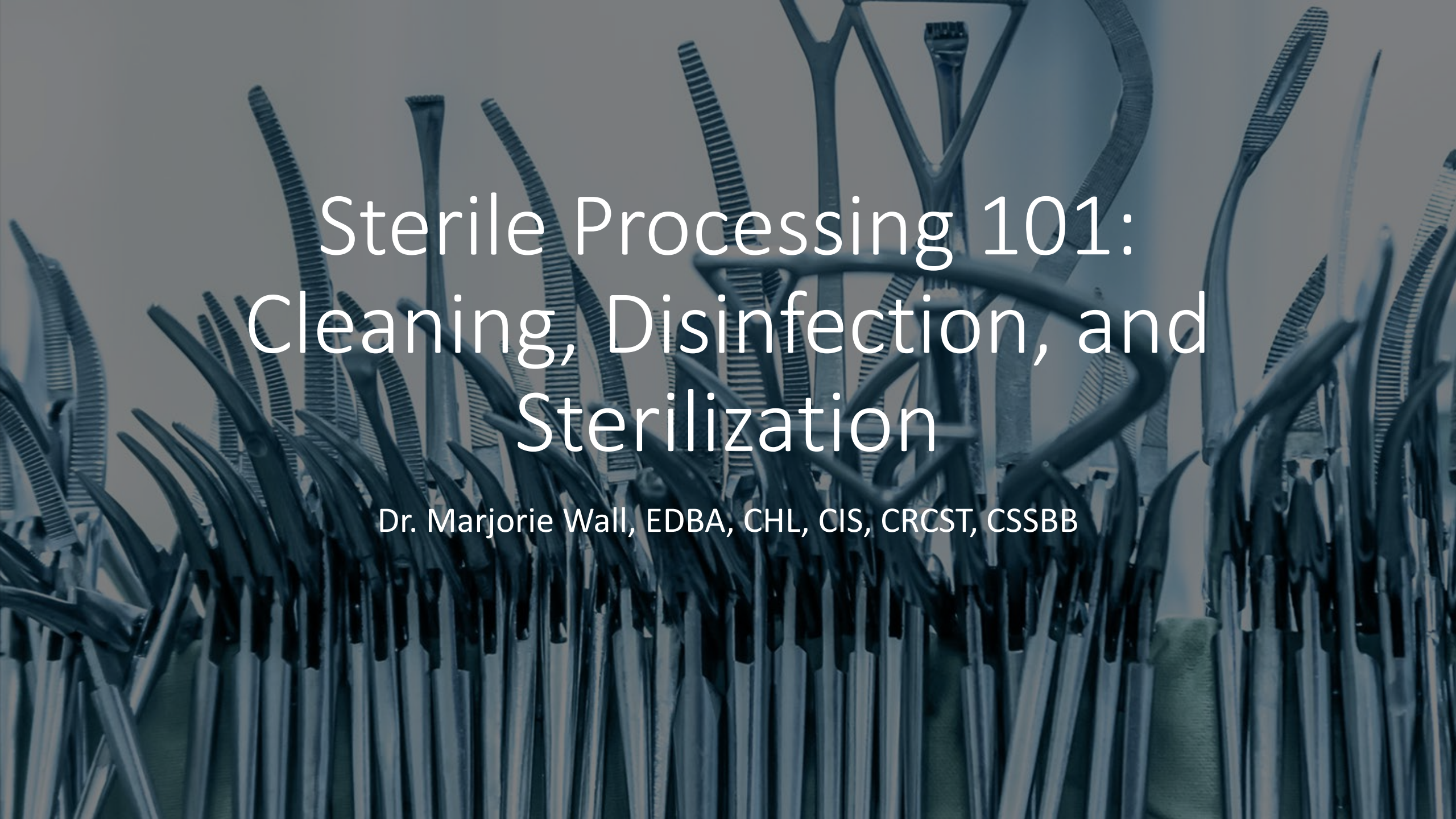
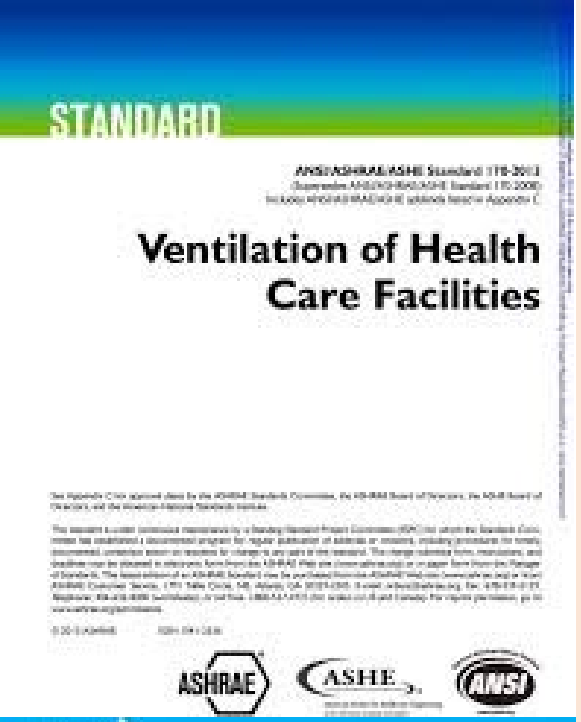


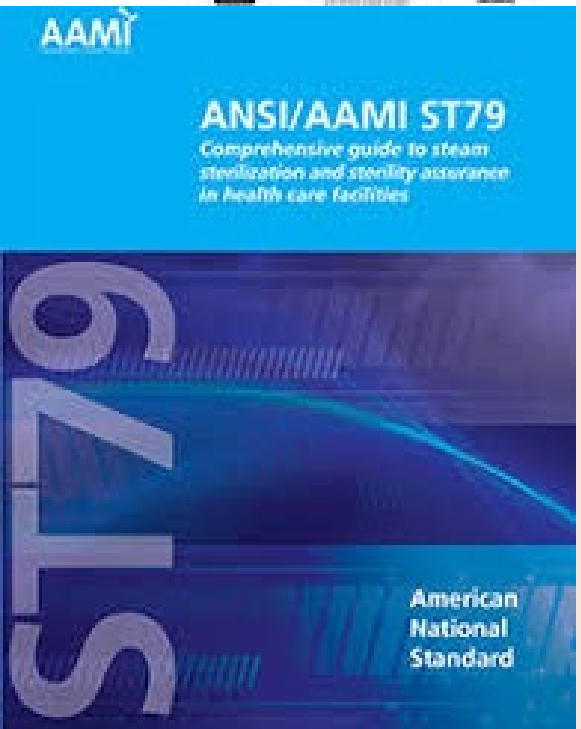
Sterile Processing 101: Cleaning, Disinfection, and Sterilization

Dr. Marjorie Wall, EDBA, CHL, CIS, CRCST, CSSBB

Objectives

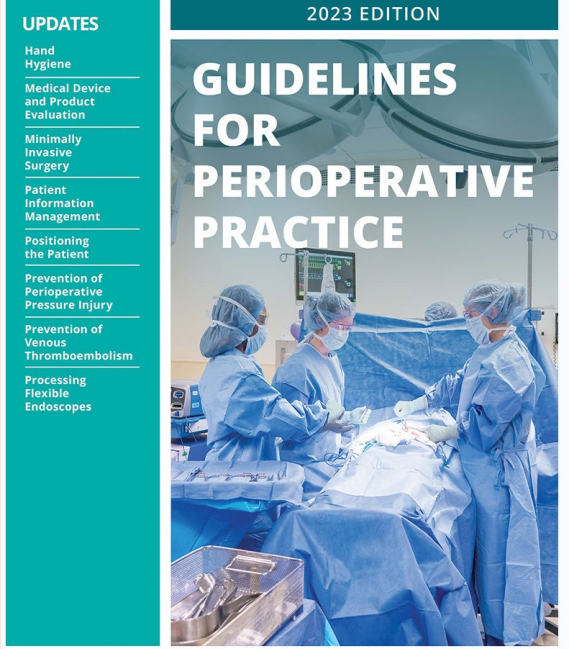
- At the end of this lecture, participants will be able to:
  - Discuss facility, personnel and decontamination best practices for instrument reprocessing.
  - Explain instrument preparation, sterilization and sterile storage best practices.
  - Identify basic steps for high-level disinfection of flexible gastrointestinal endoscopes.

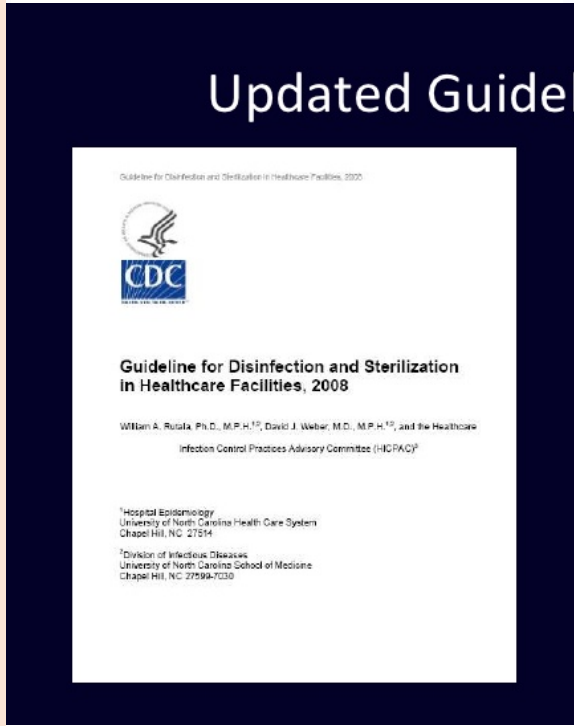




Standards

- In the United States, AAMI, AORN, ASHRAE and the CDC set the guidelines and best practices for instrument reprocessing.





Facility Design Ventilation

Functional Area	Airflow	Air Exchanges
Decontamination	Negative	10
Sterilizer Equipment Access	Negative	10
Sterilizer Loading and Unloading	Positive	10
Prep and Pack	Positive	10
Textile Pack Room	Positive	10
Clean/Sterile Storage	Positive	4

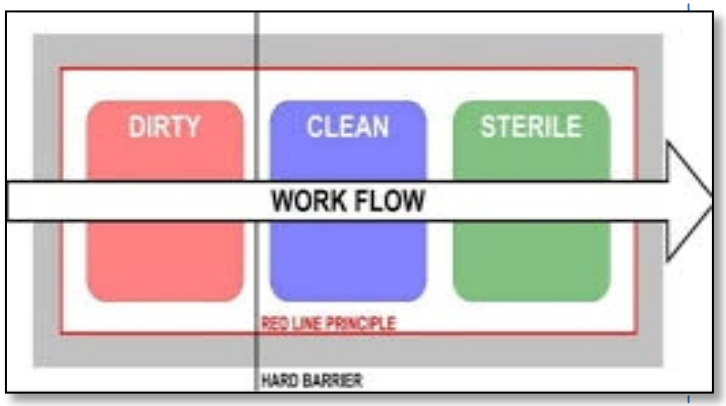
Facility Design Temperature/Humidity

Note: Conflicting Standards, Recommend Conducting Risk Assessment.

Functional Area	Temp	Humidity
Decontamination	60-65F	30-60%
General Work Area	68-73F	30-60%
Sterilization Equipment Room	75-85F	30-60%
Sterile Storage	Up to 75F	Up to 70%

Facility Design

- Clean and Dirty Areas must be physically separated or 36” apart.
- People flow must move from clean to dirty.
- Equipment flow must move from dirty to clean.



No Cross Contamination

Environmental Consideration

- Floors and horizontal work surfaces
  - Clean and disinfect daily
  - Floor should be seamless, not grout
- Walls and storage shelves should be cleaned regularly on a scheduled basis
- Ceilings and Walls should not be made of shedding or porous materials

Sterile Processing Flow

Effective Cleaning CANNOT Take Place Without Effective Precleaning

- Why is that?
- Precleaning prevents formation of BIOFILM.
- Biofilm is “a group of microorganisms that form on a solid surface that comes in contact with water.”
- Biofilm can harbor resistant microorganisms reducing the effectiveness of sterilization.

Cleaning Starts on the Procedural Field

- Wipe instruments using a sterile, water moistened sponge.
- Instruments with lumens should be flushed with sterile water.
- Saline, bleach, or other solutions should NEVER be used.

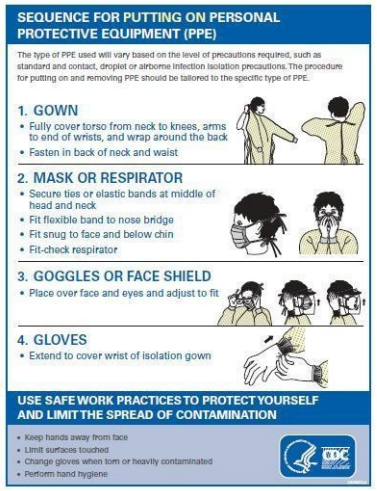
Point of Use Cleaning

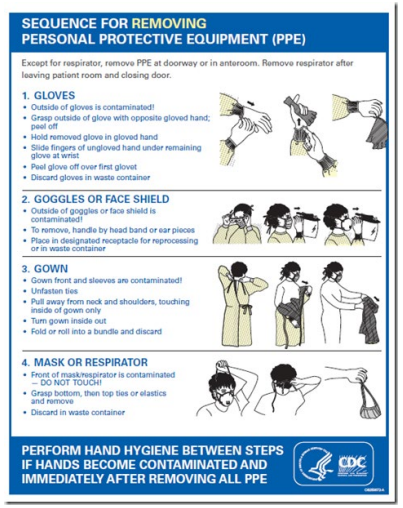
- Precleaning prevents damage of instrumentation and equipment.
- Dried blood is corrosive and causes pitting, rusting, and metal fatigue.
- Damaged instruments and equipment is unsafe to use on patients and can harbor microorganisms.

Biohazardous Transport

Must be Puncture Proof, Liquid Proof, and Labeled as Biohazardous.

Decontamination PPE





REQUIRED PPE FOR DECONTAMINATION ROOM

DONNING:

1. Hair cover
2. Shoe covers
3. HH
4. Gown
5. Mask
6. Goggles or face shield
7. Gloves

DOFFING:

1. Shoe covers
2. Gown w/ gloves
3. Goggles or face shield
4. Mask
5. Hair cover
6. HH

Full PPE must be worn by decontamination staf or those performing decontamination tasks.

Others entering must don shoe covers, gown and hair cover.

Decontamination Chemicals

- Enzymatic?
- Validate Dosing Accurate
- Validate NOT Expired
- Validate Approved by OEM
- No Topping Off

AAMI ST108

Table 5—Frequency for water quality monitoring at water generation system

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*	
			Utility Water	Critical Water
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Quarterly	Monthly
Conductivity	Conductivity meter (in line or by measurement of a collected sample)	After the last treatment step, Storage tanks (if used)	Quarterly	Daily
Total Alkalinity	Colorimetric dipsticks Alkalinity test kit**	After the last treatment step, storage tanks (if used)	Quarterly	Monthly
Total Hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit**, or Handheld meter**	After the last treatment step	Quarterly	Monthly
Bacteria	Heterotrophic plate count (see Annex H)	Loop out and loop return points	N/A	Monthly
Endotoxin	LAL test (see Annex H)	Loop out and loop return points	N/A	Monthly

*NOTE 1 The recommendations for frequency of testing in this table are the recommended minimum frequency. If problems or issues arise with the water quality, it may be necessary to increase the frequency until they are resolved.

**NOTE 2 When using these tests, the user should carefully follow the manufacturer's written IFU for accurate results. When measuring Critical Water levels, the water sample must be filled to the brim for these test kits, sealed and, if the sample is hot, allowed to cool to room temperature before testing. Testing within 15 minutes of sample collection prevents carbon dioxide absorption that can result in an inaccurate pH.

Decontamination
Manual Cleaning

- Brushing of Instruments
- Nylon brushes are used to remove debris from instruments.
- Brushing should occur as follows:
  - Under water line to prevent aerosolization.
  - Brush all Serrations
  - Brush all hinges.
  - Brush all lumens

Decontamination Ultrasonic Cleaning

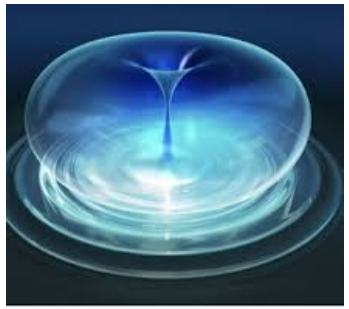
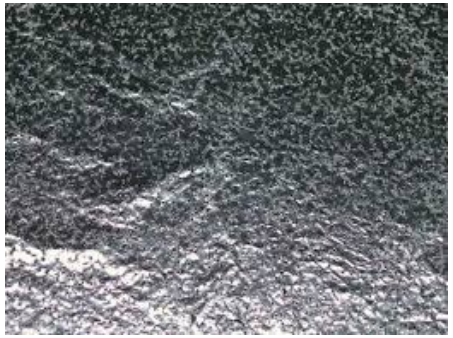


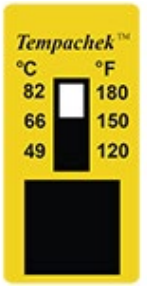
Fig. 1 - Illustration of an imploding cavity in a liquid irradiated with ultrasound

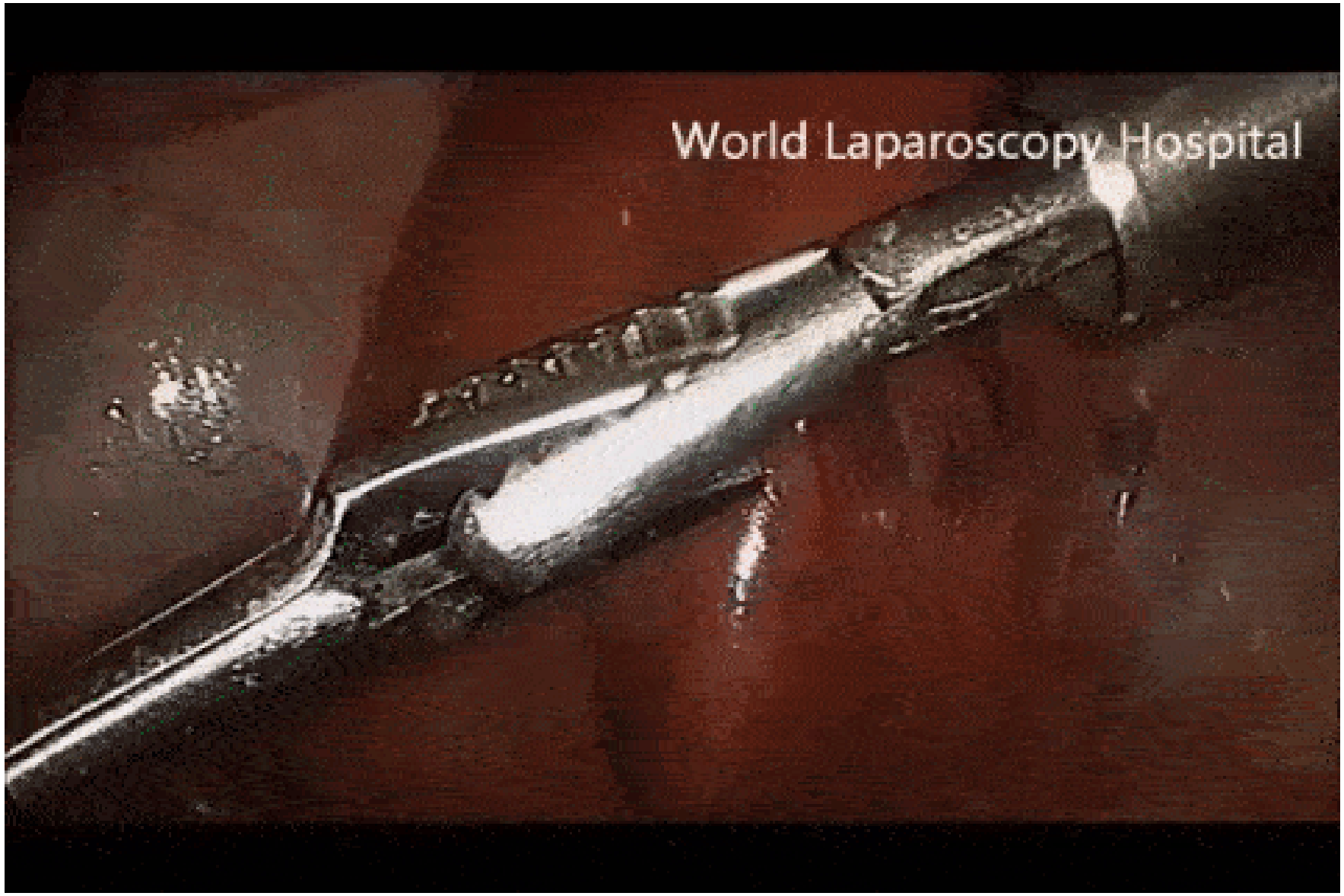


Decontamination
Automated Cleaning

- Place instruments in a position ensuring maximum exposed surface area through the automated wash process.
- Stringer should be placed so that hinged instruments are held in the open position.

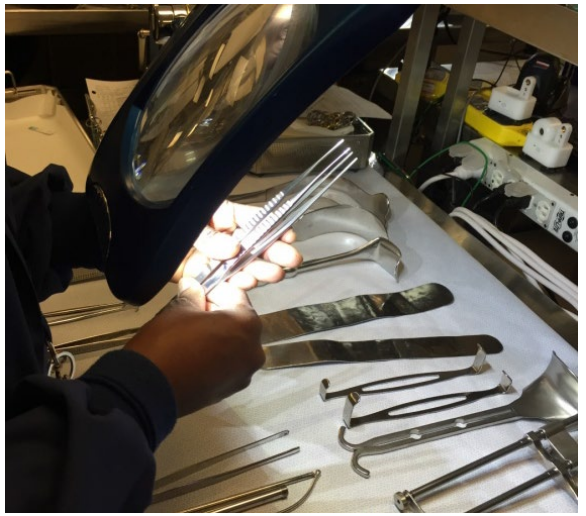
Decontamination
QA Testing




World Laparoscopy Hospital

Assembly Inspection

- Check each instrument for the following:
  - Corrosion
  - Rust
  - Pitting
  - Cracks
  - Burrs
  - Sign of wear
- If any of the above are found, remove the instrument from service.



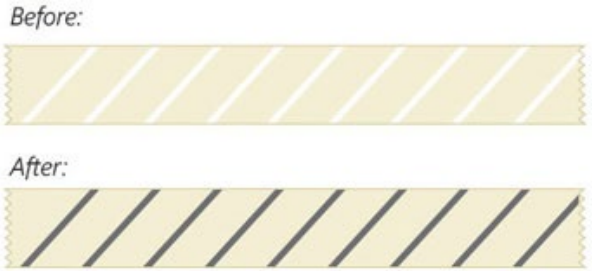
Assembly Inspection

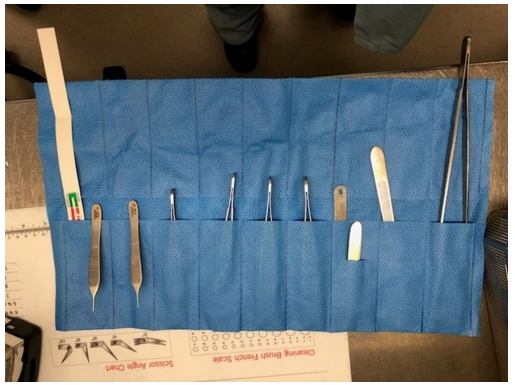
- Check each instrument for functionality:
- Scopes
  - Visual inspect lens for cracks or water penetration
  - Verify optics not damaged
- Cameras
  - Verify prisms not cracked or wet internally
  - Check for damaged cords
- Light Sources
  - Verify fiber optics not damaged

Assembly Stains

Stain Color	Probable Cause
Brown/Orange Stains	High pH - improper soaps, baked on blood, soaking in saline or using laundry soap (usually is not rust)
Bluish-Black Stains	Exposure to saline, blood or potassium chloride Reverse plating if two types of metals are placed in ultrasonic together
Light and Dark Spots	Water spots from allowing instrument to air dry
Dark Brown/Black Stains	Low pH acid stain - detergents or dried blood
Multi-Color Stains	Excessive heat - “hot spots” in autoclave
Bluish-Gray Stains	Cold sterilization solution used outside manufacturer guidelines

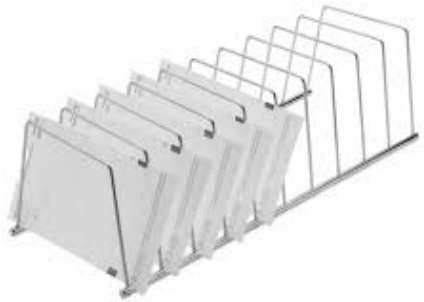
Assembly Chemical Integrators

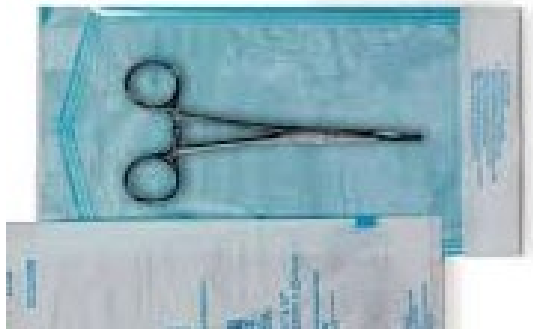


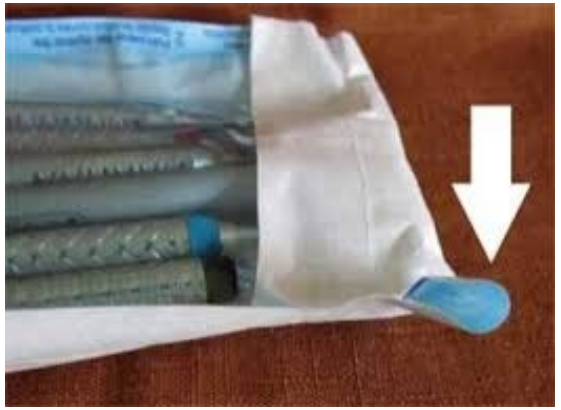


Packaging Peel Pouches

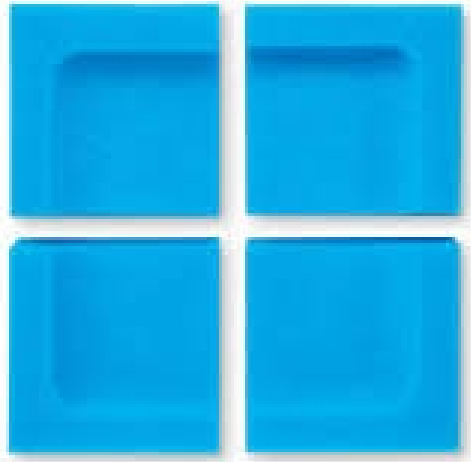
- Size of Peel Pouch: 1” around instrument.
- Handle located by cheveron
- Chemical integrator included
- Tip Protector if appropriate
- Double Peel Pack only if validated
- Do not overload with too many instruments
- Do not use inside trays
- Sterilize paper to plastic on side

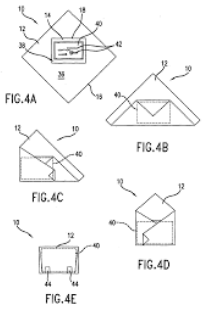


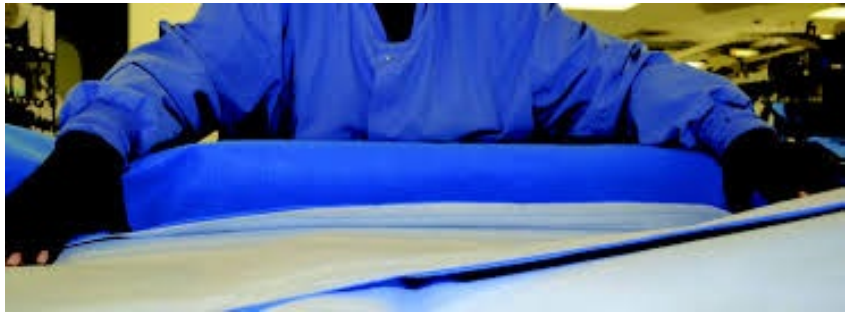




Packaging Polypropylene Wrap



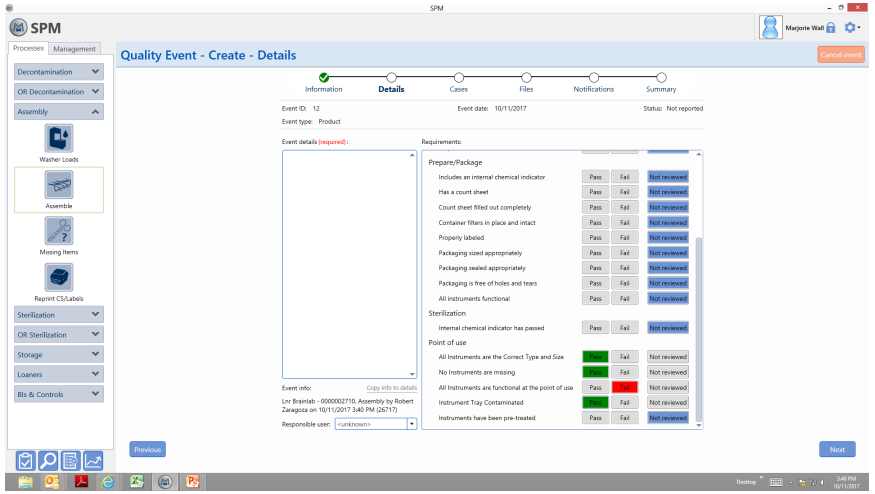




Packaging Rigid Containers

Assembly QA

- OR leadership documents tray defects in SPM.
- When process out of control, partner with SPD leadership to fix.



IUSS Sterilization

- Rapid Sterilization Process for Emergency Use
- Instruments Must Be Validated by OEM
- Implants Should Not Be IUSS'd
- Transport Closed Container
- Can Be Wet
- Tray Cannot be Stored for Another Patient

Prevac Steam Sterilization

- Minimum 270F 4min 20min Dry
- Must Not Be Wet
- Load Configuration:
  - Linen
  - Peel Pouches
  - Wrapped Items
  - Rigid Contianers

Prevac Sterilization QA

- Required Testing:
  - Bowie Dick Test 1st Load Daily
  - Biological for Weakest Cycle Daily
  - Biological in Every Implant Load
- Sterilizer Qualification Testing
  - 3 Consecutive Biological
  - 3 Consecutive Bowie Dick
- Document Lot Number and Expiration Date
- Start a new control daily or when lot number changes

Low Temperature Sterilization

- H202 Based Technology
  - Plasma or Vaporized
- Used for Heat Sensitive Items
- Only Items Validated for Cycle Can be Ran
- Weight Restrictions on Loads
- No Porous or Absorbent Materials (paper)
- Only Chemical Integrators and Tape Validated can be used

Sterile Integrity

- Items should be stored as not to crush, compress, puncture or compromise sterility of contents.
- Whenever there is a question as to whether the package is sterile or not, it is considered unsterile.

Sterile Storage

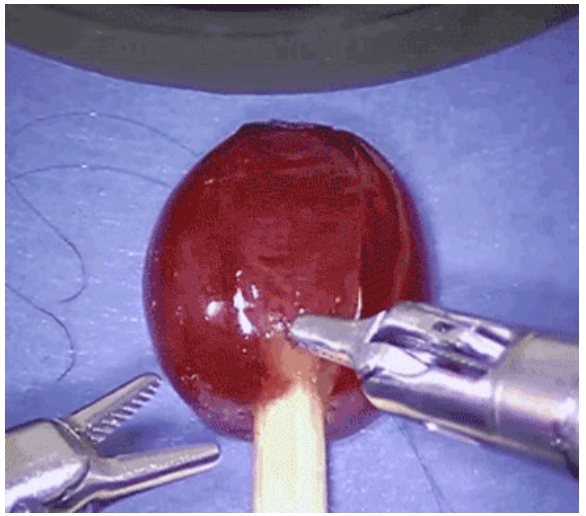
- Configure so Wrapped Trays are Not Stacked
- Items are Stored Ergonomically Correct

Sterile Transport

- Sterile Trays should be covered during transport to protect from contamination.
- Trays should be handled minimally to prevent damage to packaging.

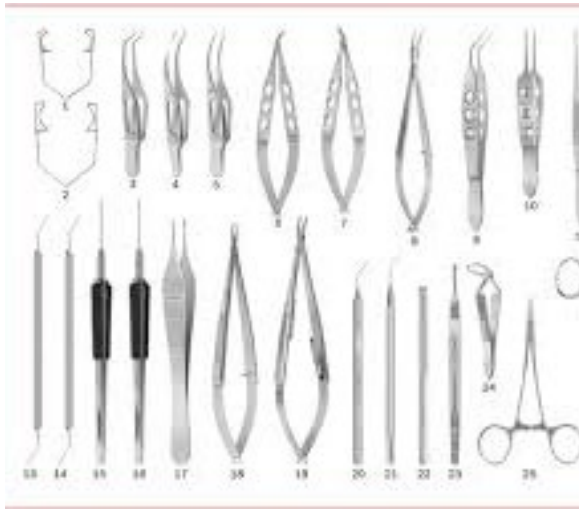
Robotic Inst Considerations

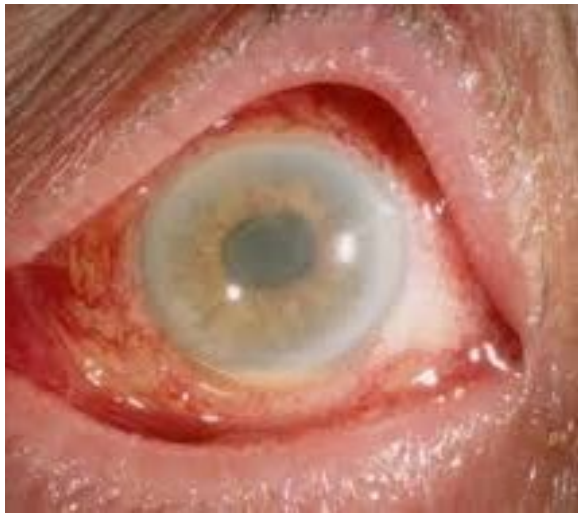
- Davinci Robotic Instruments require special processes to clean and sterilize.
- Routine Direct Observation Competencies
- Specialized Sonic
- Specialized Rigid Containers and Wraps
- Robotic Check for QA
-



TASS Considerations

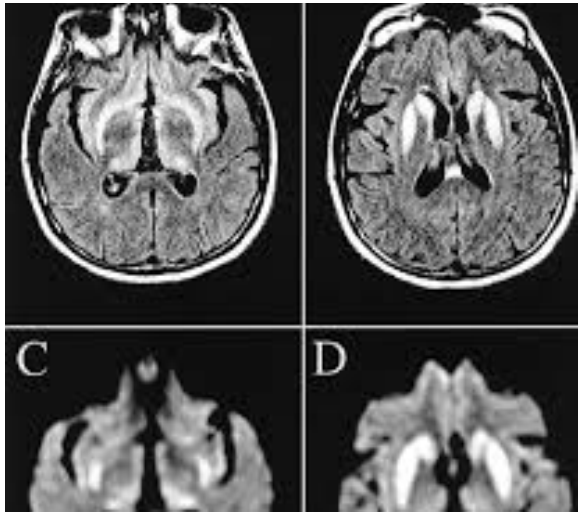
- Multiple Outbreaks
- RCA completed
- Enzymatic Detergents
- Eye Instruments MUST go through a full rinse, preferably with deionized water.
- Lumens must be flushed with water profusely prior to sterilization
-

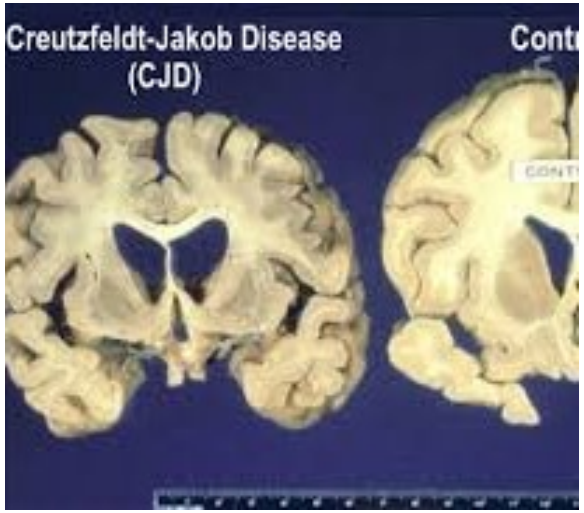




CJD Considerations

- CJD Risk for any procedures involving dura matter, spinal fluid, back of eye
- If unknown, treat as CJD.
- Process required for surgery to communicate to SPD
- Internal risk assessment for how to handle trays
- Single Use Instruments?
- CJD Cycle: 134C for 18 minutes





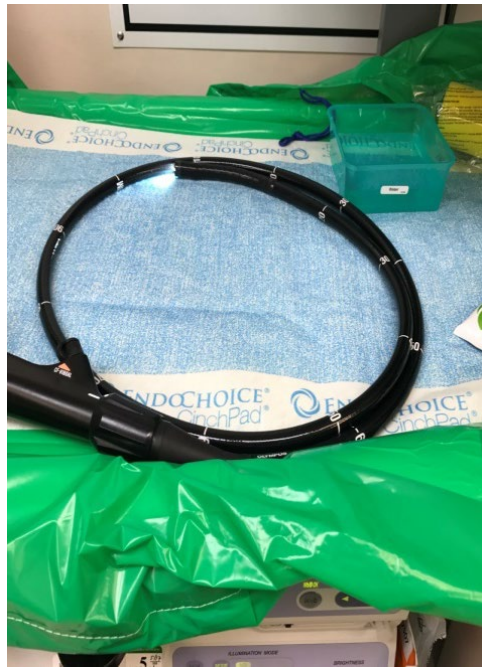
AAMI

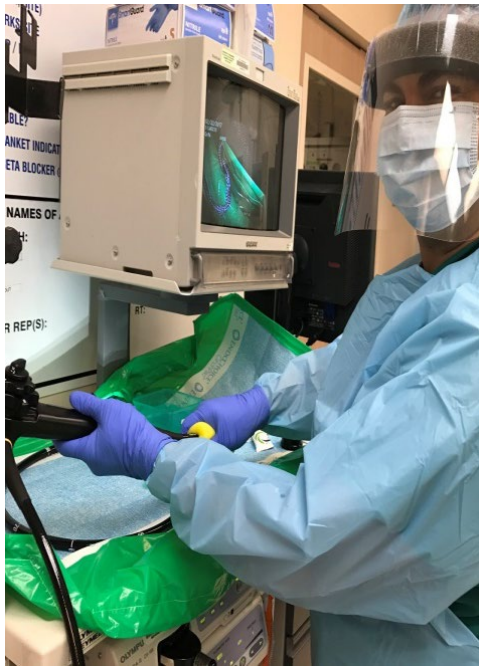
HICPAC
HEALTHCARE INFECTION CONTROL
PRACTICES ADVISORY COMMITTEE

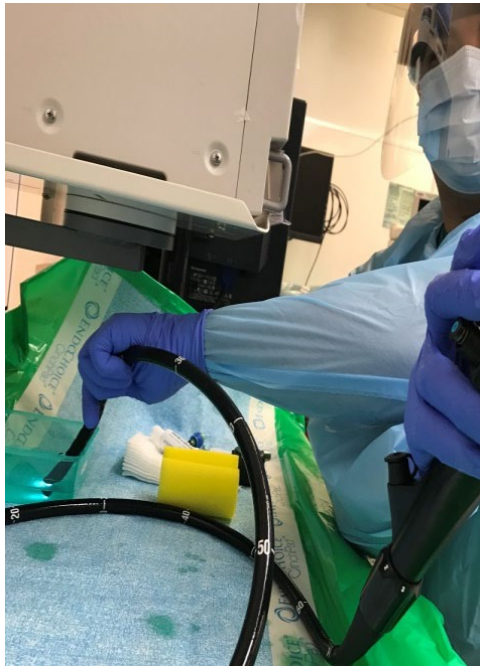
Flexible Scopes Standards

https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html

SGNA







Flexible Scopes
Point of Use Cleaning

Flexible Scopes Processing Steps

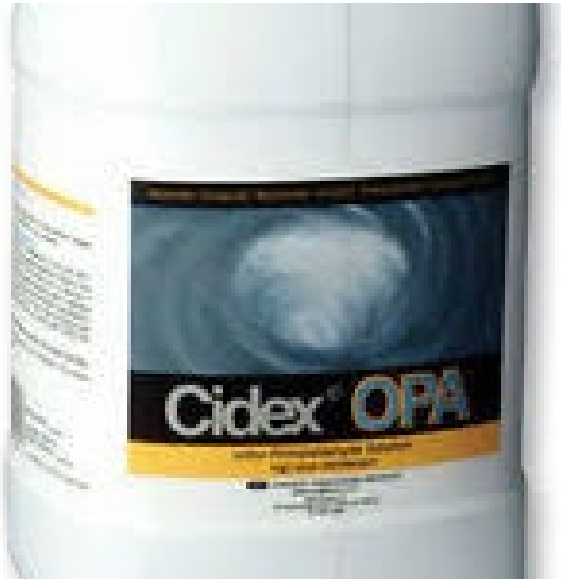
- Follow the OEM IFU!
  - Pre-Clean Scope
  - Leak Test Scope
  - Manual Clean
    - Follow Directions Exactly.
    - Includes: Brushing, Flushing, and or Suctioning
  - Rinse after Cleaning
  - Visual Inspection
  - High Level Disinfection
  - Rinse after HLD
  - Dry (alcohol if required by OEM
  - Store

Flexible Scope Decontamination

- Three Bay Sink
  - Sink 1 Leak Test
  - Sink 2 Soak/Brush/ Flush
  - Sink 3 Rinse
- Dirty to Clean Flow
- 36” or physical barrier between dirty and clean
- Same PPE and Chemical Requirements as SPD

Manual
High Level Disinfection

- Ensure chemical is validated by Scope OEM
- Manual Solutions require specific time, temperature, and length of use following manufacturer IFU.



Manual
High Level Disinfection

- Chemical may require activation.
- Date chemical opened and date expired after opening
- Chemical Strip Opening and Testing
- After expiration, chemical may need to be neutralized prior to disposal.
- PPE should always be worn when handling chemicals.
- Never Top Off
- Have a Spill Kit and Eye Wash

Manual
High Level Disinfection

- Scope must stay fully submerged for OEM required time
- Temperature must meet OEM requirement
- Rinse must be completed with sterile or filtered water according to OEM

*CIDEX SOLUTIONS TRAY NOT INCLUDED

Automated Endoscope Reprocessor HLD

- Ensure your scope is validated for your machine.
  - Ensure you have all required attachments
- Scope washers do not replace manual cleaning

Automated Endoscope Reprocessor HLD

- Machine should be self disinfecting
- No Residual water should remain in hoses and reservoirs
- Cycles for alcohol flushing and forced air drying are desirable
- Self Contained or external water filtration system
- Follow Scope OEM and AER OEM instructions exactly

High Level Disinfection Documentation

- GI Scope Processing must be traceable between patients
- Time between steps documentation is Best Practice (if too much time elapses, extended processing is required)
- Leak Testing pass or fail must be documented
  - If fail, scope must be sent out for repair
- Chemical Strip Test should be completed and documented daily and on each cycle.
- Temperature of Chemical Solution
- Exposure Time of Chemical Solution

Flexible Scopes Storage

- Storage cabinets should be made of a material that can be disinfected.
- In Conventional Storage (no drying options) scopes are hung vertically to facilitate drying.
- When using drying cabinets, follow OEM IFU for how to position scopes.

Flexible Scopes Storage

- Removable buttons and valves should be reprocessed and stored with the scope as a unique set for tracking patient to patient
- Hung scopes should not come in contact with each other, and gloves should always be worn to prevent cross contamination.
- **SGNA Supports a 7 Day Hang Time**
  - Do a Risk Assessment

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