Instrument reprocessing: cleaning, disinfection, and sterilization

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1

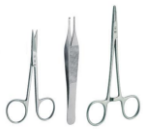
Reusable Device Reprocessing

- Appropriate sterilization or disinfection of re-useable medical devices is critical for the safety of our patients
- Multiple steps must be done correctly for sterilization and disinfection to be effective
- Infection outbreaks have occurred when one of these steps are missed or done incorrectly

2

The Goal of Reprocessing of Medical Equipment

- Safe care of our patients
- Avoid infections from improperly cleaned and disinfected/sterilized instruments
  - Bacteria
  - Viruses (HIV, Hepatitis B & Hepatitis C)
- Avoid skin/mucosal injury from disinfectant or sterilant on instruments



3

Do I sterilize or disinfect?: Spaulding Classification for Medical Devices

	Device Description	Examples
Non-critical	Does not ordinarily touch the patient or only touches intact skin.	Blood pressure cuff, ECG leads
Semi-critical	Comes into contact with intact mucous membranes or non-intact skin and does not ordinarily penetrate sterile tissue	Laryngoscope, endoscopes, cystoscope, tonometer, esophageal dilator
Critical	Enters normally sterile tissue or the vascular system	Surgical instruments, vascular catheters, implants

4

Spaulding Classification for Medical Devices and Level of Disinfection

	Minimum Required Disinfection/ Sterilization	Example
Non-critical	Intermediate to low disinfection	Alcohol swabs
Semi-critical	High level disinfection	Glutaraldehyde
Critical	Sterilization (sporocidal)	Steam sterilization (autoclave)

5

Ideal Sterilization/ Disinfection Process

- Quick
- Broad spectrum of antimicrobial activity
- Low temperature and broad material compatibility
- Non-toxic
- Simple to use
- Cost-effective
- Can cope with advances in device technology

6

Efficacy of Disinfection/Sterilization Factors for Success

- Cleaning of the object
- Organic and inorganic load present
- Type and amount of microbial contamination
- Concentration of and exposure time to disinfectant/sterilant
- Nature of the object (e.g., long, narrow lumen)
- Temperature and relative humidity

Why does sterilization and disinfection fail?

- Inadequate training of staff
- Improper cleaning prior to disinfection/sterilization
- Wrong level of disinfection/sterilization
- Failure to change disinfectant solutions
- Inadequate time or temperature for disinfection/sterilization
- Contamination after disinfection/sterilization (storage)

Steps of Reprocessing

1) **Pre-clean**
   - Necessary and critical step! Reduces risk of fluids and gross debris drying onto the scope or instrument
2) **Decontamination/Cleaning**
   - Manual cleaning/ decontamination with enzymatic and use of brushes
3) **Reprocessing (Sterilization or HLD as per device IFU)**
   - Complete reprocessing occurs when the device has been through full the cycle of sterilization or immersed in the chemical disinfectant for the required amount of time following thorough pre-cleaning and decontamination AND appropriate quality control parameters have been met
4) **Dry**
   - It is important to make sure the device is completely dry before storage to prevent growth of microorganisms
5) **Store**
   - Devices should be stored in a manner that prevents re-contamination

Pre-cleaning

- Removal of visible gross blood, body fluids, and/or bio-burden in order to prevent hardening of debris or the development of biofilm due to processing delays
- Soaking or spraying with enzymatic gel/foam
  - Prevents drying of blood, mucus, etc. on the device
  - Instruments should be kept moist between pre-cleaning and cleaning/decontamination process steps
  - Keep instruments/devices in a moist state between pre-cleaning & cleaning to prevent the drying and crusting on of blood, mucus, bodily fluids, etc.
- Must be performed at point-of-use

10

Why pre-clean instruments?

- If soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective
- Microorganisms may be protected from disinfectants by production of biofilms, a collection of microorganisms

11

Cleaning/Decontamination

- Physical cleaning w/ detergent or enzymatic cleaner is a necessary step that must happen prior to reprocessing
- Cleaning reduces bioburden &removes foreign material (organic residue & inorganic salts)
- Organic material (blood, tissue, feces) interfere w/ sterilization & disinfection by:
  - Binding chemical disinfectants (iodine)
  - Forming a physical barrier
- Narrow lumens and delicate equipment are high risk

12

Cleaning/Decontamination

- Cleaning/decontamination can be performed either by manual or mechanical means
  - Manual: Process of physically cleaning instruments/devices with enzymatic detergent, by hand
    - Must follow manufacturer's written instructions for use as it pertains to detergent type, dilution, brush type, water quality and temperature and cleaning steps
  - Mechanical: Cleaning machines (e.g. Ultrasonic washer, select scope washer cycles)
    - Automated cleaning and decontamination process
    - Often recommended for complex instruments



13

Rinsing and Inspection

- After cleaning, thoroughly rinse instruments with tap water and ensure all debris and detergent residue is removed
- Consider using treated water (e.g. deionized, distilled) as a final rinse, if tap water is of poor quality. This well help avoid staining of instruments
- Each instrument must be critically inspected after each cleaning for residual debris or damage
- Check each instrument for proper function and lubricate as required by instrument manufacturer
- Hinged instruments with stiff joints may be a sign of inadequate cleaning

14

Packaging

- Obtain and keep on file the manufacturer's instructions for use (IFU), care, and handling of packaging material
- Be sure the packaging IFU matches what is being done (e.g, double pouching, use inside of trays or rigid containers, stacking during sterile storage)
- Peel packs are for loose instruments and small, light weight items; they allow you to see the contents of the package; remove all excess air prior to sealing the peel pack closed
- For quality assurance, include a chemical indicator inside to verify the sterilant reached the inside of each package
- Sterilization indicator tape should be used to secure the wrapper
  - Class 1 indicator, changes with temperature alone
    - NOT an indicator that sterilization has been successfully achieved

15

Packaging

Effective sterile packaging should:
- Allow sterilant penetration
- Form a barrier to microorganisms
- Resist tearing and puncture
- Allow ease of presentation to the sterile field
- Be low linting and free of toxins
- Be cost effective

Sterilization

- Sterilization is the disinfection process that destroys all microorganisms on the surface of an article or in a fluid
- Sterilizers are Class 2 medical devices requiring FDA clearance
- They are available in a variety of sizes and methods (e.g., steam, ethylene oxide, hydrogen peroxide plasma, etc.)
- The CDC recommends steam as the process of choice, because it is efficient, fast, and less expensive than most other processes

Sterilization

- Minimum required for devices entering sterile tissue and vascular system
- Devices must be exposed to the sterilization process for the correct:
  - Duration of time, temperature, pressure (steam sterilization)
  - Packaged/arranged in way that allows for sterilant to penetrate all surfaces
- Monitoring of process is critical to ensure that sterilization was successful
  - Physical readout of temperature, chemical integrators, and biological indicators (BI)
- Common failure points which compromise sterilization:
  - Failure to achieve correct temp/pressure/time (autoclave malfunction or wrong setting)
  - Overpacking or poorly arranged instruments
  - Release of instruments before BI is read – with subsequent failed BI

Sterilization

- Sterilization in large facilities and institutions may occur through a centralized sterile processing department
  - Trained technicians
  - Standard process steps
- Outpatient areas may use tabletop sterilizers or autoclaves to reprocess instruments
  - Easier to account for instruments
  - Short turn around times
  - May be more cost effective in some instances

19

Sterilization process steps

- Instruments/devices undergoing sterilization within a clinic should have the following steps completed:
  - Instrument/device pre-cleaning
  - Transportation to reprocessing area
  - Cleaning/decontamination and inspection of instrument(s)
  - Drying and packaging
  - Sterilization with required monitoring
    - Physical
    - Chemical
    - Biological
      - Quarantine of instruments
  - Storage to prevent contamination
  - Sterilizer maintenance

20

Sterilization Quality Assurance

- Physical parameters, time temperature, and pressure monitoring
- Chemical Indicators
- Biological indicators
  - Quarantine of instruments
- Documentation

21

Physical monitoring

- Physical parameters must be monitored and recorded for each run of a sterilizer
  - Time
  - Temperature
  - Pressure
- Temperature and pressure monitoring can help detect sterilizer malfunctions.
- When physical conditions are outside of the required parameters adequate sterilization of instruments can not be verified
- Sterilizer printers are useful to capture and record physical parameters for each load run

Refer to sterilizer manufacturer instructions for appropriate parameter ranges

22

Chemical monitoring

- Chemical monitoring includes the use of an external chemical indicator and an approved internal class 5 chemical integrator
- External chemical indicators are used on the outside of the packaged instruments and are designed to verify that conditions inside the sterilizer chamber were adequate to achieve sterilization
  - e.g., tape that changes color with heat alone (Class 1)
- Chemical indicators do not validate that a processed item is sterile
- If a chemical indicator shows failure the items in that load are considered non-sterile and should not be used until successful sterilization has been achieved

23

Chemical monitoring

- Internal chemical integrators should be used inside each package every time a load is run
- Integrators verify that the instruments have actually reached the required temperature for the appropriate amount of time under necessary pressure
  - Requires that all three parameters are met to change color or reach the ACCEPT or SAFE designation
- Chemical integrators should be Class 5 or higher

24

Biological Indicators

- Biological monitoring involves the use of biological indicators which are microbiological devices designed to accompany items being sterilized to monitor adequacy of the sterilization process
- Tabletop sterilizer BI monitoring systems provide users with spore growth results in 24 minutes, 1, 3, 24, or 48 hours depending on the FDA clearance
- The end user is responsible for incubating and documenting the BI test results
- If a biological indicator shows failure, then items in the load are considered non-sterile and should not be used until successful sterilization has been achieved
- Biological indicators should at least weekly, but preferably everyday that the sterilizer is in use

Spore growth is indicated by a color change in the media during incubation

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25

Quarantine

- Process to segregate instruments while awaiting results from the BI
- Instruments awaiting BI results must not be returned to service until results are verified
  - quarantine area should be separate from instruments in service and clearly labeled
  - Designated place where recontamination of reprocessed items, including packaging is unlikely
- Inventory should support Inventory should support appropriate quarantine process without impacting instrument demand

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26

Storage

- Sterile items should be stored in a manner that reduces the potential for contamination
- The shelf-life of sterile items is event related and depends on the quality of the packaging material, storage conditions and amount of handling
  - Items inside of intact packaging are considered sterile for as long as the packaging integrity remain uncompromised
    - **NOTE:** items in packaging with impaired integrity should be considered non-sterile

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27

Documentation of Sterilization Process

- Thorough and accurate documentation of sterilization procedures is necessary to ensure effective reprocessing has occurred
- Complete documentation on a log is required each time sterilization is performed, and should include the following information:
  - Date and time of load
  - Load/cycle number
  - Operator initials
  - Specific contents of the load
  - Results of internal chemical integrator (include lot number)
  - Results of biological indicator, if applicable (include lot number)
    - Include "time in" and "time out" documentation for quarantine of instruments while biological results are pending
  - Results of external chemical indicator
  - Physical parameters (exposure time and temperature, if not using a printer)

Response to Failures

- If failures occur in the process it is important to remove the device from service until reprocessing can be successfully achieved
- If the necessary parameters to ensure quality processing has occurred are not met, the device must not be used on patients
- If a device is used on a patient and it is later noted that all the required parameters of sterilization were not achieved when reprocessing the device, notify the appropriate patient safety coordinator, risk management, infection prevention, and the provider

Endoscopy Specific Issues

Endoscope reprocessing steps

- Pre-cleaning
- Transportation
- Leak testing
- Decontamination
- Reprocessing
  - Manual
  - Automated
- Drying
- Storage

31

Pre-cleaning

- A crucial step in the reprocessing of channeled scope
- Evidence based best practice to remove bioburden and organic debris at the point of use
- Allows for maximum effectiveness of decontamination and reprocessing
- Promotes patient safety by reducing infection risk to patients

32

Pre-cleaning steps for channeled scopes

1. Don appropriate PPE
2. Remove and discard all disposable components that are a part of the scope
3. Wipe down the scope
   i. Remove the gross waste products
   ii. Inspect scope for damage
4. Flush the scope using room suction in the following sequence or according to department standard work:
   i. Enzymatic
   ii. Sterile water (optional if concern for low volume)
5. Place the scope into hard plastic, white transport container labeled “Biohazard”. Ensure container has a closed lid
6. Remove and discard PPE. Perform hand hygiene

33

Pre-cleaning steps for channeled scopes

- Refer to scope manufacturer's instructions for use (IFU)
- Wipe down scope with cloth or sponge soaked in fresh enzymatic detergent solution
  - remove gross soil and debris
  - inspect for damage
- Place distal end of scope in to appropriate detergent solution, and suction large volume of detergent through scope until clear. Finish by suctioning air
- Air and water channels should be flushed in accordance with manufacturer's IFU
- Detach scope from light source and suction
- Attach protective video cap (if applicable) prior to transport

Transportation

- Place pre-cleaned instruments/devices into a biohazard labeled, rigid, leak-proof container with lid applied.
  - **Note:** Containers for scope transport should be large enough to prevent damage to scopes by being coiled too tightly (SGNA)
- Transport instrument/devices to designated reprocessing area

Leak testing of scopes

- Necessary process to detect damage to the interior or exterior of an endoscope
- Must per performed each time a scope undergoes reprocessing
  - Refer to the scope manufacturer's IFU for appropriate leak testing method
- Undetected leaks can are concerning because they can:
  - increase risk of cross infection between patients by contaminated fluid leaking out during a procedure
  - Damage the scope by water intrusion

Manual cleaning/decontamination

- Clean items using water w/ detergents or enzymatic cleaners before processing.
  - Small, soft brushes should be used to clean all removable parts, including inside and under the suction valve, air/water valve, and biopsy port cover and openings.
  -
- Cleaning & decontamination should be done ASAP after the items have been used.
  - Brush size must be compatible with each channel (refer to IFU)
- All internal and external surfaces of the scope and its removable parts must be thoroughly cleaned, and all channels (even if not used) must be brushed and flushed according to the manufacturer's IFU for each scope model

AER Reprocessing

- Automated endoscope reprocessors- perform high-level disinfection of endoscopes using chemical disinfectants at a specific concentration and temperature for a duration pre-determined my the manufacturer and validated to achieve disinfection
  - variety of manufacturer's
  - Take burden of complexity away from end users
- Some AERs have additional functions for decontamination, rinsing and drying which prevents end users from having to perform these manually
  - Must be verified with manufacturer or performed manually

Drying

- Scopes must be allowed to dry thoroughly
  - Retained moisture or condensation can be a harbor for microorganisms which can be transmitted to patients during the use of the scope in a procedure
  - External surfaces of the scope should be dried with a lint free towel or cloth
  - Internal drying of channel(s), (if channeled scopes), can be achieved through the use of alcohol or air flushing
    - It is important to refer to the manufacturer's IFU for the appropriate manual drying procedure

Storage

- Store scopes in accordance with manufacturer's IFU
- Scopes should hang freely so that they are not damaged by physical impact and must be stored in a manner to prevent contamination
- Storage area must be a clean area that is well-ventilated and dust free

Documentation

- Important quality/ safety step
- Documents the details of the process
  - What was sterilized/disinfected?
  - Parameters to show HDL occurred correctly
  - Who and when?
- Why link patient to the scope used?
  - To identify patients if a problem with processing occurred or defective scope for follow-up
  - Without link to patient, may have to contact/test many more patients who might have been exposed

Process failures

- Common failure points which compromise effective reprocessing of scopes
  - Too short of time in contact with disinfectant
  - Too low of a temperature for the contact time of disinfectant
  - Insufficient concentration of disinfectant (not testing concentration)
  - Rise disinfectant off device with non-sterile water

  (If using an AER these are the result of machine malfunction or operator error)
- If failures occur in the process it is important to remove the device from service until reprocessing can be successfully achieved
- If a device is used on a patient and it is later noted that all the required parameters of sterilization were not achieved when reprocessing the device

Questions?

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