

STERILIZATION AND DISINFECTION UPDATE

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Objectives

- Describe current recommendations and standards for best practices in reprocessing sterile instruments and other reusable equipment
- Apply current recommendations and standards for quality assurance, monitoring, and documentation of the sterilization process
- Create a policy identifying actions to take should an indicator fail
- Evaluation of the training and competency process
- Create a policy for outlining the steps to follow should an infection control breach occur

Classification of Instruments/Equipment

E.H. Spaulding believed that how an object will be disinfected depended on the object's intended use

Critical: objects that enter sterile body sites/tissues

Ex: surgical stainless steel

Semi-critical: objects that touch mucous membranes

Ex: endoscopes, laryngoscopes, probes

Non-critical: objects that touch only intact skin

Ex: BP cuffs, stethoscopes, blood glucose monitors



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Training and Competency

- Training should be performed
 - Upon hire or prior to taking on reprocessing responsibilities
 - Annually and when new devices are introduced
 - By fully competent person
- Competency
 - Should be verified by return demonstration
 - Must be verified prior to performing reprocessing independently
 - Records must be maintained for each employee
- Manufacturer Instructions for Use
 - Must be available and current for all instruments/equipment
 - Must also be reviewed for any loaner pans/instruments



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Auditing/Tracing

- Regularly audit the adherence to all reprocessing steps, from pre-cleaning to storage
- Check for current manufacturers instructions and training and competency records
- Monitor sterilizer/automated endoscopic reprocessing performance (AER), including quality assurance (QA)

Auditing/Tracing (cont'd.)

- Should be conducted in all areas where reprocessing occurs
 - Can be very difficult in large facilities
 - Often do not know where reprocessing is occurring
 - Thorough review of all clinical areas should occur
- Provide feedback to personnel/department managers on audit findings
- Ensure facility follows their own policies, and that practice matches policy

Processing Critical Instrumentation

- Method: sterilization (kills all microorganisms, including bacterial spores)
- Options: steam, ethylene oxide, dry heat, hydrogen peroxide gas plasma, ozone
- Key points:
 - Ensure single use instruments are not re-used/re-sterilized
 - Ensure correct exposure times are followed
 - Ensure sterilization method chosen is validated for that instrument
- Must be properly cleaned for sterilization to be effective



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Processing Semi-Critical Patient Care Items

- Method: High-level disinfection (HLD) (kills all microorganisms, except high numbers of bacterial spores)
- Options: AERs, Trophon, manual soaking
- Key points:
 - Use of sheaths does not eliminate need for HLD after each use
 - Proper cleaning is essential for HLD to be effective



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Disinfecting Non-Critical Patient Care Items

- Method: Low- or Intermediate- level disinfection
- Options: Environmental Protection Agency (EPA) approved hospital disinfectants
- Key points:
 - Often overlooked
 - Follow manufacturer's instructions
 - Often a source of outbreaks/infections
 - Important component of any infection prevention program



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Disinfection Begins at Point-of-Use

Pre-cleaning immediately after use

- Prevents biofilm development
- Protects instruments
- Facilitates decontamination and cleaning
- Separate sharps/inspect for damage
- Use approved enzymatic detergent



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Transport of Soiled Instruments/Equipment

- Bins with lids
- Impermeable color bags
- Closed/covered carts
- Closed sterilization container systems
- Biohazard label
- Transport as soon as possible



Decontamination Area

- Environmental controls
 - Room should be negative pressure
 - Temperature: 60-65° F
 - Humidity: 30-60%
 - Must be monitored
 - No fans or portable air conditioners
 - Correct personal protective equipment (PPE) must be used



Decontamination Area (cont'd.)

- Dirty to clean workflow
- Physical separation from all other areas of processing department
- Ideally have doors and pass through windows (kept closed)
- Proper lighting

Decontamination Process



Cleaning

- Always performed prior to disinfection or sterilization
- Removes all body fluids and tissues
- Use FDA approved hospital detergents (enzymatic, ph balanced)
- Mix and maintain detergents according to Mft IFU (ratio, temperature, amount used)

Cleaning (cont'd.)

- Label solutions appropriately
- Always disassemble instruments according to manufacturer's instructions for use
- Includes manual cleaning, ultrasonics, and washer/disinfectors
- Makes it safe to handle instruments for further reprocessing in clean area

Types of Equipment

- Scope AERs
- Ultrasonics
- Washer/disinfectors
- Cart washers
- HLD machines

Clean Work Area



Prep/Clean Area

- Where instrument packaging, sterilization, and storage should occur
- Should be positive pressure
- Temperature: 68-73° F
- Humidity: 30-60 ° F
- Must use proper PPE
- Contaminated personnel/equipment should never enter this area

Wrapping and Packaging

- Pack contents to allow for steam penetration
- Pack contents so they can be opened and easily delivered onto a sterile field
- Use appropriate chemical monitor
- Use tip protectors according to manufacturer's instructions
- Double pouch only if validated by Mft
- Perform QA checks prior to wrapping/packaging

Labeling

- Water resistant marker or labeler list
 - Include sterilization date: month/date/year
 - Load number
 - Identify contents and initials of person packaging items
- Event related sterility: “Product not sterile if packaging is open, damaged. Check before using.”
- Put labels on plastic side only for pouches; label on tape for wrapped package

Rigid Sterilization Containers

- Size appropriately for the contained instruments (not too large, not too small)
- Close lids appropriately with correct filter for the system being used
- Materials should be compatible with type of sterilizer chemicals in use
- Seal with indicator tabs
- Use for heavy sets



Sterilization Wrap

- Handle with care
- Woven wrap
- Non-woven
 - Single layer (two layers sequentially wrapped)
 - One-step wrap (two layers bonded together; simultaneous wrap)



Steam Sterilizers

- Oldest, widely used, most economical
- Used with heat and moisture stable devices, instruments, materials
- Pressurized chamber, increases pressure and holds temperature, eliminates all air from the chamber
- **Dynamic:** pre-vacuum, high-vacuum, or mechanical air removal- mechanical pump sucks air from chamber resulting in shortened cycle time
- **Gravity:** downward air displacement process, relies on gravity to remove air from sterilizer

Sterilizer



Steam Parameters

- Sterilization times for surgical instruments
 - **Prevacuum:** 270° F , 4 minute exposure, 30 minute drying time
 - **Gravity displacement:** 250° F, 30 minute exposure, 45 minute drying time
- Immediate-Use Steam Sterilization (IUSS), formerly “Flash”
 - **Prevacuum:** 270° F, 3-4 minute exposure, no drying
 - **High-speed gravity:** 270°F, 3-4 minute exposure, no drying

Ethylene Oxide (EtO)

- Chemical (gas) that is used to sterilize heat-or moisture-sensitive items
- Long sterilization cycle (2 hours or longer)
- Toxic, flammable, requires special handling to store and use
- Starting to make a come back
- Only way to sterilize some items (endoscopic retrograde cholangiopancreatography [ERCP] scopes)

Liquid Chemical Sterilization

- **FDA recommendation:** only use for heat sensitive devices that are incompatible with other sterilization methods
- Does not convey same sterility assurance as other methods - no way to maintain sterility
- Chemical indicators are required for monitoring minimal inhibitory concentration (MIC)
- Know appropriate parameters
- Common chemicals used: Paracetic acid and Glutaraldehyde

Dry Heat

- Not commonly used today
- May be used for dental instruments, burrs, and reusable needles that would be damaged by steam
- Long exposure times and great variations in required parameters
 - Settings range from 30 minute exposure at 356° F to 6 hour exposure at 250° F

Interesting factoid: a pressure cooker is not a sterilizer ☺



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Quality Assurance Monitoring for Steam Sterilization

- Critical parameters for each load
 - Steam penetration
 - Adequate temperature
 - Pressure
 - Time
- Use mechanical, chemical, and biological monitors to evaluate sterilizing conditions and effectiveness



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Types of Sterilization Monitors

Physical

- Mechanical charts, printouts, or graphs

Chemical

- Indicate exposure to sterilizing agent

Biological

- Measure lethality of cycle



Physical Monitors

Information provided

- Whether or not the sterilizer performed as it should (e.g., cycle time, temperature, and pressure)
- No indication of whether sterilant reached device or if lethality was achieved



Should be kept/documentated in a log

Chemical Indicators

- Responds with characteristic chemical or physical change to one or more physical conditions within sterilizing chamber
- Used to detect potential sterilization failures that could result from incorrect packaging or loading of sterilizer, or malfunctions of sterilizer
- Association for the Advancement of Medical Instrumentation (AAMI) defines six classes of chemical indicators (CI) based on ability to monitor one or multiple sterilization parameters

Chemical Indicators (cont'd.)

- Indicates that item has been exposed to adequate sterilant concentration and/or other critical variables required for sterilization at specific location inside sterilizer chamber or processed package
- Does not prove sterilization has been achieved
- Should be placed inside each pack to verify steam penetration
- Should be on outside of each package to show it has gone through sterilization process



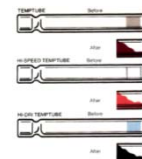
Classification of Chemical Indicators

- Class I: Process Indicators
 - React to ONE critical variable
 - Used to differentiate items that were exposed from those that were not
- Class II: Indicators for Use in Specific Tests
 - Special tests (Bowie-Dick/DART—used to assess the sterilizer’s ability to remove air)



Classification of Chemical Indicators

- Class III: Single-variable Indicators
 - React to ONE critical variable
 - Indicates performance in relation to at least one stated value
 - Not commonly used
- Class IV: Multi-variable Indicators
 - React to at least TWO critical variables
 - May be used as internal pack monitors



Classification of Chemical Indicators

- **Class V: Integrating Indicators**
 - React to ALL critical variables
 - Used as internal pack monitors
 - Performance must mimic biological performance
- **Class VI: Emulating Indicators**
 - React to ALL critical variables
 - Used as internal pack monitors
 - Performance does not mimic biological performance
 - Cycle specific
- Must be used with biological indicators!



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Placement of Chemical Indicators

- **Association for the Advancement of Medical Instrumentation (AAMI)**
 - Place in area least accessible to sterilant penetration
 - For containers: refer to manufacturer's written instructions
- **Association of Perioperative Registered Nurses (AORN)**
 - For wrapped items: one in geographical center of package, on each level (if multiple levels)
 - For containerized items: place in two opposing corners, on each level (if multiple levels)



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Biological Indicators

- Biological indicators (BI) are the only monitor that directly measures cycle lethality
- *Geobacillus stearothermophilus* spores
- Specifically designed for particular modality employed
- Sterilizers monitored on routine basis and with ALL implantable devices
 - Steam: at least weekly, preferably daily
 - ETO: every run
 - Implant: every run



Biological Indicators Steps for Use

- Write sterilizer number, load, and date on indicator
- Place directly over drain, on lowest shelf of sterilization cart/rack
- Run sterilizer per manufacturer's directions
- Ensure processed indicator and control are from same lot
- Control should be run daily and each time a new lot is used
- Incubate for specified time



BI Steps for Use (cont'd.)

- Incubation time varies with product
- Read and record results
- Processed biological should be negative (purple)
- If positive (yellow): sterilization process has failed due to improperly processed load, failure to meet temperature or exposure parameters, mechanical problems, etc.
- Positive BI indicates items should not be released or recalled



Note: Rapid-action BIs are automatically read by the incubator

BI Steps for Use (cont'd.)

- Implantable devices should not be released until BI results are known
- If emergency necessitates early release, an exception form should be used to communicate risk to provider

Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY? _____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____



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Sterilization

- Sterilize prepared items according to the directions in the manufacturer’s manual for the specific sterilizer that you use
- Be certain the sterilizer receives scheduled routine maintenance as required by the manufacturer



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Immediate Use Steam Sterilization

- Should only be used in emergencies, not as a substitute for inadequate inventory or scheduling practices
- Must be cleaned prior to sterilizing
- Staff should be trained on following Mft Instructions
- Should not be done with implants except in critical emergencies - ***must record patient name*** and that all parameters were met

Documentation

Use company documentation booklet or the sterilizer load documentation sheet to document

- Sterilizer number and/or location
- Load number
- Sterilizer operator
- Cycle exposure time and temperature
- Biological indicator use: documentation and results
- Recall documentation (if applicable)

Note: Retain records for at least three years or according to your facility policy

When Monitors Indicate Failure

- Quarantine items/remove sterilizer from service
- If reason is apparent (e.g., incorrect cycle selected, sterilizer loaded improperly), correct issue, repackage, and reprocess items
- If reason is not apparent
 - Recall all items processed since last negative biological test
 - Any items used must be communicated to infection prevention and control and to provider responsible for care of patient

If BI Test is Positive

- Record results - report and follow up immediately
- Remove sterilizer from service until reason is determined
- Check sterilizer records or logs to see if all other critical parameters were met
 - Mechanical (e.g., time, temperature, pressure) and chemical (e.g., internal and/or external)
- Identify and correct any errors found
- Retest sterilizer and evaluate mechanical, chemical, and biological monitors
- Check if other items have failed indicators from previous loads

If BI Test is Positive

- If repeat BI is negative and critical parameters are met, return sterilizer to service
- If still positive
 - Have sterilizer serviced
 - Can repeat BI using different manufacturer or lot
- Need written protocol for positive BIs and recall process when indicated

Recall Process

- Initiated when load sterility is questioned
- Recall all items processed between the failed BI (positive BI) and the previous negative BI
- Notify departments of the recall and collect unused items with questionable sterility

If Failure Results in Repair of a Sterilizer

- Minor repair
 - Routine monitors performed, then sterilizer released into service
- Major repair
 - Repairs that effect the basic performance of the sterilizer (e.g., chamber welding, major refitting of piping, software overhaul)
 - Sterilizer must be re-qualified

Steam Sterilizer Qualification

- Performed when a new sterilizer is installed, a sterilizer's location is changed, or it undergoes major repair
- Three back-to-back biological indicators performed in an empty chamber
- Three Bowie-Dick/DART tests performed back-to-back in an empty chamber
- Sterilizers quarantined until test results are obtained

Storage

- Closed cabinet that does not crush, bend, compress, or puncture packages
- If no cabinet: covered plastic container
- Open storage: lowest acceptable shelf 12" from floor and highest shelf 18" from ceiling
- Sterile supplies are considered contaminated if contact with wet or contaminated surfaces, including the floor
- Use sterile supplies on a "first in, first out" basis
- Visually inspect packaging for integrity and labeling prior to use

Storage



Loaner Instrument Policy

- If you borrow instruments from another facility, have a policy
- Manufacturer's instructions should be reviewed and available onsite to staff
- Be certain the right process for reprocessing is used (e.g., temperature, time, method)
- Keep a documentation log
- Ensure loaners are delivered in enough time to allow for safe reprocessing

Important Safety Considerations

- Wear appropriate PPE when working with high-level disinfectants (e.g., right type of gloves, protective eyewear, masks, gowns or aprons)
- Read the material safety data sheet for the product and ensure room meets safety requirements (e.g., ventilation)
- Eye wash stations
- Chemical bins should be tightly covered when not in use

Single-Use Devices

Look for single use devices (SUD):

- If SUDs are reprocessed, they are devices that are approved by the FDA for reprocessing
- If SUDs are reprocessed, they are reprocessed by an FDA approved reprocessor

Contracted Sterilization or HLD Services

If contracting sterilization or HLD services offsite, CMS will confirm there is a contract or other documentation of an arrangement for offsite sterilization or HLD

Failure to Follow Disinfection and Sterilization Principles

Watch for these events in your facility

- Human errors: inadequate pre-cleaning, inadequate exposure times (steam, HLD, EtO), documentation failures, poor IC practices (cross contamination, PPE use), improper use of detergents/disinfectants
- Equipment: no preventive maintenance, not tested/cleaned, lack of knowledge on use

Steps for Evaluating an Infection Control Breach

The CDC has established a protocol for approaching an infection control breach with potential risk of bloodborne pathogen transmission

1. Identification of 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

Steps for Evaluating an Infection Control Breach (cont'd.)

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

Steps for Evaluating an Infection Control Breach (cont'd.)

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

Steps for Evaluating an Infection Control Breach (cont'd.)

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

Steps for Evaluating an Infection Control Breach (cont'd.)

5. Decision regarding patient notification and testing

- If **Category A**, patient notification and testing is warranted
- If **Category B**, consider the following factors:
 - Potential risk of transmission
 - Public concern
 - Duty to warn vs. harm of notification

Steps for Evaluating an Infection Control Breach (cont'd.)

6. Communications and 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 is needed
- Facilitate public inquiry and communication
- Address media and legal issues



Questions to Ask

- Is the sterilizer labeled for this cycle by the manufacturer?
- What is the sterilizer manufacturer's recommended load for that cycle?
- Is the containment device used labeled by the manufacturer for use in that cycle?
- For what load is the containment device recommended by the manufacturer?

Observation Audits

- Sterilization
 - Critical equipment is sterilized
 - Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization
 - Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization
 - A chemical indicator is placed correctly in each load
 - A biologic indicator is performed AT LEAST weekly and with all implantable loads

Audits (cont'd.)

- Bowie-Dick/DART test each day for dynamic air removal-type sterilizers
- Each load is monitored with mechanical indicators (e.g., time, temperature, pressure)
- Documentation for each piece of sterilization equipment is maintained, up to date, and includes results from each load
- Items are appropriately contained and handled during the sterilization process to ensure that sterility is not compromised prior to use
- After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised
- Sterile packages are inspected for integrity and compromised packages are reprocessed

Additional Questions

- Is the chemical indicator used labeled for use in this cycle by its manufacturer?
- If a biological indicator is used, is it labeled for use in this cycle by its manufacturer?
- If the cycle is used frequently, is it checked regularly with a biological indicator?

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