A Review of Packaging Systems

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LEARNING OBJECTIVES

1. Discuss the importance of barrier packaging and how to select the appropriate packaging material
2. Review the basics of peel packaging
3. Discuss the use of flat-wrap material
4. Review the properties and use of rigid containers

Surgical patients trust they will be safe during their procedure and that their instruments will be clean, functional and sterile. Sterile Processing (SP) technicians spend many hours per shift decontaminating and inspecting medical devices to ensure they are clean and well-functioning. Once this process is complete, the items need to be sterilized. To maintain sterility, instruments must be properly packaged to prevent them from becoming contaminated from the end of the sterilization cycle to the time they are used on the patient. This lesson addresses different types of packaging and their proper use.

Objective 1: Discuss the importance of barrier packaging and how to select the appropriate packaging material

Preventing the occurrence of healthcare-associated infections (HAIs) and surgical site infections (SSIs) is among the most important tasks of any healthcare worker. One way to meet this goal is to provide properly packaged, functional and sterile medical devices for patient use. Proper selection and use of barrier packaging is an important cornerstone of this process. In healthcare settings, barrier packaging helps protect sterile devices from contamination caused by air, dust and human handling. When used correctly, barrier packaging also helps prevent microbes from entering the package.

Keeping items safely contained is the first aspect of effective barrier packaging; items should remain protected until opened at the point of use. Allowing the chosen sterilant to enter and exit the packaging during sterilization is another important factor; however, in addition to sterilant penetration and exit and device protection during storage and transport, it is important to be able to aseptically open the product at the point of use. Each type of approved packaging has its advantages and disadvantages. It is important, therefore, that SP technicians know how to select the correct packaging for each device to be sterilized.

Sterile packaging is regulated by the U.S. Food and Drug Administration (FDA) as a Class II medical device (a device that presents a potential risk). It is also addressed by standards-setting organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), guideline-making organizations such as the Association of periOperative Registered Nurses (AORN) and surveying agencies such as the Joint Commission (TJC).

All types of packaging material should be carefully inspected before a package is distributed for use. Selecting the appropriate package starts with using a package made for the sterilization modality to be used. SP technicians must always refer to both the medical device and packaging manufacturers' instructions for use (IFU) during the selection process. Packaging must allow for sterilant penetration, removal and aeration as appropriate.

Types of packaging include:

Steam packaging. This packaging must be able to withstand the high temperatures used in the steam sterilization process. Most steam cycles range from 250°F to 275°F (121°C to 135°C). Approved cloth, most disposable flat wraps and paper/plastic peel packages are typically acceptable for use with steam.

Ethylene oxide (EO) packaging. EO sterilization involves lower-temperature operation than steam sterilizers but does not use the deep vacuum of other low-temperature sterilization methods. EO sterilization is compatible with the same packaging used in the steam process as well as many of the types of packaging used for hydrogen peroxide (H2O2) sterilization.

H2O2 packaging. Packaging used for H2O2 sterilization must tolerate a deep vacuum draw and be cellulose free. Flat wrappers made of non-cellulose, nonwoven material and peel packages made from spunbond polyolefin-plastic combinations (sometimes referred to as Tyvek® pouches) are appropriate for this type of sterilization. *Note: Packaging used for H2O2 sterilization cannot be used for steam sterilization because it will melt.*

Ozone (O3) packaging. For O3 sterilization, the packaging type should be chosen based on the recommendation of the O3 sterilizer manufacturer.

Package size must also be considered carefully. A general rule is to select packaging that is not so small that items must be crowded together and not so large that the items can move around and become damaged. Too large or excess packaging may interfere with the sterilization process.

When selecting packaging, it is also important to know whether an expiration or a "do not use after" date is present, what the date indicates and where it is located. In the past few years, packaging manufacturers have begun including those an expiration or "do not use after" date. Unfortunately, the placement of such dates is often inconsistent. For flat wraps and peel packages, the date is usually an expiration date, giving the timeframe in which the barrier packaging may be used, and it can be located on each piece of wrap or package or on the box in which the product was shipped. For rigid containers, the date typically indicates the length of time during which the item(s) inside the container can be used after sterilization, and this time period is found in the container's IFU.

Expiration and "do not use after" dates must be noted and observed. Packaging should not be used after the expiration date stated by the manufacturer. Items stored in ridged containers must be removed from the shelves when the duration listed on the product is reached and reprocessed. *Note: When practicing event-related sterility, package expiration or "do not use after" dates are considered an event.*

Objective 2: Review the basics of peel packaging

Peel packaging material is used to hold a single lightweight instrument or two. Large or multiple items should be packaged using another type of packaging material. It is important to remember that no single type of peel pack is compatible with all types of sterilization; therefore, it is important to know for which processes each type of packaging can be used.

The plastic side of the pouch allows for direct visualization of the contents and the internal chemical indicator (CI). The paper side allows for air removal and sterilant penetration; the plastic side of the pouch does not. Remember, it is vital to select the appropriate package for the item being processed, and again, proper sizing matters. The peel pouch should be large enough to allow the instrument to move slightly, but not so large that it moves freely inside the package. At the same time, the package should not be so small that the item(s) are packed tightly inside; this could cause the seams to blow during the sterilization process. Packages should be approximately ¼" larger on all sides then the instrument being packaged. *Note: It is not a good practice to cut premade pouches; if the correct size pouch is not available, it is recommended that rolls of the pouching material be used, so technicians can create the proper-sized package.*

The pouch should be inspected to ensure there are no tears or holes. The instrument should be carefully placed

inside the package with the distal end (working end) at the bottom and the proximal end (end closest to the hand during use, such as the finger rings) placed at the top side of the package where it will be opened. This allows the user to grab the instrument at the top and avoid touching the end that will be used on the patient.

To prevent punctures through the paper side of the pouch, curved sharp instruments should be placed with the curved end toward the plastic side. If instruments have sharp tips, transparent-colored, vented tip protectors should be used to prevent punctures through the pouch. Transparent-colored tip protectors not only protect the package and the instrument but also allow the user to see the tip of the instrument on the sterile field better than clear protective tips. It is important to ensure the tip protectors are approved for the type of sterilant to be used.

Hinged instruments must be kept in the opened position. Several products are available to help keep the instruments opened; the product used must be approved for the chosen sterilization method.

Peel packaging comes in two forms: self-seal and open package. Self-seal is just as the name implies; the manufacturer has included a sealing strip on the packaging. The manufacturer's IFU must be followed for the proper sealing process. Open packaging needs to be sealed by the technician, usually with a heat sealer (ensure the proper heat-sealing temperature for the packaging material is used). Staples, paper clips or clamps should not be used to seal the package because the seal will not stay intact and the items will become contaminated. Using indicator tape to seal a package is also not recommended; if this is the only method available, however, it is critical to follow application instructions provided in the IFU.

Sometimes, there is a request to double pouch an item. Technicians must ensure the packaging IFU approves of this process before double packaging any item. Double pouches are prepared by placing the item(s) into one peel pouch and sealing the pouch. The pouch is then placed inside another slightly larger pouch and sealed. Care is needed when selecting the appropriate sequential sizing. The same rules apply for the inside peel pouch as for pouching instruments (leave about ¼" on each side of the package). The smaller inner pouch should never be folded because doing so can interfere with air removal and sterilant penetration. The paper side of the inner package must face the paper side of the outer package, and the plastic side must face the plastic side. This alignment helps ensure proper sterilant penetration, effective drying and content visibility.

Whichever method of package identification is used (e.g., writing on the package or using a printed label), it is important to place the identifying information on the plastic side of the package—never on the paper side. Writing on the paper side can compromise package sterility. If writing the information on the packaging, only use pens approved for this process. *Note: Plastic-paper pouches should not be used within wrapped sets or rigid containers because the pouches may be positioned in a way that interferes with air removal, sterilant contact and drying.*

Objective 3: Discuss the use of flat-wrap material

Flat wraps are used to wrap instrument sets, procedure trays and single items, and may be made of woven and nonwoven materials. As with peel pouching, the items must be wrapped in a manner that facilitates aseptic presentation of the contents, and the packaging must be compatible with the sterilization method to be used. Peel packages should never be placed inside a flat wrap because doing so will interfere with the sterilization process.

Woven wrapping materials are typically cotton, cotton blends or synthetic blends. Woven materials are reusable and require laundering, de-linting, and inspection for holes and fabric degradation before each use. Inspection and mending of holes and defects are time-consuming tasks, and many facilities select disposable wrappers for this reason. Woven wraps cannot be used with most types of low-temperature sterilization methods. If using woven material, the instruments should be wrapped sequentially (packaged within a package) using two separate layers of wrap.

Nonwoven wraps, also known as disposable wraps, are made of several different materials. Kraft-type wraps (medical-grade paper) are generally smooth-surfaced and available in multiple sizes to accommodate many medical devices. As the name implies, this product is a paper-based (cellulose) product, so it must be carefully inspected for tears and holes prior to use. It is essential to follow the IFU for the weight limit of instrumentation wrapped inside this type of wrapper. As with woven wrappers, items wrapped in Kraft wraps must be sequentially wrapped. Open pouches with both sides consisting of Kraft-type paper can be used to hold small parts and instruments inside the wrapped trays, if approved by the packaging manufacturer's IFU.

Synthetic wrappers are very popular in healthcare facilities today because they come in multiple sizes and weights, accommodating trays of different sizes and weights without easily puncturing

or tearing. Although these wrappers are stronger, they still must be carefully checked for holes prior to use. Items wrapped in single synthetic wrappers need to be sequentially wrapped. Synthetic wrap also comes as a double wrapper, with two sheets fused together by the manufacturer. When using this type of wrapper, a simultaneous wrap (wrapping the tray one time) is used. *Note: When selecting the wrapper size, ensure the wrapper is not too large, as excess wrap may trap condensation and render the package unsterile when opened.*

Whichever type of flat wrapper is selected for use, it is important to never write on the wrapper as this will compromise the package sterility. Instead, always write on the sealing tape or the printed label. Also, flat-wrapped trays should never be stacked unless approved by the packaging manufacturer (the manufacturer's IFU must always be diligently followed to ensure proper use).

Objective 4: Review the properties and use of rigid containers

Rigid containers are box-like packaging made of metal or synthetic material. This type of packaging is sturdier than the other wrapping products.

When selecting a container to package a set, ensure that the container is compatible with the sterilant to be used. Tray size is also important because using a too-large or too-small container can damage instruments. Too-small trays create the need for instruments to be stacked, and too-large trays allow items to move and shift—both of which can cause instrument damage.

It is also important to ensure the container is in good condition. A container should never be used if dents are identified in the container or on the lid. Technicians must inspect each container and lid to ensure the gasket, handles and filter locking mechanism are intact. Only approved filters, either disposable or reusable as required by the IFU, should be used and must be checked for holes before use. Check that the filter is properly locked into position or that the retention filter lid is locked in place.

When setting up the instrument set, technicians should ensure that the inner tray is the proper size for the outer container. Towels or tray liners should not be used unless approved by the manufacturer's IFU. The inner tray should be carefully placed inside the outer container. Open pouches with both sides consisting of Kraft-type paper can be used to hold small parts and instruments inside the rigid containers, if approved by the container manufacturer's IFU. Ensure that the combined weight of the instrument set and container is 25 pounds or less.

Similar to other packaging methods, not all items can be placed into rigid containers. Items already contained in a graphic tray, organizing tray or plastic tray should not be placed into a container unless approved by the item manufacturer's and container manufacturer's IFU. Although containers look like they can be stacked, some cannot. Technicians must always follow the container manufacturer's instructions regarding whether containers may be stacked and, if so, how many. If stacked too high, the weight can damage the gaskets in the lower containers.

Conclusion

Proper selection and use of a packaging system is critical to patient care. As explained in this lesson, there are several types of packaging systems available that should be carefully evaluated for each of the facility's processing needs. SP personnel should always ensure that the manufacturer's IFU are consistently and carefully followed for each type of packaging system used.

CIS Self-Study Lesson Plan Quiz
A Review of Packaging Systems

Lesson No. CIS 292 (Instrument Continuing Education - ICE) · Lesson expires July 2025

1. The primary purpose of effective barrier packaging involves:
   a. Keeping small items together while assembling a tray
   b. A 30-day product trial
   c. Keeping items safely contained until use
   d. Ensuring the packaging can be used for all types of sterilization methods

2. Barrier packaging should:
   a. Allow the chosen sterilant to enter the package
   b. Be opened aseptically
   c. Allow the sterilant to exit the package
   d. All of the above

3. Sterile packaging is regulated as a:
   a. Class II medical device by the U.S. Food and Drug Administration (FDA)
   b. Class I medical device by the U.S. Centers for Disease Control and Prevention
   c. Class III medical device by the FDA
   d. Class II medical device by the Environmental Protection Agency

4. Packaging made for low-temperature sterilization may not be able to withstand high-temperature sterilization because:
   a. It will not allow the sterilant to penetrate the package
   b. It will melt
   c. The seals will blow during the sterilization cycle
   d. It contains cellulose material

5. Packaging used for hydrogen peroxide sterilization must:
   a. Tolerate a deep vacuum cycle
   b. Contain cellulose
   c. Tolerate temperatures of at least 250°F
   d. Withstand extended cycles

6. Using a flat-wrap package that is too large for the item to be sterilized:
   a. Wastes money
   b. May help prevent damage to package contents
   c. May interfere with the sterilization process
   d. Is acceptable for steam sterilization

7. If packaging material has an expiration or "do not use after" date:
   a. Items can be used after that date when event-related sterilization is used
   b. Peel packs and wrapped items can still be used if items have been steam sterilized
   c. Items in rigid containers can still be used
   d. All items should be removed and discarded or reprocessed after the stated date

8. The paper side of a peel package:
   a. Will not allow sterilant penetration
   b. Is the side that should contain the package identification
   c. Allows for sterilant penetration
   d. Is resistant to tears

9. Instruments should be placed in peel packages:
   a. In the open position
   b. With the distal end at the bottom of the package
   c. With the instrument curve facing the plastic side of the package
   d. All of the above

10. When double peel packaging items:
   a. The plastic side of the inner package should face the paper side of the outer package
   b. The process should be approved in the packaging instructions for use (IFU)
   c. The inner package can be folded as long as the fold is over the plastic side of the inner peel pack
   d. The outer package should be sealed, but the inner package should not be sealed

11. All woven packaging material:
   a. Is compatible with low-temperature sterilization methods
   b. Should be wrapped using the simultaneous (wrap once) method
   c. Has an indefinite shelf life
   d. Should be inspected for holes before each use

12. When using rigid containers:
   a. Towels and liners can be used if approved by the healthcare facility
   b. Instruments and containers should not weigh more than 20 pounds
   c. Towels and liners should not be used unless approved by the container manufacturer's IFU
   d. Rigid containers have no shelf life

13. Rigid container systems:
   a. Must be carefully inspected before use
   b. Are FDA Class III medical devices
   c. Are compatible with all types of sterilization methods
   d. Are validated for sterilizing all plastic and organizational trays

14. All nonwoven material:
   a. Can be used with all types of sterilization
   b. Should be inspected for holes prior to use
   c. Should be sequentially wrapped (packaged within a package)
   d. Contains cellulose material

15. Kraft-type wrappers:
   a. Contain cellulose material
   b. Should be wrapped using simultaneous wrap (wrapped one time)
   c. Have no cellulose material
   d. Have not been validated for steam sterilization

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