The purpose of the sterile storage area, regardless of the location, is to store the sterile devices until they are used. Sterile storage can include facility-processed items, items from outside manufacturers and clean but not sterile items. (NOTE: Yes, they can be stored in the same location!) The sterilization process is multi-step to ensure a safe product. Best practices for sterile storage are required to ensure the sterility of the devices is not compromised. Sterility maintenance can be affected by a number of events. This Inservice will address them.

Compromise of Sterility

Basically, there are three conditions than can compromise sterility; moisture, soil and physical damage. All of these events are affected by the storage and handling of the packages after sterilization.

Moisture - the first opportunity to compromise sterility is immediately after sterilization. The Association for the Advancement of Medical Instrumentation (AAMI) recommends that after steam sterilization “items remain untouched on an autoclave rack for a period of 30 minutes to two hours (based upon the load configuration, weight and density of sets). However, denser, heavier trays could take two hours or longer to cool. Yet, how often is the Sterile Processing Department asked to release items when they are still hot? Packs should never be touched while still hot. Today, there are devices called infrared thermometer guns which read the temperature of each pack.
PHOTO ABOVE - Arrow pointing to an infrared thermometer gun to measure the temperature of each pack

These devices can be used to know when to release a package from the sterilizer without touching it first. Ambient temperature is the recommended release temperature (72°F to 80°F). AAMI is considering a recommended temperature.

Autoclave carts containing freshly sterilized items should be placed in a low traffic area away from any air conditioning vents. Never place hot packs on a cool metal surface to prevent condensation from occurring.

Other causes of moisture causing contamination of packs include:

- Excessive humidity can also cause compromise of sterility. The sterile storage area should ideally be physically separated, enclosed, located close to the sterilization area and dust free with at least four air exchanges per hour. The humidity level (measured with a hygrometer) should range from 35-70% and temperature should not exceed 75°F.¹ The temperature and humidity levels should be monitored and documented daily.

- Correct storage of packs is also important. Packs should never be placed or stored near sinks, under pipes or in any other location that could cause the pack to become wet.

- Handling packs with damp or wet hands.

- Wet packs (items not properly dried in the sterilizer then handled). Soils from unclean hands can be compressed into packs.

The second cause of compromise is soil. Soil can refer to dirty hands, shelves, storage locations, carts, shelves, etc. There should be a restriction of entry into the sterile storage area. A policy and procedure is needed to document who has access to this area, attire needed, documentation of items removed, etc. This is especially true for hours when SPD is closed. The sterile storage area should limit contaminants. AAMI recommends positive air pressure with 4 air exchanges per hour in the sterile storage area. The sterile storage area can be a separate room or adjacent to the prep/packaging/sterilization area.

Dust on implants in sterile storage area

Handling is also affected by good hand washing. Is there a hand wash sink in your sterile storage area or adjacent to it to encourage frequent hand washing? If not, you may want to consider installing a waterless hand wash dispenser.

Carts, bins, etc. used to transport sterile supplies need to be kept clean. They should be cleaned at least daily. Outside shipping cartons are not permitted in the sterile storage area nor should cardboard cartons (e.g. if supplied as an inside container) be used for sterile storage as they are porous and cannot be cleaned. Corrugated cardboard permits dust and bacteria to harbor in the grooves. It is recommended to use impervious (plastic) bins for storage to facilitate cleaning.
Regardless of the type of shelving used in the sterile storage area (open/wire or closed), the shelves and bins must be kept clean and dust free. Unfortunately, with the implementation of Event Related Sterility, the monthly ritual of checking for outdates and cleaning bins seems to have been forgotten. How can we maintain sterile supplies in dusty bins and shelves? We cannot. When was the last time you inspected your sterile storage area?

All sterile storage should be at least 8-10 inches off the floor to permit housekeeping to clean without splashing onto the packs on the bottom shelf. Fire code requires that all storage be kept at least 18 inches from any fire sprinkler so the sprinkler’s operation in a fire is not impeded. In addition, storage should be kept at least 2 inches from an outside wall to prevent condensation from the outside leaking through the wall and possibly contaminating packs. If your shelving does not meet these criteria, you can place the items on the bottom shelves in tote bins, which will protect them from splashes. Solid top and bottom shelves are recommended to protect items from contamination. Items should not be stored on top of carts since they are not protected from contamination.

The third opportunity for compromise is physical damage. One cause is the number of times a device is handled after sterilization. Do you know how many times your sterile packs are handled? What about items that are released to the OR then returned to SPD only to be released again? When did too much handling occur? How can you tell if the package is not damaged?

When packs are handled, they should never be compressed. Do not overload carts/bins. Any items that fall to the floor must be considered contaminated and returned to the Decontamination Area for complete re-processing. When was the last time you looked at the condition of your peel-packaged items? I continuously see peel packaged items where multiple creases are noted in the packaging. At what point does sterility compromise take place? Can you tell visually? Overcrowding items in sterile storage should be avoided. Soils might be compressed into sets and/or cause damage to wrapped sets or paper-plastic pouches.
When distributing items, the person releasing the pack should visually inspect the pack to ensure the packing has not been compromised; no tears, holes, stains. If noted, the pack should be re-processed.

Conversely, when receiving sterile product from outside vendors, or receiving items back into sterile storage (that have not been opened/used), it is the responsibility of the individual accepting the product to check for packaging integrity and for signs of contamination (e.g. staining of packaging material).

How the stock is arranged can affect efficient location of items. While there are many ways to arrange stock, the most common methodology is to arrange the items by body system (e.g. all the GU supplies together, chest supplies, etc.). All bins and shelves should be clearly labeled and there should be a Master Locator List, which is readily available to any hospital personnel permitted to enter this area during off-hours. Properly labeled and organized stock can reduce unnecessary handling.
The most commonly used items should be located at a convenient location, usually middle shelves. Lighter items should be on top shelves and heavier items on bottom shelves to prevent injuries. Non-skid stools may be needed if you have short personnel working in this area.

One of the most expensive costs for a facility is outdated stock. This should not happen and can be prevented if a good system of stock rotation is employed. This should include items sterilized by the facility. The “first in- first-out (FIFO) system is most commonly employed, however everyone must follow this practice in order for it to be successful and avoid costly outdates. Sometimes, sales representatives will exchange product that is not outdated as yet for product with a longer shelf life, however once it is outdated, the company will not accept it back.

Overstock

All items should be stored with sufficient space so packages are not compressed. AAMI recommends no stacking of wrapped sets. Rigid containers, because of their design, can be stacked in storage.

When handling packs, do not cradle them in your arms or crush them on carts. Items being delivered should be protected from contamination in delivery. Solid metal carts can be used (e.g. case carts), tote bins or clear plastic bags. When dispensing items to departments from SPD, you should place them in plastic bags to protect them.

Packaging

Packaging materials should be selected based upon the item being contained. Often, dust covers (plastic bags of 2-3 mils in thickness) are applied after sterilization/cooling, to provide additional protection to trays that will remain in storage for a long time or will receive excess handling (e.g. items on the resuscitation cart). If used, follow the manufacturer’s instructions for use. Generally, dust covers should be applied after items are thoroughly cooled (generally one hour). Wash your hands or apply gloves before applying the dust covers to reduce the introduction of contaminants inside the dust cover. Dust covers are available in heat seal and self-seal designs. It is important to make sure there is a good seal with no defects to prevent contaminants from entering the pack.

Environmental Control

Never store sterile product in areas when they can become wet. This includes under sinks, near windows, near doors or near/under exposed pipes or vents.
Storage Under Sink

There should be sufficient space for storage of sterile product. The only items, which are permitted to be stacked, are rigid containers. When wrapped trays are stacked, the weight of the trays may compress bacteria/dust inside sets. Packages should not be crushed or damaged.

Crushed packages, metal container on top of wrapped sets

The floors in the sterile storage area must be cleaned daily. A procedure for the SPD staff to clean the shelves and bins needs to be developed, implemented and enforced.

SUMMARY

Processing personnel spend a great deal of time to properly decontaminate, package and sterilize devices. The facility also pays for sterile product from outside manufacturers. The final step in the process is sterility maintenance of devices. Everyone involved in handling sterile product must be educated in the proper care and handling of sterile products. Maintenance of the sterile storage area, including shelves, bins and transport carts is essential. Cost containment requires that we protect, handle, rotate and store the sterile products we are entrusted with. Concern for patient safety demands no less.
REFERENCES:


QUIZ – Sterile Storage

Please click on the link below to take the quiz.

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

Good Luck!