Rigid Container Testing of Steam Sterilizers

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****This in-service has been Approved by the CBSPD, Inc. for 1 CEU.**

Objectives:

- To review the AAMI recommended protocol for rigid container testing
- To describe the process of rigid container testing

Testing of Steam Sterilizers - AAMI ST-79 recommends routine biological monitoring of steam sterilizers weekly, preferably daily. Biological monitoring with a process challenge device (PCD) containing live bacterial spores of *geo bacillus stearothermophilus* is recommended because this spore is the m*ost resistant to steam cycles.*

Biological Testing - The use of biological indicators (BIs) provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. (AAMI ST-79, 2013: Section 10.5.3.2).

Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs. Conventional PCDs are based on linen test packs, not rigid containers. Therefore, AAMI recommends periodic testing of rigid container systems.

Rigid sterilization container systems vary widely in design, mechanics, and materials of construction. Work practices, sterilizer performance characteristics, and the facility utilities supplying the sterilizer can affect the dynamics of the sterilization process. These factors can impact the specific performance characteristics of rigid sterilization container systems and their suitability for specific sterilization methods and cycles.

Health care personnel bear the ultimate responsibility for ensuring that *any* packaging method or material, including a rigid sterilization container system, is suitable for use in sterilization processing and sterility maintenance. (AAMI, ST-79)

User Responsibilities - Before purchasing any packaging system, collect all the information including the container manufacturer's instructions for use (IFU). Perform testing (pre-purchase testing) to ensure that items to be packaged can be sterilized by the specific sterilizers and/or sterilization methods to be used within the facility. Understand that the interaction of the container system, medical device, and sterilizer technologies is complex.

Containers that will be used for steam sterilization need to permit complete air removal, adequate steam penetration, and drying. The design of the rigid container system needs to be compatible with the design and performance characteristics of the sterilizer(s) in which it is used. Pre-purchase evaluation testing - assures the particular container system being considered will be acceptable to the users that it will perform properly in the health care facility's sterilizing equipment. This testing is not a substitute for the more extensive validation testing conducted by manufacturers to qualify their products**.**

Why Do We Have to Test? - Manufacturers of container systems can only test using properly designed and operating sterilization equipment. Various sizes of sterilizers having the same sterilization cycle could have different air-removal efficiencies. Manufacturers cannot possibly test all combinations of sterilizer sizes, cycles, and process efficiencies. Users need to perform testing to verify that there are no problems or to identify technical problems to be resolved in consultation with the container system manufacturer, the sterilizer manufacturer, and consultants.

Before a rigid sterilization container system is purchased, you need to determine whether your facility can verify the manufacturer's test results. If not, you should seek advice from the container manufacturer concerning instructions and guidelines for use of the system. Testing should be conducted in the health care facility to 1) ensure that the conditions essential to sterilization can be achieved and 2) that the specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use.

Sterilization process conditions such as exposure time should be evaluated by physical, biological, and chemical monitoring. In each rigid sterilization container system to be tested, BIs and CIs should be placed strategically alongside each other at locations that present the greatest challenge to air evacuation and sterilant penetration.

In gravity-displacement steam sterilizers, the corners of the container system and the underside of the lid, away from the filters, are the likeliest locations for air pockets. Consult with the container manufacturer regarding their recommended location for placement of CIs and BIs. The location should represent the areas of greatest challenge to steam penetration and air removal. Understand that the location can vary by container manufacturer, so if your facility is using more than one manufacturer's container, you may have different locations for the BIs and CIs.

Dynamic Air Removal Testing - The purpose of this testing is: to assess four (4) fundamentally essential aspects of the use of rigid sterilization container systems in dynamic-air-removal steam sterilization:

1) Will the container system design permit adequate air removal from the container system when the sterilizer chamber has reached the point of maximum air removal?

2) Does the container system design allow adequate steam penetration to reach equilibrium between the sterilizer chamber and the interior and contents of the container?

3) Will the combination of sterilizer and container system design achieve sterilization conditions?

4) Will the combination of sterilizer and container system design permit adequate drying and thus help promote sterility maintenance?

How to Perform the Test - Sterile processing needs to identify each size container (from each container manufacturer if more than one manufacturer). When measuring containers, understand that containers have three (3) dimensions; height, length and width.

Photo Above – Rigid Containers with Different Dimensions

If any one of the three dimensions is different, it is considered a different size container. The container system should represent the sizes that are available and being considered for purchase/use or are already being used at your facility for routine processing. According to AAMI ST-79, "The rationale for this is that the sterilant enters through discrete portals in a container system. The sterilant must then diffuse throughout the inside of the container system and then to the items being sterilized. Two barriers need to be overcome before the inside of the container system reaches equilibrium with the sterilizer chamber." Container systems are very different from flexible wraps in which the entire barrier is permeable.

Then, assemble five (5) BI vials (use control vials) to place inside each container. You will need one (1) additional vial to act as the control. Ensure all 5 BI vials for the container and the control vial are from the same lot #.

Once you have identified the number of different size containers, prepare the containers as follows:

Unless otherwise directed by the container manufacturer:

- Assemble set that is usually contained inside the container prepared with the largest instrument sets (including any optional absorbent material) recommended by the container system manufacturer.
- Assemble BI vials (you can use string attached to vials to keep them in place).

- Place one BI vial in each corner of the inside basket. Attach the string to the corner of the basket with autoclave tape to keep in place.
- Place a CI in the same location as the BI.
- Affix a 5th BI vial under the lid – the BI should suspend into container when lid applied. Check with the container manufacturer for their recommended location of BIs on the lid.

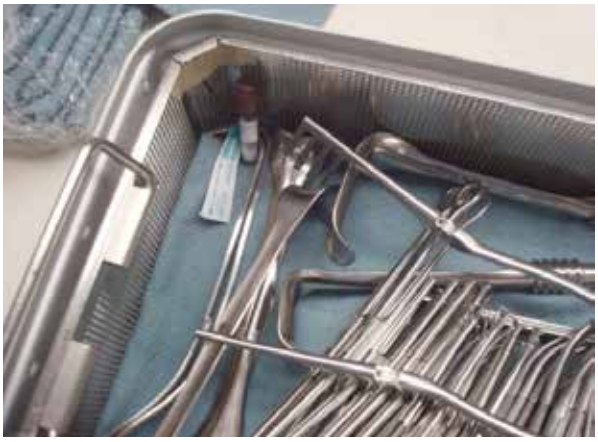

Photo Above – BI vial attached to corner Of inside basket, CI in corner

Photo Above – Rigid container with set inside and BI and CI in 4 corners

To know where the BI vials were located inside the set, you can label the vials with different letters (e.g. A,B,C,D) to identify their location. Use a photo or grid to label/document where the vials were placed. Document where the containers were placed on the sterilizer cart; i.e. top, middle, lower shelf.

Close Container. Apply locks. Affix load card; label as TEST. Prepare for sterilization.

Tests Recommended – AAMI recommends that a maximum-load test and a small-load test be performed for representative sterilizers. This means if all your sterilizers are from the same manufacturer, same age and same size, all the testing can be performed on one of the sterilizers. For the remaining sterilizers, it is necessary only to run the small-load test.

For the maximum-load test, place the container systems on the bottom shelf over the drain and two test container systems on each of the other sterilizer shelves (if space permits). To test a sterilizer having three shelves, six containers will be needed; for 2 shelves, 4 containers will be needed. The chamber is otherwise fully loaded with conventionally packaged items. A sterilization cycle is run with the exposure time recommended by the container system manufacturer.

Photo Above - Maximum Load Test Loading of the Sterilizer. Note the 2 containers on each shelf that contain the BIs.

AAMI explains the need for the Maximum Load Test is to "ensure that the large volume of air in this type of load is removed adequately and that the steam supply is sufficient to achieve sterilization in a load in

which the considerable mass results in significant condensation. Maximum-load testing also permits the user to determine if additional steps are necessary to achieve adequate drying."

Small Load Testing – With this test, only one test container is placed on the bottom shelf over the drain in an otherwise empty chamber. A sterilization cycle is run with the exposure time recommended by the container system manufacturer.

AAMI explains the need for the Small Load Test is to "identify any problems associated with the small-load effect, a phenomenon in sterilizers having dynamic air removal in which residual air in the chamber can become entrained in packaged items as steam enters the chamber.

At the end of the sterilization cycle and cooling, the containers should be removed. List the containers by size/set on documentation form. Open the containers one at a time so the test results do not get mixed up. Record the results of CIs on the log form per location in set. Activate and incubate BIs/control vial. Record BI results on documentation form, by location inside container.

Interpretation of Test Results - To qualify the container system–sterilizer combination, all BIs should be negative and all CIs should show complete endpoint responses (negative BIs and pass on the CIs). In the maximum-load test, positive BIs or incompletely responding CIs suggest that

1. the sterilization process is inadequate
2. there could be a problem with the sterilizer itself
3. a problem with the container system
4. or the sterilizer-container system combination

In the small-load test, failures indicate:

1. insufficient steam penetration
2. Insufficient air removal

Any of these failures could be caused by the sterilizer, the container system, or the sterilizer/container system combination.

Test Failures - The first step is to check the physical monitors to ensure that the cycle parameters were correct. If the cycle parameters were correct, then the sterilizer should be evaluated with BI test packs and Bowie-Dick test packs to identify any equipment malfunction. Container systems should not be used in this evaluation.

The sterilizer manufacturer should be consulted if the performance of the sterilizer is questionable. If the sterilizer appears to be functioning properly, the container system manufacturer should be consulted for assistance in resolving the problem.

Gravity Displacement Cycles – If rigid containers are used in these cycles, there is a special protocol for rigid container testing of gravity cycles. Refer to AAMI ST-79 for specific information.

Extensive testing of all gravity-displacement steam sterilizers is recommended because of the potential problem with air removal from containers in gravity-displacement steam sterilization.

Summary - Rigid container testing is an important part of quality assurance testing. Containers should be tested pre-purchase and routinely thereafter (e.g. annually). This testing does NOT replace routine BI testing and does NOT have to be performed the first load of the day. If you have more than one manufacturers' rigid container, each manufacturers' containers must be tested separately.

Quality Assurance is required to assure the adequacy of the sterilization process. QA testing is ongoing and must be performed as recommended.

QUIZ – Rigid Container Testing

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/rigid_container_testing_quiz.htm

Good Luck!