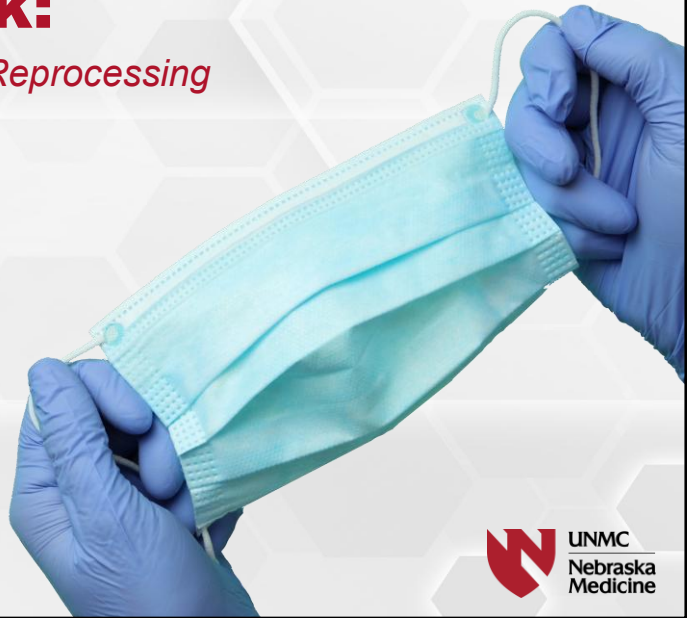


# Behind the Mask:

## *Fundamentals of Critical Device Reprocessing*

Lauren Musil BSN, RN  
Alisha Sheffield MSN, RN, CIC



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## Meet our Subject Matter Experts



### **Lauren Musil BSN, RN**

Lauren is an Infection Preventionist with a background as Registered Nurse. She has a wide variety of healthcare experience having worked in neurology, neurosurgery, ambulatory surgery, home health and with the Nebraska Biocontainment unit. As an IP, her primary focus has been in critical care, oncology, VAE prevention and as the IP to the Nebraska Biocontainment Unit. Her recent work has been spent in a grant funded role to develop innovative tools to aid IPs in rural and remote settings.



### **Alisha Sheffield MSN, RN CIC**

Alisha is an Infection Preventionist and Registered Nurse with 21 years of experience in a variety of healthcare settings including ambulatory, acute care, and surgical areas. Over the past 13 years, she has worked as an Infection Preventionist in outpatient surgery as well as at a large academic medical center. Her recent work has focused on utilizing her IPC expertise to develop infection control tools and resources to assist Infection Preventionists in under-resourced settings.

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    - E.g., RN, BSN
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## Disclosure Declaration



- We have no financial disclosures or conflicts related to this presentation.
- The views and opinions expressed during this webinar are those of the presenters and do not necessarily reflect those of the University of Nebraska Medical Center or The Nebraska Medical Center.

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## IPC Program Objectives



Identify the critical components of effective critical device reprocessing practices in healthcare settings.



Interpret evidence-based guidelines, regulatory requirements, and industry standards to ensure compliance and best practices.



Implement practical strategies to monitor, audit, and enhance critical device reprocessing within healthcare facilities.



Evaluate critical reprocessing processes through performance monitoring to identify gaps and drive continuous improvement.



Synthesize knowledge of critical device reprocessing to develop collaborative approaches, foster accountability, and promote quality infection prevention practices across interdisciplinary teams.

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# History



## 1450 BC- Ancient Egypt

- Purification by fire
- Sin and death are connected
- Separate clean from dirty



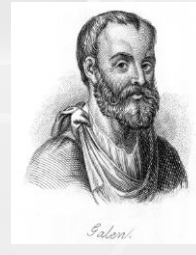
## 550 BC Greek Infantry

- Fought naked
- Dirty clothing was caught on swords wounds and would cause infection



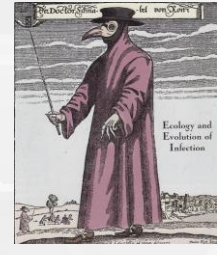
## Hippocrates 460-377 BC

- Separate medicine from philosophy-disease is not a punishment for sin
- Irrigate wounds with wine or boiled water (asepsis)



## Galen 130-200 AD

- Physician in Rome-boiled instruments



## Middle Ages

- Filth, pestilence, and the plague
- Attempts to combat disease in hospitals

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# History



## Renaissance

- Pressure cooker: TIME TEMPERATURE AND PRESSURE
- Diagnosis by tasting urine



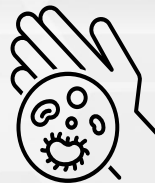
## 1683

- Developed the microscope
- Proves the existence of microorganisms



## 1758

- Earliest recorded instance of the use of the surgical glove
- Glove formed from sheep intestines and used it to deliver babies



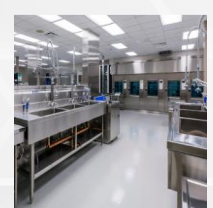
## Controversial topics

- Handwashing
- Germs cause disease
- Germs spread via contact



## Germ Theory

- Devices and hands can spread infection



## Device disinfection

- Pasteurization
- Autoclave

8

## Background

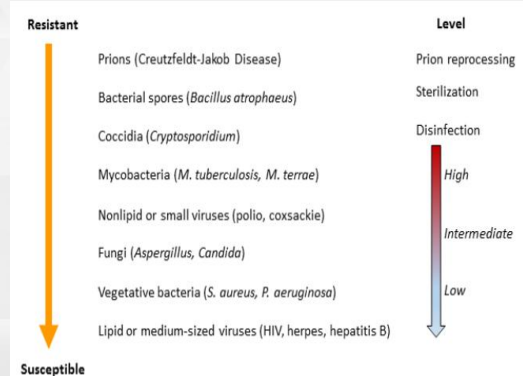
### Spaulding Classification

Patient Contact	Device classification	Minimum Inactivation Level	Examples
Intact Skin	Non-Critical	Low/Intermediate level disinfectant	Glucometers Wheelchairs Blood Pressure Cuffs Environmental Surfaces ~Bedrails, Call light, door handles
Non-intact skin or mucous membranes	Semi-critical	High-level disinfection	Endoscopes, speculums, laryngoscopes, respiratory therapy equipment, anesthesia equipment, etc.
Sterile areas of the body, including bloodstream	Critical	Sterilization	Surgical instruments, IV cannulas

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## Background

- Critical Devices:
  - Objects that touch sterile tissue
- Transmission occurs via contact
- Sterilization:
  - Process that kills or eliminates transmissible pathogens from a surface, equipment, foods, medications or biological culture medium
  - Very high margin of safety



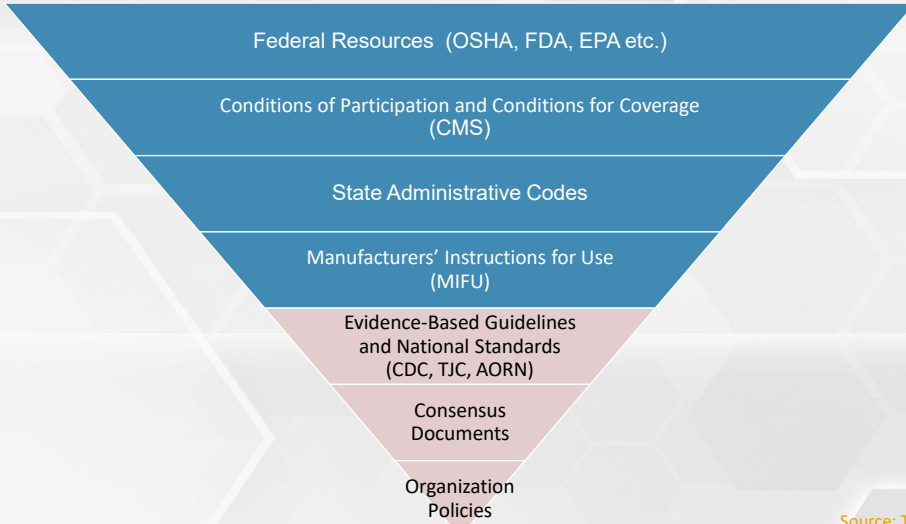
Source: CDC

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# Regulation & Accreditation



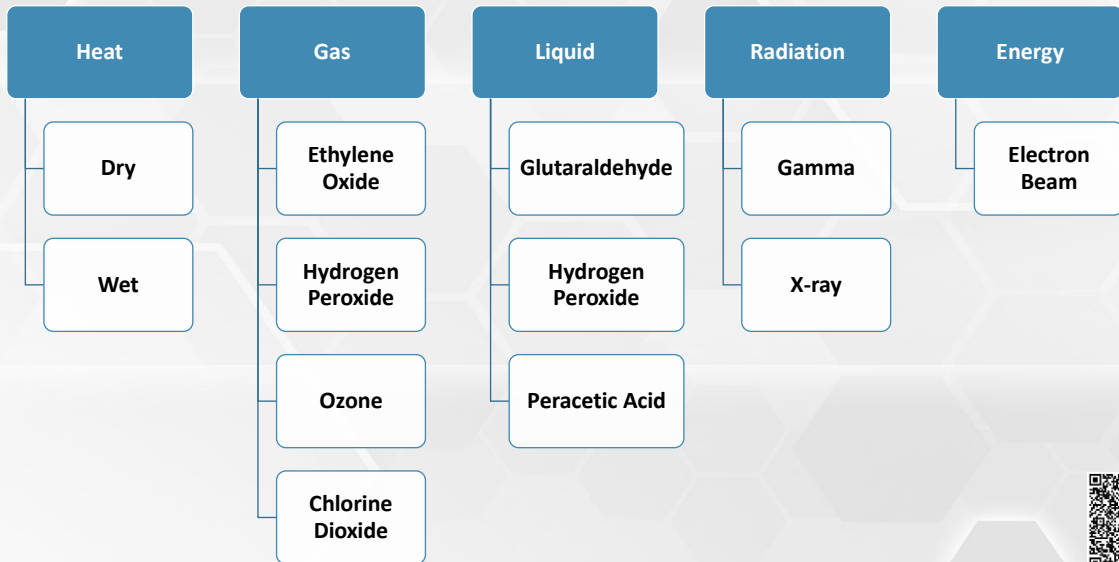
## Hierarchical Approach of Compliance



Source: The Joint Commission

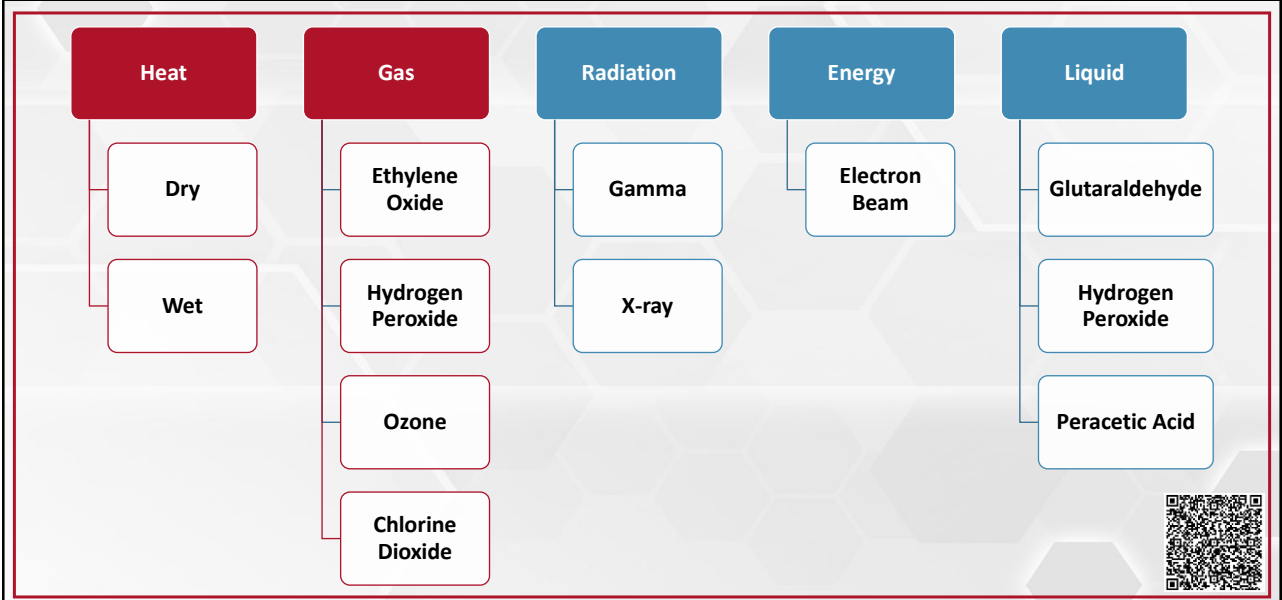
11

# Methods



12

## Methods



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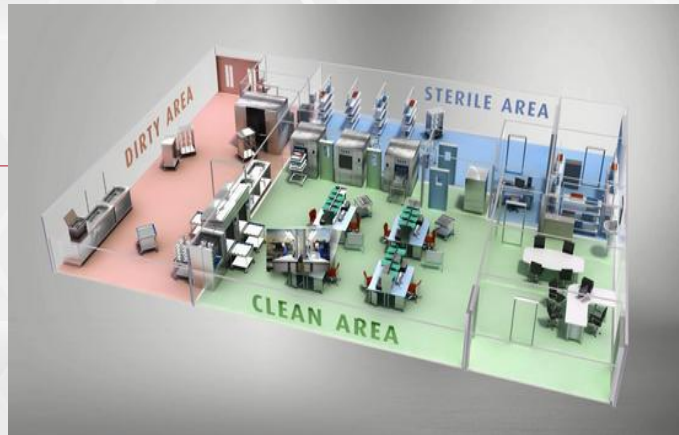
## IP Role in Device Reprocessing

<b>Policy &amp; Procedure</b>	<ul style="list-style-type: none"> <li>Partner with reprocessing personnel and other relevant departments to develop and update device reprocessing policies and procedures for device reprocessing</li> <li>Ensure policies and procedures address semi-critical devices</li> </ul>
<b>Education &amp; Training</b>	<ul style="list-style-type: none"> <li>Ensure staff training is sufficient for healthcare workers on sterilization procedures and protocols</li> <li>Ensure teams provide staff education with updated IFUs and as new products come into the facility</li> </ul>
<b>Surveillance &amp; Reporting</b>	<ul style="list-style-type: none"> <li>Collect and analyze sterile process and surgical area data</li> <li>Monitor for lab and process trends that may indicate lapses in practice</li> <li>Provide data to relevant committees</li> </ul>
<b>Performance Monitoring &amp; Evaluation</b>	<ul style="list-style-type: none"> <li>Audit critical device reprocessing practices and provide feedback to staff</li> <li>Monitor processes (e.g., adherence to standards and manufacturer IFUs) for critical device reprocessing</li> </ul>
<b>Communication &amp; Collaboration</b>	<ul style="list-style-type: none"> <li>Collaborate with reprocessing personnel and teams</li> <li>Collaborate with device and product vendors</li> <li>Utilize bi-directional communication to ensure:               <ul style="list-style-type: none"> <li>The IPC program is updated when new products are being introduced to the facility</li> <li>The IPC program shares important and relevant infection prevention information back with the reprocessing teams</li> </ul> </li> </ul>
<b>Product Selection &amp; Evaluation</b>	<ul style="list-style-type: none"> <li>Partner with the value analysis team and relevant stakeholders to review products, devices, and their reprocessing instructions for implementation at the facility</li> <li>Attempt product standardization throughout the facility</li> </ul>

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## Environment of Care

- Space Configuration/ Function
- Workflow
- Engineering Controls
  - Ventilation
  - Water/ Steam Quality
- Environmental Surfaces
- Reprocessing Equipment
- Waste Management
- Clean Storage



Source: Tuttbauer

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## Small Space



Source

16

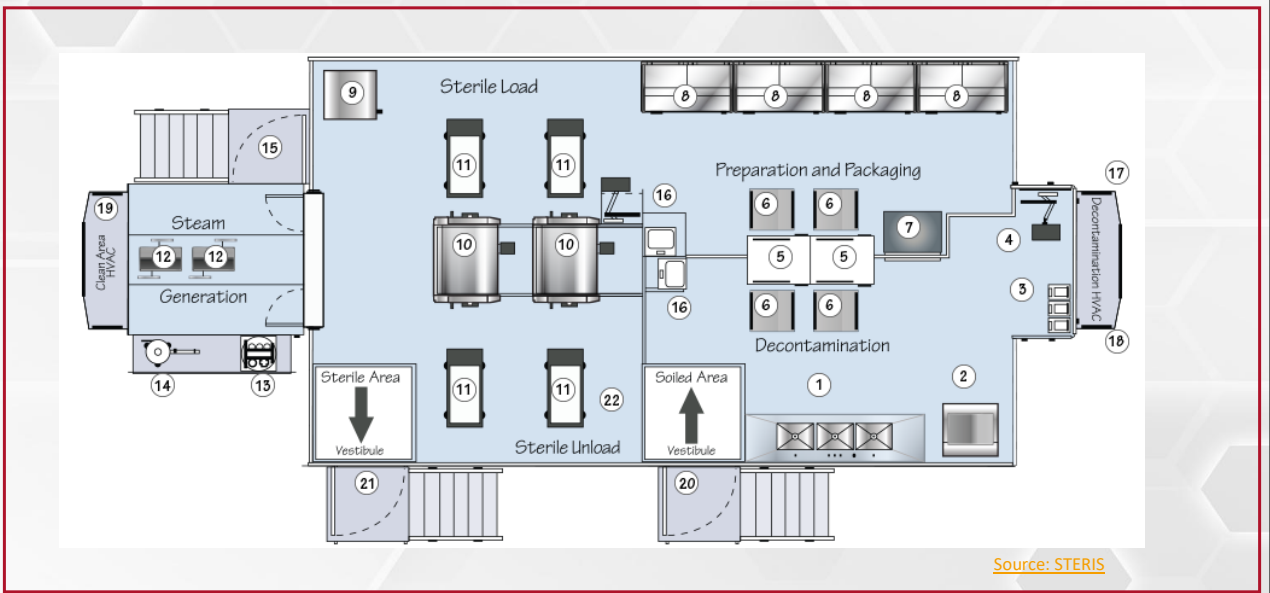
# Medium Space



Source: STERIS

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# Large Space



Source: STERIS

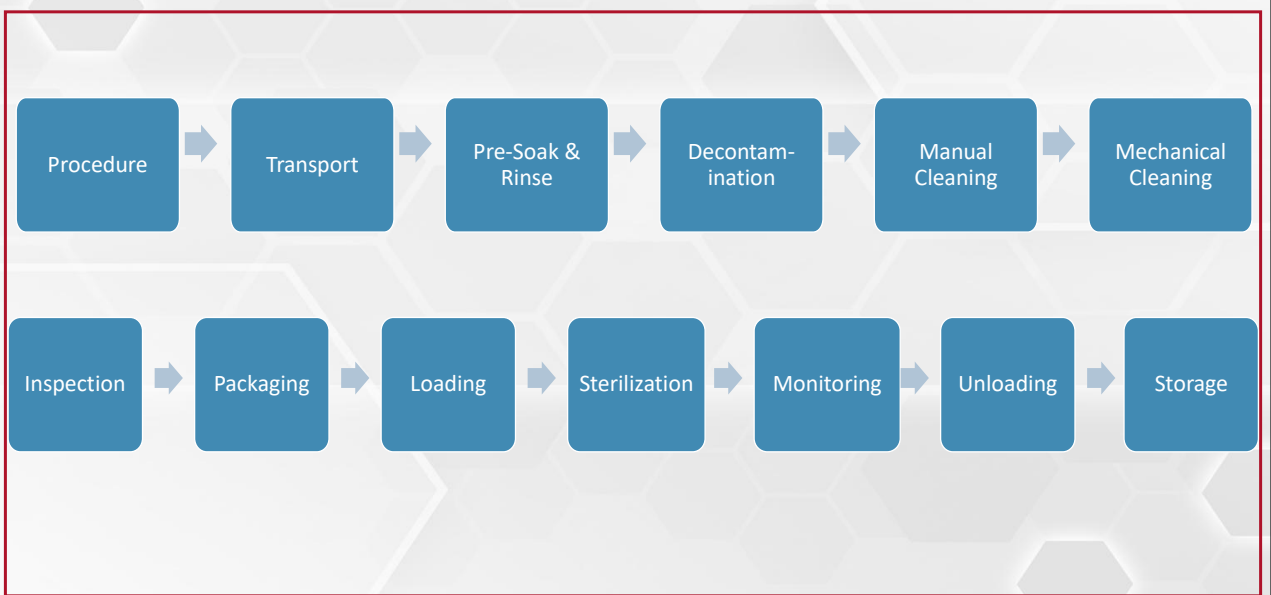
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Source: MCL

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## Process



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## Point of Use Cleaning



### During the case:

- ✓ Wipe the used instruments as needed with a sterile sponge that has been moistened with sterile water.
- ✓ Irrigate lumened instruments with sterile water



### After the case:

- ✓ Disassemble instruments as needed
- ✓ Place ALL reusable instruments in containers
- ✓ Separate sharps and place in puncture resistant container
- ✓ Open hinged instruments and place on stringers
- ✓ Place lighter instruments on top of heavy or separate
- ✓ Keep instruments moist
  - Water moistened towel over instruments
  - Place inside specific humid container
  - Apply pre-treatment agent (enzymatic spray or gel)



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## Transport



From point of use directly to Decontamination Room:

- ✓ Marked biohazard
- ✓ Transported promptly
- ✓ In a container that can be discarded or decontaminated
- ✓ If carrying device with sharp edges/points:
  - ✓ Leakproof on sides and bottom
- ✓ Closeable
- ✓ Puncture resistant

Source: Nebraska Medicine

**Soiled Sterile Instrument Process and Transport**

Before Procedure: Gather a clean, rigid, leak-proof, biohazard-labeled, reusable transport container from clean supply room

	<p>Step 1:</p> <p>Don Personal Protective Equipment (PPE) and wipe gross soiled debris with germicidal wipe from instruments. This is done at point of use (at bedside/procedure room).</p>
	<p>Step 2:</p> <p>Place cleaned instrument(s) in transport container. Place lid on container. Remove PPE and perform hand hygiene. Transport to soiled/dirty utility room.</p>
	<p>Step 3:</p> <p>Don required PPE—gloves and goggles (or face shield)</p>
	<p>Step 4:</p> <p>Place instruments in open position in the Sterile Processing Department (SPD) red biohazard bin and saturate with enzymatic spray. Place lid on red biohazard bin.</p> <p>Note: item(s) must remain saturated with enzymatic spray. Staff are required to return and spray sterile items until items are taken to SPD.</p>
	<p>Step 5:</p> <p>Disinfect reusable transport container with germicidal wipe. Allow for appropriate wet times. Return transport bin back to clean utility room.</p> <p>Volunteers will bring bins with instruments down to SPD Daily.</p>

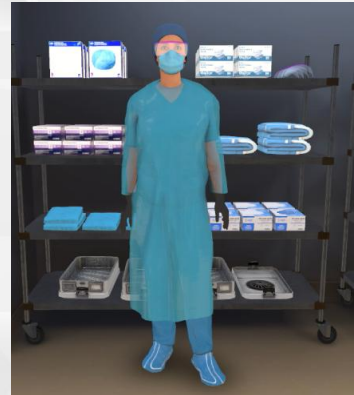
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## Personal Protective Equipment



### Minimum PPE required for decontamination includes:

- ✓ Fluid-resistant face mask
- ✓ Eye protection (*full-length face shields or goggles*)
- ✓ Utility gloves that extend beyond the cuff of the gown
- ✓ Impervious gowns and/or aprons
- ✓ Shoe covers
- ✓ Hair covers



\*Additional PPE may be recommended on the Chemical Safety Data Sheet provided by the manufacturer (*e.g., aprons, gowns with thumb loops, etc.*)

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## Decontamination



### Cleaning:

Removes all foreign matter so disinfectant can touch the surface

Manual

Automated

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## Manual Cleaning



### Device Preparation

Pre-treated  
Gross debris removed  
Sort and disassembled

### Cleaning Tools

Non-linting cloths  
Brushes  
Single Use discarded  
Disinfected daily

### Technique/Safety

Fully submerge  
PPE  
Brush, flush, wipe

### IFU

Steps vary by device  
Cleaning tool IFUs  
Solution IFU



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## Manual Cleaning



- ✓ Does not make devices safe to handle
- ✓ Measure solution AND sink water
- ✓ Use a timer
- ✓ Change water after each "use"
- ✓ Monitor water temperature

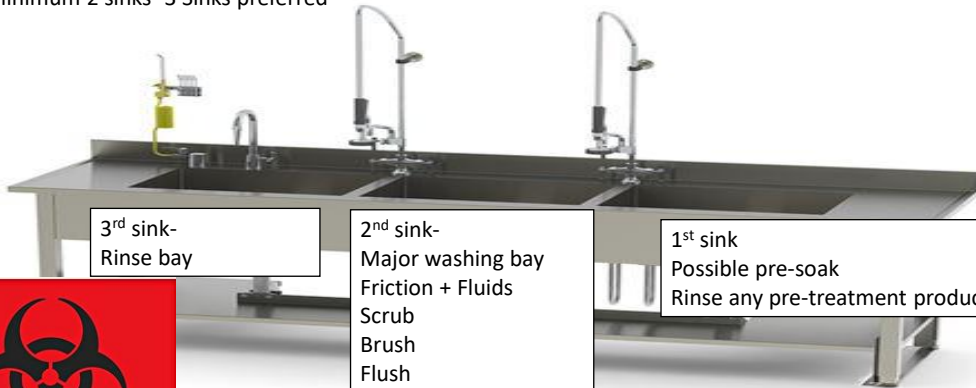


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## Manual Cleaning



Minimum 2 sinks- 3 Sinks preferred



3<sup>rd</sup> sink-  
Rinse bay

2<sup>nd</sup> sink-  
Major washing bay  
Friction + Fluids  
Scrub  
Brush  
Flush  
Clean UNDER the  
water  
Brushes for lumens-  
suitable size/ IFU

1<sup>st</sup> sink  
Possible pre-soak  
Rinse any pre-treatment product



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## Ultrasonic Cleaning



- Remove debris from hard-to-reach areas (joint, crevices, lumens)
- AFTER gross debris removed
- Detergent concentrations and temperature
- Change water after each "use"
- Clean unit daily
- Only approved devices (no plastic, soft or mixed metals)
- Cavitation testing
- Rinse afterwards
- Degas prior to use run cycle with basket and no instruments
- Keep lid closed



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# Cavitation

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## Mechanical Cleaning

### Phases

Prewash

Wash

Rinse

Thermal  
Disinfection

Dry

- Load per manufacturer IFU
- Hinged instruments open
- Heavier devices on bottom
- No silicone mats
- Expiration dates on solutions



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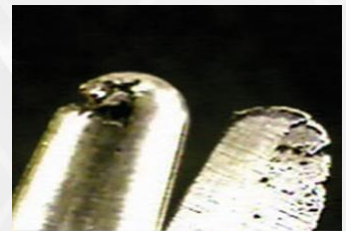
## Cleaning Verification and Inspection



### Required:

Visual inspection

- Optimal lighting
- Magnification
  - Damage- dents, pitting
  - Stains
  - Debris



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## Packaging



- Allow air removal and contact with sterilant
- Protect from contamination, tearing etc.
- Tamper evident
- Allow for aseptic presentation
- Compatible with sterilization method

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## Peel Pouches

- ✓ Appropriate size
- ✓ Appropriate number of instruments
- ✓ Instruments open
- ✓ Tip protectors
- ✓ Labeled plastic side of pouch with sharpie/label
- ✓ Visible Chemical Indicator



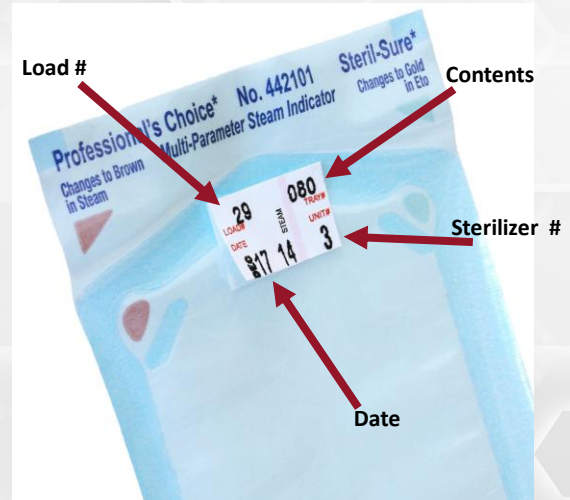
34

## Sterile Processing Department Packaging



### Every package must have:

- ✓ Sterilizer number
- ✓ Cycle and load number
- ✓ Date of sterilization
- ✓ Contents
- ✓ Person who packaged
- ✓ An indicator (internal and external)



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# Monitoring Sterilization Loads






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# Sterilization Monitoring



## Physical Monitoring

-  Time
-  Temperature
-  Pressure

```

=====
***** PREVAC *****
*****
CYCLE START AT 15:14:55
ON 8/11/09

=====
CYCLE COUNT 8675
STERILIZER: 421
CYCLE TYPE PREVAC
CYCLE NO. 4

STER TEMP = 132.2C
CONTROL TEMP = 133.3C
STER TIME = 4 MIN
DRY TIME = 40 MIN

-----
- TIME T= C P=psig V=InHg
-----
C 15:15:17 35.3 0.0P
C 15:16:18 107.6 12.1P
C 15:17:43 85.5 11.1P
C 15:19:19 129.1 26.0P
C 15:21:05 92.7 14.0V
C 15:22:24 130.2 26.1P
C 15:24:09 94.5 15.0V
C 15:25:26 130.2 26.1P
C 15:27:11 95.6 16.0V
S 15:29:45 132.2 28.3P
S 15:30:45 133.5 29.3P
S 15:31:45 133.1 29.1P
S 15:32:45 133.2 29.0P
E 15:33:45 133.2 29.1P
E 15:34:34 105.6 3.6P
E 16:14:35 40.2 28.1V
Z 16:16:11 40.9 1.9V

LOAD 081106

TEMP MAX=133.5C
TEMP MIN=132.2C

CONDITION = 0:14:28
STERILIZE = 0:04:00
EXHAUST = 0:42:26
TOTAL CYCLE = 1:00:54

=====
= READY TO UNLOAD =
=====
    
```

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# Monitoring Sterilization Loads



## Chemical Indicator (CI)

## Biological Indicator (BI)

Daily Air Removal Test

Internal CI

External CI

Process Challenging Device

Biological Indicator

Control

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# Chemical Indicators



Class 1  
Process



Class 2  
Specific Use



Class 3  
Single-variable



Class 4  
Multi-variable



Class 5  
Integrating



Class 6  
Emulating



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## External Chemical Indicators



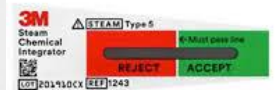
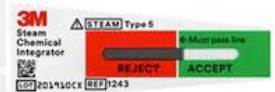
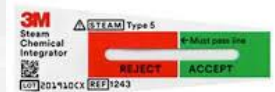
DATE DATUM DATA FECHA	EXPIRATION DATE VERFALL SCADENZA	BROWN BLACK IN STEAM 220901
STERILIZER STERILISATOR MACHINE	LOAD CHARGE CYCLE CICLO	
OPERATOR AUSFÜHRENDER OPERATORE		

**SteriTec** EN ISO 11140-1. TYPE 1



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## Internal Chemical Indicators



Internal Chemical Indicator should be placed so that:

- At least ONE CI is visible to the person opening the package
- In the area or areas considered least accessible to steam penetration
- In accordance with all applicable written IFU

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## Dynamic Air Removal Test



### Daily Air Removal Test (DART)/Bowie Dick

- Type 2 CI
- Every day sterilizer is used
- BEFORE first processed load
- Run short cycle first to heat the sterilizer
- Test same time every day
- Commercially available or facility
- Place over drain in empty chamber



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## Biological Indicators



- ✓ Measures lethality of the sterilization process
- ✓ Ran at least weekly (minimum)
- ✓ Placed inside a PCD
- ✓ Must always have a test tube and a control tube from the SAME lot number
- ✓ Control tube is placed in the incubator without going through a sterilization cycle
- ✓ Test tube is placed in sterilization cycle
- ✓ Control should be positive
- ✓ Test should be negative
- ✓ Documentation REQUIRED



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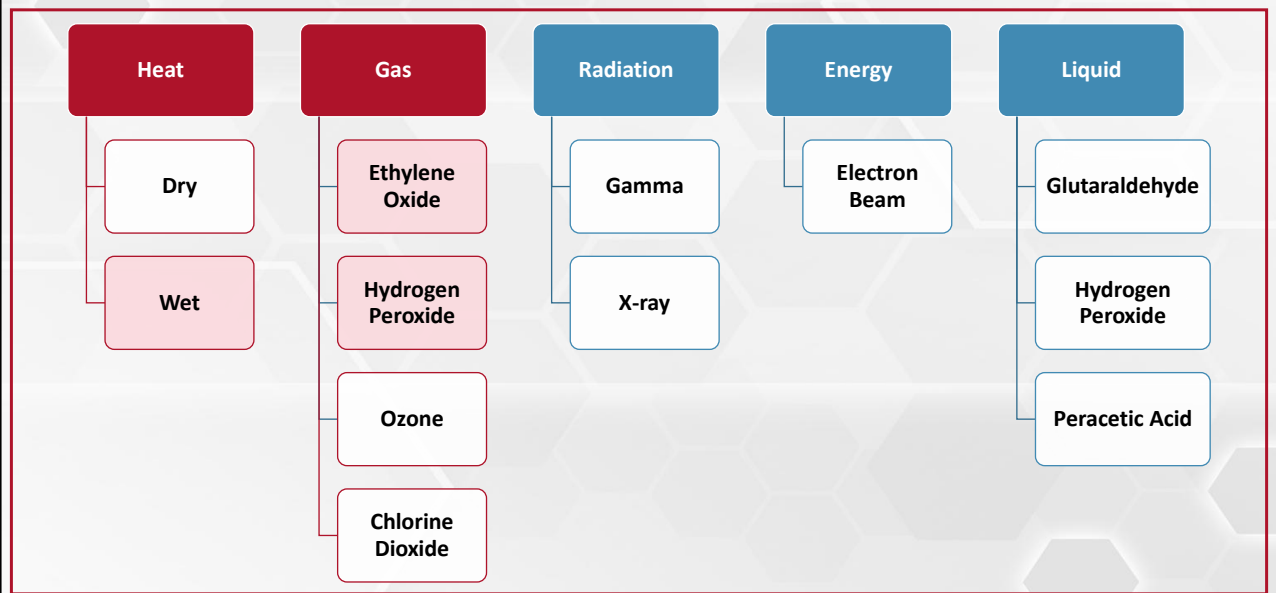
## Process Challenging Device

- Commercially available or facility assembled
- Ran in a loaded chamber
- Placed flat on the sterilizer cart
- Placed in area of greatest challenge
- Cold point is usually center of load towards front of chamber but varies by manufacturer
- Lot number of tested BI should match lot number of control



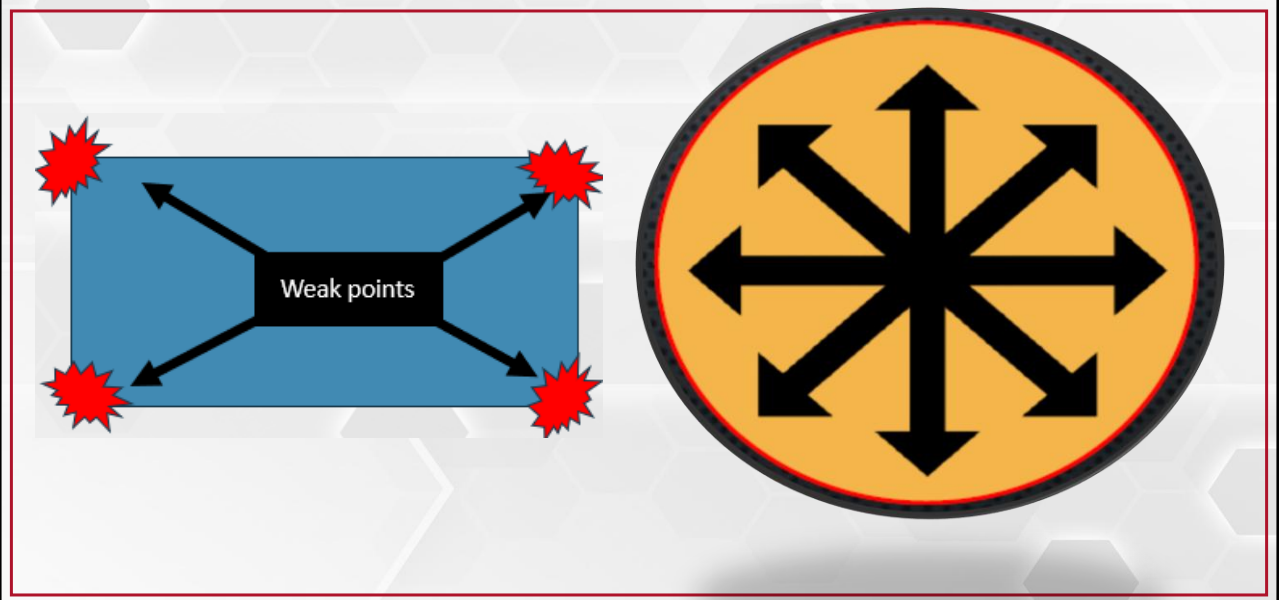
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## Sterilization Methods



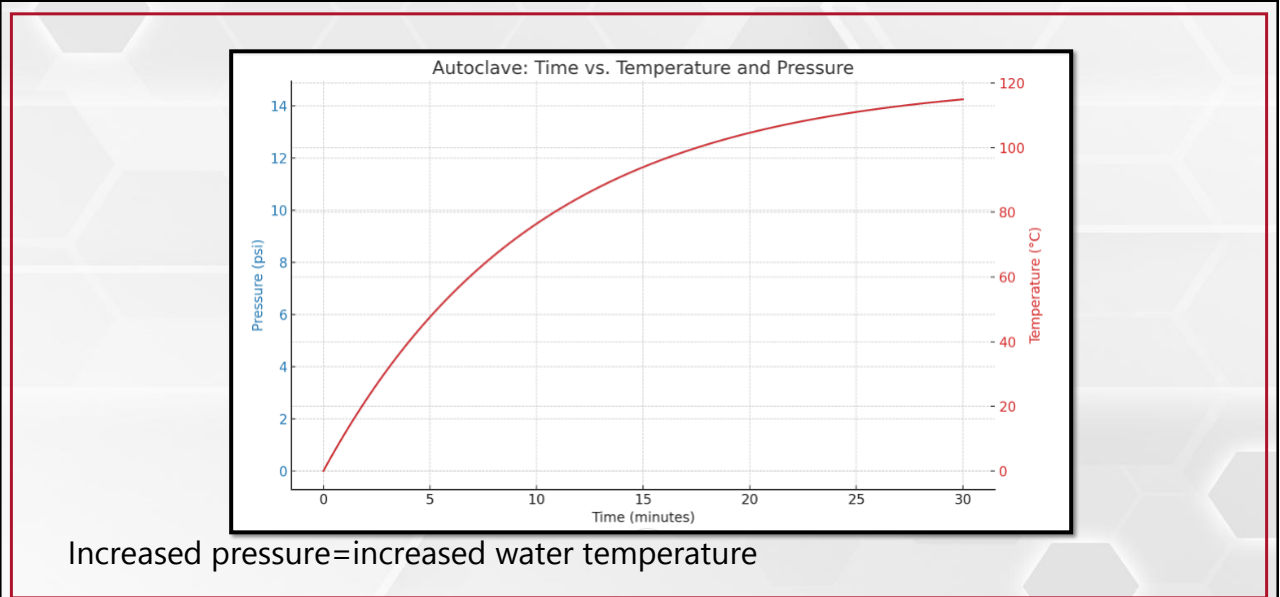
46

## How does it work?



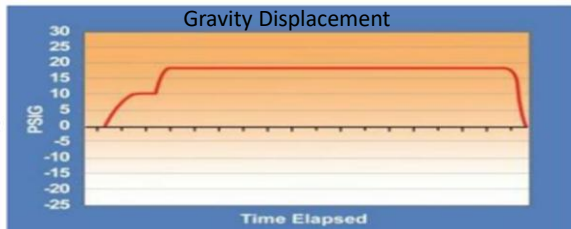
47

## How does it work?



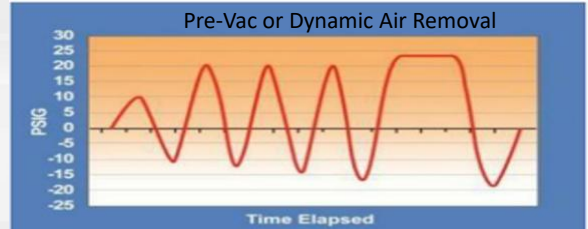
48

## Common Cycle Parameters



- Steam displaces air in the chamber using gravity
- Steam is denser than air
- No mechanical assistance

**121°C/250°F for 30 minutes**  
**15-30 dry time**  
**132°C/270°F for 15 minutes**  
**15-30 dry time**



- Air removed from chamber with vacuum
- Forces steam into instrument areas
- Shorter cycles
- Bowie Dick Test- make sure vacuum is adequately removing air

**132°C/270°F for 4 minutes**  
**20-30 dry time**  
**135°C/275°F for 3 minutes**

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## Alternative Sterilization Methods



### Vaporized Hydrogen Peroxide

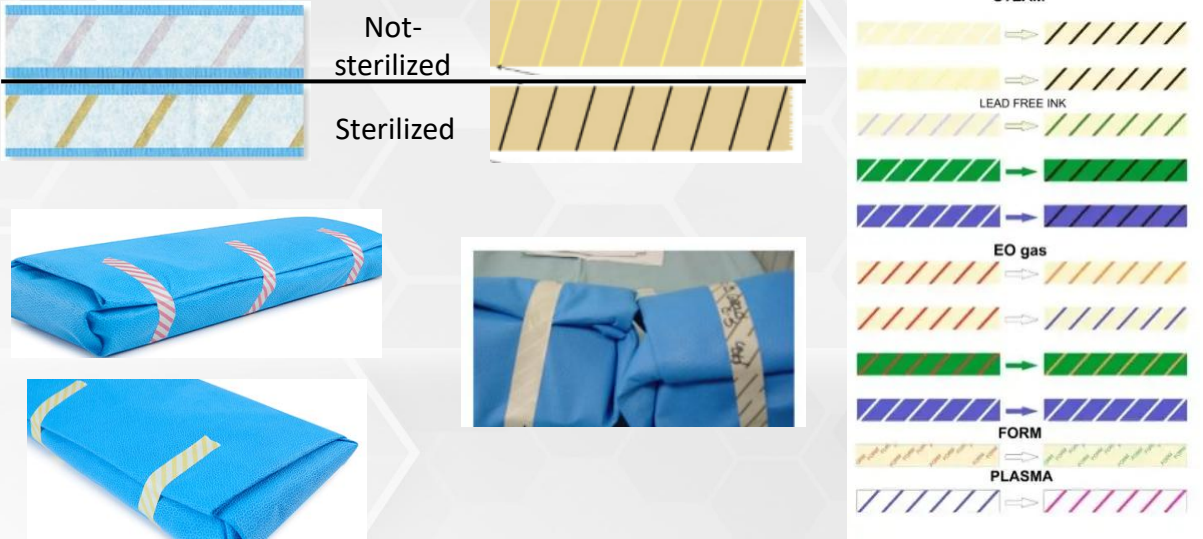
- Low Heat
- Use validated pouches, rigid containers and validation methods
- Lumen and non-lumen cycles

### Ethylene Oxide (EtO)

- Ethylene Oxide gas
- Temperature and moisture sensitive items
- LONG cycle times
- Concerns for exposure

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## Alternative Sterilization Methods



Not-sterilized

Sterilized

STEAM

LEAD FREE INK

EO gas

FORM

PLASMA

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## Loading the Sterilizer

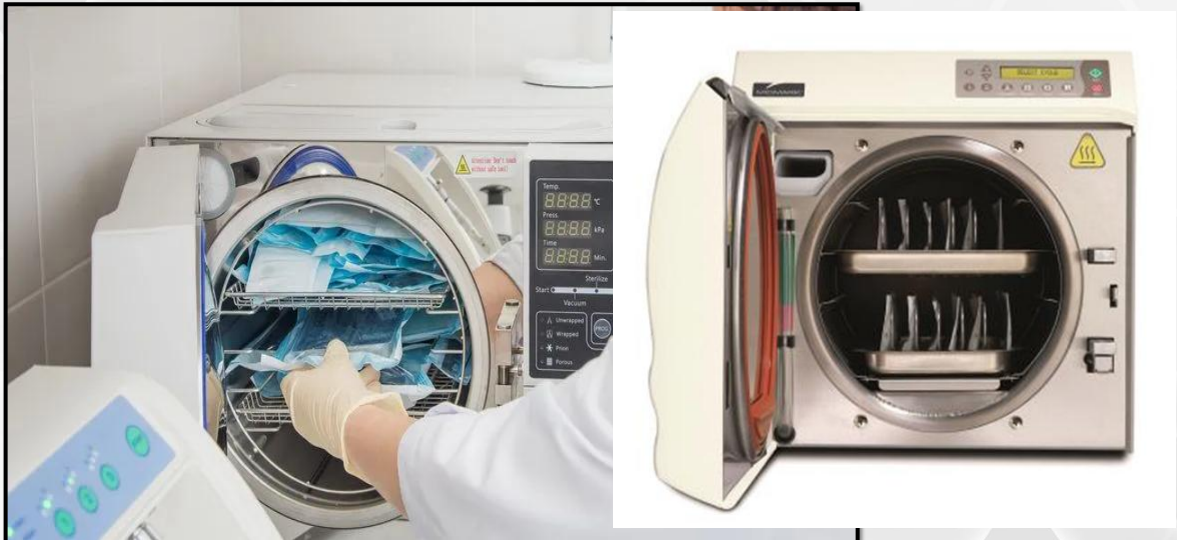
- Same cycle parameters in same load
- Configure to allow for adequate air penetration and removal
- Heavy items on bottom
- No stacking unless approved by manufacturer



- Peel pouches on edge
- Paper-plastic
- Racks to hold pouches

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## Sterile Processing Department Sterilization



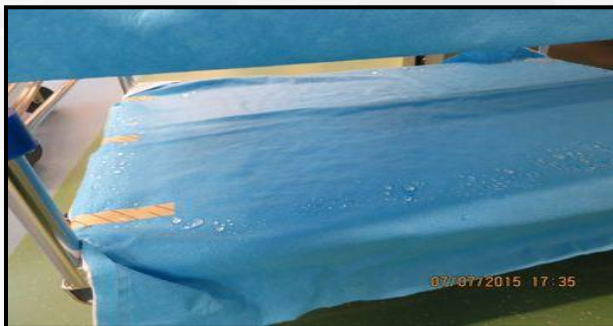
Fischer (n.d.), Arrow  
Electronics (n.d.),  
Midmark

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## Unloading the sterilizer



- Allowed to cool to room temperature
- Do not touch during cooling
- Inspect packages for moisture, damage etc.



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## Special Considerations



### Implants

- The load should be quarantined until the results of the BI testing are available
- Must document emergency release

### Loaner Instruments

- Reprocessed at facility  
Allow enough time
- Need IFU
- Must go through ENTIRE decontamination process

### Immediate Use Steam Sterilization

- Avoid when possible
- Never for implants
- Monitor rates/trends
- Frequent IUSS= add inventory or shuffle cases
- Must be documented

### Eye Instruments

- Read the IFU
- Audit processes
- Keep moist
- Minimize time between use and cleaning
- Careful use of cleaning agents
- RINSE well
- Use ultrasonic

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## Common Challenges



Delays in point of use cleaning

Decentralized Sterilization

Single-use instruments undergo reprocessing

Incomplete cleaning

Complex or damaged instruments

Inadequate drying and packaging

Sterilizer loading/unloading

Staff Turnover

Training & Education

Device Purchasing

Conflicting IFUs

Reprocessing Space

Enough sets for case volume

Immediate-use Steam Sterilization (IUSS)

Appropriate Storage

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## Funding Update

Next Month: Office Hours  
August 21<sup>st</sup> from 12-1 CST

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Questions

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## References



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## IPC Resources



CDC Disinfection and Sterilization Guideline	<a href="https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html">https://www.cdc.gov/infection-control/hcp/disinfection-and-sterilization/index.html</a>
Disinfection & Sterilization (William Rutala)	<a href="https://disinfectionandsterilization.org/">https://disinfectionandsterilization.org/</a>
Healthcare Sterile Processing Association	<a href="https://myhspa.org/">https://myhspa.org/</a>
Centers for Disease Control and Prevention. Summary of Recommendations: Disinfection and Sterilization in Healthcare Facilities	<a href="https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html">https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/summary-recommendations.html</a>
Steris Knowledge Center	<a href="https://www.steris.com/healthcare/knowledge-center">https://www.steris.com/healthcare/knowledge-center</a>
American Academy of Ophthalmology TASS Resources	<a href="https://www.aao.org/assets/df424a5c-a186-4cff-b307-d50b7368b241/635266898473330000/tass-resources-revised-2012-pdf">https://www.aao.org/assets/df424a5c-a186-4cff-b307-d50b7368b241/635266898473330000/tass-resources-revised-2012-pdf</a>
The Association for the Advancement of Medical Instrumentation	<a href="https://www.aami.org/">https://www.aami.org/</a>
SHEA Mult society guidelines	<a href="https://shea-online.org/guidance/multisociety-guidance-for-sterilization-and-high-level-disinfection/">https://shea-online.org/guidance/multisociety-guidance-for-sterilization-and-high-level-disinfection/</a>
TJC HLD and Sterilization Booster Pak	<a href="https://sdapic.org/wp-content/uploads/2015/12/TJC-HLD-BoosterPak-Dec-2015.pdf">https://sdapic.org/wp-content/uploads/2015/12/TJC-HLD-BoosterPak-Dec-2015.pdf</a>

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## Office Hours



- If you have a questions
  - Raise hand and our admin will take you off mute
- OR
- Enter your question into the chat
- If you have additional questions that are not answered, you can email us at [infoforipslice@nebraskamed.com](mailto:infoforipslice@nebraskamed.com)

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