



LEARNING FROM LAPSES: STRENGTHENING
STERILE PROCESSING THROUGH
PREVENTION
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Presenter



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Disclaimer

- Nothing to disclose
- Presentation content is for purpose of providing education for infection prevention purposes
- Product brand names or pictures do not constitute an endorsement of any kind
- CDC content and recommendations are throughout this presentation
- Thank you to the clinics that shared their pictures for this presentation

Objectives

1. Identify 3 common breaches sterile processing.
2. Identify opportunities to increase your knowledge of sterile processing
3. Describe general steps for evaluating device reprocessing errors and other infection control breaches

What Contributes To Pathogen Transmission?

Common environmental sources that can contribute to pathogen transmission include

Water and Wet Surfaces

Sinks and faucets
Drains
Ice machines
Therapy pools



Dry Surfaces

Bed rails
Door handles
Countertops
Bed curtains



Dirt and Dust

Construction
Maintenance
Repair
Renovation



Devices

Stethoscopes
Blood pressure cuffs
Endoscopes
Blood glucose meters
Surgical instruments



Device Reprocessing Is An Element Of Standard Precautions...

- Refers to methods used to ensure proper cleaning and disinfection or sterilization of reusable medical devices after each use or when soiled
- Example opportunities for pathogen transfer from reusable devices include but are not limited to
 - Transmission due to failure to clean and disinfect shared equipment between patients/residents
 - E.g., Contaminated stethoscopes, blood pressure cuffs, walkers
 - Transmission via healthcare personnel (HCP) hands or other intermediary objects
 - E.g., Contaminated blood glucose meters
 - Potential exposures due to improperly reprocessed procedural devices
 - E.g., Contaminated endoscopes

Cleaning, Disinfection and Sterilization Of Reusable Devices



Cleaning

- The removal of foreign material from objects, normally accomplished using water with detergents or enzymatic products.
- Reduces the number of microorganisms left behind but not intended to kill them
- Essential before disinfection and sterilization
- The presence of inorganic/organic material can prevent contact with the surface and inactivate disinfectants



Disinfection

- A process that eliminates many or all pathogenic microorganisms (might not kill spores) on inanimate objects
 - Low-Level
 - Intermediate-Level
 - High Level



Sterilization

- The Process that eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods
- Use of different agents will depend on factors such as instrument heat tolerance

The Spaulding Classification

The Spaulding Classification provides a strategy for approaching disinfection and sterilization of devices and other patient care items

Spaulding Classification	Indications	Minimum Process	Examples
Non-critical	Contact With Intact Skin	Low-level disinfection or Intermediate-level disinfection	BP cuffs, furniture, pulse oximetry equipment
Semi-critical	Contact with mucous membranes or non-intact skin	High-level disinfection (HLD)	Laryngoscope Blades, Scopes, Trans-vaginal ultrasound probes
Critical	Enters sterile tissue, cavities, or vascular system	Sterilization	Surgical instruments, Periodontal scalers

Device Reprocessing

- Reusable medical devices

- Devices that in accordance with manufacturer's instructions for use (IFU)* can be reprocessed between uses and used on or for multiple patients
 - Endoscopes (e.g., duodenoscopes, bronchoscopes)
 - Arthroscopes
 - Surgical instruments (e.g., surgical forceps, scalpels, clamps)

*Manufacturer's IFU

- Provide manufacturer-validated information about the correct and safe use of the product
- IFU for medical devices are cleared by the FDA and include instructions for processing the device to prevent the transmission of pathogens

Device Reprocessing Locations

Acute Care Settings

- May have onsite sterile processing departments with designated HCP to perform HLD and sterilization
- Reprocessing activities generally have higher level oversight compared to other settings

Long-Term Care Settings

- Generally, only perform low to intermediate-level disinfection of devices
- External consultants may be bringing their own instruments in (podiatry, dental, wound care)

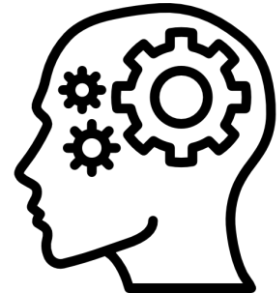
Outpatient Settings

- Ambulatory Surgery, Endoscopy clinics, Dental, Podiatry, etc.
- May provide HLD or sterilization onsite
- HCP have fewer resources, including training and education
- Reprocessing activities may have less oversight

External Vendors

- May supply or loan devices or instruments to facilities (specialized orthopedic equipment)
- Receiving facility must have a process to ensure devices are safe for use

Exercise #1



- True or False: Podiatry instruments require high-level disinfection due to their potential to contact non-intact skin

Exercise #1 Possible Answers



- True or False: Podiatry instruments require high-level disinfection due to their potential to contact non-intact skin
- Trick Question! Reusable podiatry instruments that are heat stable and have the potential to break intact skin during ordinary use (e.g., nippers, forceps, splitters, curettes) should ideally be sterilized using steam rather than a chemical disinfectant for the terminal reprocessing step
- This ensures the highest level of patient safety and reduces HCP exposure to chemicals

Reprocessing Area

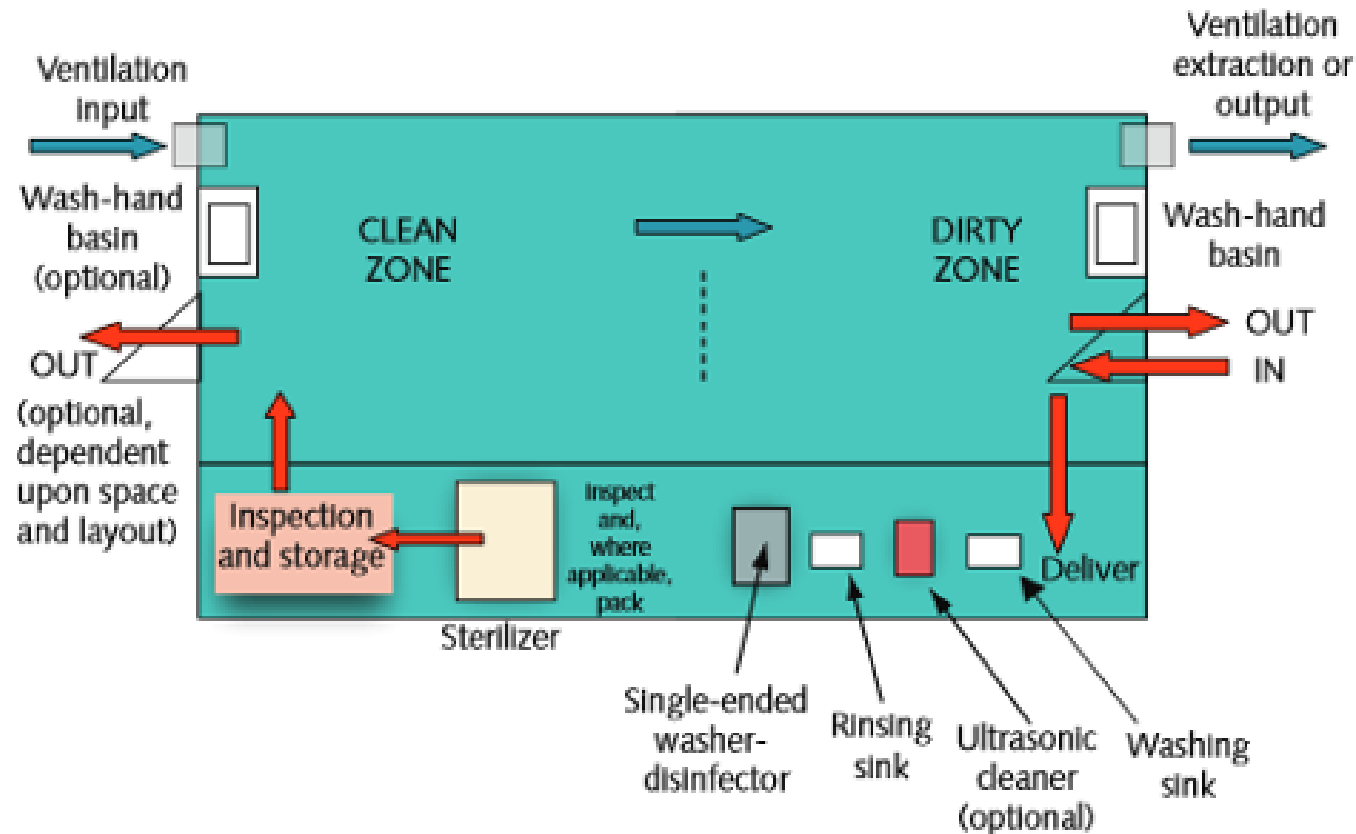
- Reprocess instruments in a dedicated work room.
- Controlled Access
- “Dirty” side and “Clean” side.
- Appropriate airflow and air exchanges.
- Hand wash sink available on both clean and dirty
- Wash instruments in separate sink dedicated to this purpose.
- Eyewash station available. NOT in instrument cleaning sink.
- Uni-directional flow from dirty to clean
 - Prevent re-contamination.
- PPE available, worn when cleaning instruments.

What are “Dirty” vs. “Clean” Steps?

- DIRTY
 - Drop-off
 - Soaking
 - Ultrasonic
 - Wash
 - RINSE with Tap Water
- FINAL RINSE with tap, distilled or deionized water (depends on IFU)
- CLEAN
 - Dry
 - Package
 - Sterilize
 - Storage



Uni-directional Flow From Dirty To Clean



Examples of Reprocessing Areas

Clinic Setting

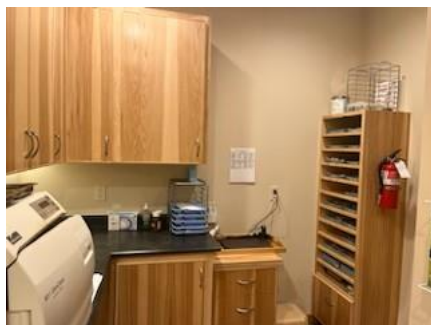


Examples of Reprocessing Areas



Examples of Reprocessing Areas

Dental Clinic



Cleaning Prior to HLD or Sterilization

- HLD and sterilization both begin at the point-of-use with pre-cleaning; general recommendations include:
 - Clean devices/instruments as soon as practical after use (e.g., at the point-of-use) with water and detergent or water and enzymatic cleaners that are compatible with the metals and other materials used in the devices/instruments
 - Cleaning helps to prevent organic or inorganic materials from becoming dried or baked onto devices which can make the removal process more difficult and HLD or sterilization less effective or ineffective



HLD and Sterilization Precleaning

- **Keep device/instrument surfaces moist** until they can be thoroughly cleaned
 - Place devices/instruments inside a puncture-resistant, leakproof sealable container to help **maintain moist conditions, prevent the formation of biofilms, and reduce corrosion** during transportation to the sterile processing/reprocessing area
 - Point-of-use soaking liquids should be discarded by HCP wearing appropriate PPE
- **Open/disassemble instruments composed of multiple pieces** according to the manufacturer's IFU and arrange in a manner that will permit contact of cleaning solutions with all surfaces of the instruments



Instrument Transport

- Label container as biohazard or color coded
- Type of container depends on items being transported
 - Bins with lids
 - Enclosed or covered carts
 - Sterilization container systems
 - Impermeable bags
- OSHA standard for sharps
 - Closable and puncture-resistant
 - Leak proof on the sides/bottom



Manual vs. Mechanical Cleaning Of Devices/Instruments

● Manual cleaning

- May involve the use of friction (i.e., rubbing, scrubbing) or fluidics (i.e., fluid under pressure)
- Often recommended for devices that are delicate, cannot be processed through automated equipment, or cannot be submerged
- HCP should wear appropriate PPE (e.g., heavy-duty utility gloves, face shield) and adhere to other recommendations

● Mechanical cleaning

- Involves specialized equipment that may or may not combine multiple reprocessing stages (e.g., ultrasonic cleaners, washer-disinfectors, washer-sterilizers)
- Generally, more consistent and reliable (e.g., reduces human error and variation)
- May not be suitable for certain types of devices/instruments with delicate components

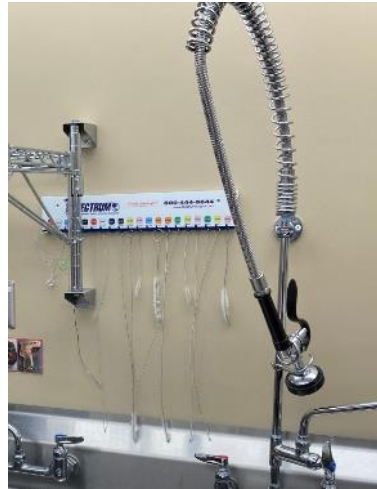
****For both methods, HCP should adhere to manufacturer's IFU****

Ultrasonic Cleaner

- Ultrasonic cleaner
 - Uses mechanical vibrations to agitate a solution to aid in the removal of soil from surfaces.
 - The sound waves in the liquid produce microscopic implosions of bubbles that collapse on contact with surfaces, creating a vacuum-like scrubbing action dislodging soil from surfaces; this effect is called **cavitation**.
 - The cavitation then removes bioburden from the surface of the items submerged in the chamber.



Cleaning



Verification Of Cleaning

- Verification is essential after manual and/or mechanical cleaning
- General recommendations include but are not limited to:
 - Visual inspection
 - Visually inspected for residual soil or debris and to assess irregularities or damage
 - May require the use of magnification or special cameras and additional illumination
 - Mechanical cleaners may have in-use verification tests or monitors/markers than can be used to test that the equipment is functioning properly



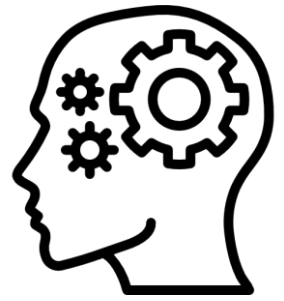
Exercise #2



Can you identify any potential IPC concerns in this photo?



Exercise #2 Possible Answers



Can you identify any potential IPC concerns in this photo?

- Instruments appear to be arranged in a puncture resistant, leakproof sealable container
- However,
 - Instruments are not opened properly to permit contact of cleaning solutions with all surfaces of the instruments
 - Instrument surfaces *may not* be kept moist





STERILIZATION

Critical Devices and Instruments Require Sterilization

- Examples include but are not limited to surgical instruments, implants, biopsy needles, ultrasound probes used in sterile body cavities, and some dental and podiatry instruments
- Sterilization Examples
 - Devices/instruments that are heat stable can undergo **heat sterilization** (i.e., steam or dry heat)
 - Some are made of materials (e.g., plastics) that require **low-temperature sterilization** (e.g., hydrogen peroxide gas plasma, peracetic acid, ozone, ethylene oxide (ETO))
 - **Flash sterilization or immediate-use steam sterilization** is another method used for processing cleaned items that cannot be packaged, sterilized, or stored before use
 - May be used in urgent clinical situations in which there is insufficient time to sterilize an item by the preferred package method but **should be minimized as much as possible**



Heat-Based Sterilization

- Most common in clinics
- Steam under pressure (autoclaving):
 - Gravity displacement
 - Pre-vacuum



Packaging

- After being cleaned, dried, and inspected, critical items must be packaged appropriately prior to sterilization
- Facilities may use different packaging methods (e.g., rigid containers, peel pouches) and should refer to guidelines provided by AAMI, AORN, and other professional organizations
- Packaging must allow **penetration** of the sterilant, **provide protection** against contamination during handling, provide an effective **barrier** to microbial penetration, and **maintain sterility** after sterilization



Other General Recommendations

- Other general recommendations include but are not limited to the following:
 - Hinged instruments should be open
 - Items with removable parts should be disassembled
 - Devices with concave surfaces should be positioned to facilitate drainage of water
 - Heavy items should not be positioned to damage delicate items
 - All items should be arranged so that all surfaces will be directly exposed to the sterilizing agent
 - **Do not overload your autoclave**



Image: [3M](#)

Mechanical, Chemical and Biological Indicators

Sterilization should be monitored routinely by using a combination of mechanical, chemical, and biological indicators



Mechanical

- Used to detect procedural errors and equipment malfunctions
- E.g., time, temperature, pressure
- Usually recorded electronically, printed or visualized on display

Chemical

- Usually either heat or chemical sensitive inks that change color when 1 or more parameters are met.
- E.g., steam-time, temperature
- Affixed on outside
- Inside to verify steam penetration

Biological

- Measure the sterilization process directly using the most resistant microorganisms (i.e., *Bacillus* spores)
- Should be monitored at least weekly
- Each Load for implantable objects

Labeling Packs and Record Keeping

- Labelling and record keeping are also essential components of sterilization monitoring
- Packages should be **labeled** with the following information
 - Sterilizer number
 - Cycle or load number
 - Date of sterilization
 - Expiration date (if applicable)
- Facilities should document and maintain records of sterilization monitoring (e.g., mechanical, biological, and chemical indicators; HCP responsible for monitoring) and equipment maintenance records
 - Ensures sterilization parameters have been met and establishes accountability
 - Documentation helps to determine if a device or instrument recall is necessary and can be useful during outbreak responses involving suspected reprocessing errors

Documentation of HLD and Sterile Processing

Sterilization Log Sheet

Date (dd/mm/yy)	Sterilizer Brand	Serial Number	Time			Temperature (°F or °C)	Pressure	Wrapped (W) Unwrapped (U)		Pouches (PO) Packs (PK) Custom (C)	Temperature-sensitive Indicator: Color Change Observed		Operator's Initials
			Start	End	Cycle Length								
								W	U	PO PK C	Yes	No	
								W	U	PO PK C	Yes	No	
								W	U	PO PK C	Yes	No	
								W	U	PO PK C	Yes	No	
								W	U	PO PK C	Yes	No	
								W	U	PO PK C	Yes	No	
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								W	U	PO PK C	Yes	No	

HLD Solution Log Sheet

WARNING: DO NOT USE  SOLUTION BEYOND ITS STATED USE & REUSE LIFE. USE TEST STRIPS WITHIN 90 DAYS OF OPENING BOTTLE.

Date Test Strip Bottle First Opened _____ Do Not Use After (Date) _____ Bottle Lot #: _____

QC Test Results _____ QC Test Date _____ Tested By (initials) _____

Location/Dept _____

Date Solution Opened	Date Solution Expires	Date Solution Tested	Time Solution Tested	Solution MEC Test Results (circle one)	Tested By (Initials)	Temp in °F Before Use	Comments
				Pass Fail			
				Pass Fail			
				Pass Fail			
				Pass Fail			
				Pass Fail			
				Pass Fail			
				Pass Fail			

Sterile Processing Log

Clinic/Department _____

Sterilizer ID _____

Instructions:

1. Be sure to record all information requested in table.
2. Chemical Indicators are to be put inside each package/pouch along with an indicator on the outside of each package/pouch.
(Tape or special markings on outside of pouch)

Date Load # & Initials	# of pouches / wraps in Load Initials	Cycle Time Temperature Pressure (All Loads)	Chemical Indicators Inside & Outside (All Loads)	Load Recalled	Biological Indicator/ Spore Test (Weekly)	Date & Time Placed in Incubator	Date & Time Out of Incubator	Spore Test Results Circle one	Spore Control Results Circle one
		Minutes _____ Temp _____ Pressure _____ Initial _____	Processed _____ Unprocessed _____ Initial _____	No _____ Yes _____ Date _____	Lot # _____ Exp Date _____	Date In _____ Time In _____ Initials _____	Date Out _____ Time Out _____ Initials _____	Growth _____ No growth _____	Growth _____ No growth _____
		Minutes _____ Temp _____ Pressure _____ Initial _____	Processed _____ Unprocessed _____ Initial _____	No _____ Yes _____ Date _____	Lot # _____ Exp Date _____	Date In _____ Time In _____ Initials _____	Date Out _____ Time Out _____ Initials _____	Growth _____ No growth _____	Growth _____ No growth _____
		Minutes _____ Temp _____ Pressure _____ Initial _____	Processed _____ Unprocessed _____ Initial _____	No _____ Yes _____ Date _____	Lot # _____ Exp Date _____	Date In _____ Time In _____ Initials _____	Date Out _____ Time Out _____ Initials _____	Growth _____ No growth _____	Growth _____ No growth _____
		Minutes _____ Temp _____ Pressure _____ Initial _____	Processed _____ Unprocessed _____ Initial _____	No _____ Yes _____ Date _____	Lot # _____ Exp Date _____	Date In _____ Time In _____ Initials _____	Date Out _____ Time Out _____ Initials _____	Growth _____ No growth _____	Growth _____ No growth _____
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		Minutes _____ Temp _____ Pressure _____ Initial _____	Processed _____ Unprocessed _____ Initial _____	No _____ Yes _____ Date _____	Lot # _____ Exp Date _____	Date In _____ Time In _____ Initials _____	Date Out _____ Time Out _____ Initials _____	Growth _____ No growth _____	Growth _____ No growth _____

Example of Log

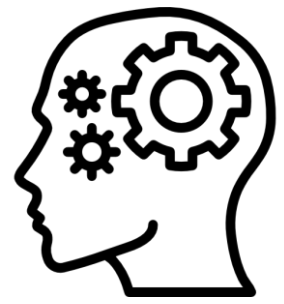


Exercise #3



- As part a prevention-focused infection control assessment in a dental clinic, your team focused IPC observations on the clinic's sterilization practices.
- Highlights from the assessment included the following:
 - Instruments were sterilized using a tabletop autoclave
 - Each package was labelled with the date and cycle number and other applicable information
 - Each package contained an internal chemical indicator visible after opening the package
 - Biological indicators were used on a monthly basis to ensure effective sterilization

Can you identify any IPC concerns in this scenario?

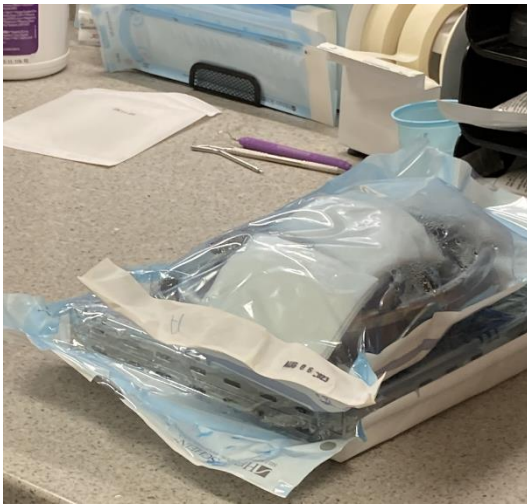


Exercise #3 Possible Answers

- If the internal chemical indicator is not visible from the outside of the package, an external indicator should also be used
 - External indicators should be inspected immediately when removing packages from the sterilizer and can help to visually differentiate between processed and unprocessed items
 - If the appropriate color change did not occur, items should be not be used
- Biological indicators should be used **at least weekly** to monitor sterilizers
 - More frequent use (e.g., daily) can allow for earlier discovery of equipment malfunctions or procedural errors
- Opportunities for HAI/AR Programs to provide education, training, and resources

Evaluation of Sterile Packs

- Evaluate sterile packages before use for loss of integrity (e.g., torn, wet, punctured) and expiration date (if applicable)
- If the integrity of the packaging is compromised or date has expired, items must be reprocessed before use



Semi-critical Devices and Instruments Require High Level Disinfection (HLD)

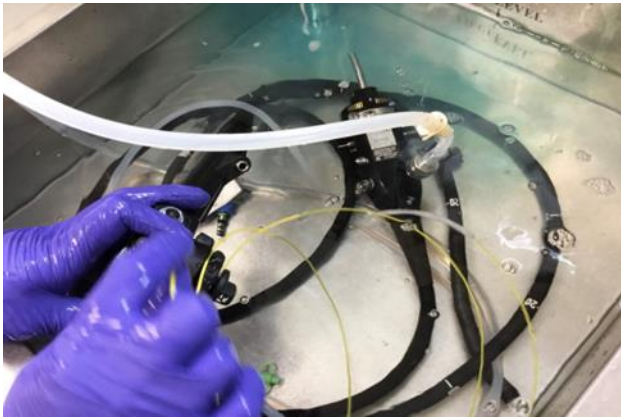
- May include certain types of heat-sensitive devices or instruments (e.g., respiratory therapy equipment, anesthesia equipment, some endoscopes, endocavitary probes)
- HLD Examples (multiple disinfectant chemical formulations)
 - Glutaraldehyde-based formulations (>2%)
 - Glutaraldehyde + phenol/phenate
 - Ortho-phthalaldehyde (OPA)
 - Hydrogen peroxide
 - Peracetic acid and Peroxyacetic acid formulations
 - Hot water pasteurization
 - Hypochlorite (via electrolysis)



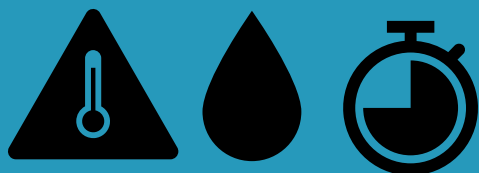
Certain devices or instruments may not be compatible with every method

Endoscope Processing Challenges

- Complexity Factors
- Channel design specifications
- Aspects of leak testing equipment
- Channel brushing requirements
- Cleaning verification challenges



Processes For Monitoring The Effectiveness Of HLD



- Monitoring **temperature, concentration** and **exposure time** must be met to ensure HLD is effective



- **Routine testing chemicals** used for HLD for appropriate concentration each day (or more frequently) using the appropriate chemical indicators and **documentation of the testing results**.
- Discard if concentration is less than the minimum effective concentration per IFUs



- For automated disinfectors, **adhere to the manufacturer's IFU** to ensure proper exposure conditions are maintained and correct steps are being followed.
- Audit the process

Documentation/Logs

- All Parameters must be met and documented.

Quality check on the new bottle of HLD check strips

Date of reprocessing medical device

Temperature of HLD prior to use

Patient identifier for tracking

Results of check strip MEC for solution prior to each use

Time medical device placed in HLD

Time medical device removed from HLD

Rinsed? How long? With what?

Initial/name of employee reprocessing the item

Documentation for every day even if solution not used (listing range of days not used is acceptable)

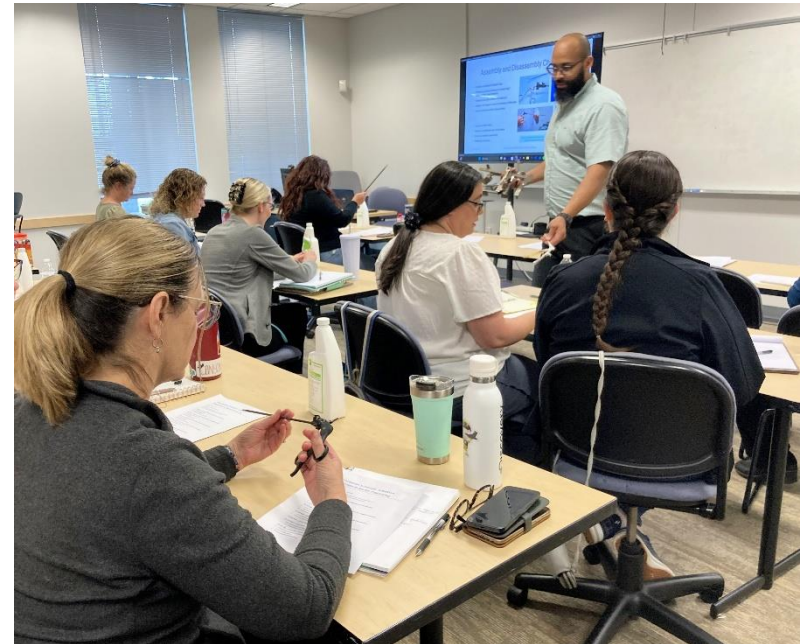


What Could Be Wrong With This Picture?



Collaboration!

- Key Collaboration Idea Areas
 - Joint development of technical assessment tools
 - Integration of SPD data with IP surveillance
 - Joint work on HAI investigations
- Observe their processes
- Know who your resources are
 - Public health
 - Training programs
 - Fellow IPs



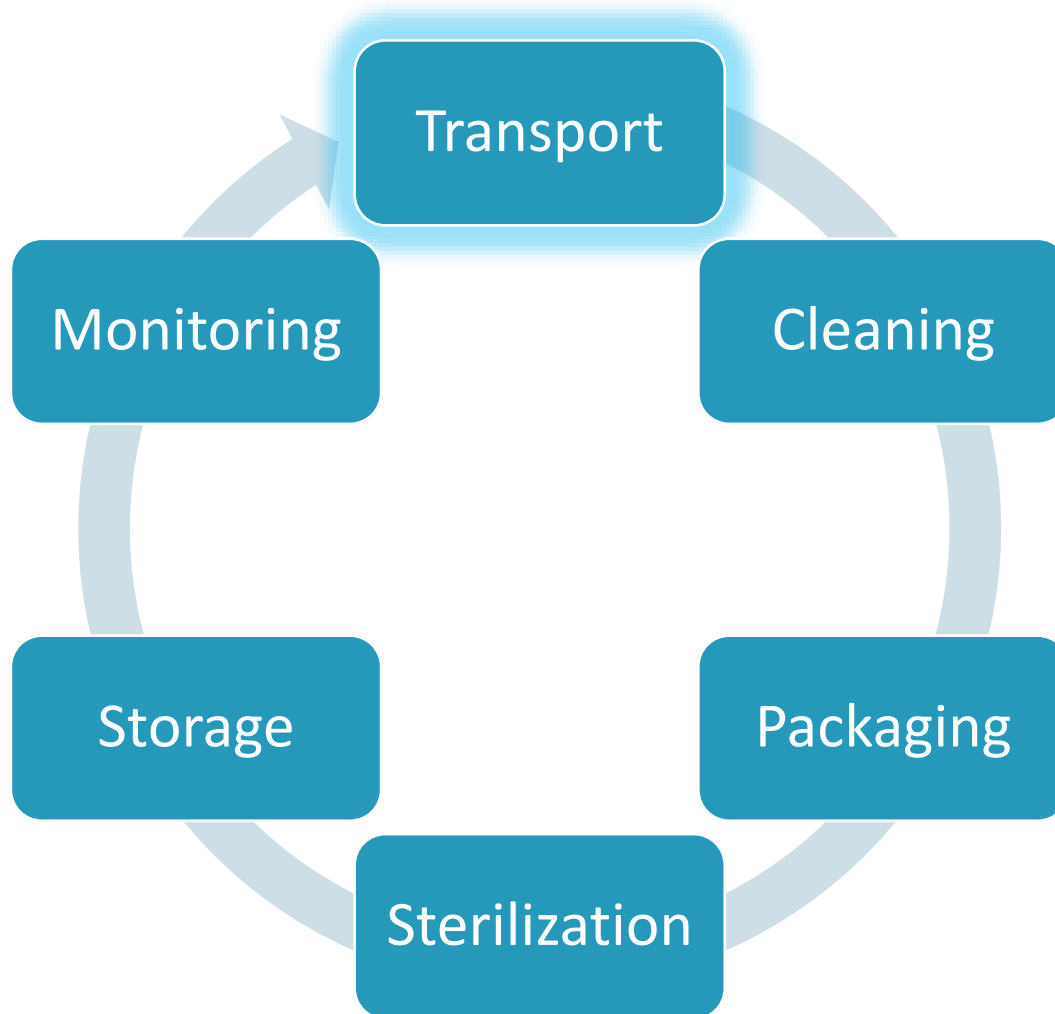
Multiple breaches were documented in a Washington hospital. Surveyors observed poor dirty-to-clean workflow due to fiberboard duct-taped over the pass-through window. A towel under the pass-through window touched both clean and dirty areas, and saturated towels were found around the sink. Personnel transported endoscopes in uncovered bins. Personal protective equipment (PPE) was stored in dirty areas near sinks and staff failed to change PPE when moving between clean and dirty areas. Detergent preparation did not align with IFU, and personnel did not document MEC test results. Surveyors stated patients were at “risk from infection due to potentially inadequately disinfected equipment.”

[Endoscope processing effectiveness: A reality check and call to action for infection preventionists and clinicians - American Journal of Infection Control](#)

Hot Topics In Washington

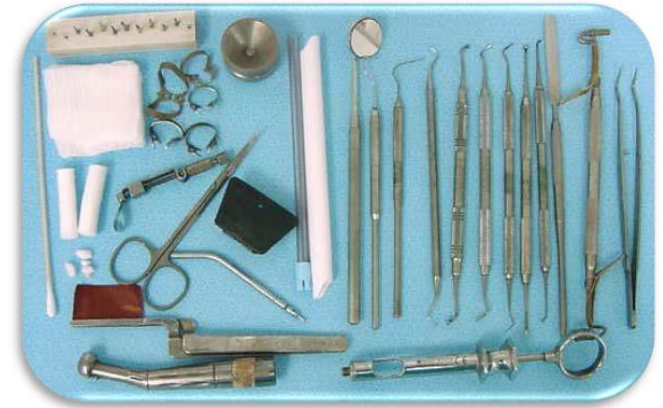
- *Instrumentation in clinics that is awaiting transport to the main SPD for reprocessing. Often will find items not properly stored in enzymatic cleaner or kept wet per policy prior to being picked up by the courier.*
- *Also have found improperly packed/stored equipment (nesting of instruments during the sterilization steps, too many pieces in one peel pack, hinged instruments not open to ensure proper sterilization, etc.).*
- *Reprocessing or sterilization equipment testing processes not being followed (biological indicators not being run as often as needed since the machines aren't used as often in the offsite clinics, test strips/product being beyond use or expired since it isn't used very often, etc.). Have also had this occur at some of the smaller facilities that don't use their central sterile that often because of low volumes.*
- Reprocessing/Sterilization Failures

Potential For Lapses...

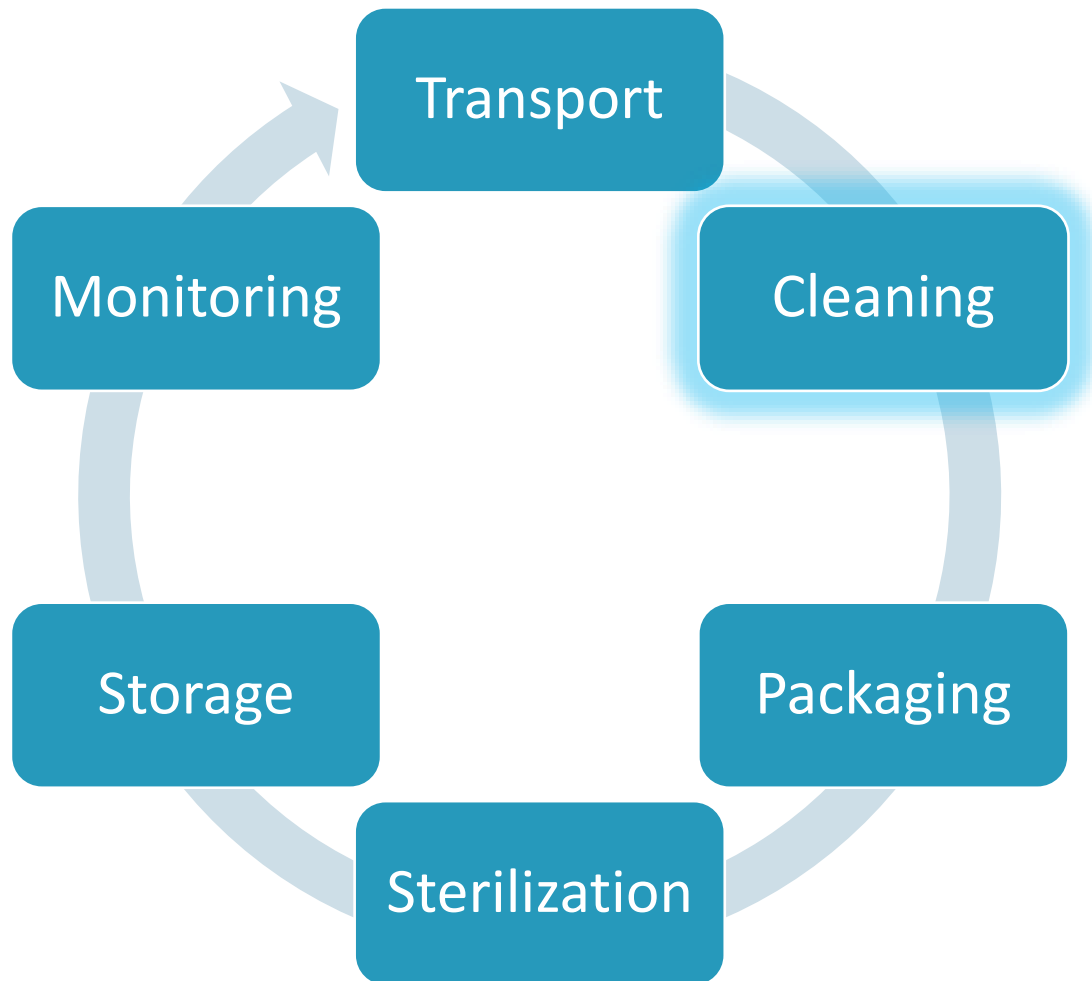


Transport

- Sharps left behind
- Carried in cassette/basin without cover
- Transport container not labeled as biohazard



Cleaning



Cleaning

- What do you observe about this picture?





High-Level Disinfection

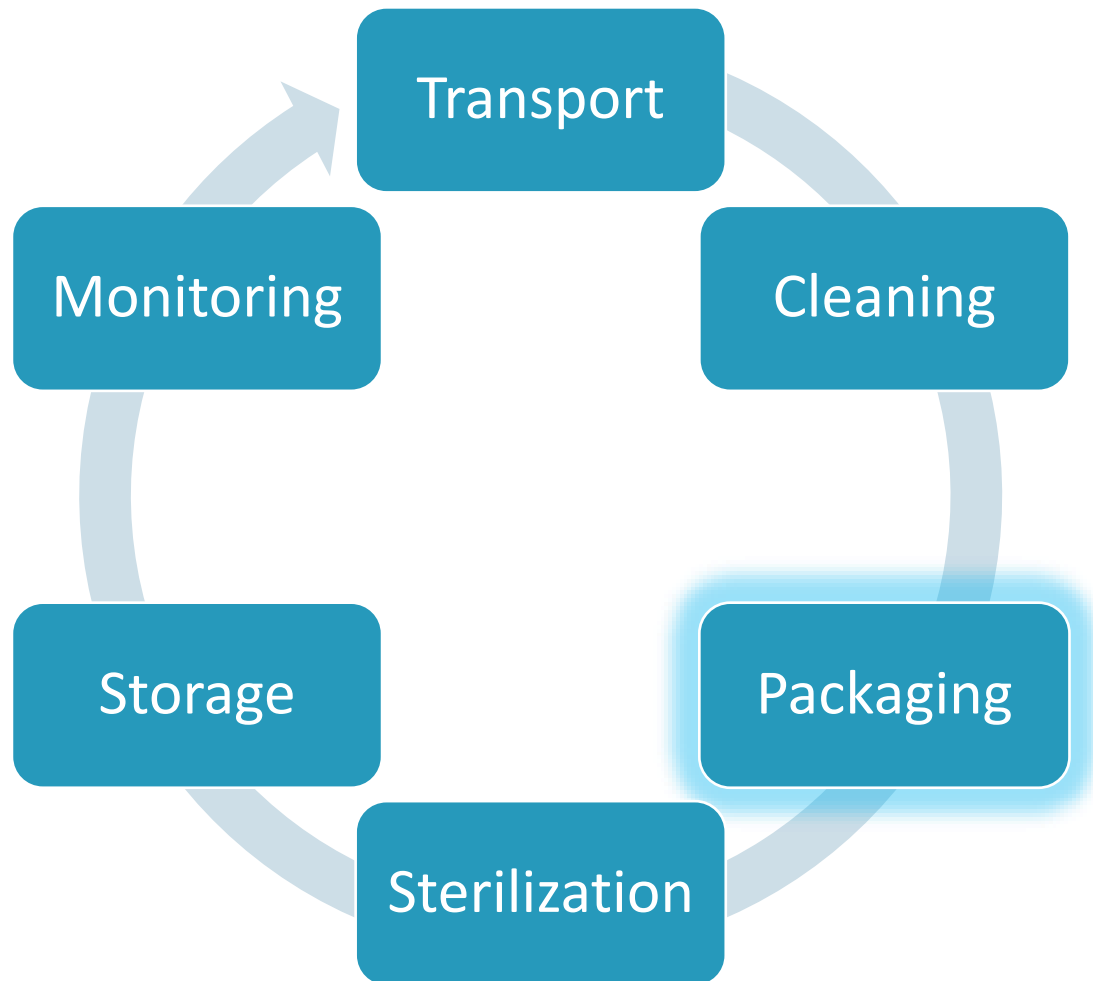
Who is cleaning this?

What product are they using?

Logs?

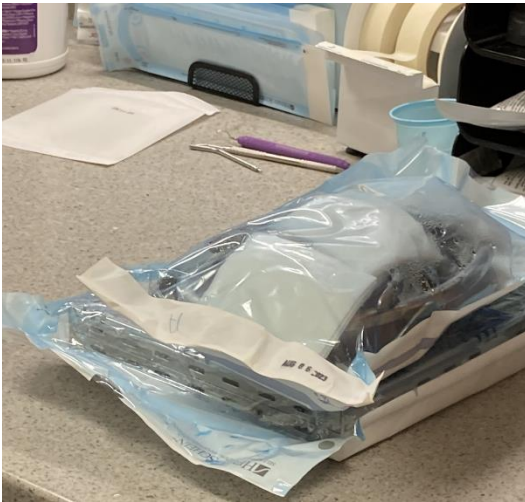


Packaging

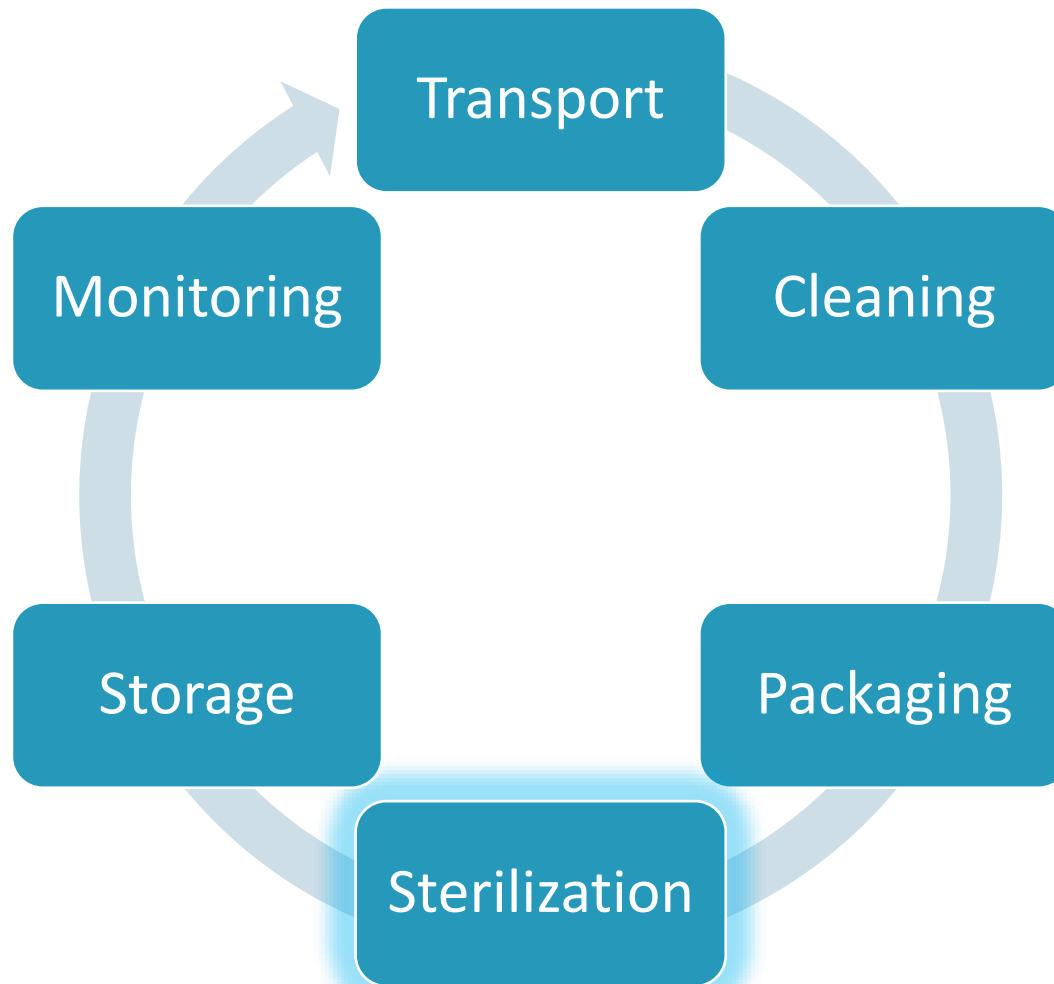


Packaging

- Do not overload your pack
- Labeling
- Chemical Indicators
- Is it sealed properly?
- Moisture



Lapses in Sterile Processing



5:00 pm, What Could Go Wrong?

- Scenario:

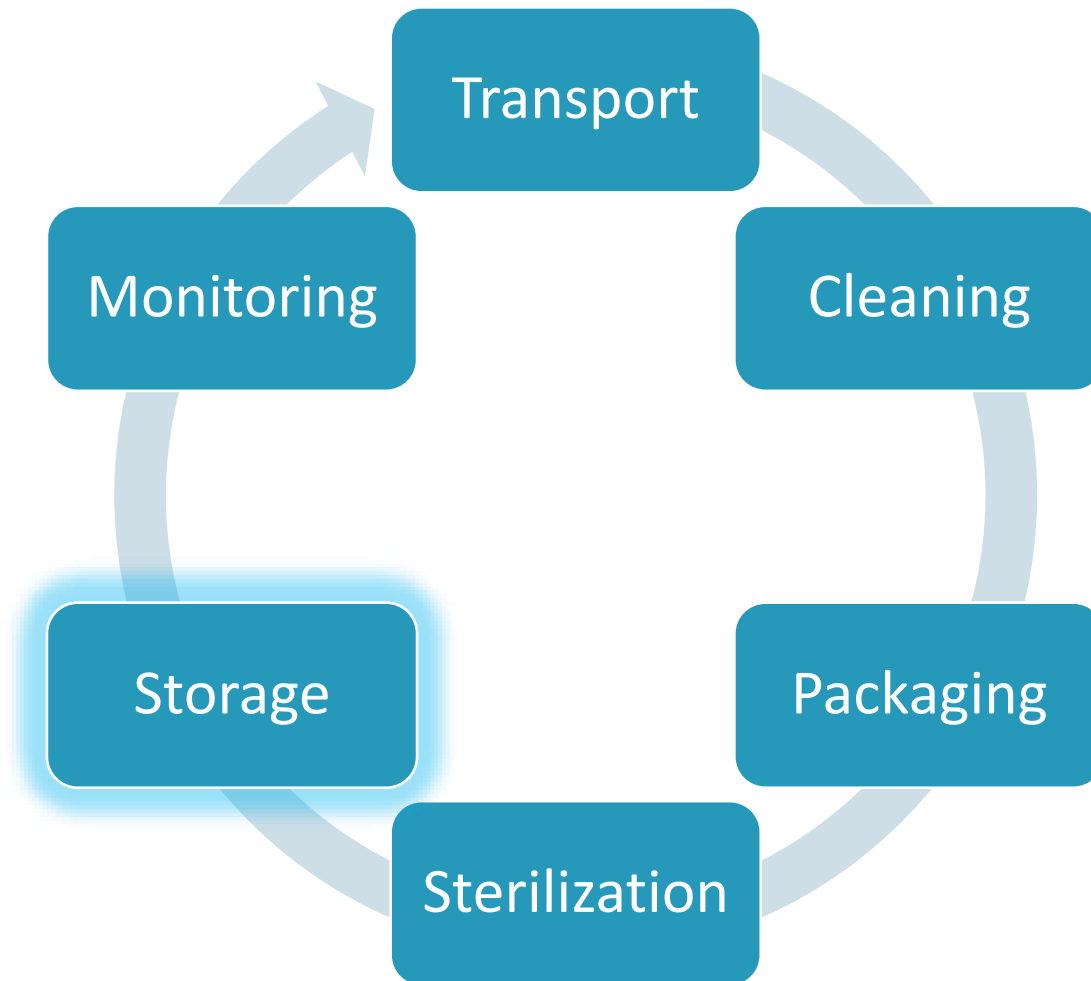
- It is Thursday at 5:00pm and the last patient is leaving the clinic.
- The instruments are cleaned, packaged and placed into the autoclave.
- The DA closes the door to the autoclave pushes start and exits the clinic with her colleagues.
- What happens next?

Evaluation of Sterile Packs

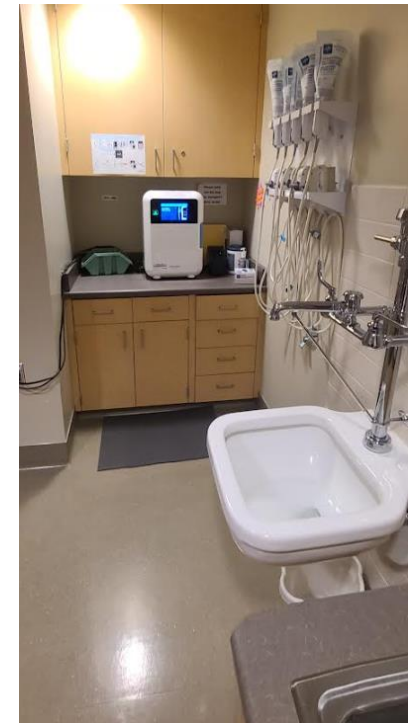
- Integrity of packaging is maintained
- Visually verify all parameters are met
- How would you recall instruments?



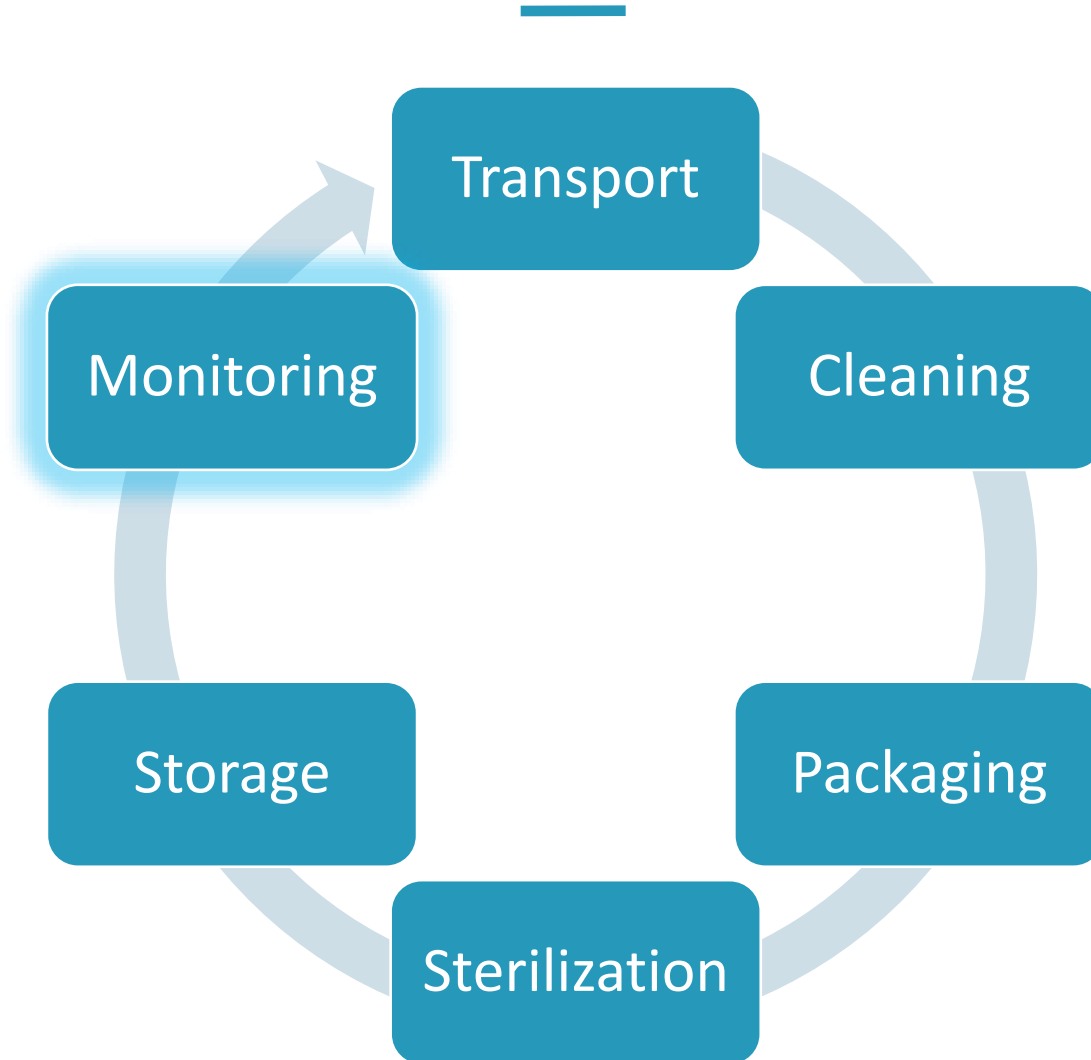
What Can Go Wrong With Storage?



- Avoid Moisture (not under the sink)
- Avoid cross-contamination
- Clearance specifications (2" from windows & walls, 8-10" from floor, 18" from sprinklers)



Event-related sterility is technically dependent on proper storage conditions. Even perfectly sterilized items can become contaminated if storage conditions aren't properly maintained.



What Does HLD or SP Look Like In Your Setting?

- Who does it?
- Are they trained?
- Competencies upon hire and annually?
- Documentation:
 - Complete
 - Accurate
 - What story does it tell?
- What to do if there is a breach?
- How to recall instruments?
- Maintenance of equipment
- Access to Manufacturer's Instructions For Use
- Red Flags

General Steps For Evaluating An IPC Breach

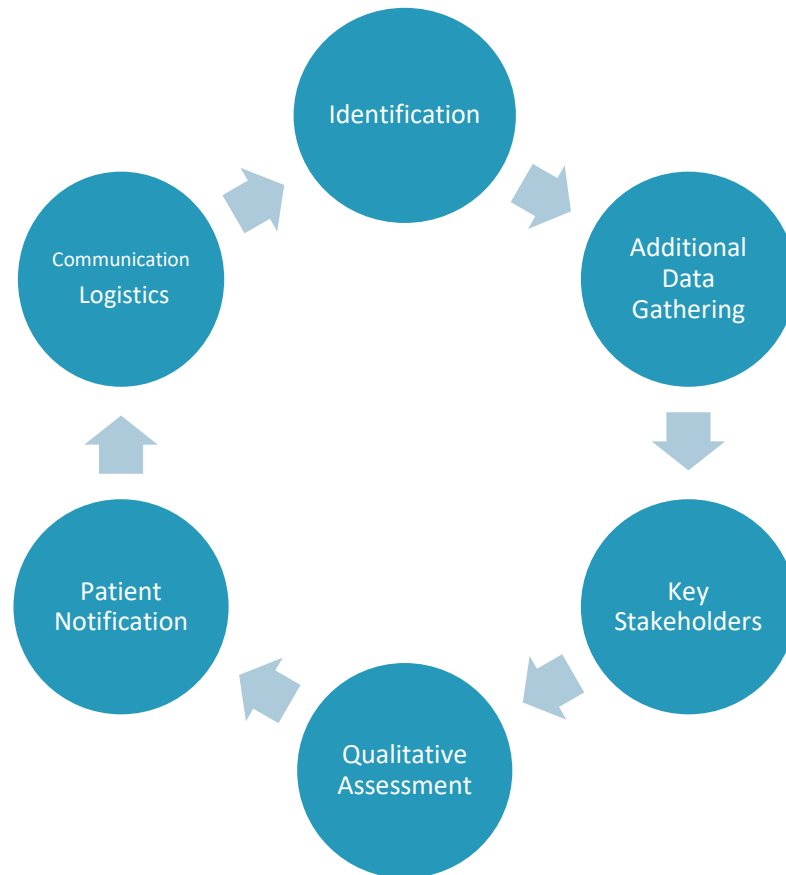


Figure 1. Approach to an infection control breach with potential risk of bloodborne pathogen transmission*

1) Identification of infection control breach

- Identify the nature of the breach, type of procedure, and biologic substances involved
- Review the recommended reprocessing methods or aseptic technique
- Institute corrective action as early as possible

2) Additional data gathering

- Determine the time frame of the breach and number of patients who were exposed
- Identify exposed patients with evidence of HBV, HCV, or HIV infections through medical records and/or public health surveillance data
- Conduct literature review and consult experts

3) Notify and involve key stakeholders

- Infection control professionals
- Risk management
- Local and State health departments
- Affected healthcare providers
- Licensing or other regulatory agencies, if appropriate

4) Qualitative assessment of breach

- If possible, classify breach as Category A or B:
- Category A involves a gross error or demonstrated high-risk practice
- Category B involves a breach with lower likelihood of blood exposure

5) Decision regarding patient notification & testing

If Category A,
Patient notification & testing is warranted

If Category B,
Consider the following factors in the decision:

- Potential risk of transmission
- Public concern
- Duty to warn vs. harm of notification

6) Communications & logistical issues

- Develop communication materials
- Consider post-exposure prophylaxis if appropriate
- Determine who will conduct testing, obtain consent, and/or perform counseling, if appropriate
- Determine if follow-up testing needed
- Facilitate public inquiry and communication
- Address media and legal issues



* (assumes no known cases of bloodborne pathogen transmission as a result of the breach)



Note: If pathogen transmission is confirmed or suspected, a more detailed epidemiologic and laboratory investigation would be warranted (not described here)

CDC Resources

- [Guidelines for Environmental Infection Control in Healthcare Facilities](#)
 - Recommendations for the prevention and control of infectious diseases that are associated with healthcare environments
- [Guideline for Disinfection and Sterilization in Healthcare Facilities](#)
 - Recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment
- [Essential Elements of a Reprocessing Program for Flexible Endoscopes](#)
 - Recommendations provided to assist healthcare facilities, including clinical and administrative staff, to achieve a reliable, high-quality reprocessing program
 - While specific to endoscopes, many of the essential elements in this guidance are more broadly applicable to other semi-critical devices/instruments

Questions?





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