Objectives

- Discuss Sterility Assurance Level (SAL)
- 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

Common Terms we Use

- **Soil**: Visible soil or debris which may protect, harbor or assist the growth of microorganism. It includes organic substances, residual soil, inorganic matter, blood and body substances.
- **Contamination**: The presence of microorganisms (bugs) dead or alive, foreign matter including blood, body substances, body tissue; cement, chemical residues, dust, soil, dressing material, foreign material/ debris or rust on an item and living tissue.
- **Bioburden**: The number and type of microorganisms present on an item that has not been sterilized.
- **Biofilm Colonies**: A collection of microorganisms that attach to surfaces and each other to form a colony. The colony produces a protective gel that is very difficult to penetrate with detergents and disinfectants.

STERILITY ASSURANCE LEVEL (SAL)

Definition: Probability of a single viable microorganism occurring on an item after sterilization.

Goal of Sterilization

10⁶ Six-Log Reduction

1,000,000

- A SAL of 10⁶ is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers).
- A SAL of 10⁵ is considered acceptable for items not intended to come into contact with compromised tissue.
- **SAL cannot be directly measured by a sterilization indicator**

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
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)

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 (ETO, 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

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 preconditioned (held at room temperature) 68°F - 73°F (18°C - 24°C) at a relative humidity of 30% - 60% for a minimum of two hours prior to sterilization (ANSI/AAMI ST79:2017)

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 ST79:2017)

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 cannot 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

Acceptable Closure Methods
- Indicator tape
- Heat seals
- Self-adhesive seals
- Rigid container seals

Indicator Tape
- Considered best practice because they are made specifically to withstand sterilization.
- Will change color after being exposed to the sterilization process.
- Should be used on every package to avoid mixing up processed and unprocessed packages.
- Does not provide proof that adequate sterilization of package contents has occurred.

Heat Seals
- Used for paper/plastic seals
- Follow the IFU for the heat sealer and the packaging manufacturer to ensure appropriate exposure times and temperatures
- Inadequate exposure times and temperatures may cause inadequate seals
- Exceeding manufacturer’s recommendations may cause package damage

Self-Adhesive Seals
- Do not require heat
- Adhesive covered with a removable strip at one end of the self-adhesive peel pouch
- Once removed, the sticky portion of the seal should be carefully folded over opening of the package
- Care must be taken to avoid gaps, wrinkles or creases that will compromise the seal integrity

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
Locking Tags
- Most commonly used with rigid containers
- Designed to break when the container has been opened
- Most commonly made of plastic
- Tamper-resistant
  - Lock in place and must be broken to open the container

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

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

Preparation of Package Contents, Wrapping & Labeling

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

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, Storage and Transportation

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)
- Environmentally controlled conditions in a manner that reduces the potential for contamination are necessary (i.e. positive pressure)
- When supplies sensitive to extremes of relative humidity are stored in the room, the relative humidity should be maintained at the level recommended by the product manufacturer
- Temperature should be between 72-78°F (22-26°C) with less than 60% humidity (ANSI/ASHRAE/ASHE 170-2013)

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
- Wrapped packages should not be stored beneath rigid sterilization containers on the same shelf
- 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 large enough for all packages to be placed flat without extending beyond the edge of the cart shelf
- Cart shelves with solid bottom construction
- Sterile packages that contain instrumentation and that are transported by hand should be carried in a position parallel with the floor.
- Vehicles used to transport sterile packages between health care facilities:
  - should provide for the complete separation of clean and sterile items from contaminated items
  - have a storage compartment that is completely enclosed
  - allow for ease of loading and unloading
- Follow policies and procedures to maintain cleanliness and proper cart maintenance
Transportation continued…

- Lift! Don’t pull!
- Important: watch for expiration date, tears, abrasions, punctures, compromised seals, dirt and moisture
  - *If any of these adverse conditions are noted, the package should be considered contaminated!
- Check sterilization process indicator to ensure sterility in the operating room

PLEASE REMEMBER!

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

Sources

- ANSI/AAMI ST79: 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST77:2013 Containment devices for reusable medical device sterilization
- Image sources: [Link]

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