Processing of Medical Devices

Module 2: session 5

Learning Objectives

By the end of this session, the participant will be able to:

- Explain the Spaulding classification system for processing medical devices
- Discuss the importance of effective cleaning prior to high level disinfection or sterilization
- Outline the steps in instrument processing
- State the common products used in chemical disinfection
- Describe proper storage of processed reusable equipment
- Know factors Affecting Disinfection and Sterilization Effectiveness
- Explain the dangers of reprocessing single-use medical devices;

Equipment Processing and Infection Prevention

- Invasive procedures involve **contact** between a medical **device** or surgical instrument and a patient's **sterile tissue** or mucous membrane

- A major risk of all these procedures is the transmission of pathogenic microbes that could lead to infection

- Provision of safe, reliable, cleaned, disinfected or sterilized reusable patient care equipment is critical in preventing infections in healthcare facilities

Definition of Terms

- **Cleaning**
  - Is the process used to remove soil/dirt and reduce the number of acquired micro-organisms
  - Accomplished using **water and detergents** or **enzymatic products**
- **Disinfection**
  - Is the process used to eliminate many or all pathogenic microorganisms on inanimate objects, except bacterial spores
  - Accomplished by boiling, steaming or use of chemical disinfectants
- **High-Level disinfection**
  - Complete elimination of all microorganisms in or on a device, with the exception of small numbers of bacterial spores

Definition of Terms (cont.)

- **Sterilization**
  - Is the process that completely eliminates or destroys all forms of microbial life (**including bacterial spores**)
  - Accomplished in healthcare facilities by either physical or chemical process

- **Decontamination**
  - Physical or chemical means used to remove, inactivate, or destroy pathogens on an item to the point where they are no longer capable of transmitting infectious particles
  - Renders the item **safe for handling and use**
  - **Accomplished by cleaning, disinfection or sterilization**

Definition of Terms (cont.)

- **Disinfectants**
  - Chemical agents that inhibit or kill microorganisms (but not spores). Usually used on inanimate objects
- **Antiseptics**
  - Disinfecting agents with sufficiently low toxicity for host cells, can be used directly on skin, mucous membranes, or wounds
- **Sterilants**
  - Chemical agents that kill both vegetative cells and spores when applied to materials for appropriate times and temperatures

Spaulding's Classification

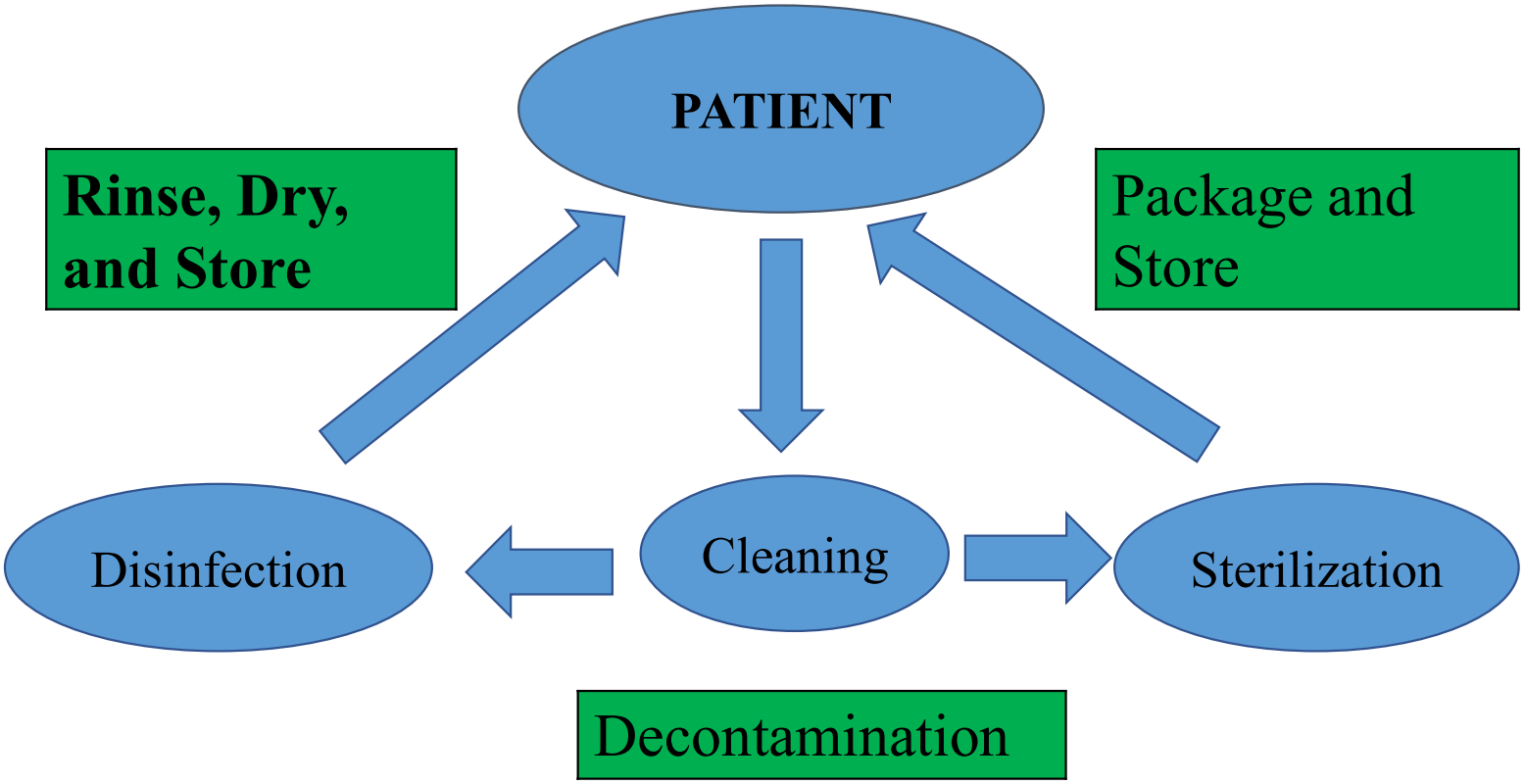
Device classification	Devices (examples)	Goal	Appropriate processing
Critical items	Items that **enter sterile tissue** or vascular system, non intact mucous membranes, e.g. needles, other surgical instruments	Items will be sterile (free) of all microorganisms including bacterial spores	Sterilization – Single use sterile product, autoclaving, chemical sterilization, e.g. peracetic acid, glutaraldehyde)
Semi-critical items	Items that make contact with **intact mucous membranes**, e.g.. Flexible endoscopes, laryngoscopes, endotracheal tubes, and other similar instruments	Items will be free of microorganisms with exception of high bacterial spores	High-level disinfection – Thermal disinfection, chemical disinfection, e.g. chlorine, glutaraldehyde. Preferable to sterilize semi-critical items if compatible with the available sterilization process
Noncritical Items	Items that come in contact with **intact skin**. e.g. thermometers, hydrotherapy tanks, stethoscopes, tabletops, bedpans	Items will be clean	Low-level disinfection

Factors assessing the risk of reusing medical devices

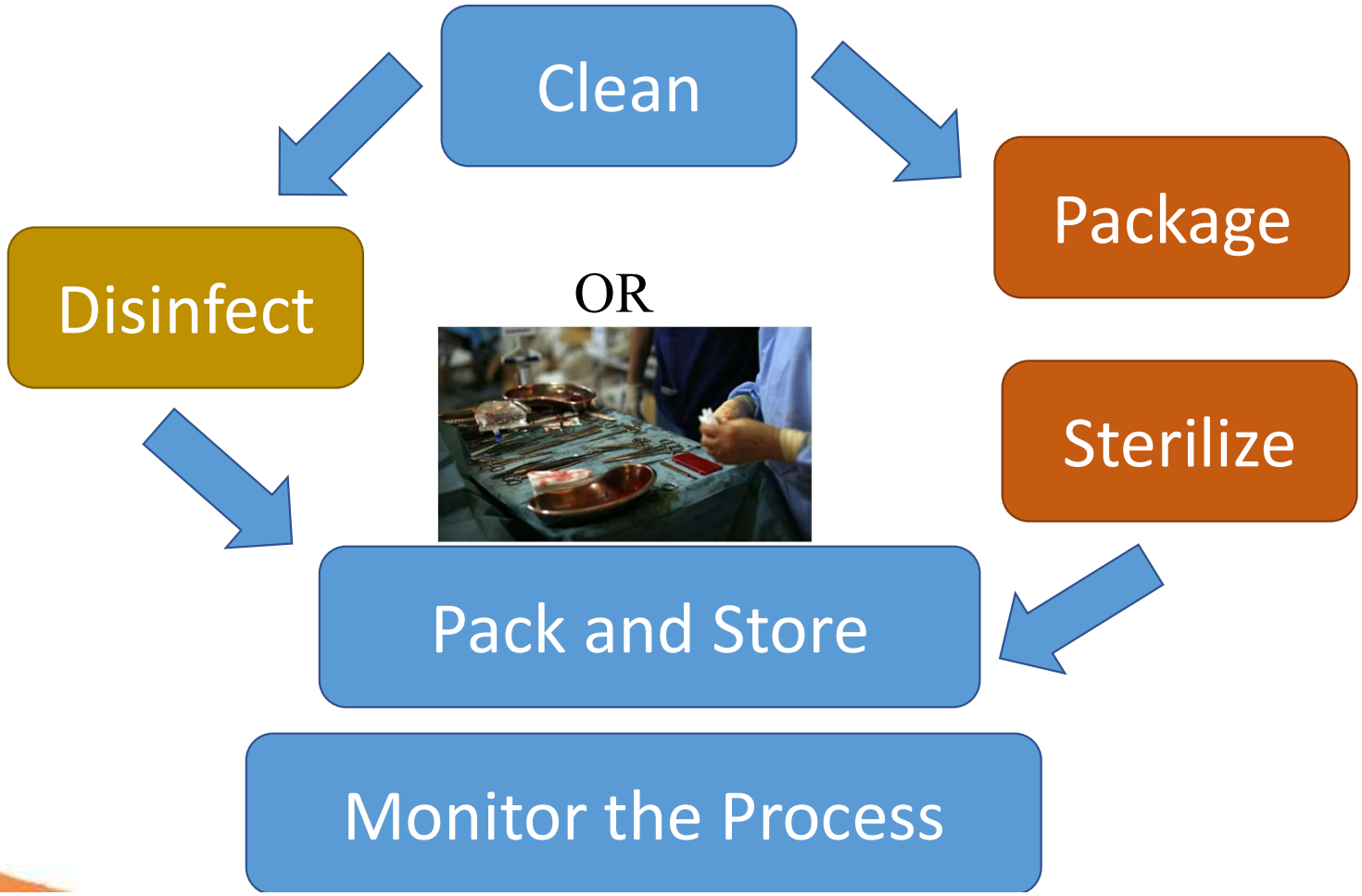
- The **type of item** or device: critical, semi-critical or non-critical.
- **Type of microorganism:** bacteria, spores, viruses or prions.
- Presence of microorganisms in **number (bioload)** and availability to cause infection.
- **Patient susceptibility:** whether the type of procedure is invasive or non-invasive.

The layout and flow of the decontamination unit

Instrument Processing Cycle



Steps in Instrument Processing



Factors Affecting Disinfection and Sterilization Effectiveness

- Organic and inorganic load present on equipment
- Pathogen type and level of microbial contamination
- Concentration and exposure time to disinfectants
- Physical and chemical factors such as temperature, pH and relative humidity
- The nature of the object—the design and construction of equipment

Decontamination cycle and Instrument Processing

1. Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners (e.g, cidenzyme, endozime, biozyme) before disinfection or sterilization

- Cleaning **reduces the bioburden** and removes foreign material (organic residue and inorganic salts) that interferes with the disinfection and sterilization process

Cleaning (cont.)

- Cleaning should be done as soon as possible after the items have been used, as soiled materials become dried onto the instruments makes it harder to clean

- Instruments that cannot be cleaned immediately after a procedure should be kept wet to prevent drying of blood and debris

Cleaning Methods

1. Manual cleaning - Two essential components of manual cleaning are:
   - Friction - rubbing or scrubbing with non-abrasive brushes and non-lint disposable clothes
   - Fluidics (fluids under pressure for internal channels)

2. Machine cleaning
   - Use of ultrasonic cleaners of washer disinfectors (follow specific manufacturer's instruction manual)

Steps of Manual Cleaning

1. Soak the instruments in tepid water (NEVER HOT) with detergents or enzymatic cleaners to soften and loosen the soil (protein and/or fat)
   - Duration is dependent on the amount on soil and type of detergent, usually 5 minutes maximum
   - Soaking metallic items too long leads to rust formation that damages items

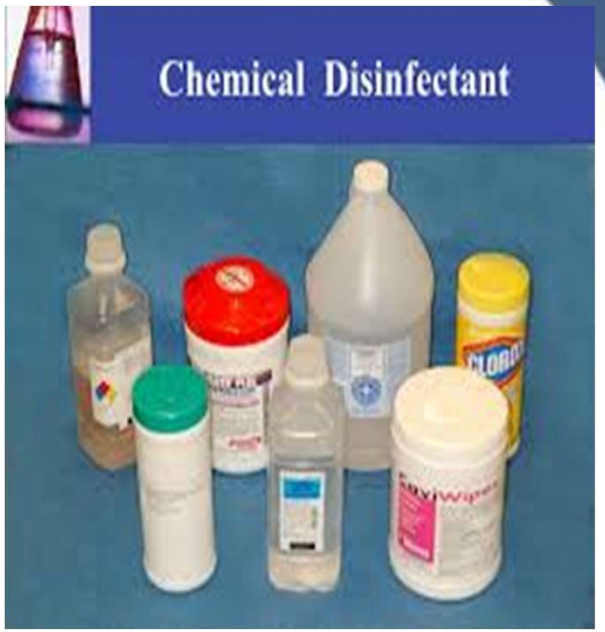
2. Brush instruments with a soft brush while in the soak bath

3. Rinse the instruments with clean water

4. Allow instruments to air-dry or carefully pat them with a towel

2. Disinfection

- Disinfection can be accomplished by:
  1. Application of chemical agents
  2. Use of physical agents (ionizing radiation)
  3. Boiling water heated minimum 71◦C at least 30 minutes



- There two levels of disinfection
  - **Low level** - kills some viruses and some bacteria
  - **High level** - kills all organisms except bacterial spores

Features of an Ideal Disinfectant

- Effective at room temperature
- Noncorrosive and nontoxic
- Inexpensive
- Capable of killing the vegetative form of all pathogenic organisms
- Require limited time of exposure

Low Level Disinfection

- Used for non-critical items that will come in contact with intact skin
- used for disinfection of surfaces
- Use lower but effective concentration of disinfectant

STEPS:

1. Immerse the cleaned item completely in the solution and wait for exposure time as per manufacturer's instructions
2. Remove items rinse and air dry

High Level Disinfection (HLD)

- Used for semi-critical devices
  - Items that come in contact with mucous membranes or non-intact skin
- Disinfection can be:
  - Physical (e.g. boiling)
  - Chemical – involves use of disinfectants
- Chemical disinfectants include:
  - Orthophthaldehyde (OPA), glutaraldehyde, peracetic acid, Sodium hypochlorite (bleach), hydrogen peroxide, chlorine

High Level Chemical Disinfection Process

1. Wash hands
2. Wear appropriate protective clothing
3. Prepare the chemical solution as per manufacturer's instructions
4. Label the soak bin with the identity of the chemical agent and time solution is prepared
5. Immerse the clean and dried instruments in the chemical solution making sure all surfaces of the item are completely in contact with the disinfectant

High Level Chemical Disinfection Process (cont.)

6. Cover with lid and keep the immersed items for the **time** recommended by the chemical manufacturer
7. Record time last item is immersed and start timing
8. Once the soak time is complete, remove items and thoroughly rinse with boiled or sterile water
9. Air dry the instruments and store in a covered clean sterilized container (avoid contamination even by exposure to dust)

STERILIZATION

Sterilization

- Process of rendering items free of all living microorganisms including spores

- Two methods commonly used for instrument sterilization
  - Heat sterilization
    a. Steam sterilization
    b. Dry heat sterilization
  - Chemical sterilization

Steam Sterilization

- Steam sterilization should be used whenever possible on all critical and semi-critical items that are heat and moisture resistant
- Process involves exposing each item to **direct steam contact** at the **required temperature** and **pressure** for the **specified time**
- The two common cycles for wrapped items are:
  - 121°C for 30 minutes (gravity displacement autoclave)
  - 132°C for 4 minutes (Pre-vacuum autoclave)

Advantages of Steam Sterilization

- Widely recognised process (Autoclaving) with many years of evidence of its effectiveness
- High microbiological kill potential
- No residues, no waste
- Easy to control
- High penetrability
- Fast & cheap

Steam Sterilization Process

1. Place the packs into the sterilizer
   - Insert or place heavier instruments in the packs first
   - Separate packs with spaces in between for steam penetration

2. Sterilize instruments following the manufactures' operating instructions and the recommended time

3. Check temperature and ensure exposure time is adequate

Steam Sterilization Process (cont.)

4. Wear PPE and remove load from sterilizer once the sterilization cycle is complete

5. Ensure that the load is dry and cool
   - If packs are wet when removed, re-sterilize them

6. Keep sterile items separated from non-sterile items

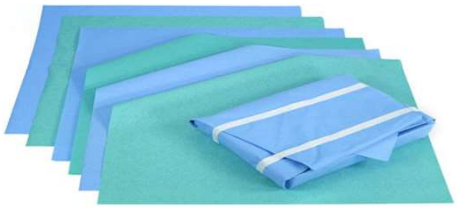
Restrictions of Steam Sterilization

- To be used only with heat and moisture resistant goods
- Only safe, when residual air is removed

Packaging of Instruments for Steam Sterilization

- Packaging protects sterilized articles by providing a microbial barrier against contamination up until the time of use
- Once cleaned, dried, and inspected, items are wrapped or placed in a rigid container
- If lubrication is necessary, use a non-toxic, water-soluble lubricant before wrapping

Packaging- Sterilization Wraps

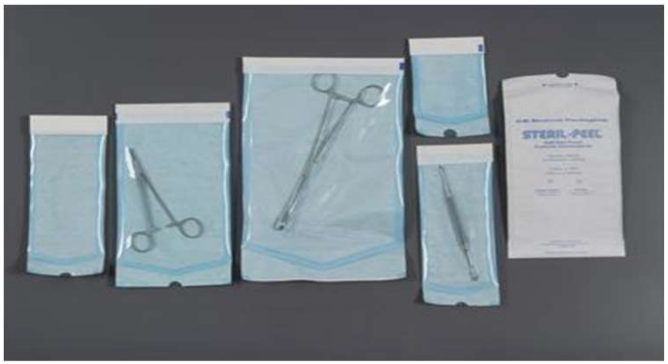


- An effective sterilization wrap should:
  - Allow penetration of the sterilant
  - Be free from loose fibers and particles
  - Provide an effective barrier to microbial penetration
  - Maintain the sterility of the processed item
  - Be puncture resistant and flexible
  - Be drapeable and easy to use on a sterile field

- Multiple layers are still common practice due to the rigors of handling and use of monitoring tape to secure the items

Packaging of Instruments for Steam Sterilization (cont.)

- Packaging choices to maintain sterility of instruments include:
  - Rigid containers
  - Peel pouches
  - Sterilization wraps

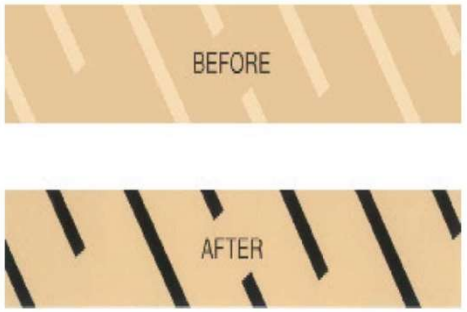


Packaging of Instruments for Steam Sterilization (cont.)

1. Arrange instruments in tray/basket according to guidelines
   - Open the hinged instruments
   - Disassemble Items with removable parts
   - Point items with curved tips in the same direction to facilitate penetration of steam
   - Position cupped or concave instruments downwards to avoid collection of water/condensation
   - Position heavy items at the bottom to avoid damage to delicate items
2. Place chemical indicators in appropriate position in the packaging

Monitoring Sterilization Process

- Sterilization is routinely monitored by a combination of physical, chemical, and biological parameters
  - Physical - cycle time, temperature, pressure
  - Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters are present
  - Biological – *Bacillus stereothermophilus* spores that directly measure effectiveness of sterilization process



Recommendations for Monitoring Sterilizers

- Monitor each load with physical and chemical (internal and external) indicators
  - If the internal indicator is visible, an external indicator is not needed.
- Use biological indicators (BIs) to monitor effectiveness of sterilizers at least weekly as well as :
  - Whenever a new type of packaging material or tray is used
  - After training new sterilization personnel
  - After a sterilizer has been repaired
  - After any change in the sterilizer loading procedures
  - For every load containing implantable devices

Recommendations for Monitoring Sterilizers (cont.)

- Quarantine implantable devices (whenever possible), until the biological indicator results are out and it is negative

- Following a single positive biological spore test
  - Repeat the spore test immediately using the same cycle that produced the positive BI (possibly caused by user error)
  - If repeat BI is positive, do not use the sterilizer until it has been inspected or repaired and re-challenged according to policy
  - Treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator
  - Non-sterile items should be retrieved (recalled), if possible, and reprocessed

Dry Heat Sterilization

- Used only for materials that might be damaged by moist heat
- Typical cycles:
  - 160°C for 120 minutes
  - 170°C for 60 minutes
  - 150°C for 150 minutes
- Two types exist:
  - Static air- oven
  - Forced air or mechanical convection

Chemical Sterilization

- Process that involves use of chemical germicidal agents that make equipment and instruments free of micro-organisms including spores
- Indicated for equipment that are heat sensitive e.g. scopes
- Can be liquid or gaseous

Types of Chemical Sterilization

- Liquid
  - Glutaraldehyde
  - Orthopthaladehyde (OPA)
- Gas
  - H_2O_2 ("Gas *Plasma*")
  - Ethylene oxide
  - H_2O_{2+} O_3 (peroxone)

Liquid Chemical Sterilization Process

1. Wash hands

2. Wear appropriate PPE, especially for eyes.

3. Test sterilizing solution for efficacy (using test strips are available)

4. Once the instruments have been properly cleaned and dried immerse them completely in the sterilizing solution as per manufacturers recommendation

Liquid Chemical Sterilization Process (cont.)

5. Once the soak time is complete, remove items and thoroughly rinse with sterile water (not boiled water). Rinse at least three times

6. Air dry the instruments and store in a covered sterile container for up to 7 day

STORAGE

Recommendations for Storage of Sterile Items

- Dedicated sterile storage area should be a well-ventilated area that provides protection against dust, moisture, temperature and humidity extremes

- Open shelving should be:
  - Above floor level by 250 millimeters”(6”)
  - From ceiling fixtures a minimum of 440 millimeters (18”)
  - Protected from direct sunlight

Recommendations for Storage of Sterile Items (cont.)

- Sterile items should be stored so that packaging is not compromised (water, dirt, tears etc.)
- Sterilized items should be labeled indicating the sterilizer, cycle or load number, the date of sterilization, and the expiration date (if applicable)

Recommendations for Storage of Sterile Items (cont.)

- Factors which influence shelf life are event related and include:
  - Package design
  - Packaging materials
  - Likelihood of product material deterioration
  - Storage and handling
  - Transportation of sterile stock

Single-Use Devices

- Single-use items or devices should not be reprocessed by healthcare facilities because they can lead to infection transmission.

- Single-use items or devices should be discarded after **one** use.

Exceptions for Single-Use Devices

- Evaluate the item in question for suitability for possible reprocess
  - e.g. avoid hollow items or implants
- Consult the manufacturer first
- Determine the history of use of the device
  - Identify the patient, their infection status, etc.
- **Sterilize only**— do not use high level or low level disinfection

Staff training

Staff must be **trained**

- At the appropriate levels of activity, including using **PPE** and how to **handle chemicals safely**.
- At all aspects of the **decontamination cycle** and on all **reprocessing equipment**.
- Recognize problems and **interpret validation tests**
- On occupational hazards and how to manage them.

Session summary

- Delivery of sterile items for use in patient care depends not only on the effectiveness of the sterilization process, but also on cleaning, disassembling, packaging of the device, and monitoring the process.
- Disinfection and sterilization guidelines must be followed to prevent exposure to pathogens that may lead to infection transmission.

Session summary (cont.)

- Different items require different methods of disinfection or sterilization. The Spaulding Classification provides guidance on which to use.
- Common chemical disinfectants include orthophthaldehyde, glutaraldehyde, peracetic acid, sodium hypochlorite (bleach), hydrogen peroxide.

References

Thank You
Questions ?