Sterilization containers: A surgeon’s toolbox

by Susan Klacik BS, CRCST, FCS

The miraculous surgical procedures we see today are accomplished in part due to surgical instrumentation. All aspects of a surgical procedure are carefully orchestrated to achieve a positive patient outcome. Specific instrumentation is selected for cutting, clamping, suturing, retracting, dilating, draining or any other procedure a surgeon performs. At the time of use, instrumentation must be sterile, properly functioning and prepared in accordance with the surgical team’s requirements. Sterilization containers are used for this instrumentation. They are designed and validated for instrument preparation, sterilization, and storage and for the important aseptic presentation of contents. The sterilization cycles used are those that are commonly available in health care facilities. Instrumentation is sterilized in the containers without damage, in fact instrumentation may be better organized in a sterilization container with the use of posts and dividers. Manufacturers of the containers have documented performance testing to demonstrate sterilization, drying, sterilant residual removal, and sterility maintenance. This article will discuss the proper use of sterilization containers by following standards and recommended practices. The Advancement of Medical Instrumentation (AAMI) standards that address sterilization containers are: ANSI/AAMI ST 79:2010 & A1:2010 & A2:2011 & A3:2012 Comprehensive guide to steam sterilization and sterility assurance in health care facilities which provides guidance to healthcare facilities on the proper use of sterilization containers; and ANSI/AAMI ST77:2013 Containment device for reusable medical device sterilization which is a manufacturer’s document that apprises manufacturers of the minimum labeling, safety, performance, and testing requirements. AORN’s Perioperative Standards and Recommended Practices For Inpatient and Ambulatory Setting addresses sterilization containers under the Recommended Practices for Selection and Use of Packaging Systems for Sterilization.

Variations of sterilization containers

Rigid sterilization container systems differ in design, size, mechanics, indicated sterilization modality and materials of construction. For these reasons it is important to review the instructions for use (IFU) from the container manufacturer. The newly published ANSI/AAMI ST 77:2013 Containment device for reusable medical device sterilization specifies the information that must be available to users. This information includes:

- **Methods of sterilization** such as steam, hydrogen peroxide, ethylene oxide; and types of cycles, including cycle parameters (e.g., steam, dynamic-air-removal, sterilization time, temperature, and dry time).

- **Recommended type of instrumentation** – including whether those with lumens are permitted and, if so, if there is a lumen size restriction. The placement of medical devices may also be specified.

- **Method of decontamination** for the container and its reusable accessories by means of either a manual or automated method. If reusable accessories are intended by the manufacturer to allow for decontamination of specific instrumentation within the accessory, then the accessory is validated for this purpose.

- **In what manner internal stacking can occur**: Internal stacking occurs when two or more instrument baskets are stacked within a container. Considerations are the ability of the sterilant to reach all surfaces, the ease of removal of the stacked items, the maximum density of contents to allow for proper sterilization and drying; adequate perforations to allow for sterilant penetration, sterilant evacuation, and drying, and the stability of the stacked items during transport and handling.

- **External stacking for sterilization** may take place during the sterilization process, transportation, or storage. External stacking refers to rigid sterilization container systems stacked directly one on top of another. External stacking can affect the ability of the sterilant to adequately penetrate each of the stacked rigid sterilization container systems and any reusable accessories of the rigid sterilization container systems and achieve sterilization of the enclosed medical devices.

- **Quality monitoring information**: Instruction is provided from the sterilization container manufacturer for areas within the
sterilization containers that are the most challenging area of the rigid sterilization containers for the placement of internal CIs and BIs for routine monitoring and product testing.

**Recommended preparation of sterilization containers**

After a complete review of the sterilization container and instrument IFUs, the processing of the instrument sets can begin. Sterilization containers must be thoroughly cleaned before each use. Container systems can be cleaned either manually or mechanically. The sterilization container’s IFU for cleaning and rinsing must be followed. When cleaning, all disposables such as locks, labels and filters are removed. The basket is removed from the container for thorough decontamination. The sterilization container is disassembled, which may include removing the posts or dividers if they interfere with the cleaning.

Instrumentation must be cleaned according to its IFU and standard cleaning practices. All instruments or devices made of more than one part should be disassembled following the device manufacturer’s written IFU and all jointed instruments should be opened to make sure that all surfaces are effectively cleaned, rinsed and dried.

The inspection process not only includes the typical instrument inspection for cleanliness and flaws, the containers must also be inspected to confirm they are working effectively. This inspection covers the critical parts of the container. The latching mechanism or closure should be checked to ensure that it will remain secure. The sealing or mating surfaces or edges of the container system and lid should be checked to ensure that they are not dented or chipped. If filters are used, the filter retention mechanisms and fasteners such as screws and rivets should be secure and should not be distorted or burled; the securing mechanism should function properly, and the filter media should be examined for integrity. If the valve type is used, valves should work freely and not have any breaks, cuts, chips, or dents. The gaskets should be clean, flexible, securely fastened, and without breaks or cuts. The gasket provides the seal between the lid and base of a reusable rigid sterilization container providing the microbial barrier.

Instrument sets should be prepared in containers large enough to equally distribute the mass. The total weight of a container set should not exceed 25 pounds. When placing instruments in containers the same practices for perforated or wire-mesh-bottom trays apply. All instruments should be held open and unlocked. Multipart instruments should be disassembled for sterilization unless the device manufacturer’s IFU states they can be sterilized in the closed position. All parts of the containers and instrumentation must be clean and dry. Instrument placement may be organized using standard instrument stringers or by using posts. Dividers may also be used to separate instrumentation. Instrumentation must stay in the baskets and not be placed outside of the basket. Combination paper/plastic peel pouches should not be placed in a container, as it may not be possible to position pouches to ensure adequate air removal, steam contact, or drying. The practice of using wraps or pouches inside container systems has not been validated by pouch or container manufacturers. Medical-grade, all-paper pouches or small baskets designed for sterilization and validated for this purpose should be used. The chemical indicator (CI) should be placed in that area of the container considered least accessible to the sterilant.

The container is prepared by placing filters in place or if valves are used, they are checked to assure they are functional. The instrument basket is placed into the container and locked using the latching mechanism. A tamper-evident device lock is engaged. A tamper-evident lock is designed so that it cannot be resealed after opening. It is intended to indicate that the container has not been opened.

**Sterilization of sterilization containers**

Sterilization containers are designed and validated for one or more of the specific sterilization methods and cycles used in health care facilities, including immediate-use steam sterilization. This information is available in the container manufacturer’s IFU.

Sterilization containers are placed on the sterilizer cart so that the bottom of the tray or container system is parallel to the shelf. This will maintain the distribution of metal mass and allow for air removal, sterilant penetration, condensed drainage, and drying. It also helps keep instruments in orderly arrangement and prevents instrument damage. In a mixed load, sterilization container systems should be placed on shelves below absorbent items. Containers should not be stacked directly on top of each other, unless recommended by the manufacturer. Nothing should obstruct the filters or venting mechanism. Some containers may require a cool down period after being removed from the sterilizer before it can be “touched”. For terminal sterilization, the container must be completely dry, or the container is considered non-sterile and must be reprocessed. Moisture can create a pathway for microorganisms to enter the container and contaminate the instrumentation inside. Sterilization containers used for IUSS are expected to be wet.

**Immediate-use steam sterilization (IUSS)**

In 2010, AAMI released the multi-society position paper on immediate-use steam sterilization (IUSS), which has replaced what was formerly referred to as “flash sterilization”. Healthcare organizations and regulatory agencies supported this paper in which the critical steps of cleaning, decontamination, and aseptic transport are followed at all times including items that must be sterilized immediately. The consensus of this group was that IUSS should only be used when there is not enough time for terminal sterilization. Immediate use is the shortest time possible between when instrumentation is removed from the sterilizer and is aseptically transferred to the sterile field.

The practice of IUSS requires that only containers that have been validated for IUSS can be used. Validated IUSS containers have studies that demonstrate sterilization can be achieved. They enable sterilization, then protect instrumentation from contamination during transport to the point of use and facilitate aseptic presentation. Instrumentation must be prepared so that steam can contact all surfaces. Specific preparation includes differentiation of containers processed through terminal sterilization, as opposed to IUSS, to prevent a mix-up between them. AORN recommends only class 5 or class 6 chemical indicators should be used as internal quality monitors for IUSS. The instrumentation is sterilized according to the manufacturers’ IFU with little to no dry time. Upon completion of IUSS sterilization, the container will be hot, wet and possibly heavy. For these reasons, they are carefully transported to the point of use to prevent contamination and injury. As with all sterilization containers, they are cleaned after use in preparation for the next use.

**Incorporating medical devices into rigid sterilization container systems**

Healthcare CSS and surgery department personnel would sometimes like to place medical devices in containers. The placement of medical devices, such as loaner sets, into sterilization containers has been debated over the past several years as most manufacturers only utilize flat packaging (i.e., sterilization wrap) for their sterilization validation testing. The decision about this integration is made between the medical

---

**Sponsored by 3M Health Care**

**SELF-STUDY SERIES**

www.hpnonline.com • HEALTHCARE PURCHASING NEWS • August 2013 • 37
Sterilization modality and cycle compatibility:

Sterilization container systems vary in their use, size, and validated sterilization methodologies and therefore may not be compatible with a device. To address these requests, an Annex for assessing sterilization of medical devices in containers was added to ANSI/AAMI ST 77:2013 *Containment devices for reusable medical device sterilization*. This new annex, titled Annex A Medical device integration with rigid sterilization container systems, provides medical device manufacturers a tool to use when considering the placement of medical devices, such as loaner sets, into sterilization containers. The determination is made by reviewing claims and labeling for each device to decide if the device is compatible with the sterilization container. Listed below are some of the criteria manufacturers consider to determine compatibility:

- Sterilization modality and cycle parameters
- Total combined weight (devices, internal trays, and rigid sterilization container system)
- Lumen dimensions (i.e., internal diameter and length) and lumen material
- Complexity of device(s) (e.g., powered instruments, endoscopes, channels, etc.)
- Material compatibility
- Stacking of inner trays, including limitations
- Size of package and proper fit of contents
- Aseptic removal of contents
- Corrosion resistance to the specified sterilization method
- Verification of worst-case scenario for testing

To assure complex medical devices achieve sterilization when placed in sterilization containers, material and sterilization modality compatibility are essential. The medical device manufacturer must evaluate the sterilization container manufacturer’s written IFU to assure it is compatible.

Table A.1 contains the following critical assessment tool to assess whether the device considered for placement in a rigid sterilization container packaging system falls within the rigid sterilization container indications for use.

The last line contains the worst case Volume to Vent (V-to-V) ratio that has been validated. The V-to-V ratio is a statistic for measuring a worst-case challenge of a sterilization container. It is a measurement of the ability for the sterilant to flow into and out of the sterilization container. This critical ratio is defined as the interior volume of the sterilization container divided by the total cross-sectional area of the perforated vent holes. When comparing V-to-Vs, the number desired will be the lower one. The type of sterilization method used will affect the criticality of the V-to-V ratio. For instance, a low V-to-V ratio is of greater importance to sterilization containers being evaluated for gravity-displacement steam sterilizers than containers being evaluated for use in dynamic-air-removal steam sterilizers. The V-to-V ratio is a critical performance attribute of the container system under consideration; a higher V-to-V ratio presents a more difficult challenge to achieve sterilization. The V-to-V challenge is not based solely on the size of the container, it includes the vent or filter area. Testing performed on a full-size container with a solid bottom compared to one of the same size with a perforated bottom will show the solid bottom container having a higher V-to-V ratio. This is because it is more challenging to have the steam enter and exit only through the lid. The bottom perforations make it easier for the steam to enter and exit the container.

**Product testing**

Product testing on sterilization containers is performed to demonstrate that sterilization conditions are being achieved. Before purchasing a sterilization container system, product testing should be performed. The use of containers varies from each facility in the way that they are packed and loaded into the sterilizer. The same holds true for sterilizer performance and facility utilities. All of these variables can affect the sterilization process; for these reasons, healthcare facilities perform product testing to verify the containers can be sterilized in-house. Product testing is a quality assurance check that demonstrates the entire sterilization process is effective.

To perform product testing on sterilization containers, biological indicators (BIs) and chemical indicators (CIs) are used. CIs are used to verify that one or more conditions necessary for sterilization have been achieved. BIs verify that the conditions are adequate to kill microorganisms resistant to the sterilization process. Physical monitors are also used to verify that the parameters of the sterilization cycle have been met. When performing product testing on sterilization containers, they are labeled as “test containers” to prevent them from being used on a patient. The container is prepared as if it would undergo regular sterilization, filters are put in place, valves, if used, are checked, and instruments are placed in the basket. BIs and CIs are placed next to each other in areas that pose the greatest challenge to air evacuation and sterilant penetration. Their location in the container is marked on the BI, this will be important later. If there is a positive BI result, it will be able to be traced to the exact location. The results should be documented in the BI record. The biggest challenges for air pockets are the corners of the container and the underside of the lid, away from the filters. The container manufacturer has performed the validation studies which show the most challenging area of the container, they may be contacted for information regarding the appropriate monitoring locations to place the CIs and BIs.

Should a sterilization container manufacturer require suspending a BI from the underside of the container lid as part of the testing process, consult the BI manufacturer for guidance on performing this type of testing.

After the sterilization cycle, the container is opened and checked for evidence of moisture. The CIs are checked for endpoint responses and the BIs are removed and

---

**Table A.1 – Critical Assessment Comparison Tool**

<table>
<thead>
<tr>
<th>Medical Device(s)</th>
<th>Rigid Container Packaging System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material(s) of the device</td>
<td>Material(s) of the container</td>
</tr>
<tr>
<td>Material compatibility</td>
<td>Validation for lumens: Diameter, length and material</td>
</tr>
<tr>
<td>Lumens: Diameter, length and material</td>
<td>Testing for complex devices and multiple layers</td>
</tr>
<tr>
<td>Complexity of the device*</td>
<td>Sterilization method(s)</td>
</tr>
<tr>
<td>Total weight</td>
<td>Total weight including devices</td>
</tr>
<tr>
<td>Sterilization method(s)</td>
<td>Cleaning guidelines</td>
</tr>
<tr>
<td>Cleaning guidelines</td>
<td>Can device be disassembled</td>
</tr>
<tr>
<td>Can device be disassembled</td>
<td>Corrosion resistance to avoid galvanic reactions</td>
</tr>
<tr>
<td>Corrosion resistance to avoid galvanic reactions Passive layer</td>
<td>Passive layer</td>
</tr>
<tr>
<td>Passive layer</td>
<td>Dimensional fit</td>
</tr>
<tr>
<td>Dimensional fit</td>
<td>Aseptic removal</td>
</tr>
<tr>
<td>Aseptic removal</td>
<td>Stability of contents</td>
</tr>
<tr>
<td>Stability of contents</td>
<td>Stacking</td>
</tr>
<tr>
<td>Stacking</td>
<td>Worst-case Volume to Vent (V-to-V) ratio validated</td>
</tr>
</tbody>
</table>

Reprinted from ANSI/AAMI ST77:2013 with permission of the Association for the Advancement of Medical Instrumentation. ©2013 AAMI www.aami.org. All rights reserved. Further reproduction or distribution prohibited.
incubated. Any test results that indicate a problem, such as positive BIs, unresponsive CIs, or wet packs, need to be investigated. The planned container purchase should be discontinued until the problem is resolved. The solution may be to change the configuration of the load and/or of items within the container or to service the sterilizer. Test protocol, results, and any corrective actions taken should be documented and maintained as part of the sterilization log or quality assurance program data.

**Conclusion**

Sterilization containers are a surgeon’s toolbox; they contain the critical instruments the surgeon uses. Rigid sterilization containers are an effective packaging method, validated for specific methods of sterilization and types of instruments. Instrumentation can be assembled, sterilized, stored, transported, and removed aseptically. There are many variations between sterilization containers. For this reason, it is imperative to read, understand and follow the sterilization container’s written IFU. The IFU contains important information regarding use and types of medical devices validated for sterilization within the container. HPN

**References:**


ANSI/AAMI ST77:2013, Containment devices for reusable medical device sterilization


Sue Klacik BS, CRCST, FSC, ACE, CHL Klacik is an Educational Consultant to 3M Health Care. Klacik has been the IAHCSMM Representative to the Association for the Advancement of Medical Instrumentation (AAMI), from 1997 to present. The Central Sterile Services Manager at St. Elizabeth Health Center in Youngstown, Ohio with over 30 years’ experience in CSSD, Klacik has been a CRCST since 1980 and an instructor since 1986. She possesses a Bachelor’s Degree in Business Administration. She is an international speaker on CSS topics.