**Objectives**

- Describe sterile packaging
- Discuss packaging materials and their differences
- Identify acceptable closure methods and their proper uses
- Describe pack preparations and procedures
- Identify key factors of sterile storage
- Discuss proper transportation of sterile products

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**Packaging**

- Food Packaging vs. Sterile Packaging
  - Protect contents from contamination
  - Maintain necessary internal atmosphere characteristics
  - Provide a tamper resistant seal
  - Appropriate for the item being packaged

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**Objectives of Sterile Packaging**

- Allow penetration of the chosen sterilant
- Compatible with any other requirements of the specific sterilization process (i.e. drying)
- Maintain the sterility of the package contents until it is open
- Open aseptically (without contaminating the contents)

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**CS-OR Technician Responsibilities**

- Understand the various packaging materials advantages, limitations, etc.
- Be able to select the packaging that is most appropriate for each item
- Apply the selected packaging in a manner that ensures:
  - Success of the sterilization process
  - Protection of the item during storage and transport
Selecting Packaging Material
- Different types of packaging are needed for different sterilization methods
- May vary based on package contents
- Specifically designed for sterilization packaging
- Approved by the FDA
- Two types of sterile packaging
  - Reusable
  - Disposable

Packaging Considerations for Sterilization
- Steam sterilization
  - Withstand temps of 250°F - 275°F (121°C – 135°C)
  - Allow for air removal and steam penetration
  - Permit drying of contents and packaging material
- Ethylene oxide sterilization (EO, EO)
  - Allow for adequate penetration of gas sterilant and removal of gas residual (aeration)
- Gas plasma sterilization
  - Able to tolerate a deep vacuum draw without absorbing the sterilant, interrupting the cycle or damaging the contents
- Approved by the FDA

Reusable Packaging Material

Textile Packaging
- Still the packaging method of choice for some healthcare facilities
  - Often driven by costs and/or the environment
  - Some facilities contract with off-site companies to pick up used textile wraps, launder, inspect and return for use
  - Requires more labor
    - Must be laundered and inspected for tears or punctures
      - If damaged, must be discarded or repaired
    - Must be de-linted as needed to minimize the risk of lint entering the sterile pack and field
    - Must be held at room temperature
      - ST79 8.3.1: 68°F - 73°F (20°C - 23°C) at a relative humidity of 30% - 60% for a minimum of two hours prior to sterilization

Textile Packaging Continued...
Woven Textiles
- Muslin – Broad term describing a wide variety of plain-weave cotton or cotton/polyester fabrics having minimum 140 threads per square inch.
- Other woven textiles
  - Duck cloth
  - Twill
  - Barrier cloth
  - Treated barrier fabrics
- NOTE: Canvas should never be used as a sterile packaging material

Rigid Container Systems
- Box like structures with sealable and removable lids
- Made of anodized aluminum, stainless steel, plastic or a combination of these materials
- Have lids and filters that allow sterilant penetration while providing a microbial barrier
- Filters may be:
  - Disposable (synthetic product)
  - Reusable (ceramic filters or a valve system)
- Consist of an inner basket to hold the instruments
- The weight of the container should not exceed 25lbs (ANSI/AAMI ST79 4.2)
Cleaning and Inspection of Rigid Containers
- Remove disposable filters or release the filter protector/holder
- Valve-type closures must be cleaned according to manufacturer’s instructions for use (IFU)
- Interior baskets removed and cleaned
- Chemical indicators, disposable labels and locks removed
- Inspect all container system components for proper function
- Inspect gasket for debris, cuts or tears
- Inspect valves, filter mechanisms and latches for proper operation

Advantages of Rigid Containers
- Provide an excellent barrier to microorganisms
- Easy to use
- Eliminate waste
- Protect instruments from damage during processing, storage and transport

Disadvantages of Rigid Containers
- Safety issues linked to ergonomics
  - A large empty container can weigh 8-9lbs
- Additional cycle time may be required
  - Impacted as a container’s weight increases because of excess condensation
- Plastic containers may require longer dry time
  - Lack of metal, which produces heat by conduction
- Additional space is needed for storage
- Additional labor is needed to clean
- Additional space is needed in the mechanical washers
- Sharp edges/corners can injure employees

Disposable Packaging Materials
- Popular choice for sterilization
- Excellent barrier effectiveness
- Three common types of disposable packaging materials
  - Non-woven wrap
  - Paper
  - Peel pouches
Non-Woven Wrap
- Commonly referred to as “Flat wrap”
  - SMS (spunbond-meltblown-spunbond)
  - Polyolefin materials are exposed to high heat and are pressure bonded together to form sheets
  - Most popular flat wrap
- Designed for single use
- Available in a variety of sizes and weights
- Available in single sheet or double sheets
  - Double sheets are bonded together

Paper
- Papers that contain cellulose can not be used in gas plasma sterilizers
- Medical grade
  - Generally smooth-surfaced
  - Available in many sizes to accommodate various devices
- Pouches of medical grade paper specifically formulated for sterilization are also available

Peel Pouches
- Used for small instruments and lightweight items
- Two basic types of peel pouches
  - Paper/plastic
    - Typically compatible with steam or EO sterilization
    - Not compatible with gas plasma sterilization
    - Consists of a paper side and a plastic side
  - Paper (spunbond polyolefin)/plastic combination
    - Used for gas plasma sterilization
    - Often referred to as “Tyvek®” pouches
    - Consists of a plastic side and a polyolefin side
- Both types have the plastic side to allow viewing of contents
- Sterilization penetration through the paper side

Methods of Packaging Closures

Do Not Use
- Pins, staples or other sharp objects
- Paperclips or binding clips
- Tapes that are not designed specifically to withstand the rigors of sterilization

Acceptable Closure Methods
- Indicator tape
- Heat seals
- Self-adhesive seals
- Rigid container seals
**Preparation of Pack Contents**

- **Instruments that disassemble**
  - All parts should be arranged for easy assembly after the package is opened.

- **Instruments that open (scissors, hemostats, etc.)**
  - Should be kept in unlocked, open positions to enable the sterilant to reach all parts.
Delicate and Sharp Instruments

- Should be protected while being handled and when assembled for sterilization
- Use specifically designed holders or tip protectors
- Protectors must be permeable to the sterilant being used

Package Assembly

- Instruments are placed on a stainless steel, heat-tolerant plastic or anodized aluminum tray with a perforated or mesh bottom
- Tray liners (surgical “huck” towels) may be used to absorb moisture and provide cushion for instruments
- Non-absorbent silicone liner mats may be used to cushion instruments
- Include a sterility indicator
- Peel pouches are not recommended to be used inside instrument trays
- Gauze squares should not be used as packing or wicking material

Packaging Procedures

- Peel Pouches
  - Tip protectors help to protect the pouch contents and prevent the tips from penetrating the pouch
  - If used, ensure that the material is appropriate for the type of sterilization to be used
  - Instruments should be placed in the pouch so the end of the item to be grasped will be presented first when the pouch is opened
  - Pouches must be sized to properly allow for adequate air removal, sterilant penetration and drying

Excess stress on the sides of the peel pouches will compromise the integrity of the pouch!

Packaging Procedures

- Flat wraps
  - Sequential
    - The package is wrapped twice and is a “package within a package”
  - Simultaneous
    - The package is only wrapped once
    - Can be two single layer wrappers or special double-layered synthetic non-woven
    - Both are acceptable recommended practices

Considerations For Wrap

- Must be large enough to completely contain the contents without leaving excess material
- Wrap must be snug but not tight
- If wrap is also being used to create a sterile field, it must be sufficient size to extend at least 6” below the edge of the surface being covered
- Corner protectors will help in preventing tears in wrap!
Packaging Labeling
- Label information should include:
  - Description of package contents
  - Initial package assembler
  - Lot control number
  - Identification of sterilizer and cycle used
  - Date of sterilization
  - Requesting department or surgeon’s name may be included
  - Assigned storage location
- Standardized abbreviations and terms avoid confusion
- Slang terms and nicknames should be avoided

Sterility Maintenance
- Sterilized packages must maintain their content sterility until they are intentionally opened
- Traditionally, sterility of a package has been thought of as “time-related”
- Joint Commission (TJC) and the Association of peri-Operative Registered Nurses (AORN) now recognize that sterility is “event related”
- Event-related sterility depends on the quality of the wrapper material, handling procedures, storage and transport conditions

Basic Sterility Concerns
- Primary conditions that can adversely affect the sterility of a package
  - Moisture and liquid/fluid contamination
  - Dirt, dust and debris
  - Physical damage to the package

Storage Considerations
- Proper use of stock rotation principles- assure that packs with time-sensitive expiration are used before they must be discarded.
- Sterile Storage areas for sterile supplies located outside of the CS department must be included in the quality assurance and infection control audits conducted for the sterile storage area in the department.
- If satellite storage sites are used, personnel responsible for areas should be trained about requirements of sterility maintenance during transportation.

Sterile Storage Areas
- Must be kept clean
  - All storage units should be cleaned routinely with a hospital approved germicidal agent
  - Cleaning should begin in Sterile Storage and move to assembly and end in decontamination (cleanest to dirtiest)
  - Air supply to the storage area should be as clean and dust-free as possible (usually requires filtration)
  - Room should be under positive pressure with at least 4 air exchanges per hour
  - Temperature should be approximately 75°F (24°C) with less than 70% humidity
Sterile Storage

- Sterile packages should not be stored near or under sinks
- 8” - 10” off the floor
- 18” below the ceiling or the level of the sprinkler head
- At least 2” away from exterior walls & windows
- Located away from heavy traffic and access to the area should be restricted

Sterile Stock Arrangement

- Packages should be arranged so that they are not crushed, bent or compromised
- Easy to locate
- Heavier items should be on the lower or middle shelves
- Lighter and less cumbersome items can be placed higher
- First In, First Out (FIFO) system should be followed
- The goal of proper stock arrangement is to provide minimum pack handling while allowing FIFO rotation

Transportation

- Transport in covered or enclosed carts
- Cart shelves with solid bottom construction
- Follow policies and procedures to maintain cleanliness and proper cart maintenance
- Lift! Don’t pull!
- Important: watch for expiration date, tears, abrasions, punctures, compromised seals, dirt and moisture
- Check sterilization process indicator to ensure sterility

If any of these adverse conditions are noted, the package should be considered contaminated!

PLEASE REMEMBER!

Even the most minor break in protocol can cause great harm to patients.

Sources

- ANSI/AAMI ST79:2011
- ANSI/AAMI ST77:2013

Contact Information

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