Unloading, Storage, Distribution, Transportation and Aseptic Presentation of Sterile Items

Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006)

by Rose Seavey, RN, MBA, CNOR, ACSP

Objectives

Many thanks to the team at 3M Health Care for working with Managing Infection Control to provide the following accredited course. IAHCSMM has awarded one (1) contact point for completion of this continuing education lesson toward IAHCSMM recertification. The CBSPD has preapproved this inservice for one (1) contact hours for a period of five (5) years from the date of publication, and to be used only once in a recertification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 100.

Managing Infection Control and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of Managing Infection Control.

After completion of this self-study activity, the learner will be able to:

1. Describe appropriate handling, storage and distribution techniques.
2. Write a policy and procedure on unloading the sterilizer, sterile storage, distribution and transportation.
3. Demonstrate aseptic presentation of sterile packages.
4. Describe aseptic practice of isolating flashed implants while waiting for the biological indicator results.

Test Questions

True or False

1. The cool-down period starts inside the sterilization chamber.
2. Warm packs should be placed in sterility maintenance (dust covers) before they are cool.
3. Items that are flash-sterilized should be used immediately and not stored for a later use.
4. If an item is dropped on the floor and the integrity of its packaging is compromised, it does not need to go through decontamination before being reprocessed.
5. Shelf life is not simply a matter of sterility maintenance but is also a function of device degradation and inventory control.
6. Sterilized packages should be handled as little as possible.
7. Transportation carts should have a solid bottom shelf.
8. When transporting sterile packages containing instruments, the package should be kept vertical to the floor.
9. AORN recommends opening sterile packages and tossing items onto the sterile field.
10. When an implantable device is sterilized at a healthcare facility, a rapid-action biological monitor should be run with the load, and the implant should be quarantined until the results of the biological indicator are known.
Introduction

Finally it is here! The newly revised, master document to help CS/SPD professionals wade through the issues of steam sterilization. What am I talking about? Well, it’s the Association for the Advancement of Medical Instrumentation’s (AAMI’s) most up-to-date comprehensive recommended practice, the Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006). It is now available to order. ST79 is a comprehensive guideline for all steam sterilization activities in healthcare facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all healthcare personnel who use steam for sterilization. The five recommended practices incorporated into the new standard are:

- ANSI/AAMI ST46, Steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST42, Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities
- ANSI/AAMI ST37, Flash sterilization: Steam sterilization of patient care items for immediate use
- ANSI/AAMI ST35, Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings
- ANSI/AAMI ST33, Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

Since ST79 is a combination of the five steam documents, it is a large document with the contents in most instances equivalent to the five previous documents. The information is not really all that new, but what this document does is simplify and clarify a lot of previous issues.

Every healthcare facility, big or small, should have this document to meet the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) leadership requirements. It contains important information that will assist the leadership of the healthcare facility in making informed decisions to improve the quality of the steam sterilization process and improve patient outcomes. Ordering information is provided at the end of this inservice.

In the past these documents were separately revised every five years. Now they will be up for review annually. Plus, the document is in a three-ring binder, making it easier for facilities to update annually.

This document covers everything from personnel consideration to quality control. No doubt you will be seeing a lot of articles about this newly published document. This inservice will concentrate on the recommended practices from Sections 8.8 to 8.12, which includes unloading the sterilizer, sterile storage, distribution, transport of sterile packaged items and aseptic presentation of sterile supplies. It will also list the sections where the information can be found so that you can reference them when you purchase a copy of this comprehensive steam document.

Unloading the sterilizer (Section 8)

Large chamber sterilizers (Section 8.8.1)

All items that are removed from the sterilization process should remain on the sterilizer cart until adequately cooled. This includes rigid sterilization
container systems. During the cooling process the items should not be handled or touched. “Packs should not be touched until they are cool because hot packs act as wicks, absorbing moisture and hence, bacteria from hands.”¹

The cool-down period starts inside the sterilization chamber. The chamber door may be slightly opened at the end of the cycle leaving the packages inside for a period of time in order to decrease the potential for condensation. (See Figure 1.)

Figure 1

The surfaces of rigid sterilization container systems should be cool to the touch, allowing them to be handled safely by the operator with bare hands. Recondensation of steam can result if rigid sterilization containers systems are not properly cooled before they are removed from the sterilizer cart. Because the containers are not absorbent, the condensate may form small droplets on or within the container system. The condensate on the outside of a container may flow onto the filter of another container, or onto packages below contaminating them. “Condensate within any container system can compromise the sterility of the contents if the condensate is able to come into contact with outside contaminates.”¹

The amount of time necessary for the cooling phase depends on:
- The design of the item being sterilized,
- The temperature and humidity of the ambient environment, and
- The packaging type used.

The minimum cooling time recommended for a sterilized load is 30 minutes; however, adequate cooling could require 2 hours or more. Therefore, the allowed cooling time must be based on professional opinion and experience in your individual healthcare facility. Cooling times will depend on load contents, steam quality, and temperature and humidity of the environment.

“During cooling, the sterilizer cart should be placed in a low-traffic area where there are no air-conditioning or other cold-air vents in close proximity.”¹ Low traffic areas help to reduce exposure of the packages to particles settling from the environment and decrease the likelihood of unintentional staff contact with the sterilized items when they are particularly susceptible to contamination.

Items that are warm should not be transferred from the cart to a cold metal rack or shelf for cooling, since condensate could form and cause the package to become contaminated. Warm packs should also not be placed in sterility maintenance (dust covers) before the cooling process has been completed. This is because the inside of the dust cover is not sterile, so that any condensate that forms may contaminate the package contents.

**Table-Top sterilizers (Section 8.8.2)**

At the end of the tabletop sterilizer cycle, the door may be slightly opened and the packages left inside for a period of time in order to reduce the potential for the formation of condensation. A 10-minute minimum cooling time is recommended; nevertheless, the time allowed should take into consideration the type of sterilizer used, the design of the item(s) being sterilized, the temperature and humidity of the environment, and the type of packaging used.

**Open-tray flash cycles (Section 8.8.3)**

Items that are flash-sterilized should be used immediately and not stored for a later use. “Procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present within the tray so care should be taken to avoid contamination of the sterilized items.”¹ When removing items from open tray flash cycles, personnel
should be careful to avoid burns because the tray and the items within it will be very hot. The staff should wear sterile gloves when removing items from the sterilizer. (See Figure 2.) Sterile towels may be used as “potholders” when taking items from the sterilizer. Do not place the tray on a nonsterile surface.

“Rationale: It is particularly important that the flash sterilization method of steam sterilization processing be carried out in a clean environment and that devices processed by this method be transferred and handled as little as possible, because the items are not protected by packaging before or after the sterilization process.”

**Flash cycles with single wrappers or other textile packaging** (Section 8.8.4)

All items that have been flash-sterilized should be used immediately and not stored for later use. There are some sterilizers that will allow for flash cycles with a single wrapper or other packaging. These must be distinguishable from wrapped or packaged devices processed in the conventional way. This cycle should include a very brief drying time.

“The wrapped/packaged tray should never be placed on a nonsterile surface. A sterile, impervious drape, placed on a surface separate from the sterile field, should be used so that the wrapped/packaged tray can be placed there and then opened by the circulator. The sterile items may then be removed from the tray by the scrub person and taken to the sterile field.”

**Flash cycles with sealed containment devices** (Section 8.8.5)

All items that have been flash-sterilized should be used immediately and not stored for later use. There are specially designed sealed containment devices for flash cycles. These must be distinguishable from other sealed containment devices processed in the conventional way. As is typical of flash sterilization, condensate will be present in the containment device; therefore, transfer procedures should be developed to minimize the chance of burns. The amount of condensation created will depend on the types and number of instruments being sterilized. Both the containment device and the contents will be hot. As with open tray flash cycles, the staff should wear sterile gloves when removing items from the sterilizer, and sterile towels may be used as “potholders.” “The containerized items should never be placed on a nonsterile surface. The sterile items may be removed from the containment device by the scrub person and taken to the sterile field.”

**Handling and inspection** (Section 8.8.6)

Procedures for minimizing the handling of all sterile items should be developed and placed in writing. When packages are removed from the sterilizer cart, they should be inspected visually for any tears or wetness. Torn or wet packages should be considered contaminated. “If an item is dropped on the floor and the integrity of its packaging is compromised, it should be returned to the decontamination area for reprocessing.”

**Sterile storage (Section 8.9)**

**Sterility maintenance covers (Section 8.9.1)**

Sterilized packages should be handled as little as possible. If properly sterilized packages are thought to be exposed to environmental challenges or multiple handlings before use, sterility maintenance covers (dust covers) may be used to protect and extend the package shelf life. The product used must be labeled exclusively as sterility maintenance covers. These covers are designed to provide protection against outside elements such as dust. These sterility maintenance covers should be applied immediately after the items from the sterilizer are thoroughly cooled.

Sterility maintenance covers must be sealed in order to be an effective barrier. Some of the covers are designed to seal on to itself with a sticky strip (e.g., self seal). Others may need to be sealed with a specifically designed plastic-to-plastic heat sealer. Be sure the lot or load control number containing the expiration statement as well as the description of the items can be seen though the dust cover. (See Figure 3.)

**Figure 3**

**Storage facilities (Section 8.9.2)**

Sterile packages should be stored in a controlled environment to help reduce the potential for contamination. Generally speaking, the sterile storage area should be approximately 24°C (75°F), have at least four air exchanges per hour, and have a relative humidity level that does not exceed 70%. Traffic needs to be limited to personnel who know how to handle sterile items properly.

“Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that might form on the interior surfaces of outside walls.”
Sterile items should be stored at least:
- 8-10 inches above the floor,
- 18 inches below the ceiling or the level of the sprinkler heads, and
- 2 inches from the outside walls.

Care should be taken to ensure the packaging is not bent, crushed or punctured, or otherwise compromised. Packages of sterile supplies, which include items in rigid container systems, should not be stored in any area that may cause them to be exposed to moisture. For ergonomic reasons, heavy trays should be placed on the middle shelves, without stacking. (See Figure 4.) Transport trays may be used with larger trays to prevent tears in the wrappers during handling.

Rigid sterilization container systems should be stored on shelves or racks designed to hold the weight and configuration of the containers. If containers must be stacked due to space constraints,
it is imperative that they are firmly seated, one upon the other, and can be easily removed. Facilities should create and enforce policies and procedures for the storage, handling, rotating and labeling of container systems.

Seldom-used supplies should be stored in closed or covered cabinets. When items are stored in closed cabinets, dust is limited, handling is discouraged, and inadvertent contact with sterile items is minimized. If open shelving is used, it requires special attention to traffic control, housekeeping and environmental ventilation. Sterile storage shelves should be maintained in a clean and dry condition. The bottom shelf of an open-wire cart requires a physical barrier between the shelf and housekeeping activities. “Shipping containers serve as generators of and reservoirs for dust; hence, shipping containers should never be allowed in the sterile storage area.”

Shelf life (Section 8.9.3)

The period of time during which a sterile package is considered safe to use is called the shelf life. “The shelf life of a packaged sterile item is event-related and depends on the quality of packaging material, the storage conditions, the conditions during transport, and the amount of handling. Shelf life is not simply a matter of sterility maintenance but is also a function of device degradation and inventory control.” The probability of an item becoming contaminated grows with increasing handling. Each facility should establish specific written policies that state how shelf life is determined. Specific policies and procedures should be established describing how to assess the shelf life in the event that a sterility maintenance cover is removed but the packaged items are not immediately used. In most cases, stock rotation should be according to the “first in, first out” (FIFO) principle.

Distribution (general) (Section 8.1)
Handling and inspection (Section 8.10.1)

Sterile supplies should always be carefully handled. Personnel should avoid compromising the sterility of the item by not dragging, crushing, bending, compressing or puncturing the package. Appropriate care and handling of sterile packages will help to prevent contamination of the items inside. All items should be inspected for integrity before being dispensed.

It is the responsibility of the end user to carefully inspect the package visually for integrity and labeling immediately before opening and using a sterile item.

Distribution containers (Section 8.10.2)

A covered or enclosed cart with a solid bottom shelf should be used to transport all clean or sterile items. “A solid bottom shelf on the cart prevents contamination via the so-called “rooster-tail effect,” in which the wheels pick up contaminants from the floor and spin them upwards.” If plastic or paper bags or boxes are used to contain and transport items, they should be placed in the container in such a way that would prevent them from being crushed, damaged or contaminated.

Unintentional contact with staff and other sources of contamination along the transportation route can be avoided if covered or enclosed carts are used for transportation of clean and sterile items. If reusable covers for carts or other transport vehicles are used, they should have a reclosable opening and should be cleaned after each use. “Carts should be decontaminated and dried before they are reused for transporting sterile supplies. For automated cart distribution systems and pneumatic systems, the manufacturer’s instructions on distribution and decontamination procedures should be followed.”

Transport of sterile packaged items (Section 8.11.2)
Tables and carts (open or closed) (Section 8.11.2)

Packages should be placed securely in a flat position and should not extend beyond the edge of the cart shelf or table surface.

Hand Transport (Section 8.11.3)

When transporting sterile packages containing instruments, the package should be kept parallel with the floor in order to avoid shifting of the instruments. Good body mechanics should be used when transporting any items.

Dedicated lifts (Section 8.11.4)

If a dedicated lift is used to transport clean or sterile items from the processing area to the user area, the lift should be located in a designated “clean area.” (See Figure 5.) The clean or sterile items should be contained in a closed bin, a closed case cart or a plastic bag when being transported via a dedicated lift.

Figure 5
**Off-site transportation (Section 8.11.5)**

When sterile packages are transported between healthcare facilities, the vehicle used to transport these items must be able to completely separate clean and sterile items from contaminated items. In this situation, all external shipping cartons (corrugated or otherwise) are to be considered contaminated, even if they contain wrapped sterile items.

“Transport vehicles must be completely enclosed and should be checked periodically, at least annually and more frequently as needed, to ensure that they do not leak. Carts containing sterile packages should be secured within the vehicle to prevent damage or contamination. Transport vehicles and handling practices should allow for ease of loading and unloading.”

“When motor vehicles are used, environmental conditions should be assessed while the vehicle is in motion and when it is not in motion.” In areas of the country that frequently have high humidity, specific tests should be done to determine whether potential sterile items have the potential to become contaminated through absorption. Evaluations should be done to determine if there is potential for the contents of sterile packages to become wet through condensation. Condensate can occur on plastic or metal surfaces that are moved from air-conditioned environments to non-air-conditioned environments and then back to air-conditioned environments.

All transport vehicles (motorized or manual) should be constructed of materials that allow for proper decontamination processes. This is even more important if the vehicle will transport alternating sterile and soiled items. Loaded transport vehicles should never be left unattended or in an unsecured location.

**Aseptic presentation (Section 8.12)**

**Opening sterile packages (Section 8.12.1)**

Sterile items should be opened aseptically following specific guidelines.

1. Position package at the level of the sterile field on dry flat surface.
2. Inspect the physical integrity of the packages or rigid containers as well as the external chemical indicator (CI).
3. Break the seal of the exterior tape and unfold the wrap, layer by layer.
4. Peel packs should be opened by folding the top down half way, and then presenting the contents.
5. For rigid containers, the manufacturer’s recommendations for lid removal should be followed, making sure there is no contact between the lid and the inner rim or any part inside of the container.
6. The internal CI should be checked on all packages to confirm appropriate end point response.

The 2006 Association of PeriOperative Registered Nurses (AORN) Recommended Practices for Maintaining a Sterile Field (RP III) states: “Items used within the sterile field should be sterile. To ensure that only sterile items are presented to the sterile field, all items should be inspected immediately before presentation to the field for proper packaging, processing, seal, package container integrity, and inclusion of a sterilization indicator. The indicator should be inspected immediately to verify the appropriate color change for the sterilization process selected.”

The 2006 AORN Recommended Practices for Maintaining a Sterile Field (RP IV) states: “All items introduced to a sterile field should be opened, dispensed, and transferred by methods that maintain item sterility and integrity. Sterile items should be presented to the scrubbed person or placed securely on the sterile field. Items tossed onto a sterile field may roll off the edge, create a hole in the sterile drape, or cause other items to be displaced, leading to contamination of the sterile field.” (See Figure 6.)

**Figure 6**

*Removing items from sterile packaging and transferring them to the sterile field (ANSI/AAMI, Section 8.12.2)*

When removing the contents from a sterile package and transferring the contents to the sterile field specific guidelines should be followed.

1. The internal CI should be checked for proper endpoint response by the surgically attired scrub person before removing the sterile contents.
2. The scrub person should avoid all contact with the wrap or peel pack. When removing the inner basket of a rigid container, both handles should be used in order to lift the basket straight up to clear the container. (See Figure 7) Care should be taken to avoid the inner rims. If a container has more than one basket, they should be moved to the sterile field one at a time.
3. Visually inspect the bottom of the wrapper or container system for integrity and moisture before placing contents on the sterile field.
4. The circulator should inspect container system for proper alignment and the integrity of the filter system per the manufacturer’s recommendations.

While discussing the aseptic practice of maintaining a sterile field, we should also address the need to quarantine any implants that are flashed until the results of the biological indicator (BI) are known.

**Figure 7**

The 2006 Association of PeriOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings states:

“Flash sterilization should not be used for implantable devices. Implants are foreign bodies, and they increase the risk of surgical site infections. Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices. When an implantable device is sterilized at a health care facility, a biological indicator should be
run with the load and the implant should be quarantined until the results of the biological indicator are known. If an emergency situation makes flash sterilization unavoidable, a rapid-action biological monitoring device should be used along with a class V chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result. After the rapid-action negative result is obtained, the implant can be released for use in the immediate situation.”

Because of this stringent standard, I wanted clarification on how to quarantine a flashed implant and maintain the sterility, while waiting for the BI results. I questioned Ramona Connor, RN, MSN, CNOR, who currently represents AORN on the AAMI Sterilization Standards Committee. She stated, “The sterilized implant can be placed on a corner of the back table and segregated from the rest of the sterile field until the rapid-readout BI is ready to read. When the BI result is negative, then the implant can be placed in the patient. If the BI is positive, the implant hasn’t been used; and the rest of the sterile field hasn’t been contaminated.” Remember, the recommendation to not flash sterilize is because of the risk of surgical site infection.

Summary
The AAMI Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2006) is the principal resource for steam sterilization and should be part of every healthcare facility’s library. The key recommended practices in Sections 8.8-8.12 are:

- When unloading large chamber sterilizers, all items including rigid sterilization container systems should remain on the sterilizer cart until cooled.
- The minimum cooling time recommended for a sterilized load is 30 minutes; however, adequate cooling could require 2 hours or more.
- All items (except implants) that have been flash-sterilized should be used immediately and not stored for later use.
Sterile Process and Distribution CEU Information

CEU Applicant Name ____________________________

Address ________________________________________________________________
City__________________ State____ Zip Code __________________

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1 contact hour for a period of five years from the date of publication and to be used once in a re-certification period. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, 2 Industrial Park Road, Suite 3, Alpha, NJ 08865 or call 908.454.9555 or visit Web site at www.sterileprocessing.org.

IAHCSMM has awarded 1 contact point for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

3M Health Care provider approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five years from the date of publication.

1. Make a photocopy of this form.
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3. Add your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the CE questions.
6. Submit this form and the answer sheet to:
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Sterilized packages should be handled as little as possible.

Sterilized packages should be stored in a controlled environment to help reduce the potential for contamination.

A covered enclosed cart with a solid bottom shelf should be used to transport all clean or sterile items.

All transport vehicles (motorized or manual) should be constructed of materials that allow for proper decontamination processes, this is even more important if the vehicle will transport alternating sterile and soiled items.

All items introduced to a sterile field should be opened, dispensed and transferred by methods that maintain item sterility and integrity.

The internal chemical indicator should be checked for proper endpoint response by the surgically attired scrub person before removing the sterile contents.

In addition, the 2006 Association of PeriOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings states:

Flash sterilization should not be used for implantable devices.

If flash sterilization is used, implants should not be released until the rapid-action biological monitor devices provides a negative result.

Ordering Information

AAMI

ANSI/AAMI ST79:2006, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Order code: ST79 or ST79-PDF

Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section

ANSWERS

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References

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