recommended practice. No manufacturer has validated using peel pouches within a container system. However, there are ways that have been validated to organize groups of small delicate instruments, and these methods should be used instead of paper/plastic pouches.

In addition, accessories can be used in rigid sterilization containers to organize and protect instruments and other devices, but they should be tested for appropriate use in each type of container a facility is using. This testing should be a collaborative effort between the device manufacturer and the container manufacturer.

Silicone mats and reusable and/or disposable absorbent materials can also be used to contain and protect instruments in containers, but each container manufacturer should be consulted about the appropriate use of these types of protective and absorbent devices in its particular containers. Silicone mats can contribute to moisture retention, especially when the mats are used to cover the entire surface of a container and if the mat does not contain sufficient drain holes. Silicone mats should have enough perforations to enable adequate sterile penetration and moisture drainage.

There are also a number of organizing devices for instrument sets that are provided by rigid sterilization container manufacturers. For example, dividers can separate heavier instruments from delicate ones, pegs can hold hinged instruments in the open position, and flexible fasteners can protect delicate scopes from being tossed around in the sets during handling.

See **Self-Study Series** on page 30
Tray liners prevent delicate instruments from sticking through the holes in the mesh basket. If tip protectors are needed, only those designed for sterile processing applications should be used, and the manufacturer’s instructions should be followed. Tip protectors must be adequately perforated or designed to ensure sterilant penetration and drying.

Regardless of the sterilization method, container systems should always be placed flat on sterilizer shelves. Flat placement assists with air evacuation, adequate sterilant penetration, drainage of moisture, and efficient drying or aeration. In addition, container systems should always be placed on shelves below any items wrapped in absorbent materials in the same load. This prevents condensation from the container systems from dripping on and wetting the absorbent items.

To stack or not to stack
Before stacking container systems for sterilization, the user should consult the manufacturer’s recommendations and documentation to ensure that container stacking is recommended and that stacking techniques are performed correctly. The type of sterilization process may also dictate whether or not containers can be stacked during a cycle. Users are responsible for conducting their own verification testing in their sterilizers, and should be aware that container systems from different manufacturers should not be stacked together because the properties of the containers and their required configurations might not be compatible.

Proper cooling
Sterilized containers should remain on the sterilizer cart until container surfaces are cool to the touch and can be handled safely with bare hands. As stated in AAMI ST79 2010, 8.8.1, page 85, “the sterilizer door may be opened slightly at the end of the cycle and the items left inside for a short period of time in order to reduce the potential for condensation formation.” After the containers are removed from the sterilizer, they should be placed in a draft-free area that is not near cooling or air-conditioning vents. If containers are not properly cooled before they are removed from the sterilizer cart, re-condensation can occur, resulting in wet packs. If transfer carts are not used, sets should be removed after sterilization and placed on wire shelf cool-down carts in an area where they can reach room temperature. Hot/warm sets should never be placed on solid metal surfaces, because doing so can cause condensation to form.

Sterile storage, transport and handling
Proper sterile storage of rigid containers follows the same guidance as storage for any other type of sterile packaged items. Distance from floor, ceiling and outside walls will allow air circulation, ease of cleaning, and compliance with fire codes.

Rigid sterilization containers should be transported in such a way that the sterile items inside are protected from contamination by moisture, excessive humidity, condensation due to temperature extremes, insects and vermin, dust and dirt, excessive air pressure and microbial contaminants. When transporting rigid containers to offsite locations, the contaminated items must be completely separated from the clean and sterile items being transported. Also, transport carts should be securely anchored, to avoid movement of the carts that could cause damage to the containers and the instruments inside them.

Before removing an instrument tray for use at the sterile field, OR personnel should check the internal chemical indicator for the appropriate endpoint response. At this point, it is important to check the filters once more to confirm that they are properly placed. They should also inspect the container bottom filter for integrity and placement, and if applicable, inspect the appearance of the valve to assess proper function and monitor the container bottom for residual moisture.

What to expect from container manufacturers
Rigid sterilization container manufacturers must provide documentation regarding appropriate sterilization methods, sterilization cycle exposure times, drying times, ethylene oxide residual removal (if applicable), and shelf life. They must also provide information regarding the placement and use of any inner wrapping and protective and/or absorbent materials included in containers that could affect sterilization.

On the topic of sterility maintenance, the manufacturer must provide information regarding the design characteristics of the container system that limit microbial migration and penetration of contaminants to the contents, such as the tortuous pathways of the filter system or valves. The manufacturer must also provide a statement with supporting documentation that explains if moisture within the container system after sterilization will compromise the sterility of the contents. Although some container manufacturers assert that moisture remaining inside containers after sterilization should be deemed sterile, steam purity should be considered,
Michael E. Russell, MSN, RN, CNS is a senior clinical education specialist at STERIS Corporation, and is responsible for customer education, clinical support, troubleshooting, and issues concerning sterilization and infection control.

References:

CONTINUING EDUCATION TEST • JANUARY 2012

Rigid sterilization containers

Selecting, using and maintaining them for optimal productivity

Circle the one correct answer:

1. A maximum weight of 25 lbs. includes instruments and their container.
   A. True  B. False
2. Rigid container integrity can be compromised by:
   A. Hole in the filter
   B. Absence of a filter
   C. A dented lid
   D. A torn or flattened gasket
   E. C and D
   F. All of the above
3. Rigid containers should be decontaminated between uses.
   A. True  B. False
4. Which of the following should be supplied by container manufacturers?
   A. Validation of sterilization methods
   B. Cleaning recommendations
   C. Test data
   D. Recommended exposure and dry time
   E. All of the above
5. When transporting containers offsite, sterile items need not be separated from dirty ones.
   A. True  B. False
6. Before purchasing, the evaluation of a container should include:
   A. Worst case scenario test
   B. Small load test
   C. Maximum load test
   D. Check for retained moisture
   E. A and C
   F. All of the above
7. Peel pouches should be used inside a container:
   A. If my supervisor says so
   B. When there are small parts of a larger instrument to contain
   C. Never
   D. If there is no written policy about it
8. AAMI recommends that contaminated items be contained during transport. Which of the following is true?
   A. All container manufacturers meet this requirement
   B. Some of the container manufacturers meet it
   C. No manufacturers currently meet this requirement
9. Container accessories currently being offered include:
   A. Dividers and silicone mats
   B. Peel pouches and dividers
   C. Tray liners and pegs
   D. A and C
   E. All of the above
10. When cleaning containers, staff:
    A. May use only exam gloves
    B. Does not need to clean them at all if the container was removed from the OR prior to patient exposure
    C. Wears all proper personal protective equipment (PPE) at all times
    D. Check for retained moisture
    E. A and C
    F. All of the above

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