Considerations for use of rigid sterilization containers

by Susan Flynn, BESc, CSPDT

A fter reusable medical instruments have been decontaminated they arrive in Prep and Pack to be inspected, assembled into sets and trays, and packaged for subsequent terminal sterilization. Manufacturers of rigid containers turn to ANSI/AAMI ST77, "Containment devices for reusable medical device sterilization," for guidance on labeling and performance requirements. As a user of these products, it’s helpful to be aware of some of these requirements. For example, ST77 states that the combined weight of the containment device and the instruments to be sterilized should not exceed 25 pounds (Section 4.3.5). This weight limit was set both in consideration of the attainment of sterilization and drying, and also in recognition of ergonomic concerns of technicians repeatedly handling these containers. Container manufacturers must conduct sterilization validation studies demonstrating that the contents of the container can be sterilized to a sterility assurance level of 10^-6 in the sterilization cycles for which the container is labeled. ST77 encourages manufacturers to validate sterilization cycles commonly available in healthcare facilities (Section 4.4.1.1). For steam sterilization (other than “flash”), manufacturers also need to design containers such that they are dry after typical hospital cycles. For ethylene oxide sterilization, manufacturers need to validate the container and its contents can be adequately aerated.

A comprehensive list of the information container manufacturers should provide to users in their Instructions for Use (IFU) is also included in ST77. As with any medical device, the IFU is a thorough document that addresses common questions related to the safe and proper use of the product. In the case of containers, the user may wonder whether the container can be stacked, where CIs should be placed, or how to disassemble and clean the container. All of these questions should be addressed in the IFU.

Container anatomy

While designs vary, reusable rigid containers generally employ filters or valves to create the barrier that permits penetration of sterilant and air but prevents microbial penetration; a gasket that serves as a seal between the container base and lid to prevent entry of contaminants; carrying handles that permit safe handling of the container; and an inner basket or tray, also with handles, that facilitates presentation of the contents to the sterile field. It is important to follow the recommendations of the container manufacturer for inspection and maintenance of gaskets and reusable filters, if applicable. Additionally, reusable rigid containers feature a locking mechanism that ensures a secure gasket seal between the base and the lid and a tamper-evident seal closure system that allows the user to determine whether the container has been opened.

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Users of rigid containers refer to AORN’s Recommended Practice (RP) for Selection and Use of Packaging Systems for Sterilization for practical guidance. For example, the reader is cautioned that paper-plastic pouches should not be placed inside containment devices as doing so could hinder air removal, sterilant contact, and drying. (Recommendation V.7) The RP states that a chemical indicator (CI) should be placed inside (to verify sterilant penetration) and outside each package to be sterilized. In the case of rigid containers, AORN further recommends that “two chemical indicators be placed inside rigid containers, one in each of two opposite corners of the inside basket.” (Recommendation IX.5) In concurrence with guidance given to container manufacturers in ANSI/AAMI ST77, AORN also states that “the total weight of instrument containment devices should not exceed 25 pounds including the contents and containment method” (Recommendation I.4), giving users double ammunition to tackle the issue of excessively heavy sets.

As with any reusable device, rigid container systems should be disassembled and cleaned after each use. Follow the manufacturer’s written instructions for this cleaning, as well as for the inspection and maintenance of the containers, gasket, and any reusable filters or valves. (RP VI)

A theme of the AORN packaging RP is user verification, before purchase, that the container system works in the intended sterilization method and cycles. In addition to reviewing the manufacturer’s test results and FDA clearance, the importance of in-house biological testing of containers is discussed. AORN recommends pre-purchase biological testing of each size container and routine biological indicator (BI) testing of containers after purchase. (RP VI.2) Further guidance related to BI testing is provided in the quality section of the RP where it states, “Evaluation and biological testing of rigid containers should be performed periodically in each specific sterilizer and with each cycle type used.” (RP X.4)

AORN provides detailed guidance on performing pre-purchase evaluation of rigid containers in AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Section 10.10.3.2.4 Pre-purchase evaluation is recommended so that users can verify, before purchase, that the container system will perform as expected in the healthcare facility’s sterilizers. Although the container manufacturer has conducted sterilization validation studies, the user is responsible for verifying that the containers are compatible with sterilizers in their facility. In the case of steam sterilizers, the user needs to verify the rigid containers will permit complete air removal, adequate steam penetration and adequate drying. Consult the container manufacturer for advice on the appropriate (i.e., area of greatest challenge to air removal and steam penetration) placement of BIs and CIs in the rigid container. The BIs, CIs, and instruments are placed in the test rigid container systems, along with any required filters. Worst case testing is simulated by using the largest instrument sets recommended by the container manufacturer and testing both a maximum and small load. To create a maximum load, place two test container systems on each sterilizer shelf and use other traditionally packaged items to create a fully loaded chamber. To test a small load, place one container system on the bottom shelf over the drain of an otherwise empty sterilizer. After running the cycle recommended by the container manufacturer, examine all chemical indicators and incubate all BIs. The CIs should have reached their endpoint and the BIs should be negative. Any unacceptable results should be investigated and resolved before purchase of the rigid container system.

Steam sterilization

As discussed, it is the responsibility of the rigid container manufacturer to validate sterilization parameters, including exposure time. Users must obtain these recommended parameters and reconcile them with the sterilizer manufacturer’s programmed cycle parameters. (ST79, Section 8.6.1) It cannot be assumed that all surgical instruments should be steam sterilized in rigid containers. Always consult the medical device manufacturer’s written instructions to determine whether container systems have been tested and found to be appropriate packaging for the device. (ST79, Section 8.4.4) An internal chemical indicator should be placed inside each rigid container. (ST79, Section 10.5.2.2.2) An external chemical indicator should be used with each container. This external indicator is often a feature of the rigid container’s tamper-evident seal.

When loading the sterilizer, place rigid containers flat on the sterilizer shelf or cart i.e., such that the bottom of the container is parallel to the shelf. The rationale for this recommendation explains that this placement “maintains distribution of metal mass and allows air removal, sterilant penetration, condensate drainage, and drying.” (ST79, Section 8.5.3) If textile packs and rigid containers are sterilized in the same load, the textiles should be placed above the containers to avoid condensate run-off onto the textiles.

Flash sterilization

The use of rigid containers or sealed containment devices designed for flash sterilization warrants discussion as there are a few special considerations. AORN is clear in their recommendation that “Rigid sterilization containers designed and intended for flash-sterilization cycles should be used.” (RP for Sterilization, IV.e) This recommendation has been widely adopted across the country as OR staff accept the rationale that rigid containers protect flash-sterilized items during transport, thus reducing the risk of contamination, and facilitate aseptic presentation of the contents to the sterile field. It is also recommended that containers used for flash sterilization be differentiated from other types of containers, and that the contents be used immediately and not stored for later use. (RP for Sterilization, IV.f) AORN recommends the use of Class 5 chemical integrating indicators within each flash sterilization container. (RP for Sterilization, IV.c.3)

Knowing that the use of rigid containers for flash sterilization is widespread, it is worth mentioning that AAMI recommends that each type of tray configuration in routine use be tested as part of the routine biological monitoring of flash sterilization cycles. (ST79, Section 10.7.4.1) This is because each type of tray configuration presents a different challenge to air removal and steam penetration. Facilities using rigid containers for flash sterilization should therefore construct a representative process challenge device (PCD) by placing a BI and CI in the most challenging area of a rigid container. The PCD is then placed on the bottom shelf of an otherwise empty sterilizer and the appropriate cycle is run. After sterilization, appropriate readings on the sterilizer print-out, a chemical indicator that has reached its endpoint, and a negative BI provide evidence of an acceptable sterilization process.

Low temperature sterilization

A few special items must be considered when rigid containers are used for low-temperature sterilization. It is critical that the container itself is compatible with the sterilant whether that is ethylene oxide, vapor phase hydrogen peroxide, or ozone. See SELF-STUDY on page 54
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Circle the one correct answer:

1. The combined weight of the containment device and the instruments to be sterilized should not exceed 25 pounds.
   A. True  B. False

2. To verify the compatibility of rigid containers with a facility’s sterilizers, prospective buyers should conduct an in-house, pre-purchase evaluation of any containers being considered for purchase.
   A. True  B. False

3. When loading steam sterilizers, rigid containers should be placed on edge so that as many containers as possible can fit in the chamber.
   A. True  B. False

4. When items must be flash sterilized, AORN recommends the use of rigid sterilization containers designed and intended for flash sterilization cycles.
   A. True  B. False

5. According to AAMI, each type of tray configuration routinely used should be tested as part of the routine biological monitoring of flash sterilization cycles.
   A. True  B. False

6. Cellulose based filters are acceptable for use in rigid containers intended for hydrogen peroxide sterilization.
   A. True  B. False

7. For flash sterilization, AORN recommends the use of Class 5 chemical integrating indicators within each container.
   A. True  B. False

8. Paper-plastic pouches may be placed inside containment devices that are to be steam sterilized.
   A. True  B. False

9. Rigid container systems should be disassembled and cleaned after each use.
   A. True  B. False

10. Before purchase, review the rigid container manufacturer’s written instructions to ensure the container has been validated for use in the desired sterilizers and cycles.
    A. True  B. False

References

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