Specialty Testing of Steam Sterilizers

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**This in-service has been Approved by the CBSPD for 1.5 CEUs.

Objectives

1. To describe the types of specialty testing of steam sterilizers as recommended by AAMI
2. Routine, qualification, rigid container and product testing
3. To review the protocols for each type of testing

There are four types of specialty testing of sterilizers:

1. Routine BI Testing
2. Qualification Testing
3. Rigid Container Testing
4. Product Testing (will be covered in a separate inservice).

Routine BI Testing - AAMI ST-79 recommends routine biological monitoring of steam sterilizers weekly, preferably daily. Biological monitoring with a process challenge device (PCD), formerly called a test pack, containing live bacterial spores of *geo bacillus stearothermophilus is recommended* because this spore is the most resistant to steam cycles. For other sterilization methods, check with the sterilizer manufacturer which spore should be used.

The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. In addition, biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs.

BI testing should be performed in the first working load of the day. This is a load that contains trays and devices to provide maximum challenge to the sterilizer. In addition, BI testing is recommended whenever a load contains implantable devices.

The location of the Process Challenge Device (PCD) is critical. The PCD should be the FIRST item on the cart, not an afterthought. It must be placed over the drain line, flat, face up and on the sterilizer rack.

PCDs should never be placed directly on the floor of the sterilizer as this does not provide the greatest challenge to the sterilizer.

Always check the expiration date on the PCD before use. If you have more than one sterilizer, you should place lot control label on each of the PCDs to avoid mix-ups.

PCD in wrong location and positioned incorrectly.

PCD placed flat in correct location

The PCD should be located over the drain line which is the coldest spot in the sterilizer. This creates the most difficult challenge to the sterilizer. In addition, the PCD should be placed FLAT because this also is the greatest challenge to the sterilizer (it is more difficult to remove air and get steam inside the pack when it is FLAT). Understand that the location of the drain line may vary with the sterilizer manufacturer; some are closest to the door while others may be further inside the sterilizer.

Qualification Testing - A faulty sterilizer cannot be made operational without identifying the exact cause of the malfunction and correcting it. Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem; the sterility of future loads will be jeopardized if the sterilizer continues to be used without repair. (ST-79) Sterilizer testing after installation, relocation or major repairs of the sterilizer itself or its utilities is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction.

Common problems detected by physical, chemical, and biological monitoring include inadequate temperature, air removal, exposure time, and drying time. (ST-79)

Testing Protocol – The AAMI recommended testing protocol for pre-vacuum steam sterilizers in The Sterile Processing area is:

3 PCDS on standard pre-vac cycle back-to-back in empty chamber
3 PCDs on gravity cycle (if used)
3 Bowie-Dick tests

NOTE: The Bowie-Dick tests are performed LAST to present the greatest challenge to the sterilization process.

All of the test results should be negative before the sterilizer is put into use or returned to use. You can shorten the dry time on the cycle to 5-10 minutes to decrease the time for testing. However, it is important to return the sterilizer dry time to the usual dry time when testing is completed to avoid wet packs.

Rigid Container Testing - AAMI recommends periodic testing of rigid container systems (i.e. pre-purchase and annually). 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. (ST-79). Before purchasing any packaging system

- gather all the information
- 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.

You need to understand that the interaction of the container system, the medical device, and a sterilizer technology 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 and 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 even 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 the container manufacturer.

Dynamic Air Removal Testing (in a pre-vacuum steam sterilizer): 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?

For this testing you need to identify each size container (not each container in use). Understand that rigid containers have three dimensions; height, length and width. 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. This is because 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.

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

Control vials

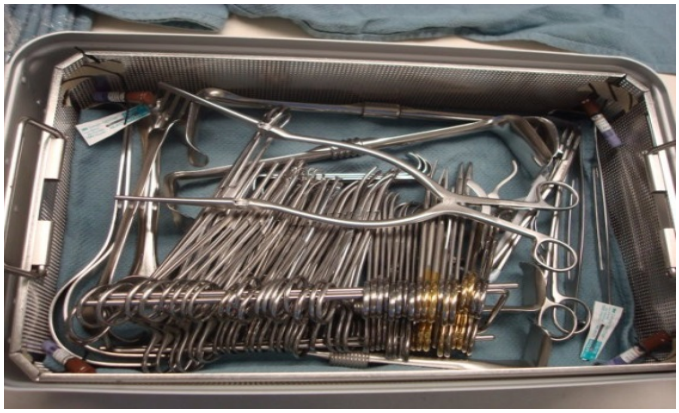
Once you have identified the number of different size containers, prepare the containers as follows (unless otherwise directed by the container manufacturer):

1) Assemble the set that is usually contained inside the test container prepared with the actual instrument set (including any optional absorbent material) recommended by the container system manufacturer.

2) Assemble the BI vials. You can use string tied around the vials to keep them in place, or place them directly inside the set taking care not to move the vials around when placing the set on the sterilizer cart.

3) 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. (NOTE: do NOT place tape on the BI vials which can interfere with the test results).

4) Place a CI in the same location as the BIs.



BIs and CIs inside instrument set

5) Place another BI vial under the lid. The BI should suspend into container when the lid is applied (for pre-vac only).

BI vial suspended from under the lid

It is important to know the location of the BIs; a suggestion is to label the BI vials with different letters (e.g. A,B,C,D) to identify their location inside the set. Use a photo or grid to label/document where the vials were placed. You also need to identify where the containers were placed on the sterilizer cart; i.e. top, middle, lower shelf, front or back. Close the container, apply the locks. Affix a load card; label as "TEST". Prepare for sterilization.

Tests Recommended - A maximum-load test and a small-load test should be run for each representative sterilizer. This means if you have three steam sterilizers and all are from the same manufacturer, same age and same size, you only need to perform the maximum load testing on one of the three sterilizers. For the remaining sterilizers, it is necessary only to run a small-load test. Otherwise, maximum and small load testing must be performed on all three sterilizers.

For the maximum-load test, the user places two test container systems (prepared as above) on the bottom shelf over the drain line 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.

Sterilizer Cart with 2 test containers on each shelf

The chamber is otherwise fully loaded with conventionally packaged items. It is important to have a full load as this represents the greatest challenge to the sterilizer. A sterilization cycle is run with the exposure time recommended by the container system manufacturer.

Sterilizer cart with test containers and other items

A Maximum Load Test is needed 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 is performed using one test container which is placed on the bottom shelf over the drain in an otherwise empty chamber. No other items are placed in the load. A sterilization cycle is run with the exposure time recommended by the container system manufacturer.

A Small Load Test identifies 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.

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

- ✓ the sterilization process is inadequate
- ✓ there could be a problem with the sterilizer itself
- ✓ a problem with the container system
- ✓ or the sterilizer-container system combination

In the small-load test, failures indicate insufficient steam penetration and/or insufficient air removal. These could be caused by the sterilizer, the container system, or the sterilizer/container system combination.

After Sterilization – Cooling - Remove the test containers and allow to cool. Open the containers one at a time so the BIs and Cis do not get mixed up. List the containers by size/set on a documentation form. Record the results of CIs on log form per location in set. Activate and incubate BIs/control vial on the form. Record the BI results on the documentation form, by location inside container.

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 - There is a special protocol for rigid container testing of gravity cycles. Refer to AAMI ST-79 for this protocol. 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: Sterile Processing personnel must be knowledgeable in the AAMI recommended testing of sterilizers to ensure devices can be safely processed. Performing the tests correctly as well as documentation of the testing is critical to quality assurance of the sterilization process.

QUIZ: SPECIALTY TESTING OF STEAM STERILIZERS

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/2017/stss_quiz.html

Good Luck!