

Rigid Container Systems

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****This in-service has been Approved by the CBSPD, Inc. for 1.5 CEU.**

Introduction - A rigid container is a device that serves as a packaging material for items prior to, during and after sterilization. They are reusable and come in a variety of materials and sizes (various metals, aluminum and polymers).

Container usage was imported from Europe and they entered the US market approximately 20 years ago. Over the past 15 years they have become increasingly popular because they are cost effective; prevent instrument damage; they can be an effective barrier to contamination; ability to stack them and can save storage space.

As with any major change in packaging, the facility needs to evaluate the containers. First obtain the container manufacturer's instructions for cleaning and disassembly. Reduction of bioburden essential so all components must be cleaned including filters, valves, internal baskets, etc. There should be reusable identification system (tags) inside and outside of container.

When cleaning, remove all disposable process indicators, locks, filters, etc. prior to cleaning. Dividers/sorting pins may have to be removed if they interfere with proper cleaning. Follow the container manufacturer's instructions for detergent selection and usage (manual or mechanical). Anodized aluminum containers and some polymer containers require neutral pH detergent. This is important because if you are going to process your containers in cart washers, you will have to switch your detergent. Cart washers use high alkaline detergents which can corrode your containers.

After cleaning, inspect the container. Understand that how you load the container in the washer will impact on the cleaning. All parts should be separated so the detergent and water can make contact with all surfaces of the container. If the base of the container is upright, it will be filled with hot water and you could get burned.

Many SPD technicians feel that rigid containers do not have to be inspected. **WRONG!** Each time the container is used, it should be checked for; dents/chips in lids, surfaces, making sure the filter retention mechanisms fits tightly against the filter, there are no loose screws, check gaskets for nicks, cracks; and all valves should work freely without chips, breaks, dents (for reusable filters). The three most critical inspections include:

- 1) No dents in the base or lid, which could prevent a good seal and lead to contamination of the contents.
- 2) No defects in the gasket
- 3) Firm fit of the filter plate over the filter.

If any of these fail, the container should not be used.

Configuration of sets inside container - how instruments are placed inside the container can affect drying. Do not use of absorbent materials (e.g. towels) unless the container manufacturer has tested their use inside the container. The same is true for silicone mats. Peel packs should not be used inside containers because they cannot be kept on their side and the container manufacturer did not test the container for use with peel packs inside. Instead, medical grade paper bags; peel roll (small pouches on a roll that are not sealed) can be used instead. Make sure the manufacturer has approved any special baskets or trays. Obtain written verification from the container manufacturer that the container was tested for use with complex devices, lumened items and power equipment inside. Only use the security (lock) system recommended by the manufacturer. **And never pre-sterilize security locks.** If a container is found to be missing a lock, the container must be completely reprocessed!

It is important to obtain written verification of the recommended sterilization cycles; some containers require extended exposure times. The container manufacturer must provide in writing their recommended cycles parameters for pre-vacuum, gravity displacement, ethylene oxide gas cycles, low temperature gas plasma, etc. The manufacturer should also provide documentation as to the biological testing performed; the cycle parameters tested; the temperature and length of aeration for the containers and the recommended load configurations (low to properly load the sterilizer). Another major issue is drying inside containers. Containers made of metal add more metal mass to the already heavy instrument set and can make drying of sets difficult. At a minimum, containers require 30 minutes of drying on a pre-vacuum steam cycle. The manufacturer should also provide written verification of shelf life studies.

The Association for the Advancement of Medical Instrumentation has published a new document: Containment Devices for Health Care Facilities (ST-77). It will be available later this summer. This document addresses all the issues with rigid containers, cassettes and organizing cases. It also puts a weight limit on the weight of sets, including the container (25 lbs). If you are using rigid containers you should have a copy of this document.

User Responsibilities - Before-purchase an evaluation should be performed. You need to determine if you need vents on top and bottom of the container (depends on what methods of sterilization you will be using). You will need to also perform pre-purchase evaluation with biological testing to evaluate your sterilizer's ability to achieve sterilization inside the containers at your facility. It is important to contact your rigid sterilization container manufacturer for guidance on the most challenging location for the biological and chemical indicators for this testing. Unless otherwise specified, the following is recommended.

Since rigid containers can entrap air in the corners and under lid (away from the filter), it is recommended that chemical indicators be placed in 2 opposite corners of the inside basket of rigid containers (as opposed to the center of the pack/tray when wrapped in cloth or paper).

To perform this test:

1. Obtain a rigid container (you will need to test one of each size container in use **note: not all containers, just one of each size: e.g. 4" full size, 6" full size; 3" half size, etc.**). A total of 6 BI vials, all from the same lot number (use control vials) are needed. Five of the vials will be used inside each container and one is for the control vial. Place (1) BI vial in each corner of the *inner basket of the container*. The vials should be affixed to the corners by tying a piece of string around the vial then taping the vial to the corner of the basket, making sure the vials do not make contact with the metal surface of the basket.
2. After securing the vials in each corner, place a chemical indicator/integrator in two opposite corners of each of the containers. *Place a full set of instruments inside the containers.*
3. Affix another BI vial as described above (using string and tape) to the underside of the lid of the containers so the vial is suspended inside the container.
4. Close the container; **affix locks**. Label the - CONTAINER TEST PACK.

Testing Protocol:

Maximum Load Testing - tests the sterilizers ability to sterilizer under actual conditions

5. Place 2 containers (prepared as noted above) over the drain line.
6. Place an additional 2 containers on **each** of the remaining autoclave shelves.
7. Fill the remainder of the autoclave cart with containers or other items.

Small Load Testing - tests the sterilizers ability to sterilize under worst case scenario

8. Place one container (prepared as noted above) over the drain line. **Do not place any other containers or items in the load.**
9. Perform a maximum load test (or as many as needed to test each size container) and a small load test.
10. Each **representative** sterilizer should be tested; e.g. if there are 4 each 48" steam sterilizers, only one has to be tested).
 - a) At the end of the cycle, open the containers with the BI vials, allow the vials to cool.
 - b) Incubate the BI vials and record the results as "container test pack testing".
 - c) Reprocess the container and all the instrumentation.

11. When testing new containers, the contents should **not be used for patient care unless all container BI tests are negative.**

ETHYLENE OXIDE STERILIZATION

12. EO sterilizers only require a small load test. Prepare as noted above.

LTGP

13. Currently AAMI does not have a standard for LTGP and containers.

Routine Container Testing - Once the containers are purchased:

14. Routine container testing should be performed at least annually (maximum and small load tests).
15. NOTE: This test does not have to be performed the first working load of the day.
16. This BI test DOES NOT replace the routine BI test pack performed daily.
17. Any positive BI results should be reported to the SPD Manager immediately for follow-up.

RESULTS:

18. All rigid container testing BI results should be negative.
19. If any positive vials turn positive, the test should be repeated. If the repeat BI test is positive, the container manufacturer and the sterilizer manufacturer should be contacted to resolve the problem. The specific size container that had the positive BI result **should not be used until the problem is identified and corrected.**

It is important to understand that this testing should be performed during the evaluation of the containers and then yearly after purchase. *If you have several different types of containers (different manufacturers) they all have to be tested separately as noted above.*

Drying - It is important to know if your sets are dry at the end of the sterilization cycle; especially since you cannot see inside the container. Drying should be evaluated by sterilizing the largest (heaviest) sets you have; allow to cool and then opening set at completion of drying/cooling time and observe for residual condensate. If there is any moisture on the instruments or the towel inside is damp/wet or there is visible water inside the container action must be taken.

First look at the way the instruments are assembled on the set. Is the metal mass spread out evenly on the set? If not, drying can be a problem. Are you giving the required amount of dry time? If not, extend the dry time. Each time a change is made, the set must be re-

sterilized, cooled and opened to see if the problem was corrected. If the set is still wet pre-conditioning the load may help. To pre-condition the load, place the items in the steam sterilizer, close the door and allow the heat in the chamber to heat up the instruments for 15 minutes. Then start the cycle (note: it may be helpful to use a timer to remind you to start the cycle). If pre-conditioning the load does not resolve the problem, then evaluate the weight and density of the set. The set may have to be broken down into two sets. Also evaluate use of absorbent materials inside containers; some materials such as silicone mats do not absorb moisture and may make drying difficult.

Other QA Issues - Filter material - you should always use the filter material specified by the container manufacturer. **Never** substitute or assume you can use another filter. Also make sure you use non-paper filters in containers being used in low temperature gas plasma. Obtain information if the containers can be stacked during the sterilization process, if so, is there a restriction how high they can be stacked. (NOTE: many people do not stack containers even if the manufacturer indicates it can be done). Obtain information on transport of soiled instruments in containers.

Conclusions

Rigid Containers must be cleaned each time they are used. They should not just be "wiped out" but completely cleaned. They must be inspected carefully--gasket, filter holding plate. They must be handled carefully. Containers are a major capital investment for your facility—you need to take care of them

Don't assume you can sterilize anything in a container - get it in writing. Verify ETO aeration requirements; some container manufacturers have extended aeration times. Verify if the container can be used with low temperature gas plasma. Verify your ability to dry sets inside containers. Perform BI testing before purchase and routinely thereafter.

Rigid containers are an excellent packaging system however they require special training and good attention to detail.

POST TEST QUESTIONS: Rigid Container Systems

This in-service is Approved by the CBSPD for 1.5 CEU. Complete this post test and follow the directions at the end of the test for payment and results.

1. The recommended biological testing for rigid containers is:
 - A) routine Bi test pack daily
 - B) routine BI test pack annually
 - C) maximum and small load tests weekly
 - D) maximum and small load tests annually

2. When assembling a set inside a rigid container, the chemical indicator should be placed:
 - A) in the center of the set
 - B) in the bottom of the container
 - C) in 2 opposite corners of the basket
 - D) on the stringer of instruments

3. Most rigid containers require which type of detergent?
 - A) enzyme
 - B) alkaline
 - C) acid
 - D) neutral

4. Which of the following would **not** have to be checked each time the container is used:
 - A) dents/defects in the lid
 - B) filter retention plate holds filter
 - C) name of the patient the instruments will be used on
 - D) integrity of the gasket

5. Which of the following is **not** acceptable for use inside a container:
 - A) peel pouches
 - B) surgical towels
 - C) absorbent disposable towels
 - D) medical grade paper bags

6. When performing biological testing of containers, how many BI vials are needed?
 - A) 2
 - B) 4
 - C) 6
 - D) 8

7. A small load BI test for containers tests
 - A) the sterilizer's ability to dry with one only container
 - B) the sterilizer's ability to sterilize under worse case scenario
 - C) the sterilizer's ability to sterilize under actual conditions
 - D) the sterilizer's ability to pull a vacuum

8. For ethylene oxide sterilizers, which biological testing is recommended for rigid containers?
 - A) Routine BI test pack
 - B) AAMI ETO test pack
 - C) small load test
 - D) maximum load test

9. All of the following should be investigated if experiencing wet sets with containers
EXCEPT:
- A) pre-conditioning the load
 - B) evaluate the density of the set
 - C) evaluate weight of the set
 - D) how the container was washed
10. After use, rigid containers should:
- A) disinfected with alcohol
 - B) disinfected with glutaraldehyde
 - C) completely disassembled and washed
 - D) completely washed assembled
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Directions for Payment and Results

This in-service = \$15

Re-do's = \$15 each

No refunds (all sales are FINAL), prices subject to change.

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.
Sorry, no personal checks.

Please see the form on the following page.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

Sterile Processing University, 59 Allerton Road, Lebanon, NJ 08833.

Name: _____

Mail to: Home Work

Full Address: _____

Phone: _____

Email: _____

For Credit Card Orders Only: Visa MasterCard

Credit Card Number: _____ Exp. Date: _____

Person's Name on Card: _____

Card Billing Address: _____

If you have any questions, please email heidi@spdceus.com

Thank you!