Handling and Storage of Sterile Packages

LEARNING OBJECTIVES
1. Discuss proper handling temperatures of sterilized items
2. Identify conditions in the storage area that can be detrimental for sterilized items
3. Understand recall and reporting processes

THROUGHOUT THE LIFE CYCLE OF A STERILIZED INSTRUMENT OR set, numerous obstacles can arise that may create an opportunity for sterile packages to become contaminated during handling, transport and storage. To better understand these obstacles and potential risks for contamination, it is important that Central Service (CS) professionals assess all aspects and impacts of handling and storage – from completion of the sterilization cycle and the transport of instruments to the storage area, to evaluating conditions of the storage area(s) and, finally, transporting the sterile packages to the point of use. Having a solid understanding of systems, policies, procedures and best practices is key to maintaining the integrity of sterile items.

OBJECTIVE 1: DISCUSS PROPER HANDLING TEMPERATURES OF STERILIZED ITEMS

Post-sterilization temperature monitoring begins when the CS technician first loads the sterilizer rack or chamber. When loading the rack or chamber, it is important to consider the location of metal containers. Containers must be placed below any wrapped or peel pouched items. Placement of the contents, as well as the type of devices being placed into the sterilizer, must be considered to ensure a properly balanced load; densely packaged or heavy sets can adversely affect the sterilization and cooling processes. Items must be placed in a way that ensures proper circulation of the sterilant. This is important not only for proper sterilant penetration, but also for heat disbursement and transfer, which will influence the cooling time after the cycle is complete. Adequate spacing between the packages also assists with the cooling process.

When selecting the area for sterile items to cool, considerations should be given to both the traffic patterns and proximity of air vents. Cooling time will be impacted not only by load configuration, set weight...
and density, but also the location of the cart and the environmental conditions. ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, states that a 30-minute minimum cool-down time is recommended; however, it could require up to two hours or more for sterilized items to cool enough prior to being transferred. It is not recommended to check the temperature of sterilized items by touching them; an infrared temperature reading device that allows the external temperature of the sterilized items to be measured without direct contact is recommended. Items should not be handled until the items have cooled to ambient (room) temperature.

Employee safety and potential contamination of the sterilized items are two key factors to consider when handling sterilized items. Burns are a potential safety risk to the CS technician because the rack and sterilized items coming out of the sterilizer can reach more than 270°F. Care must be taken when handling or working around the cart during the cooling process.

Additionally, regardless of the type of wrap or containment device used, the possibility of contamination from moisture transfer, condensation or mishandling can occur during the cooling process. CS technicians must review and understand the manufacturer’s Instruction for Use (IFU) and the national standards for load releasing based on time and temperature.

**OBJECTIVE 2: IDENTIFY CONDITIONS IN THE STORAGE AREA THAT CAN BE DETRIMENTAL FOR STERILIZED ITEMS**

Sterile storage areas are not always designed in a manner that is optimal for sterility conditions, and these design shortcomings could lead to potential contamination. Carefully assessing the design and space utilization of sterile storage areas will help identify challenges and specific obstacles that may prevent CS professionals from following standards and adhering to the manufacturer’s IFU. There are several considerations that must be accounted for to ensure that the sterility of stored items does not become compromised.

- **Traffic**
  - Who needs access to the sterile storage area? Only properly attired personnel who need access to the sterile items should be admitted.
  - Entry and exit points to the storage area should be located to prevent unnecessary movement around sterile items. Sterile storage areas should never be used as a shortcut through the department.

- **Travel and movement distances**
  - Travel and movement distance studies should be performed to ensure that sterile items will be protected from excessive handling. Care and protection during movement and transport will help minimize the potential for sterile package contamination or compromise. Moving items from the cooling area on the sterilization cart or a clean cart will help prevent contamination. Items should not be stacked when being placed on the transport cart. Items should be transported to the storage area as soon as possible after cooling. If transporting sterile items to a storage area out of the immediate department, the use of closed carts will help maintain package sterility. During transport, the cart should never be left unattended in hallways.

- **Space and shelf configuration**
  - When assessing the storage space, items should be stored to allow adequate circulation from all angles. If there are multiple choice options...
for shelving in the department, the decision to use closed, semi-closed or open shelving should be based on the items being stored and the availability to the type of storage. Closed shelving may be used for items that are moved infrequently; closed storage will help keep items protected until used. Semi-closed and open shelving should be sturdy enough to hold the items. All storage shelving must be kept free of dust and other contaminants.

» Wrapped items should not be stacked on shelves. Care must also be taken to ensure the packaging is not crushed, bent or folded (each of which will compromise sterility). Containers should be stacked only as high as approved in the IFU. Figure 1 shows the proper way to store wrapped sets. Figure 2 show the incorrect way to store wrapped trays.

» Shelving should be checked regularly to ensure there is no damage. Dents and burrs can damage packaging.

» When placing items on the shelf or retrieving items for issue, the tray should be lifted and not dragged across the shelving. The transport cart should also be free from damage that can compromise the integrity of sterile items. Figure 3 shows the proper way to retrieve a tray from the shelving.

• Personal hygiene

» When handling sterile packages, it is important for CS technicians to follow proper hygiene practices. Clean scrub attire must be worn to protect sterile items from potential contamination from outside the facility, as well as from skin cells and bacteria that can be transferred from the body to the packages. Hair coverings should be worn to prevent shedding hair and skin from contaminating sterile packages. Jewelry, such as rings, watches or bracelets, should not be worn in the sterile storage area because they can snag or otherwise damage the packaging. Practicing good hand hygiene is also essential when handling sterile items.

• Environmental Controls

» The three major areas in sterility assurance related to environmental controls are temperature, humidity and air exchanges. When temperature and humidity are too high, this can promote microbial growth within the storage area; when temperature and humidity levels are too low, this can also compromise the performance of some products and material. Correct ventilation and air exchanges help reduce the spread of potentially dangerous microorganisms and environmental contamination. CS professionals must refer to the current standard for specific temperature and humidity ranges and air exchange rates. Temperature and humidity levels should be monitored and recorded at least daily. Air exchanges should be tested and monitored (usually by the Facilities Management Department) per facility policy.

OBJECTIVE 3: UNDERSTAND THE RECALL AND REPORTING PROCESSES

Even when all processes are carefully followed, a recall of sterilized items may
Recalled items do not always occur because of a positive biological indicator (BI). There are a number of other reasons that can lead to a recall, such as moisture in items, sterilization tape failure and environmental control failures, just to name a few. Ongoing monitoring and surveillance is necessary, and involves a recall reporting procedure and recall report.

Initiating a recall procedure and report can be done several different ways, but all methods involve specific components to ensure a complete and accurate report is created to clearly identify what happened and how the recall was handled. The reporting procedure should be written and easy to follow. It should outline the circumstances surrounding the recall. It should also designate a person(s) who is authorized and responsible for initiating the recall and reporting the results. The official recall report should be detailed and specific in order to provide clarification with action/mitigation steps that need to be taken. Upon completion of the reporting procedure, the recall report will include the following, at minimum:

- Circumstances that led to the recall.
- Total number of items impacted and recalled, with corresponding number of items located in the recall.
- Corrective actions taken to prevent recurrence.
- List of items and quantities not located, and documentation of which departments were affected and who was notified.
- Verification that all recalled items were destroyed or reprocessed, as appropriate.
- Documentation of who was notified of the recall and their role in the recall process.

**IN CONCLUSION**

Even though many CS departments must deal with space constraints and unique challenges in regard to sterile storage, there are guidelines policies and procedures that the CS department can refer to that will help outline, define and develop the most current and appropriate practices that pertain to sterile storage. Taking assessments of sterile storage areas and practices, and making necessary changes to ensure that standards, best practices and IFU can be properly and consistently followed will help ensure that sterile items are not compromised during handling, transport and storage.

**RESOURCES**

Association for the Advancement of Medical Instrumentation. 2013. ANSI/AAMI ST79, Comprehensive guide for steam sterilization and sterility assurance in health care facilities, Section 10.11.

Association for periOperative Registered Nurses. 2016. AORN Guidelines for PeriOperative Practice. Guideline: Sterilization, Recommendations XV, XVI, XX.

Marrs, B. Sterile inventory: Handling with Care. Infection Control Today, July 2011.
### OBJECTIVE 1

1. Package temperature monitoring begins:
   a. After the sterilization cycle is complete and the sterilizer door is opened
   b. After the sterilization cycle is complete before the door is opened
   c. When loading the sterilizer cart
   d. All the above

2. When loading a sterilizer cart, it is important to balance the load:
   a. To help with the cooling process
   b. To keep the heavy trays on the bottom
   c. For technician safety
   d. All the above

3. The best method to check sterilized items for proper cool down is:
   a. Placing a hand on the sterilizer rack
   b. Gently touching the bottom of the tray
   c. Using an infrared device
   d. All the above

4. Wrapped items are at risk for moisture transfer during the cooling process.
   a. True
   b. False

5. Two of the key factors for proper handling of trays after sterilization are:
   a. Room air exchanges and humidity
   b. Room air exchanges and the temperature of the sterilizer cart
   c. Employee safety and tray contamination
   d. Tray contamination and room air exchanges

### OBJECTIVE 2

6. When assessing traffic flow in the sterile storage area, consideration should be given to:
   a. The amount of distance from the sterilizing area to the cooling area
   b. Where the return air vents are located
   c. Who needs to access the area
   d. All the above

7. Adequate circulation around the sterile packages in the sterile storage area is an important factor.
   a. True
   b. False

8. It is acceptable to stack containers following the manufacturer’s Instructions for Use; however, wrapped sets should not be stacked.
   a. True
   b. False

9. Semi-closed shelving is the best type of shelving for items that are moved infrequently.
   a. True
   b. False

10. High temperature and humidity in the sterile storage area:
    a. Compromises the performance of some products
    b. Can promote microorganism growth
    c. Can cause the indicator tape to fail
    d. Has no effect on sterile packages

11. When sterile items are placed on the shelf, they should be lifted to the desired storage space, not slid across the shelf.
    a. True
    b. False

12. Part of the recall reporting process involves verifying that all items were destroyed or reprocessed, as appropriate.
    a. True
    b. False

13. Recalls can occur even if all processes have been carefully followed.
    a. True
    b. False

14. Recall procedures should include:
    a. The name and extension number of everyone who should be notified
    b. The name of the person authorized to initiate the recall
    c. The amount of time trays should cool, and their storage location
    d. All the above

15. The recall report should contain:
    a. The corrective action taken
    b. The number of items impacted by the recall
    c. The number of items located
    d. All the above