2019
APIC Applied Learning Conference

APIC EDUCATION

Becoming an Expert IP for the Sterile Processing Department

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APIC
Association for Professionals in Infection Control and Epidemiology

Disclosures

- No relevant disclosures

About me:

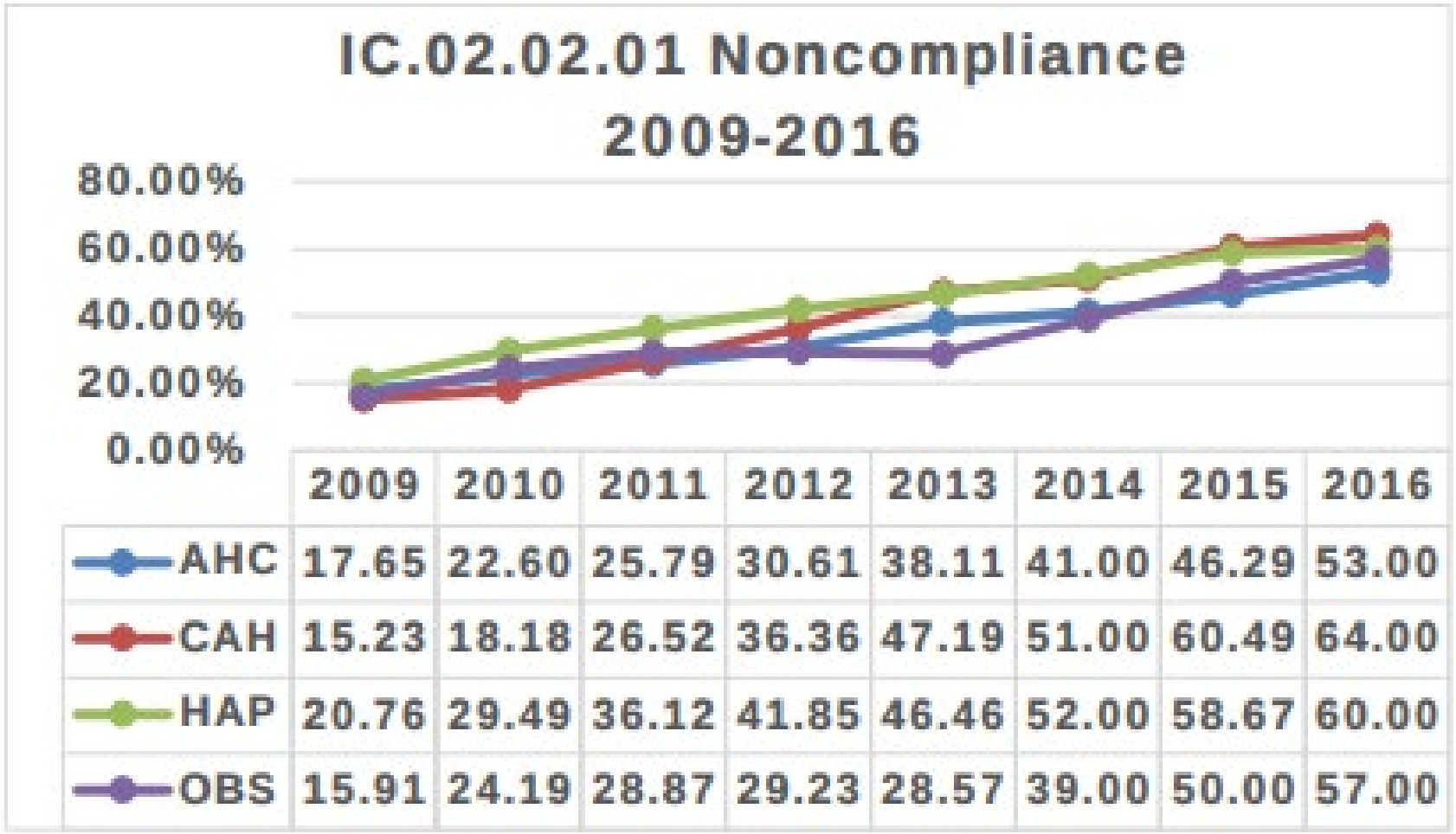
- AAMI ST79 – Steam Sterilization Practices working group – 2016 - present
- IAHCSMM member, CRCST & CHL certifications
  - Prairie Pioneers (North Dakota chapter) Vice President, 2015 - present
  - IAHCSMM nominating committee, 2016
- AHRMM member
- NoCoast Consulting, LLC

Objectives

- Gain understanding of tools and equipment
- Examine critical survey areas
- Develop strategies to enhance collaboration between Sterile Processing and Infection Prevention and Control

This icon indicates a topic frequently addressed in surveys

TJC Standard IC.02.02.01 requires organizations to reduce the risk of infections associated with medical equipment, devices and supplies.



	2009	2010	2011	2012	2013	2014	2015	2016
AHC	17.65	22.60	25.79	30.61	38.11	41.00	46.29	53.00
CAH	15.23	18.18	26.52	36.36	47.19	51.00	60.49	64.00
HAP	20.76	29.49	36.12	41.85	46.46	52.00	58.67	60.00
OBS	15.91	24.19	28.87	29.23	28.57	39.00	50.00	57.00

- AMB = Ambulatory
- CAH = Critical Access Hospital
- HAP = Hospital
- OBS = Office-Based Surgery

*Courtesy of jointcommission.org

General Considerations for Cleaning & Disinfection

FDA defines reprocessing as:

- A validated process used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use.
- These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection and sterilization. (FDA 2015)
- Reprocessing involves the following sequential steps: 1) point-of-use processing, 2) thorough cleaning, and 3) disinfection and sterilization

Spaulding Scale and Manufacturer's IFU's Determine Processing

Processing Critical Devices

- Penetrate or enter normally sterile tissue or spaces, including the vascular system
  - Surgical instruments
- Must be sterilized between uses or used as single- use disposable devices
- **Goal: Sterility, devoid of all microbial life**

Processing Semi-Critical Devices

- Contact mucous membranes and non-intact skin
  - Mouth mirrors, cheek retractors, laryngsocope blades
- Must be sterilized or immersed in high-level disinfectant
- **Goal: High-level disinfection = free of all microorganisms except low numbers of bacterial spores**

Processing Non-Critical Devices

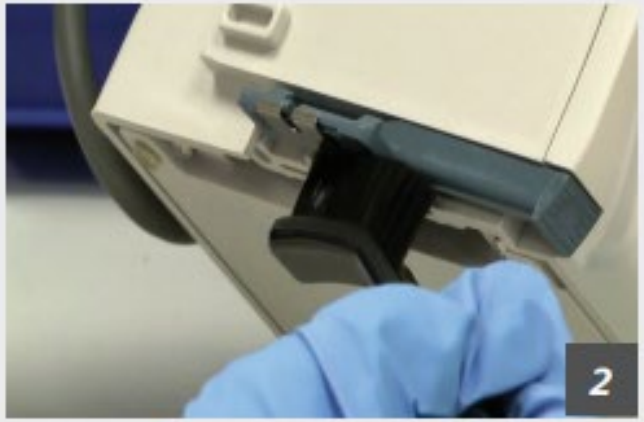
- Contact intact skin
  - BP cuffs, electrocardiogram (EKG) leads, stethoscopes
- Environmental surfaces are also in this category
- Disinfect using a low level disinfectant
- Can be cleaned in the environment they were used, do not have to be centrally processed
- **Goal: Kill vegetative bacteria, fungi, viruses**

Some non-critical items SHOULD be centrally processed

Cleaning the case—use recommended cleaners when possible

Make sure the instrument is upright and turned off, unplug the power cord and wipe all exposed device surfaces **EXCEPT** the inter-unit interface (IUI) connectors.

DO NOT use an oversaturated cloth. Be sure to squeeze out excess liquid.



Use a dedicated soft-bristled brush to clean the case to remove any visible residue. The brush may also be used to clean narrow or hard-to-reach areas.

DO NOT use any hard, abrasive or pointed objects to clean any part of the instrument.

Follow the cleaner manufacturer's instructions on the time to leave it on the device surface. Then, remove the cleaner using a soft cloth dampened with water.

DO NOT allow the cleaner to collect on the instrument.

Cleaning the IUIs—70% isopropyl alcohol (IPA) ONLY

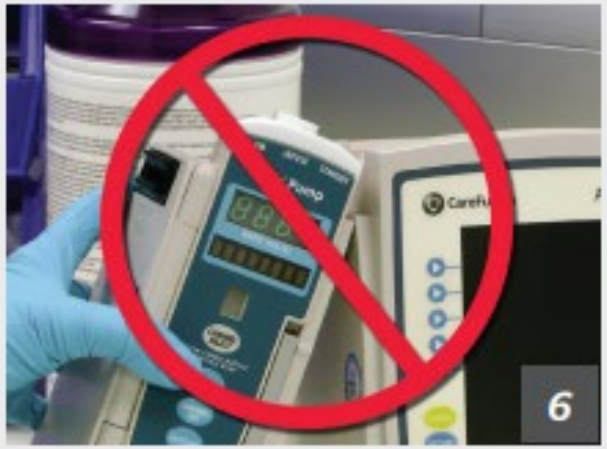
Apply 70% IPA directly to the dedicated IUI cleaning brush. To prevent cross-contamination, do not dip the brush into the IPA.

DO NOT use the same brush used on the case to clean the IUI connectors. Doing so could inadvertently transfer the cleaner or contaminants to the electrical contacts.

Clean both IUIs with the dedicated IUI cleaning brush.

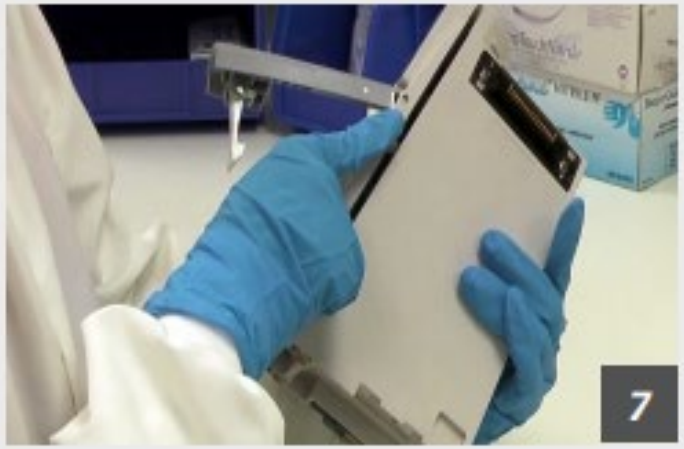
To avoid accidental fluid deposits on the connectors, DO NOT use any spray cleaners anywhere near the IUI connectors. NEVER ALLOW ANY CLEANER OTHER THAN 70% IPA TO CONTACT THE IUI CONNECTORS.

Drying and inspection



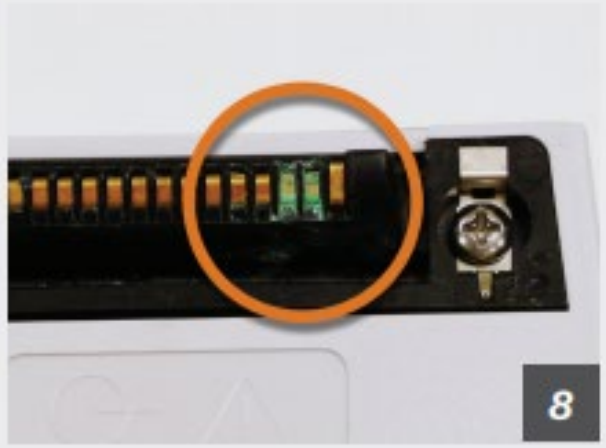
Confirm that the instruments and IUI connectors are thoroughly dry before using them again.

DO NOT attach devices that have not fully dried to one another. "Wet mating" can hinder proper instrument operation.



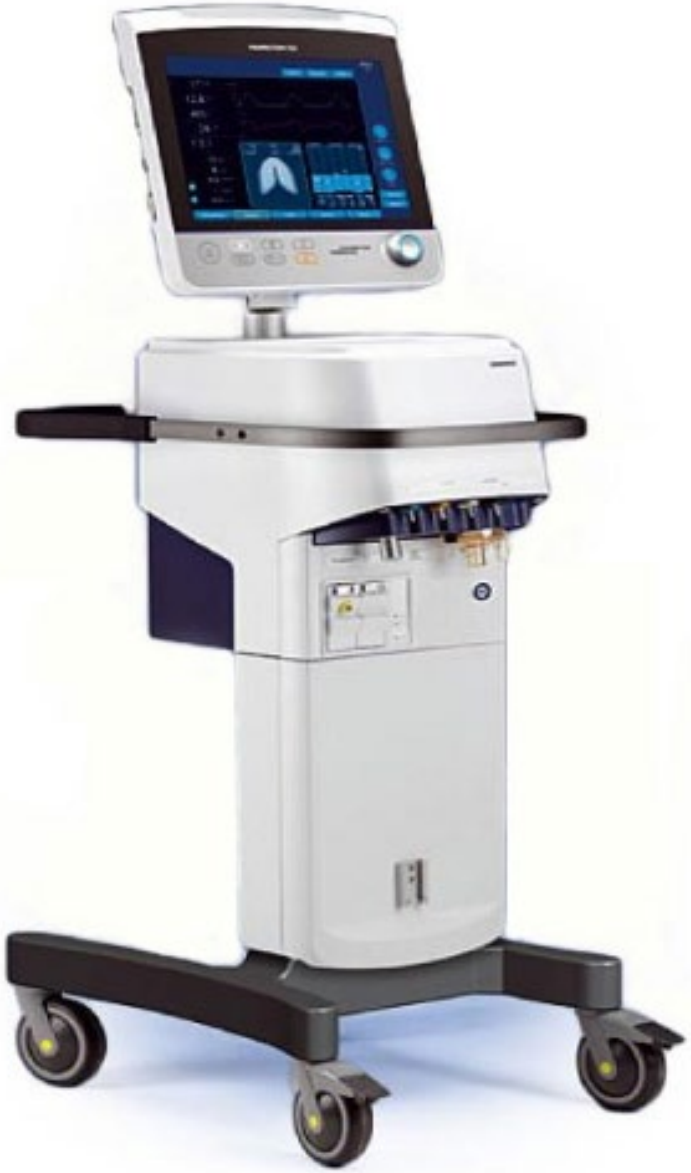
Fully inspect the instrument during each cleaning. Look for any visible external damage, such as a cracked or broken door, handle or latch. Open the door of each pump module, and inspect the platen and hinge for cracks or other damage.

DO NOT use a device with any damage. Send it to Biomedical Engineering for repair.



Inspect the IUI connectors on each Alaris PC unit and module prior to use. Replace any IUI connector with surface contaminants, blue or green deposits, damaged contacts, ribs or cracks.

DO NOT use a device with any cracks or surface contaminants on the IUI connectors. Send it to Biomedical Engineering for repair.



- Best practice may be to centrally process certain non-critical devices
- Review complexity and IFU for cleaning to determine, then usage and “ownership”

How are practices determined?

- Manufacturer's IFU's must be followed for reprocessing
- Evidence-based standards
  - AAMI ST79, ST91
  - AORN
  - CDC 2008
- **We need you!**
- Policies should be developed with Sterile Processing, Operating Room, Infection Prevention, and other stakeholders

The Basics

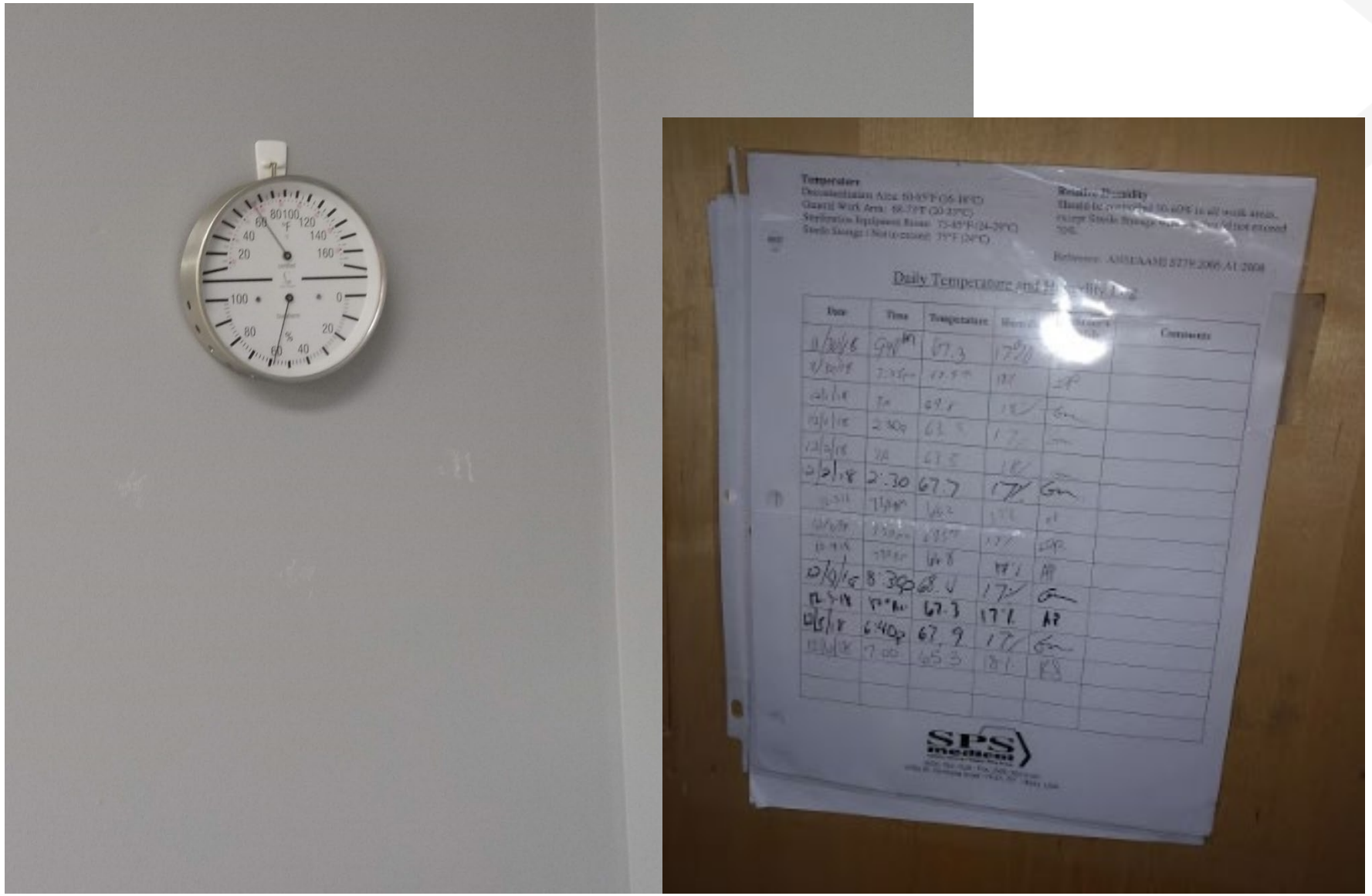
- Sterile Processing Departments consist of the following areas:
  - Decontamination
  - Prep and Pack
  - Sterilization
  - Sterile Storage (not ALL have this)
    - Some store product in the OR

Facilities Considerations

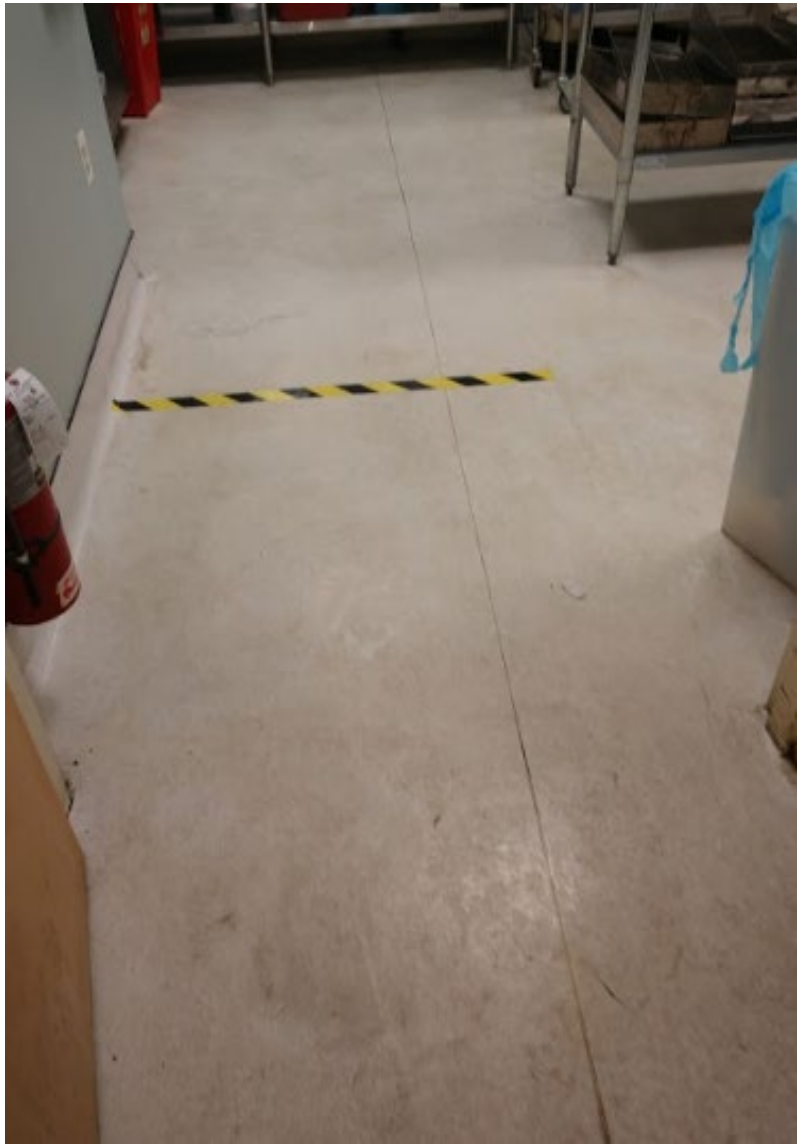
- Work closely with facilities to
  - Define temperature and humidity parameters (ASHRAE)
    - Develop policies for when these get out of range
    - Electronic monitoring is most consistent
  - Adjust positive and negative air pressure
  - Address environmental concerns (floors, ceilings)
  - Electrical outlets, wiring etc needs to be safe


POSITIVE
PRESSURE
ROOM
NEGATIVE
PRESSURE
ROOM

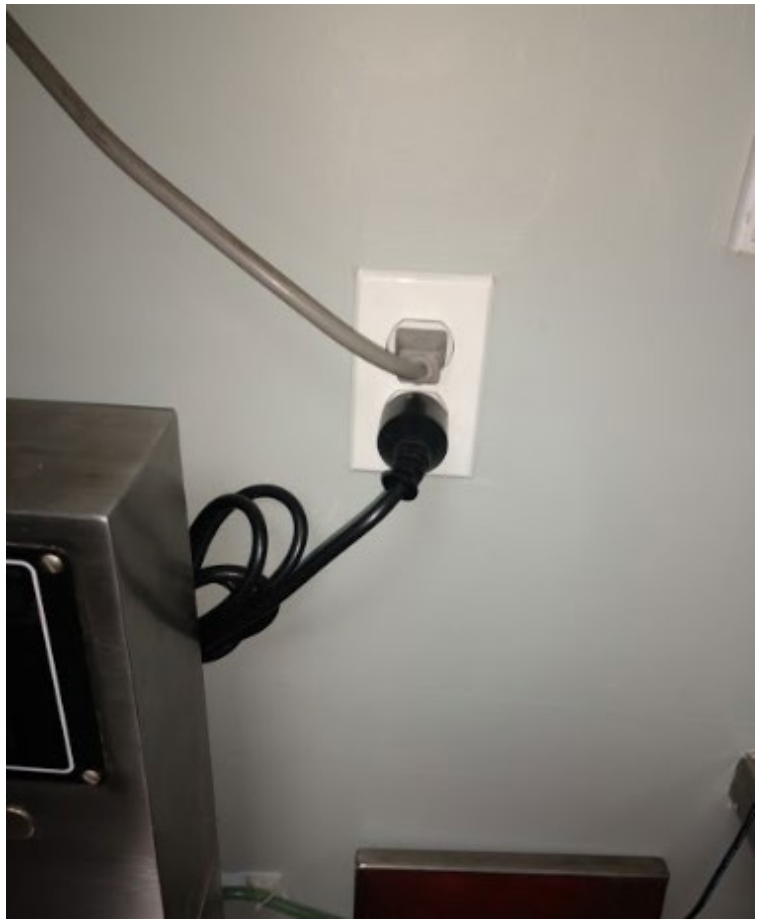

NEGATIVE
PRESSURE
ROOM

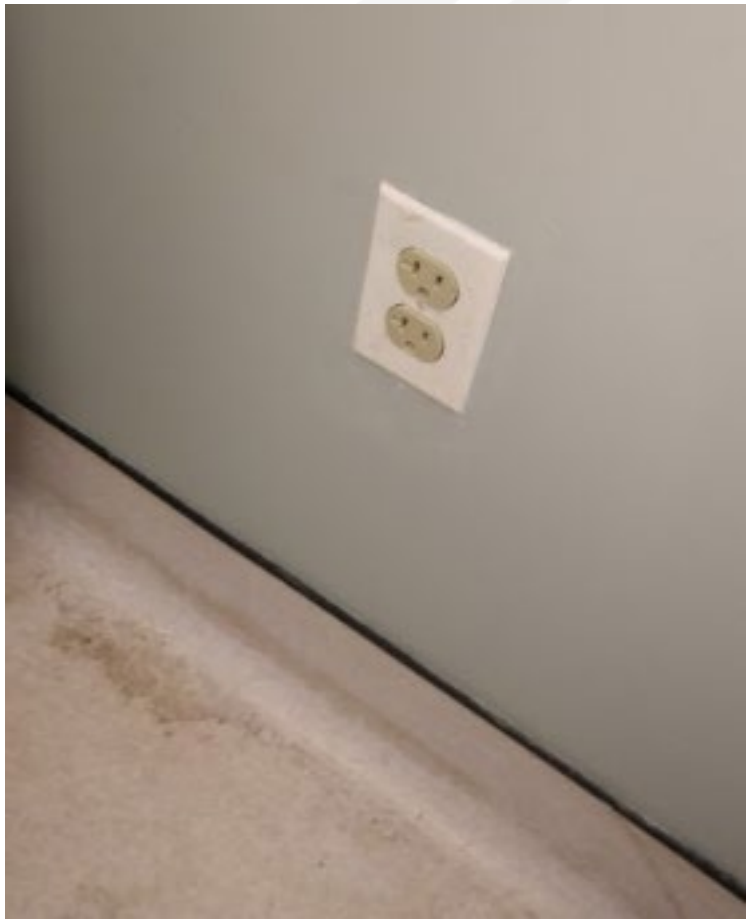

Daily Temperature and
Date
Time
Temperature
Comments
SPS medical

Anytime or place you see damaged ceiling tiles and light fixtures, these need to be replaced



All outlet should be GFI - **SERIOUS HAZARD**



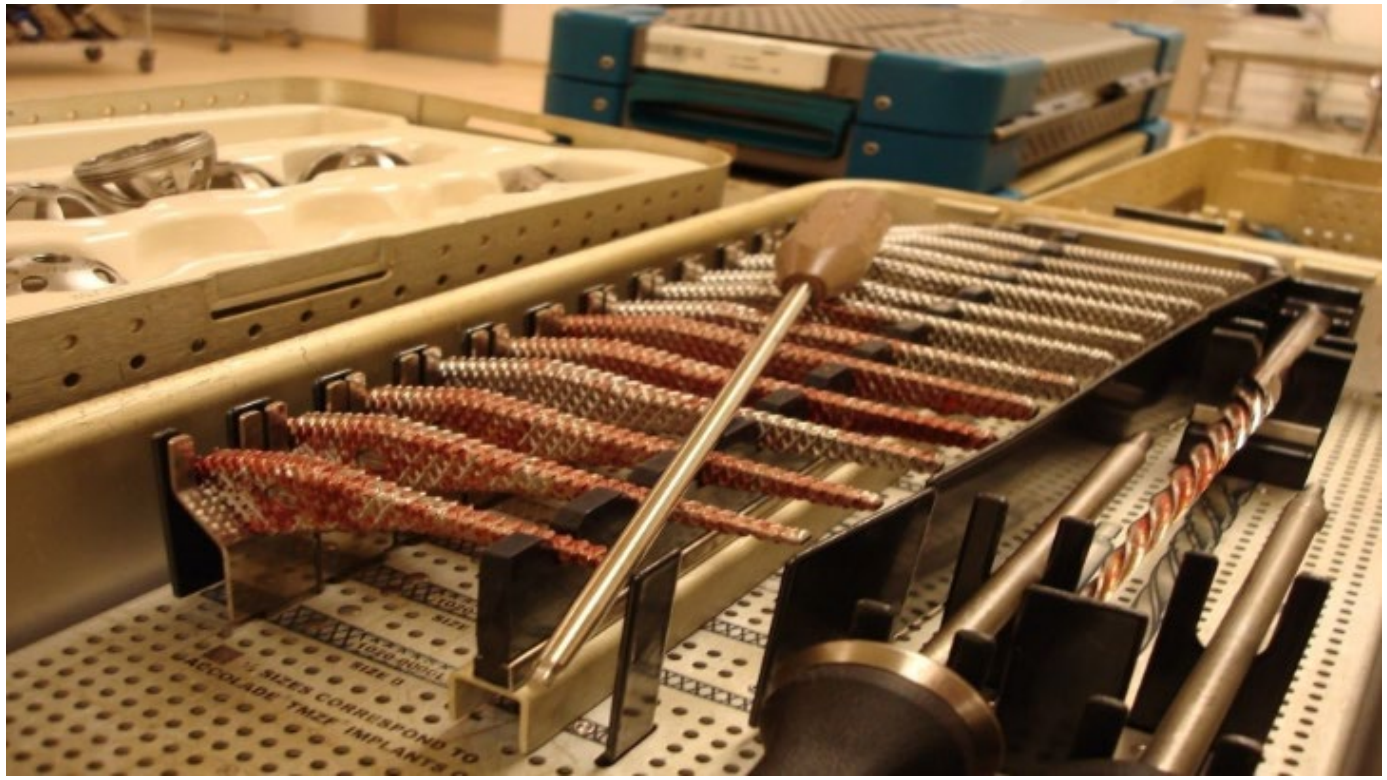


Point of Use Cleaning and Transport

- AAMI ST79, OSHA, and DOT have standards and guidelines
- Evidence-based groups may suggest a higher standard than surveying bodies
- Conflicting information between accreditation bodies, evidence-based guidelines, and manufacturer's IFUs

When blood or bioburden dries on instruments, it is difficult to remove

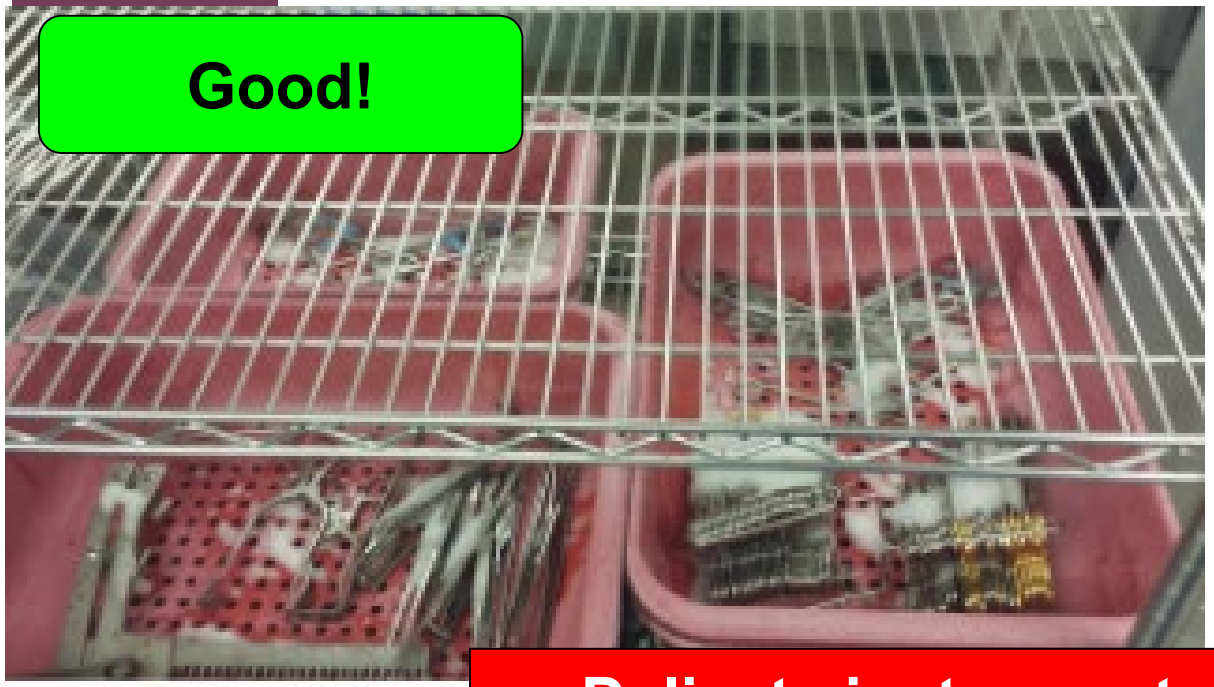
- Formation of biofilm
- Rusting and pitting of instruments
- Affects subsequent decontamination and sterilization processes

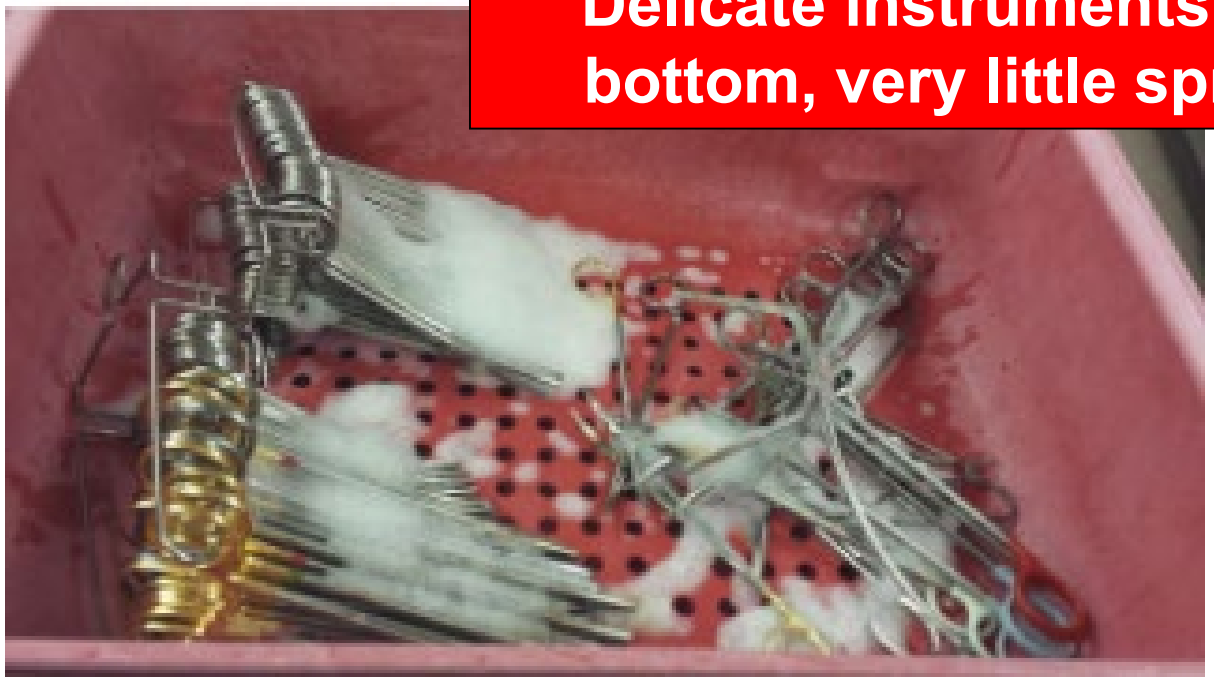


- Instruments should be wiped and/or flushed during the procedure
- Contaminated items should be handled as little as possible
- Sharps must be placed in a puncture-resistant container
- Contents of the container should be marked so they're easily identifiable as biohazardous
- Prior to transport, instruments should be prepared in such a way to keep soil from drying

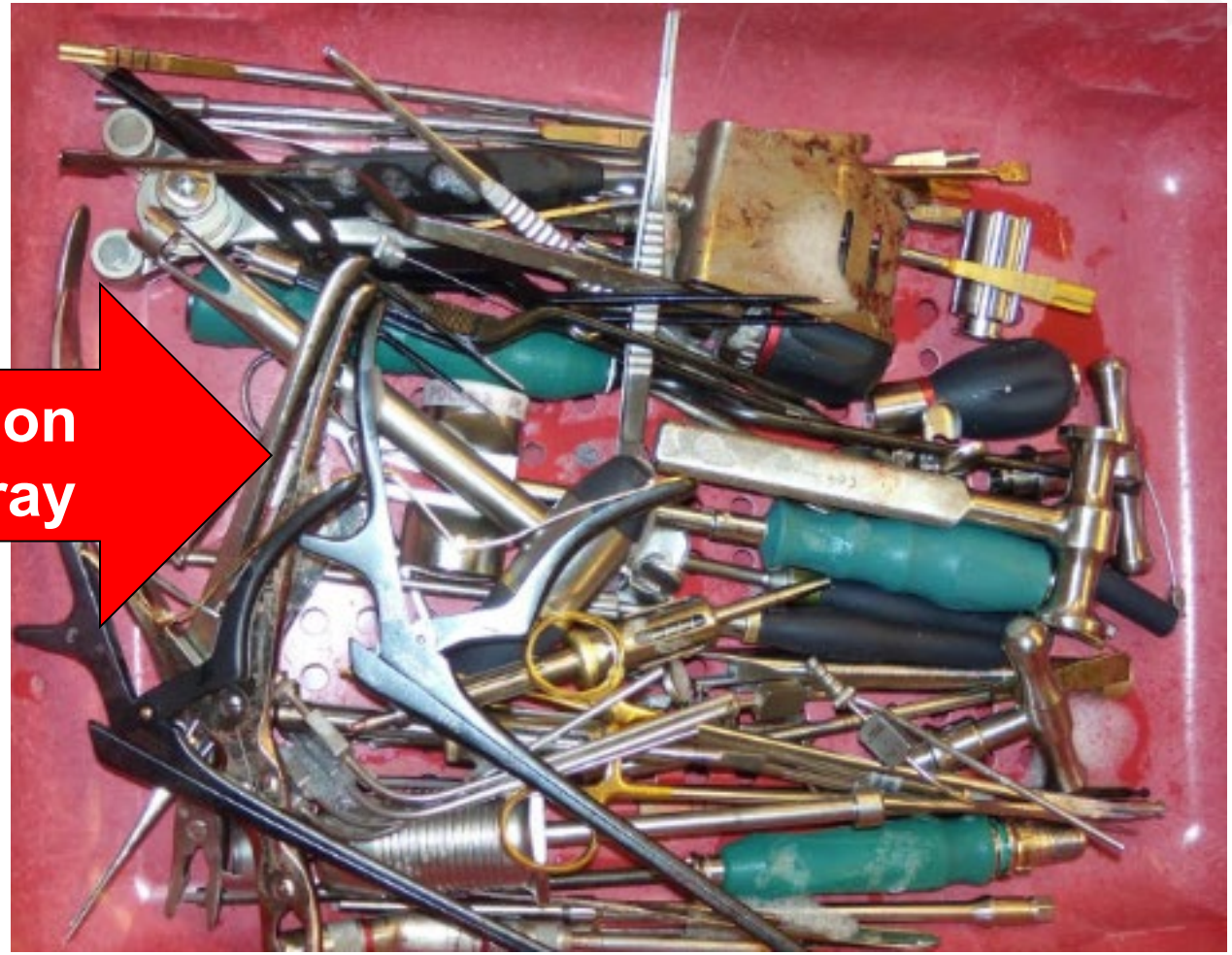
Consult AAMI ST79 Section 6

Good!





Delicate instruments on bottom, very little spray



TJC 4-1-1 - Effective 9/1/18

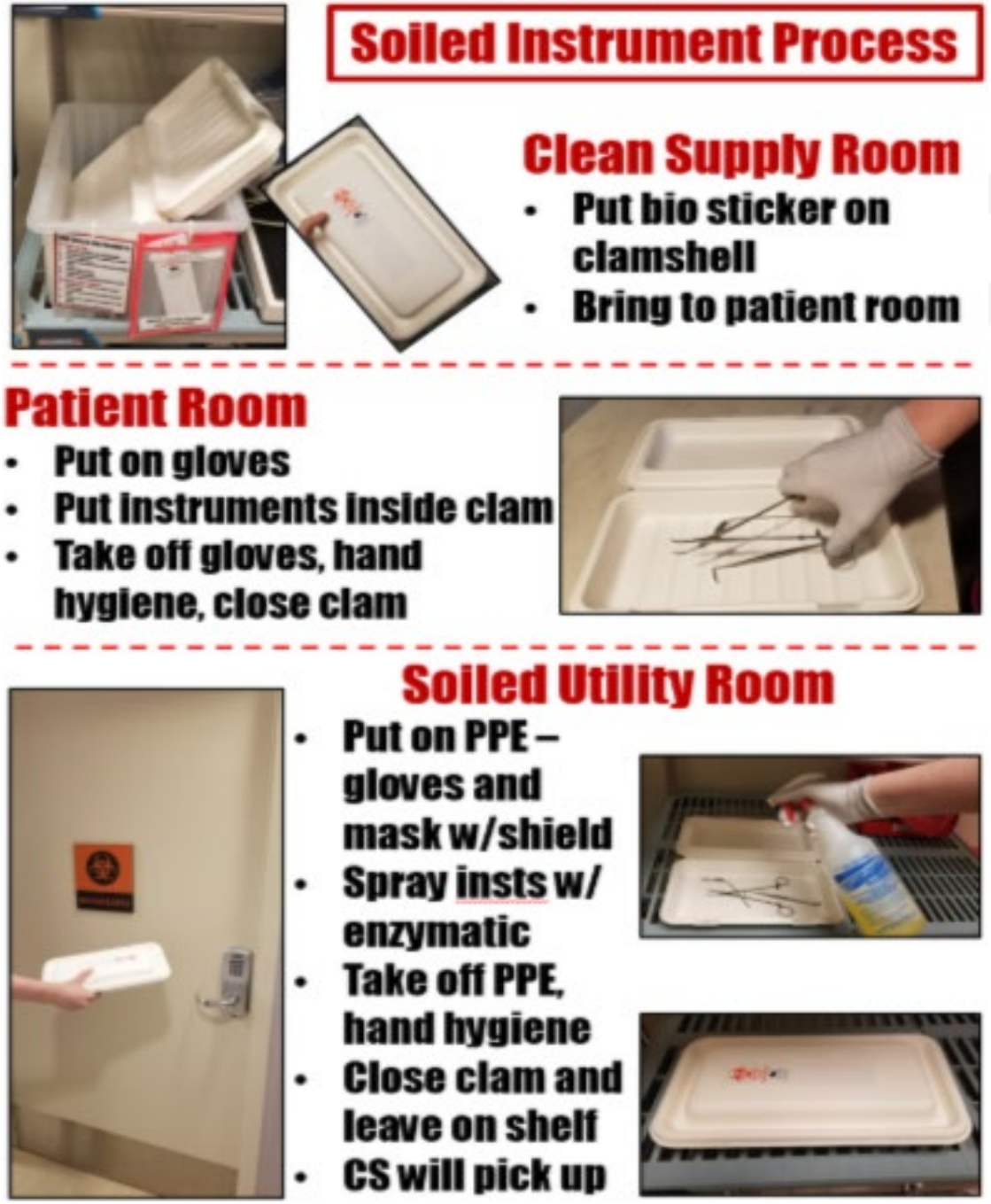
"There is no expectation that **all** visible blood or tissue be removed from instruments at the point of use."

Facilities may be asked about their wiping/flushing policy.

Instrument cleaning should be performed in the decontam area with appropriate PPE, facilities, and equipment to protect employees from injury/exposure.

Inpatient Areas

- Process needs to be developed for non-procedural areas
- High volume of traffic (patients, visitors, employees)
- PPE must be worn



Interactive Activity

Role play with a partner

Partner 1: Sterile Processing Leader

Partner 2: OR Leader

Part 1

A sterile processing technician working in decontam opened a container to find instruments with dried blood and a knife handle with a blade still attached. The technician calls the Sterile Processing leader and informs them of the situation and says this happens “all the time.”

With your partner, discuss your concerns from your respective department

Part 2

You and your partner are infection preventionists that are approached with this problem by one or both of the leaders. Work together to develop a plan to help the departments become compliant with AAMI standards.

Decontamination

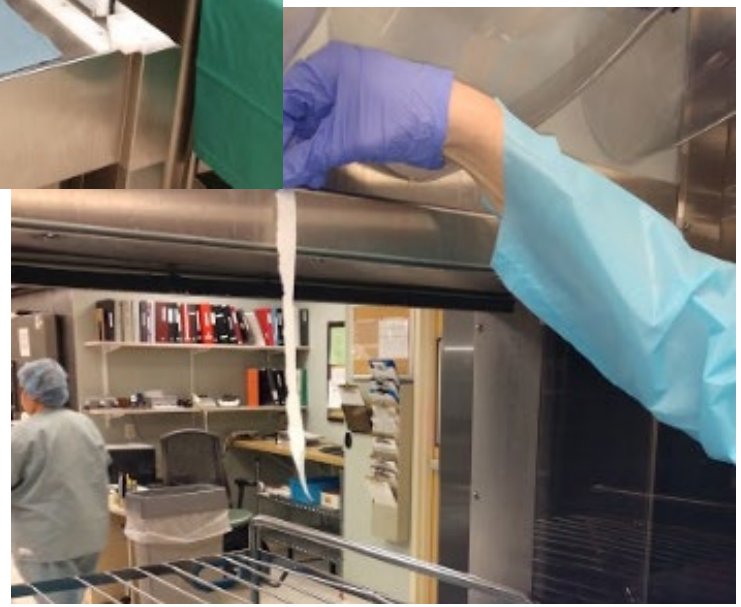
- Render devices safe for subsequent disinfection and/or sterilization processes
- All equipment, chemistries, and devices have instructions for use

Decontamination

AAMI ST79 3.3.6.1.1

The decontamination area/room should

a) be physically separate from all other processing areas and from areas in which clean or sterilization procedures are carried out, with any **connecting doors and pass-through windows remaining closed.**



Decontamination

In ambulatory surgery or office based settings, separate rooms might not be possible

- The decontamination sink should be separated from the clean work area by either a 4-foot distance from the edge of the sink or a separating wall or screen. If a screen is used, it should extend a minimum of 4 feet above the sink rim

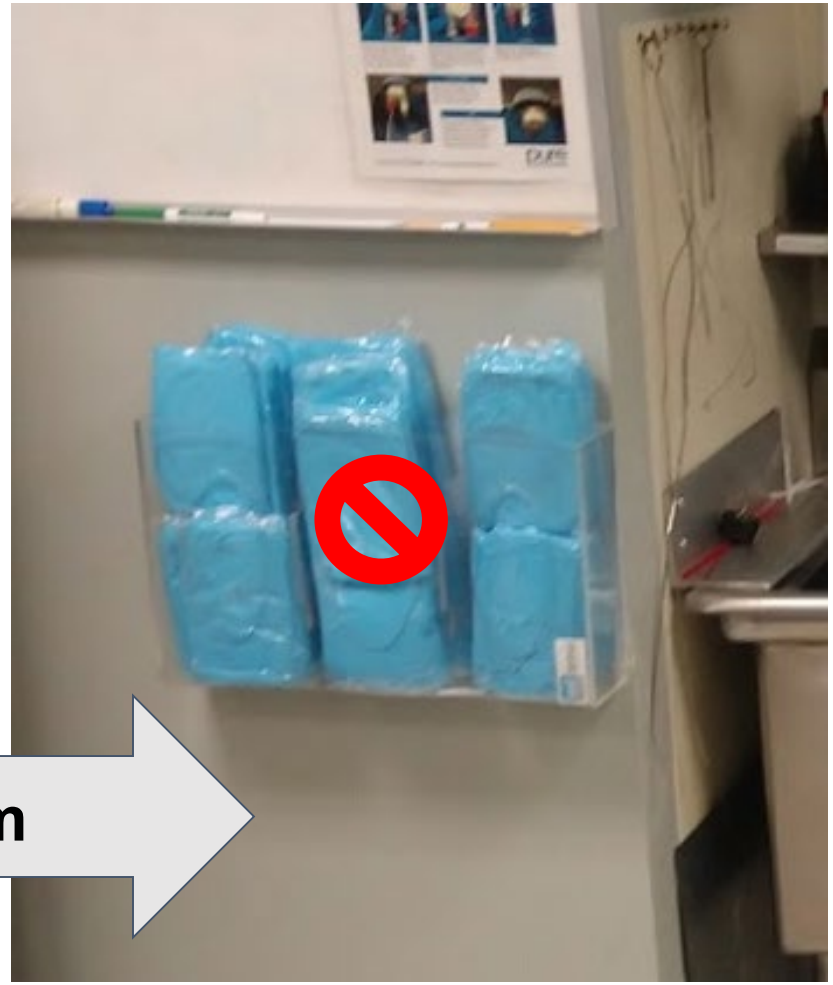
Decontamination

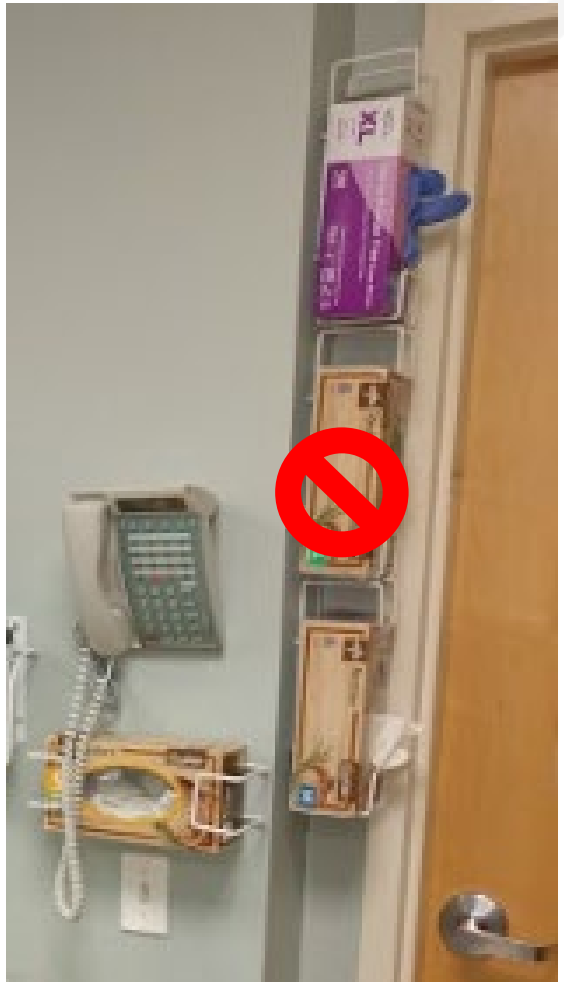
PPE

- OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)
  - requires that each facility have in place an exposure control plan that outlines the potential hazards that personnel might encounter while on the job.
  - Appropriate PPE must be used to prevent exposure to blood and other potentially infectious materials.

- Donning of PPE should take place in a clean area
- Doffing of PPE should take place before exiting decontam, in a “clean” area of decontam

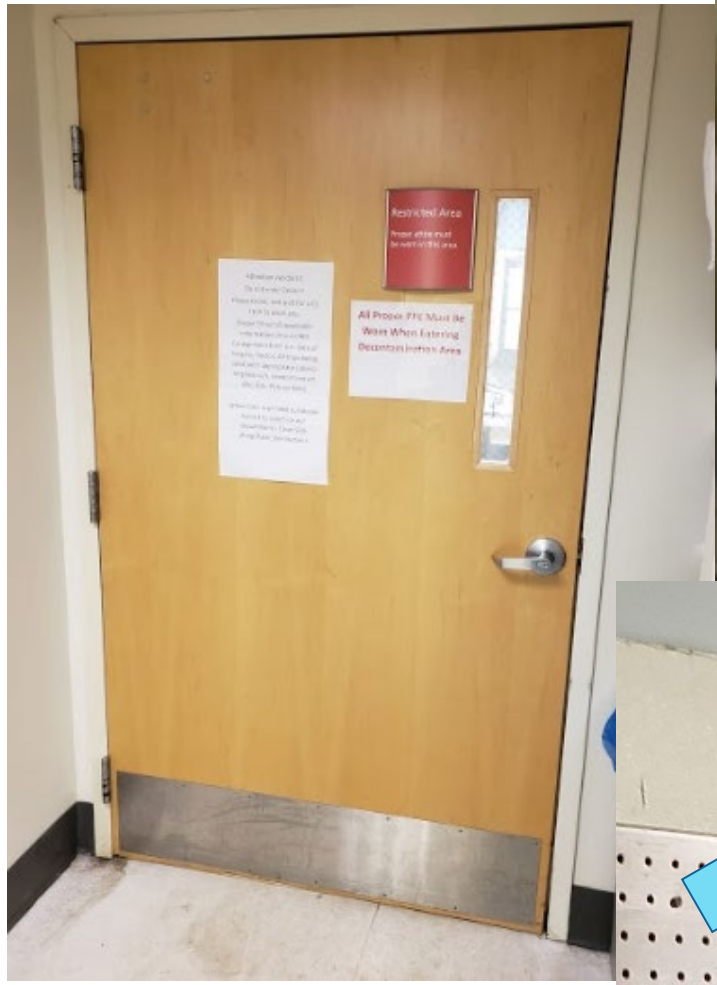
In Decontam

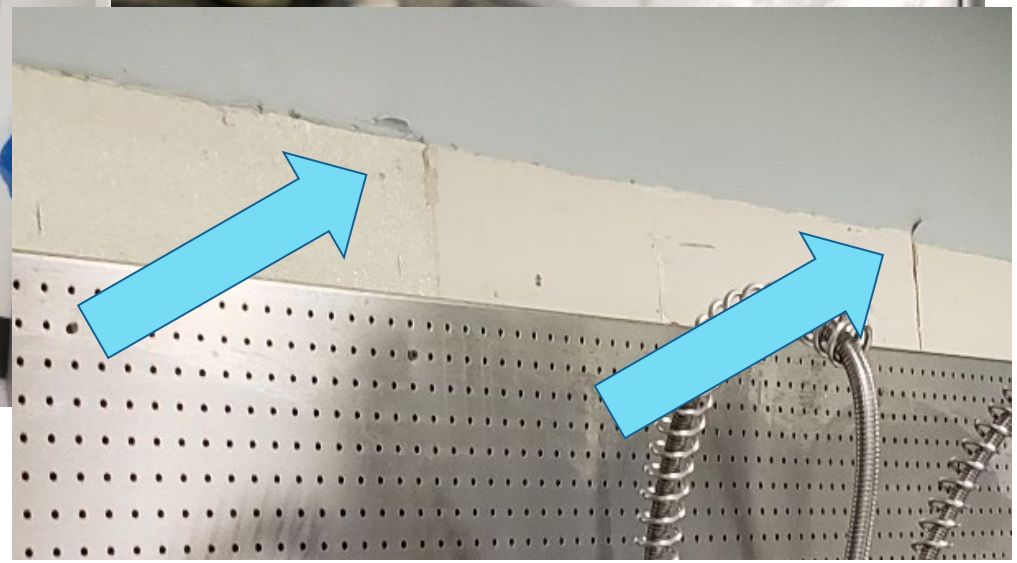




Decontamination

- Work tables and walls should be constructed of non-porous materials that can withstand frequent cleaning
- Doors should be made of durable material and open easily, following the one-way directional workflow





Decontamination

The equipment:

- Handwashing/Prep Sink
- Ultrasonic
- Automated Washer
- AER (Automated Endoscope Reprocessor)
- Cart Washer/Disinfector

ALL equipment has an IFU, includes routine maintenance/cleaning

Decontamination

Proper Tools

- Brushes
  - Need to be correct sizes
  - Some are single use
  - Others need to be cleaned and/or disinfected or sterilized
- Non-linting cloths
- Leak Testers
- Temperature monitors - water temp

Decontamination

Chemistries

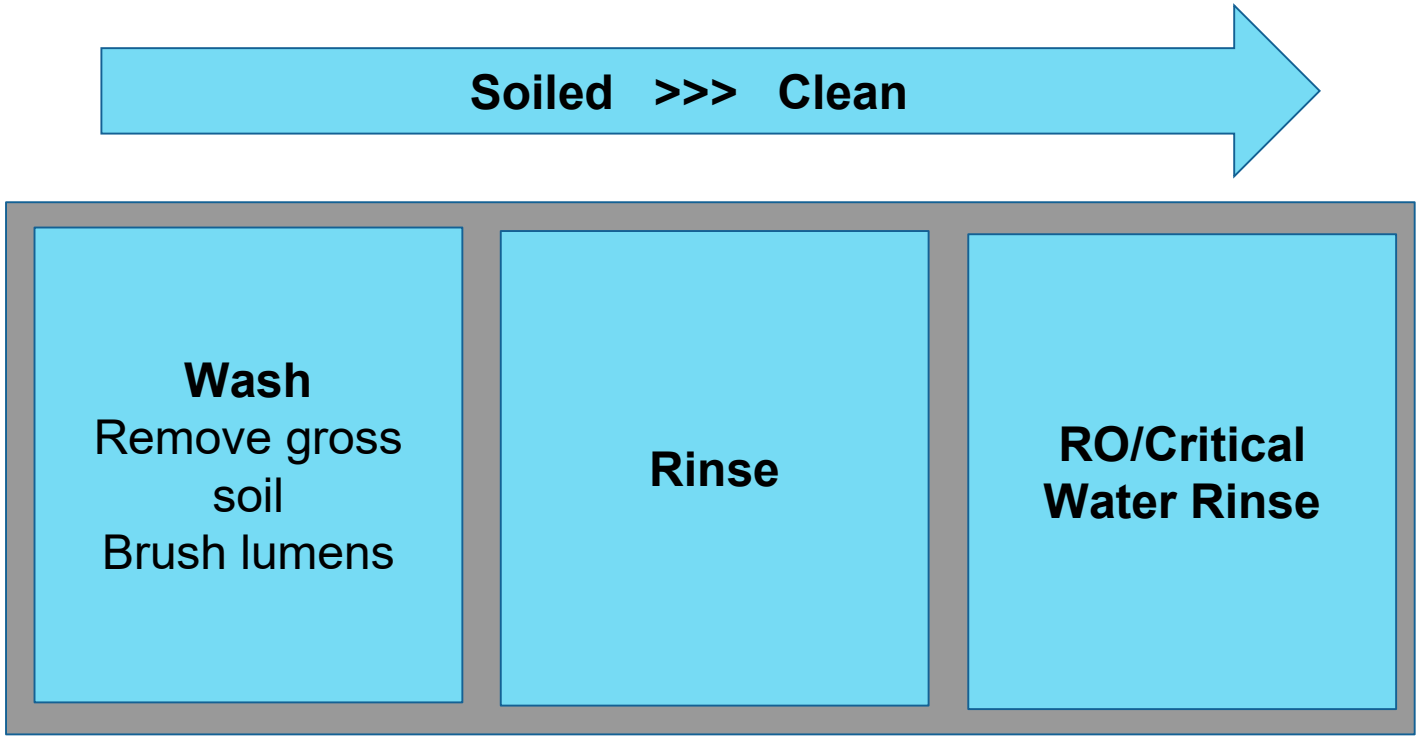
- Enzymatic detergent
- Lubricant - should it be in the washer?
- Drying agents
- Disinfectants
  - OPA/Gluteraldehyde - special considerations
- Eye Instruments require non-enzymatic chemistries

SDS need to be available for all chemicals and any materials needed

Eye wash, hand washing sink need to be available and monitored

Handwashing

- Follow manufacturer's IFU for chemistries
- If not specified in IFU, refer to AAMI TIR34 for water quality
- ST79 3.3.6.1.1 d)
  - three section sinks
- Separate processes and chemistries for each sink



- Follow manufacturer's IFU for chemistries
- If not specified in IFU, refer to AAMI TIR34 for water quality

What is happening in these sink bays???

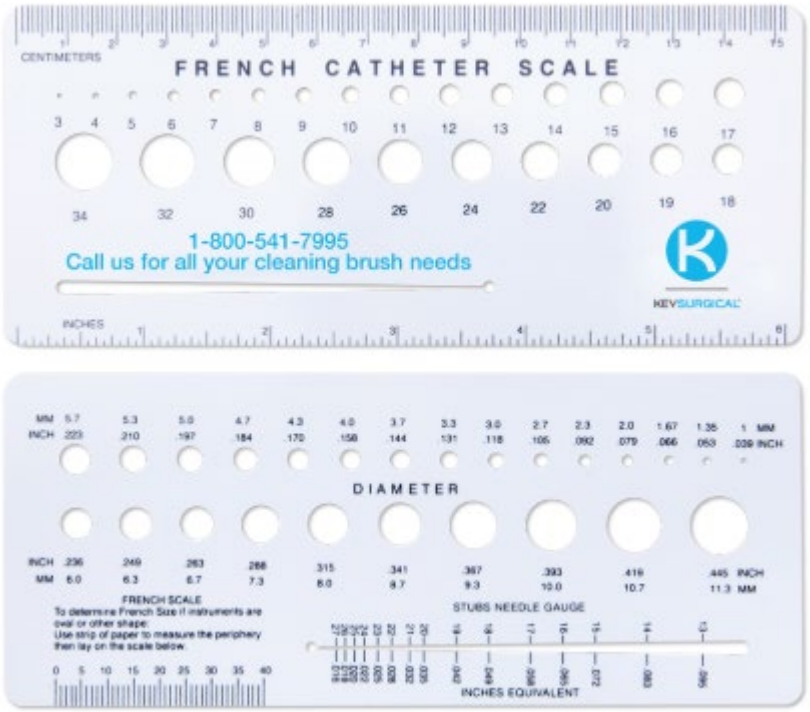
Is this product diluted properly?

Brushes

- Use brushes intended for use on medical devices
- Should be checked for visible soil and damage following each used
- Should be frequently cleaned and disinfected
- If the device manufacturer specifies a specific brush or cleaning implement, it should be used

Correct brush sizes should be used

- 7fr suction tube needs a 7fr brush



Ultrasonic

Used for fine cleaning to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods

- Used ONLY for devices for which ultrasonic cleaning has not been contraindicated in the device manufacturer's written IFU
- Used only after gross soil and detergents have been removed
- Use cleaning solutions labeled for use in ultrasonic cleaning equipment
- Performed with "fresh" cleaning solution
- Followed by thorough clean water rinsing or detergent washing

Ultrasonic

- ALWAYS FOLLOW IFU
- Best practice - attach to ports on lumened devices, laparascopic instruments, robot arms, etc.

Ultrasonic

Products available to test how well the ultrasonic is functioning

- Beads in these vials will break and cause color change
  - Problems such as insufficient energy, overloading, water level, improper temperature and degassing will increase the time needed for the color change
  - Major problems will result in no color change

Washer-disinfector

- Provide automated processes that combine
  - mechanical cleaning technologies
  - application of cleaning chemistries
  - treated water in critical phases
  - a microbiocidal process
  - drying
- Produce clean, disinfected, and safe to handle devices

Example of validated programmable process

Pre-rinse - COLD water

Detergent Wash Phase 1 - enzymatic with heated water

Rinse 1 - Flush chemical residues and retained bioburden

Detergent Wash Phase 2 - (if alkaline detergent is used in phase 1, would use a neutralizing detergent with an acidic pH

Rinse 2 - clean hot water rinse, should be 180^F or greater for 1 minute or longer for thermal disinfection. Uses critical water

Lubrication - is this appropriate

Drying - hot air, usually HEPA filtered. Items should show no signs of moisture at the end of the cycle

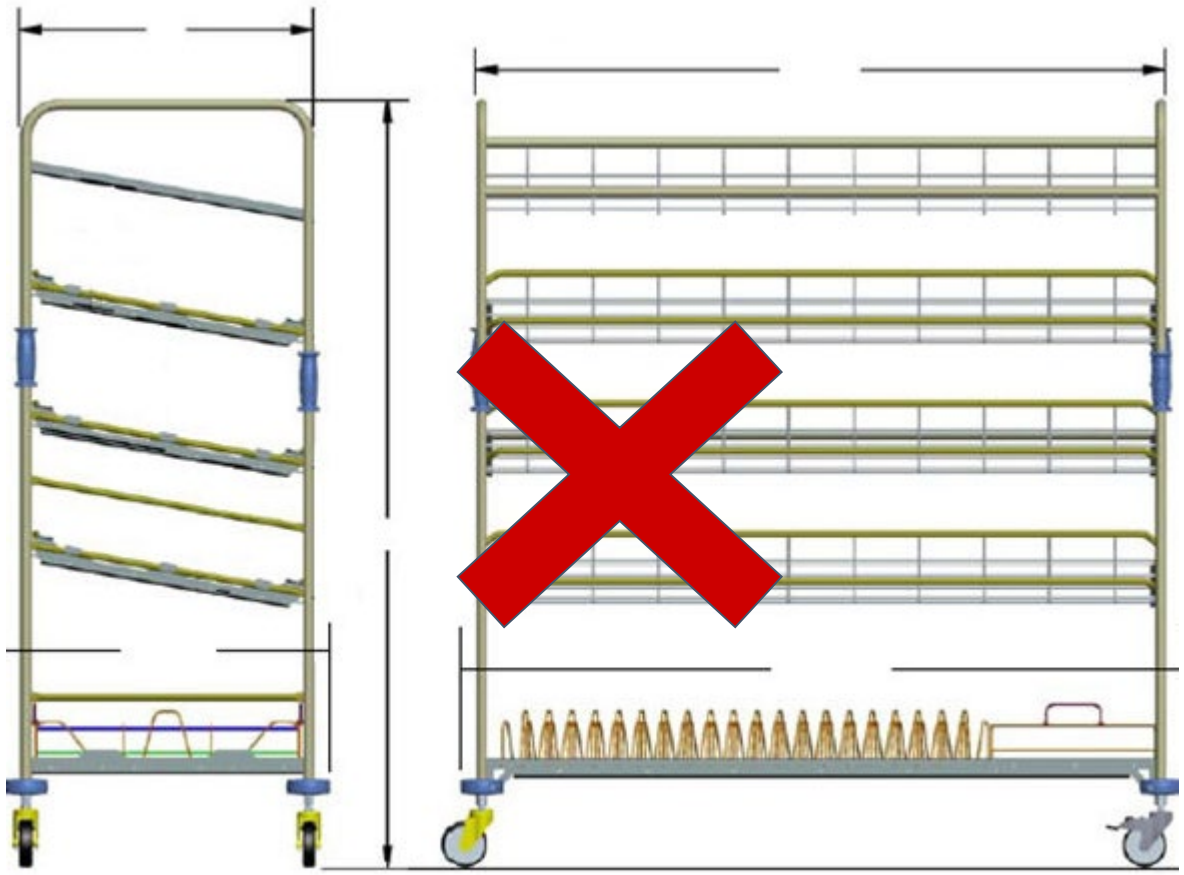
Three main types commonly used

- Single chamber washer-disinfectors
- Multi-chamber washer-disinfectors
- Cart washer disinfectors (also validated for instruments)

Multi Chamber (tunnel washer)

Single chamber

Cart Washer Disinfector - Validated for Instruments

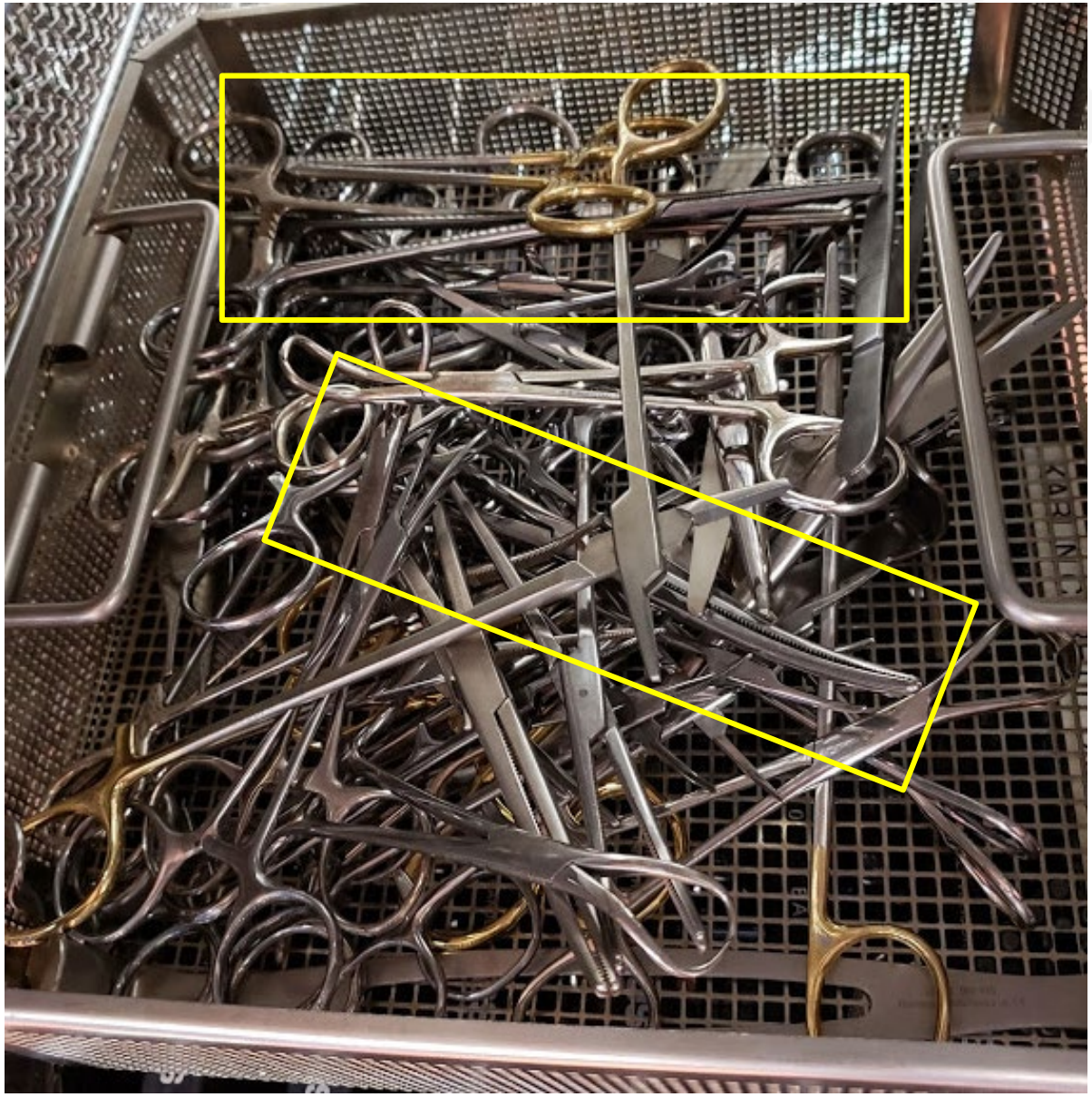


Lumens

Racks can be modified to add lumen flushing ports - best practice

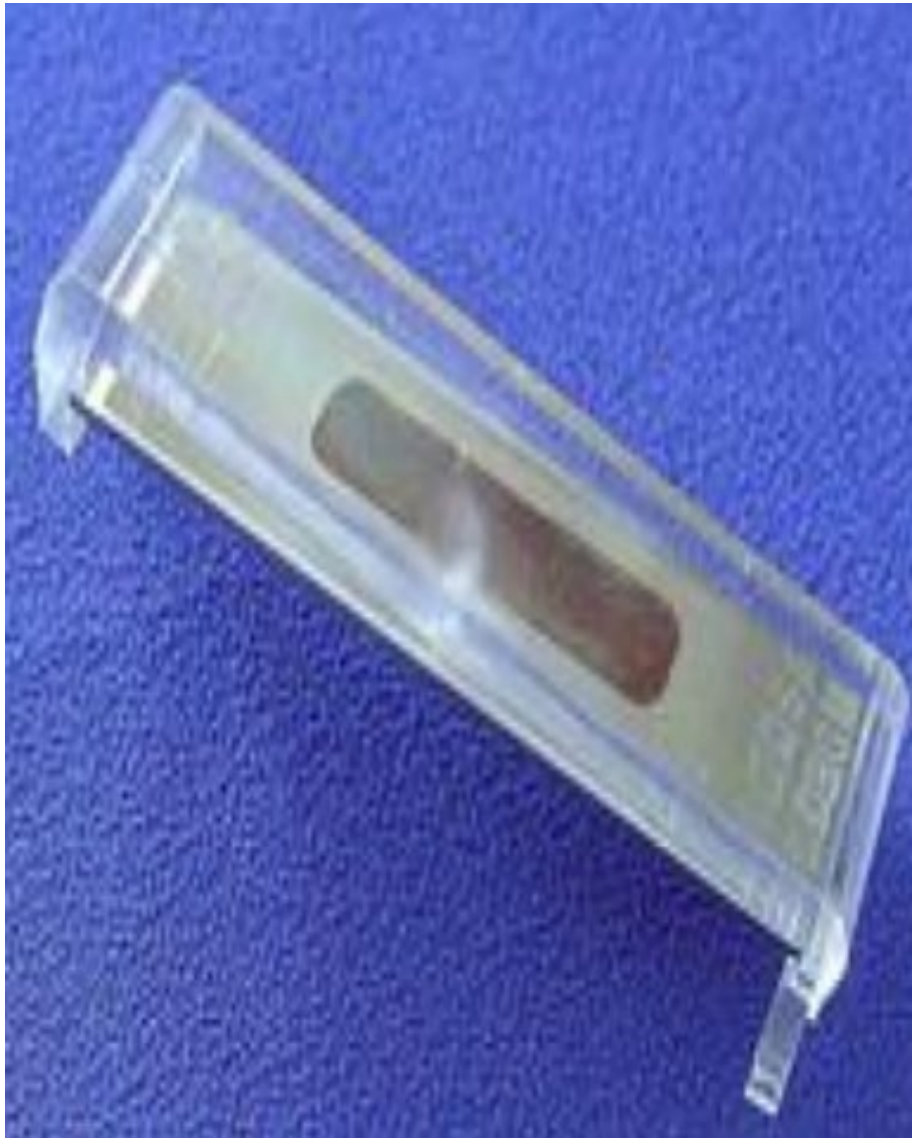
“Open” Instruments

Surveyors observing on clean side whether instruments went through wash in “open” or “closed” position



Washer testing

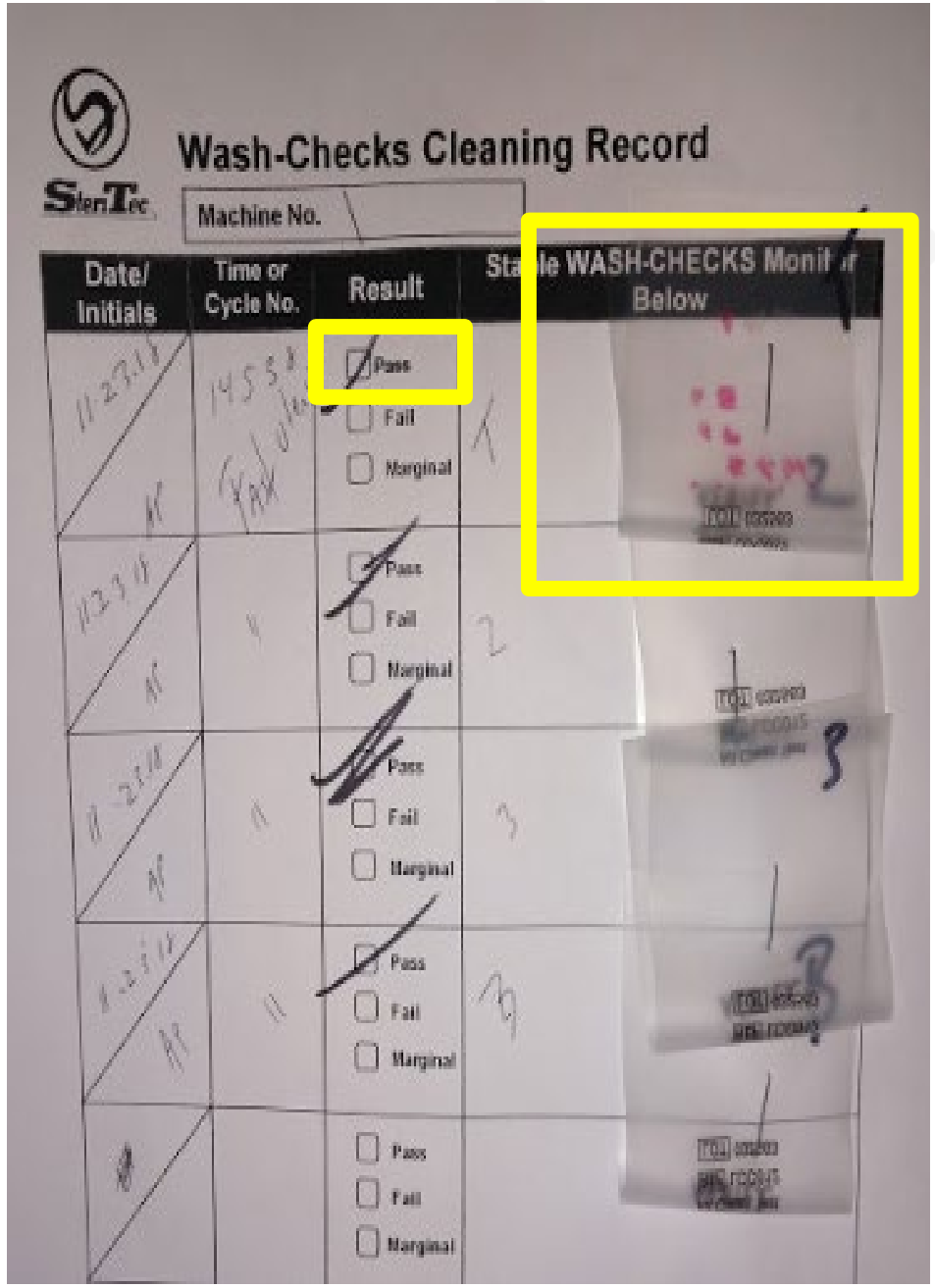
- Should be done weekly, preferably daily
- Several tests available, different price points
- Some are “pass/fail” and others are interpretive
- Tests need to be recorded



- TOSI directly correlates to the cleaning challenges of instruments
- Uses fibrin and hemoglobin

- Steris Verify All Clean
- Tests impingement and chemistry

- Team should be educated on interpreting results
  - Visuals available from suppliers
- Policy/process should be in place for one or multiple failed tests



Failed Tests

- Can be contributed to one or more of the following
  - water temperature
  - chemistry, pH, water hardness
  - mechanical (impingement)

Chemistry/pH/Hardness

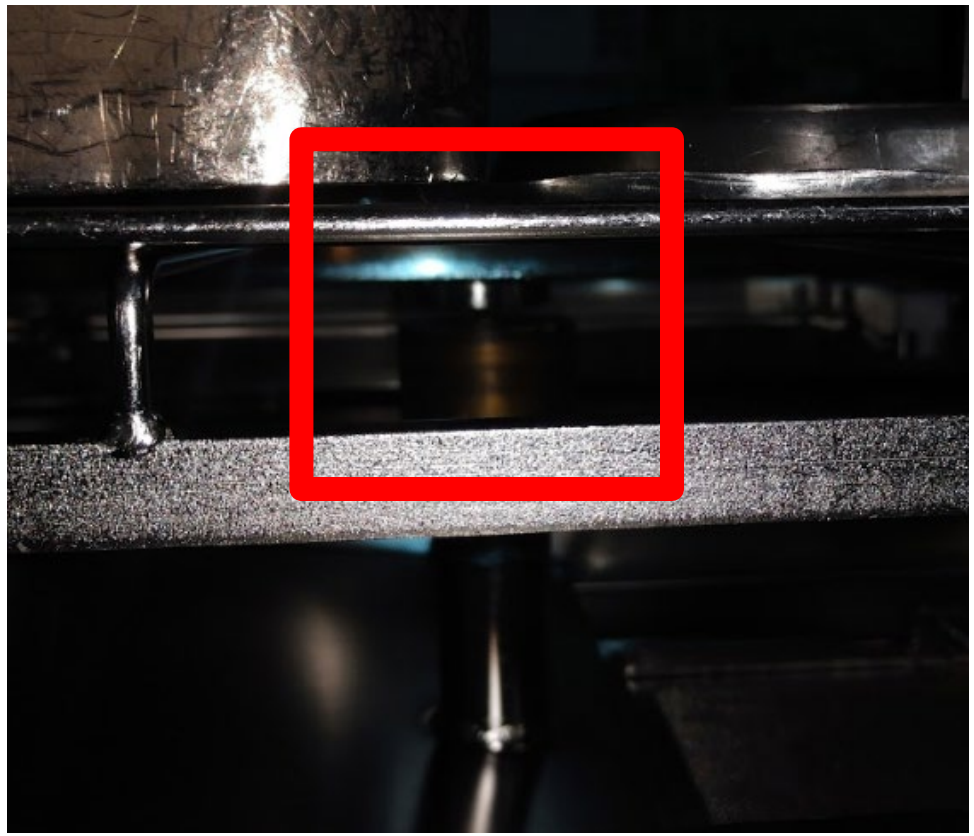
- Verify that correct “dose” of chemistry is used in cycle
- Measurements need to be more precise now
- Test hardness and pH of water

Mechanical

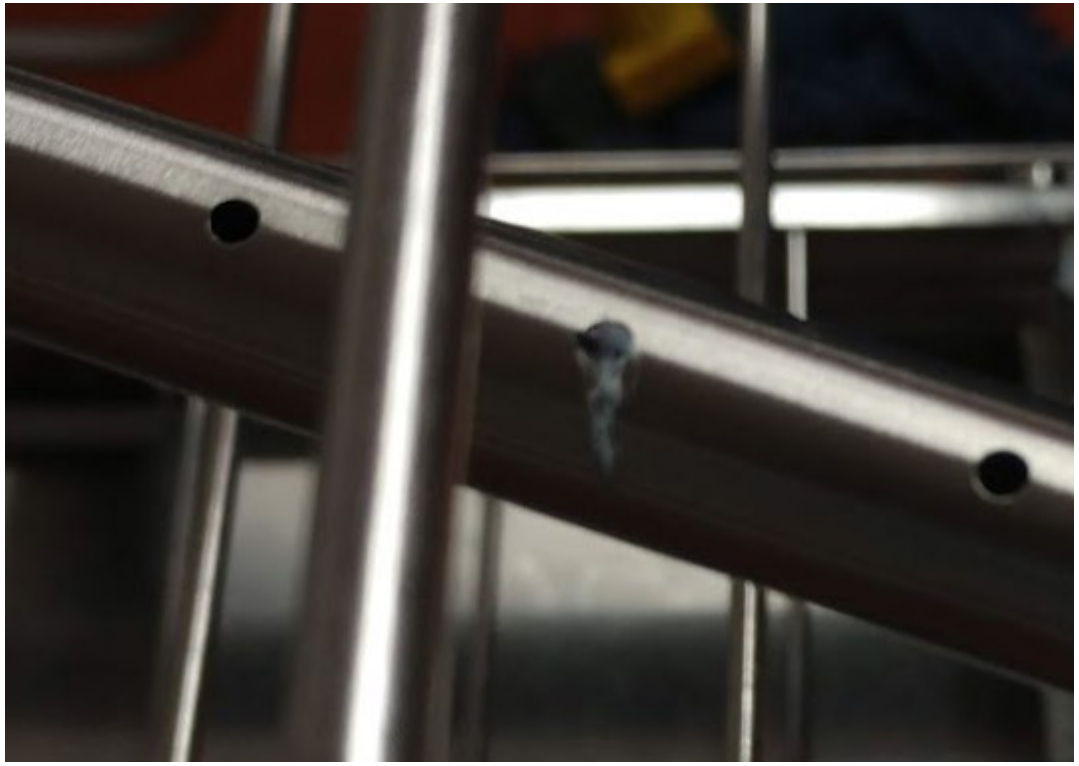
- Verify that equipment IFU for regular maintenance is being followed (routine cleaning, descaling)
- May need rep to conduct repairs for broken or malfunctioning equipment
- May be simple fix for fixing impingement

Mechanical Failures

Manifolds need to line up correctly between washer and basket



Spray arms and drains should be checked for debris



Prep and Pack

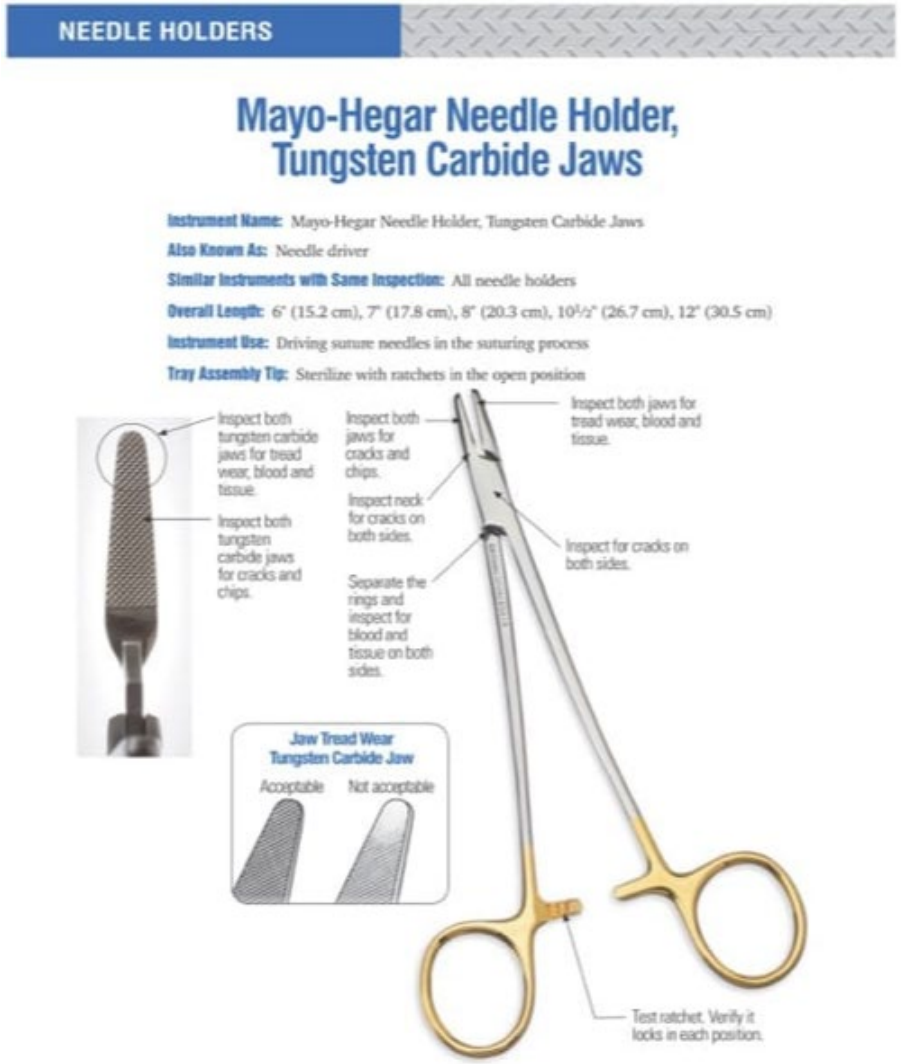
In preparation for sterilization, devices should be

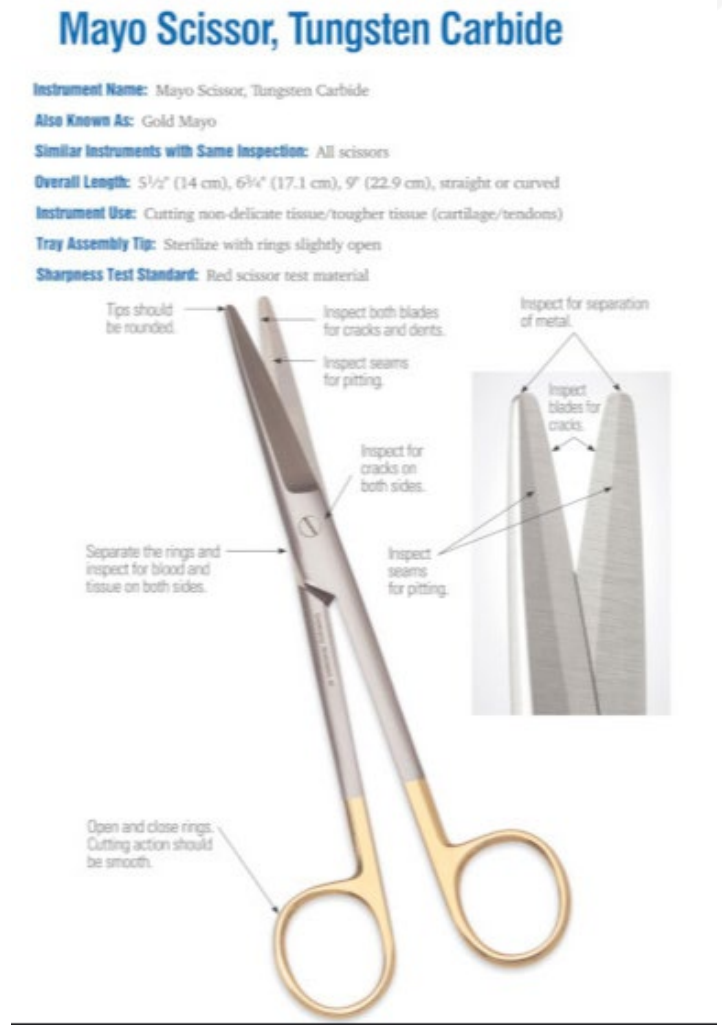
- cleaned
- dried
- inspected for cleanliness, flaws, and damage
- assembled
- packaged according to the manufacturer's IFU

Inspection

Many resources available

- IAHCSMM CIS textbook
- Rick Schultz: The World of Surgical Instruments, The Definitive Inspection Textbook





Sharpness

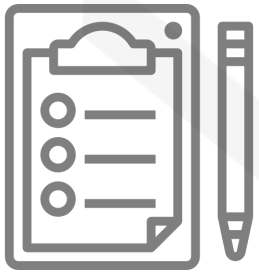
Kits available to test sharpness

Dull instruments can cause surgeon frustration and safety issues

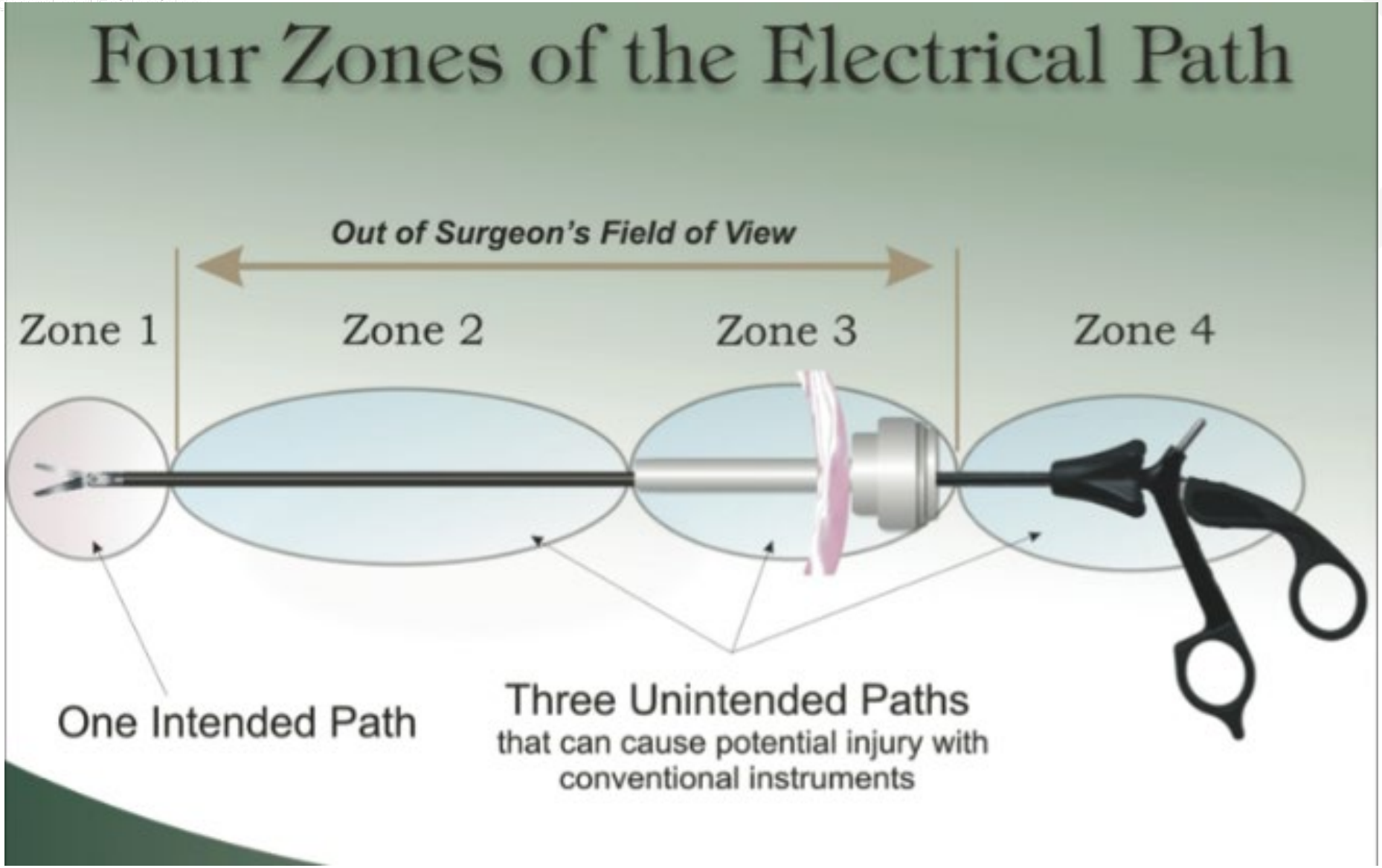
Lighting

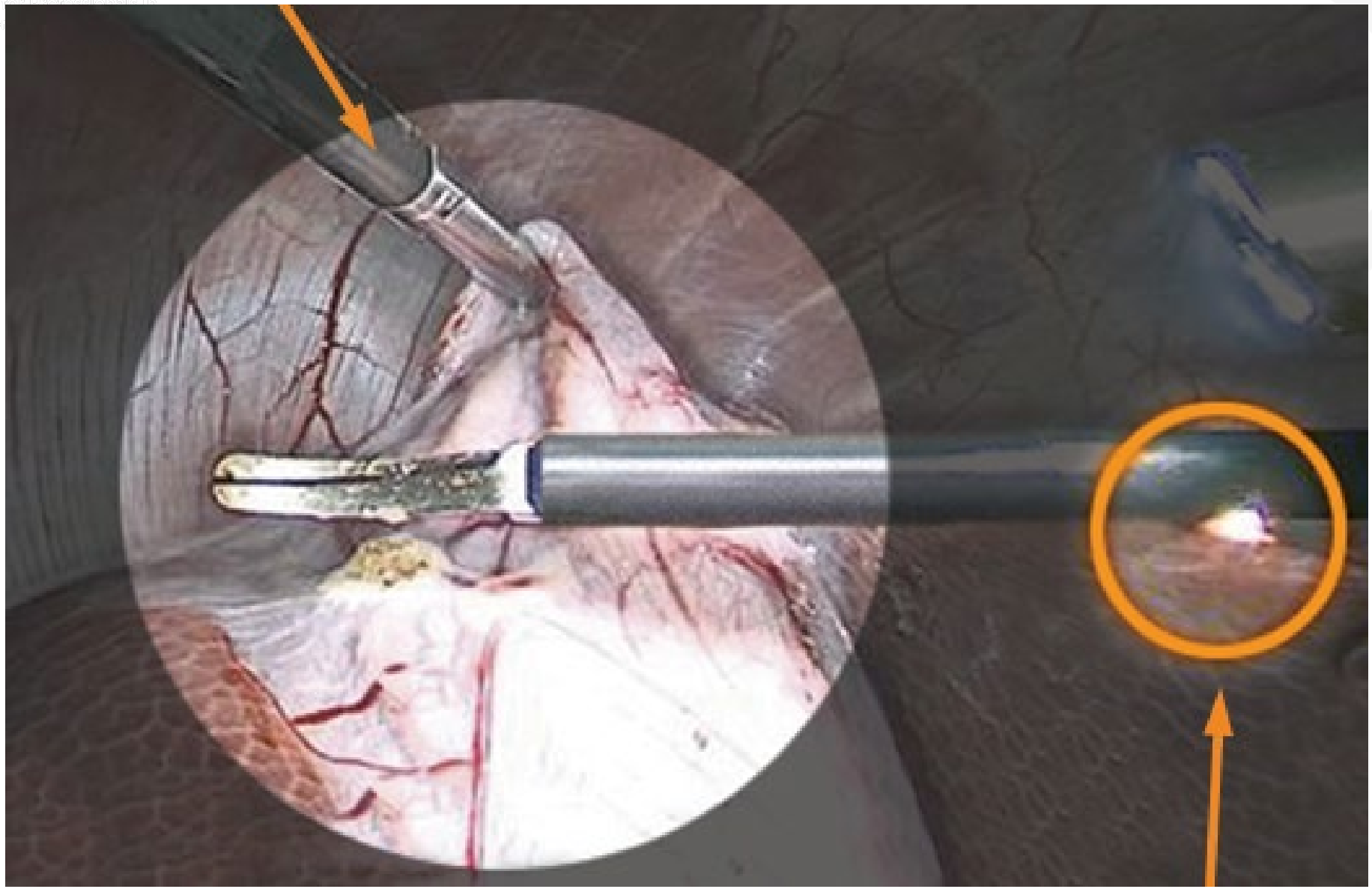
- The un-aided eye can miss defects
- Lighted magnification is best
- Check AAMI ST79 (3.3.5.6) for lighting recommendations
  - Average illuminance in general inspection is 750 lux
  - Average illuminance in detailed inspection is 1,500 lux

Insulation Testing



- AAMI ST79 Revision to include insulation testing for all insulated instruments
- Check device IFU for recommendations
- If your facility is not testing insulation, your patients are getting **BURNED**
- The smaller the insulation defect, the more intense the arc will be


Four Zones of the Electrical Path
Out of Surgeon's Field of View
Zone 1
Zone 2
Zone 3
Zone 4
One Intended Path
Three Unintended Paths
that can cause potential injury with conventional instruments



Insulation Testers

Before you start…

- If this is new, have your repair company on-site
- You will find defects
- Start on a day that works with the OR schedule
- Let the OR know you are starting and possible ramifications in instrument availability

Insulation Testing Recap

- AAMI ST79 Revisions coming out soon
- Should be done following IFU for device and tester
- Best practice would be during assembly, prior to sterilization, for ALL insulated instruments
- <u>If you take ONE thing back from this presentation, check your department's insulation testing procedure.</u>

Packaging

- Sterile Barrier Systems
  - allow air removal to permit sterilant penetration
  - provide a barrier to microorganisms
  - resist tearing or puncture
  - allow for aseptic presentation
  - non-linting
- **Follow IFU - be able to speak to it!**

3 main types

- Sterilization Wrap
  - Woven (muslin)
    - track number of uses
    - require inspection for holes and damage
  - Non-woven (polypropylene)
- Paper-plastic pouches
- Rigid container systems

Double Pouching

Should only be performed if the pouch manufacturer has validated the product for this use

If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.

Event-Related Sterility?

- Most manufacturer's IFUs contain a "shelf life" for their packaging
- Develop a policy for managing shelf life dates
- Wrap manufacturer's IFUs should be consulted for stacking wrapped sets

Sterilization

- Steam
- Low temp
  - Vaporized hydrogen peroxide
  - ETO
- Sterilization cycles
- Properly loading a sterilizer
- Process monitoring

Loading a Sterilizer

- Sterilizer IFU should be consulted for weight and load configuration
  - Some sterilizers are only validated to run a set weighing up to 17 pounds
- Items requiring the same parameters should be processed on the same load
- Load configurations should ensure adequate air removal, penetration of steam in each package, and steam evacuation

Load Configurations

- Peel pouches should be on their side
- Wrapped instruments should not be on top of peel pouches
- Rigid containers should not be on top of wrapped instruments
- Textiles should be run separately
- Basins should be tipped at an angle

NO

2019
APIC Applied Learning Conference

Fake News

Wet Packs

Cause is either

- Mechanical
- Chemical
- People

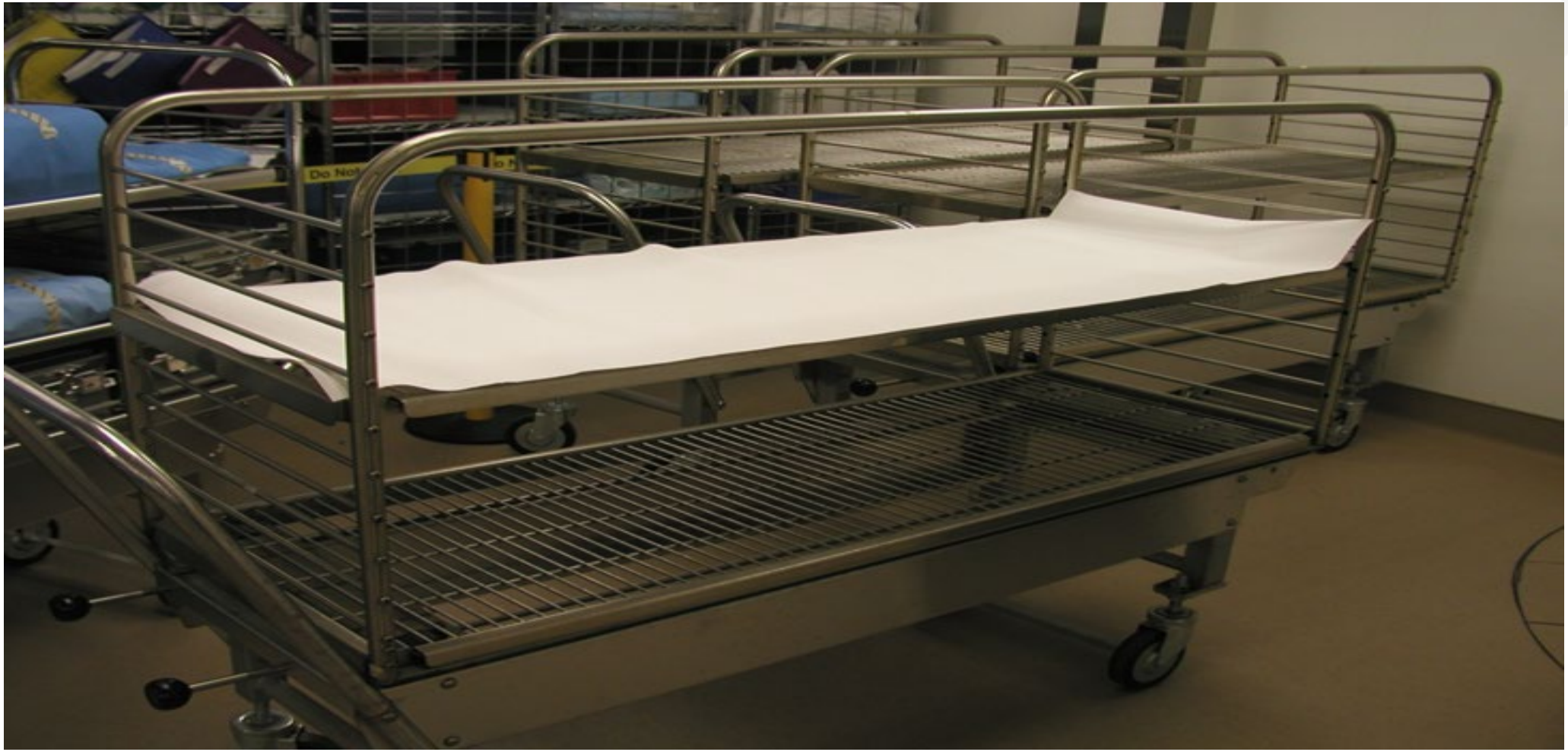
Troubleshooting Wet Packs

People Factors

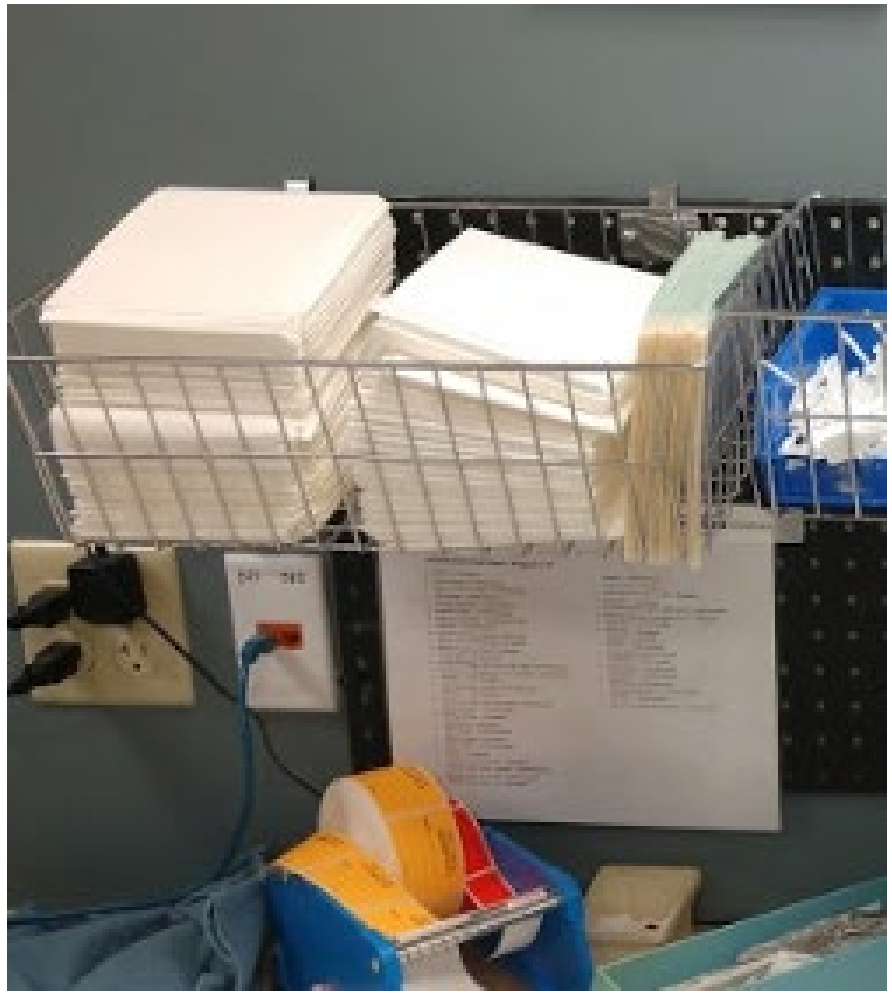
- Improperly loaded sterilizer cart
- Unevenly distributed metal mass
  - Heat sinks
- Improper cooling
- Adding too many extra items to the load
  - towels, plastic items, protectors, etc

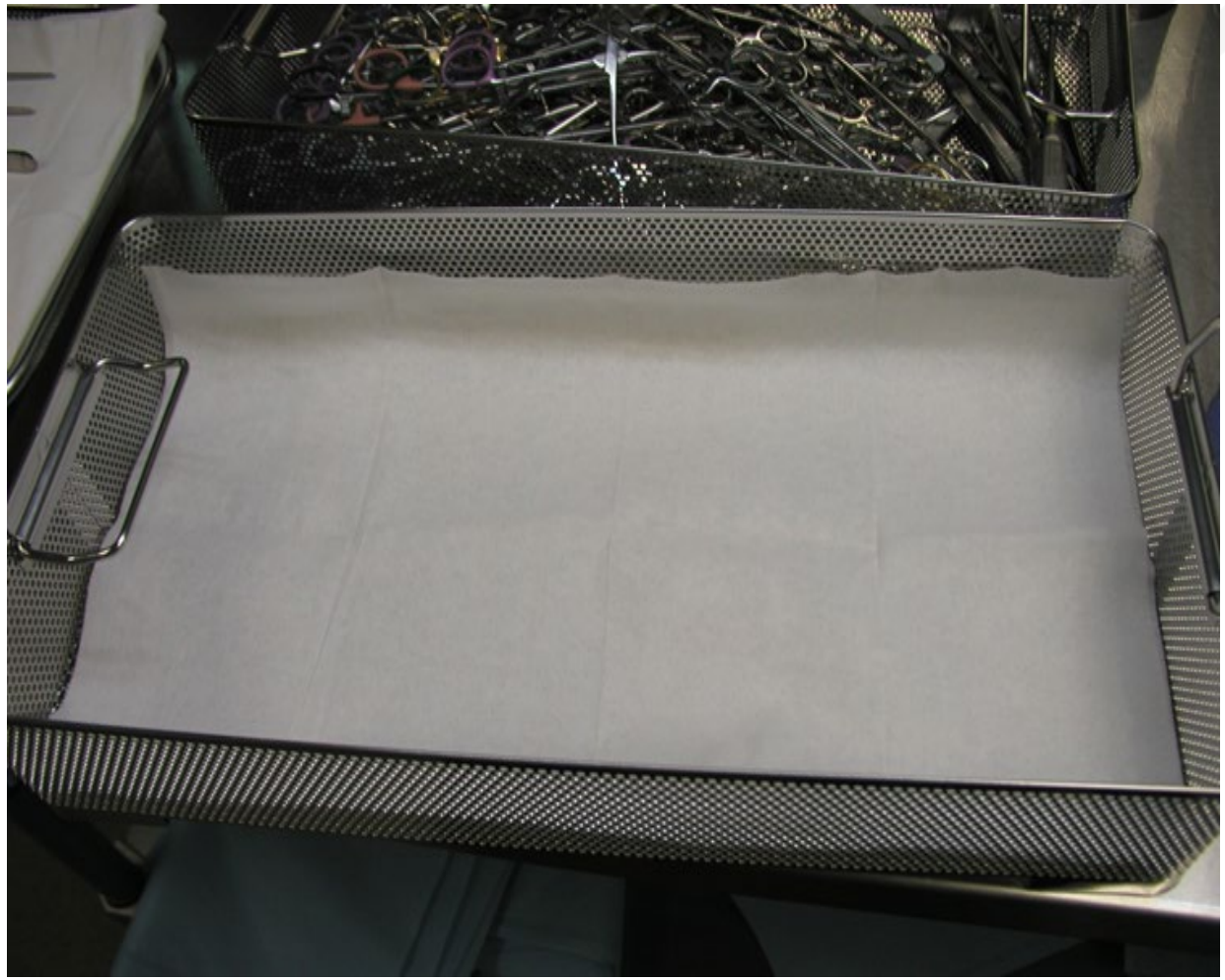
Too many towels!

Towels also inside the sets



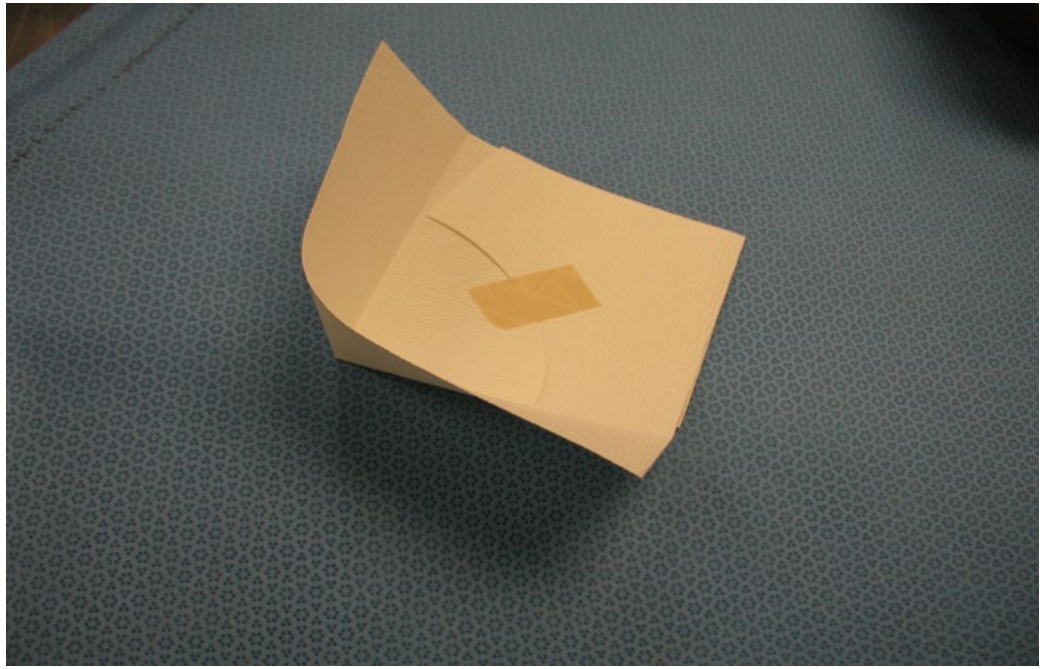
Disposable tray liners are better than towels - Non-linting, do NOT cut!





Silicone corner protectors cool faster than metal and can harbor moisture

Paper options available



Pay attention to where instruments cool

- Do not place under vents, will cause condensation
- Check condition of ceiling tiles - should not be in a place where there have been frequent leaks

Non-human factors

If human factors are not contributing

- involve facilities
  - water and steam quality
  - piping
  - steam saturation
- sterilizer manufacturer
  - ensure cycle parameters are being met
  - ensure equipment is functioning properly
- may need to get a 3rd party involved

Sterilizer Process Monitoring

- Includes physical monitors, CIs (chemical indicators) and BIs (biological indicators)
  - Parametric release is currently done in other countries
- Process monitoring should include
  - monitoring of every package and sterilization load
  - routine monitoring of sterilizer efficacy
  - qualification after installation, relocation, or major repairs
  - periodic quality assurance testing

Consult AAMI ST79 13.4

Physical Monitors

- verify that the parameters of the sterilization cycle have been met
  - Time, temperature, and pressure recorders, displays, gauges
  - digital printouts
  - electronic recording/data capture
- Should be used **EVERY LOAD**
- Part of record keeping

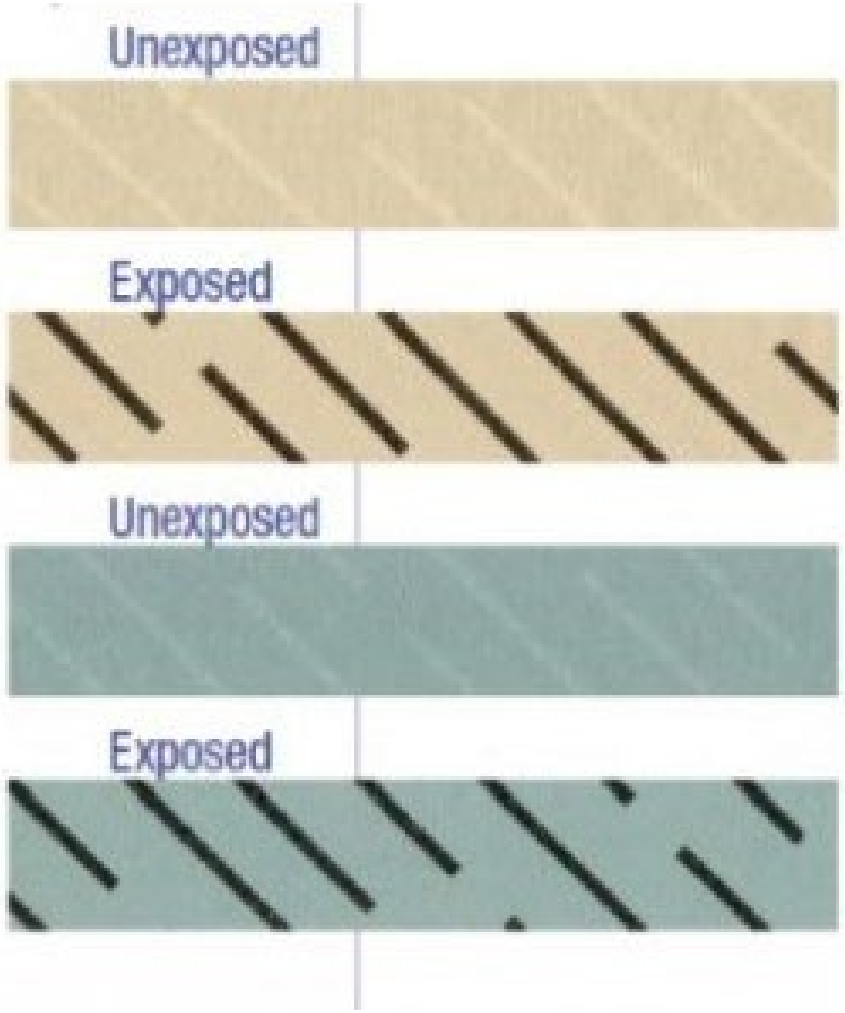
Chemical Indicators

Verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location in the load

Type 1 (external)

- should be used on outside of every package unless the internal CI is visible
- (Tape, dots on container locks)

- Tape is a type 1 indicator
- Verify that the type of tape is correct for the sterilization method
- Steam vs. Sterrad



Type 2 (external)

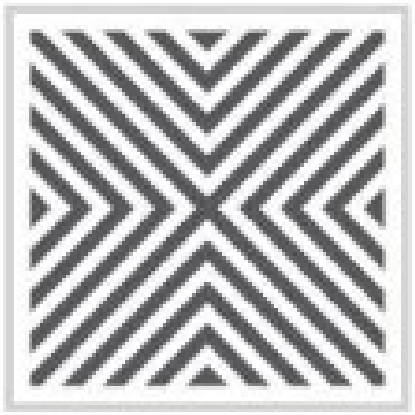
Bowie Dick tests

- For routine sterilizer testing - should be run, within a test pack, each day in a sterilizer before the first processed load
- Qualification testing - should be run three times consecutively in an empty chamber AFTER BI tests

Bowie-Dick (Dynamic Air Removal)

UNPROCESSED

PASS

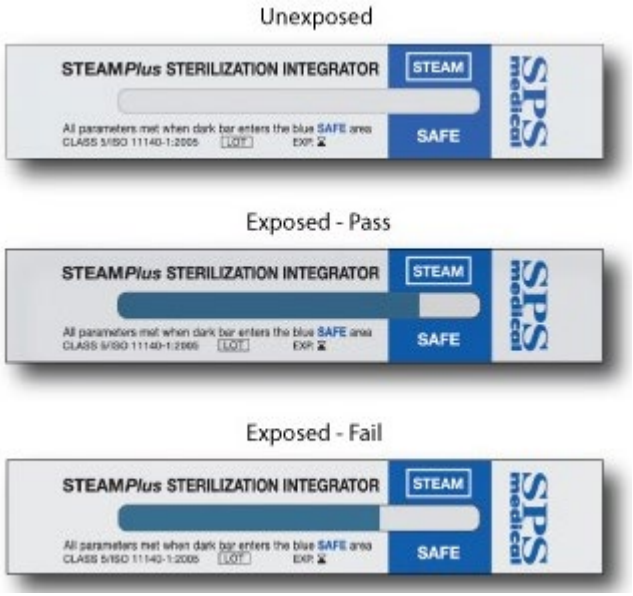


FAIL

Type 5 (internal, integrating indicator)

- Designed to react to all critical process variables
- May be used to meet internal CI recommendation
- Within a PCD, may be used to monitor non-implant loads
- Within a PCD, should be used to monitor implant loads - should also contain a BI

Internal Chemical Indicator



Process Challenge Device

Type 6 (internal, emulating indicator)

- Designed to react to all critical process variables for specified sterilization processes
- May be used to meet internal CI recommendation
- Within a PCD, may be used to monitor sterilizer loads

Biological Indicators

- Verify that it is for the correct sterilization method
- Should be used within PCDs
- At least weekly, preferably daily
- BIs with Type 5 integrating indicators within PCDs should be used to monitor every load containing implants
- Implants should be quarantined until results are available

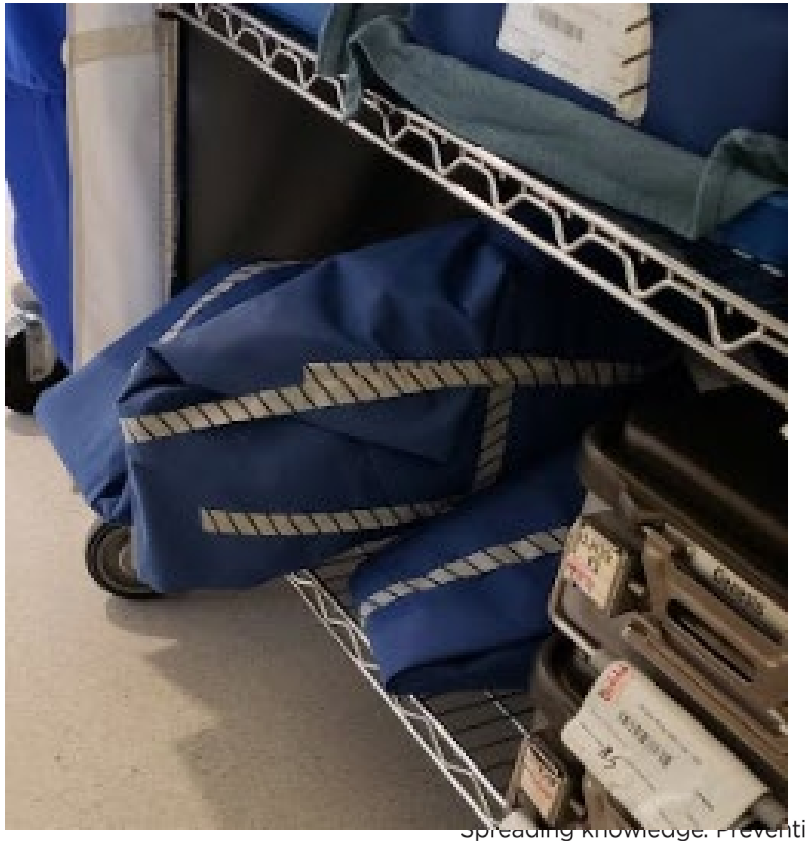

3M
Attest™
Super Rapid 5
Steam-Plus Challenge Pack
Super Rapid Readout Biological Indicator
Type 5 Chemical Integrator
THIS SIDE UP IN STERILIZER
STEAM
For Dynamic Air Removal Steam Sterilization Cycles
270°F (132°C)
275°F (135°C)
REF 41482V
LOT 3335CE
2019-11-04
REJECT
ACCEPT

A case for every load monitoring

- What is the window of liability?
  - How many instrument sets need to be recalled if there is a positive bio?
  - Have those instruments already been used?
- The biological indicator is currently the only test that demonstrates lethality
- What is best for patient safety?

Sterile Storage

- Sterile items should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination.
- 8-10 inches off the floor, 18” below ceiling or sprinkler heads, 2 inches from outside walls
- bottom shelves should be solid
- wrapped packages are not stored beneath rigid containers
- positioned that packaging is not crushed, bent, compressed or punctured
- not stored under sinks, on floors or windowsills



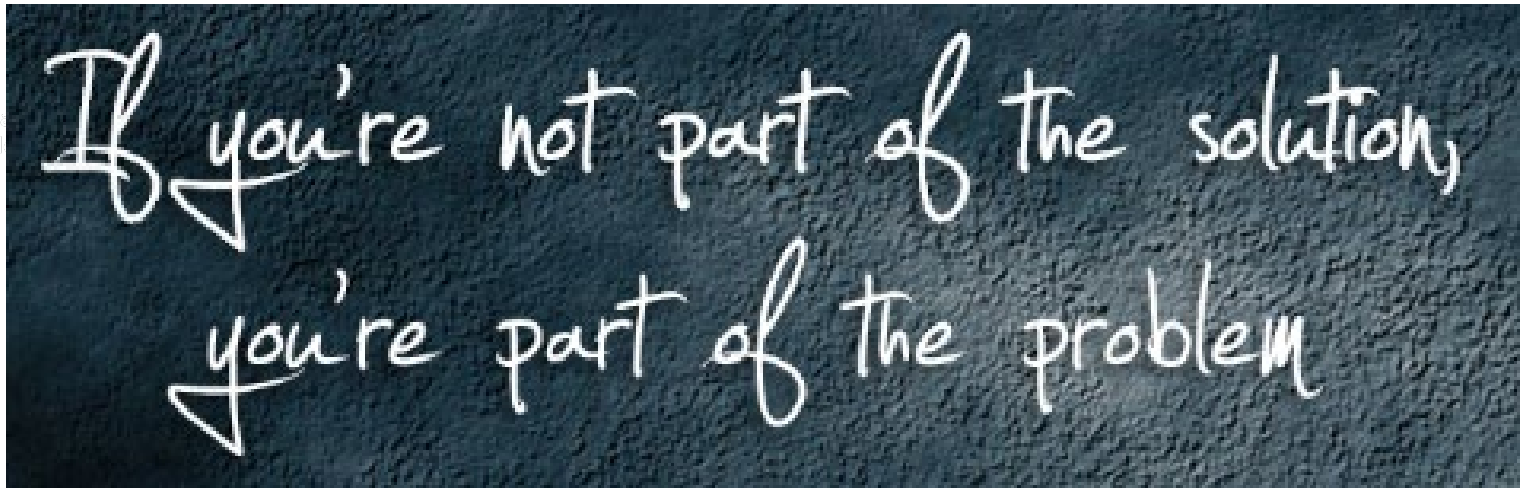

3X FORCEPS
CATH GLOVES

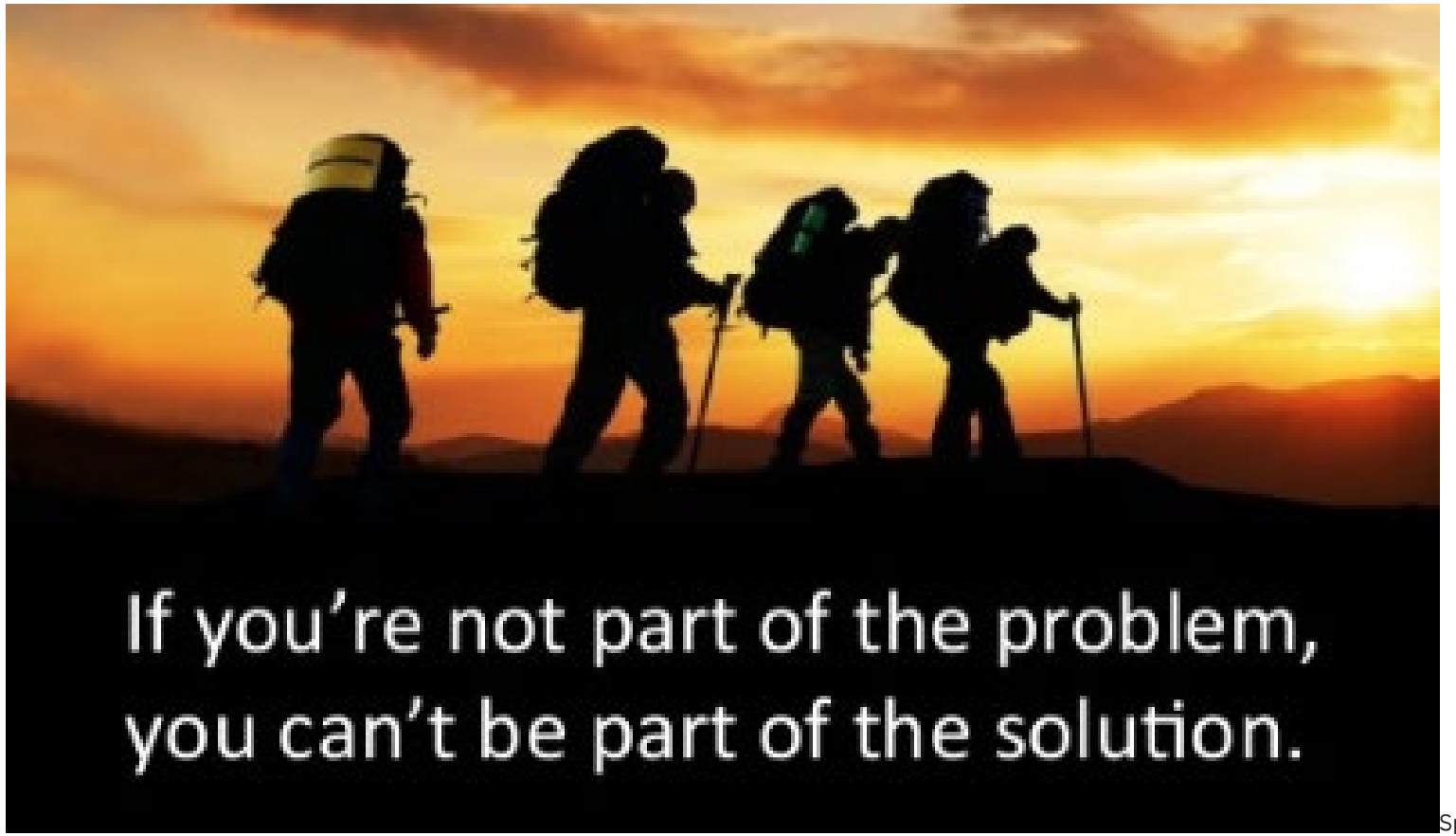

Flexline

- Cleaning and date checking schedules should be established
- Frequent rounding and auditing will help
- Monitor storage in SPD, OR, and inpatient areas

Recap

- Review AAMI ST79, AORN, and TJC Scoring
- Review manufacturer's instructions for use for devices, chemistries
- Infection Prevention and Control should collaborate with, and be an advocate for the sterile processing department
  - WE NEED YOU
- **Review your insulation testing!**


If you're not part of the solution,
you're part of the problem


If you're not part of the problem,
you can't be part of the solution.

QUESTIONS?

APIC

Association for Professionals in
Infection Control and Epidemiology

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