Surviving Your Next Survey!

Bob Marrs BA, CRCST, CIS, CHL

Objectives

At the end of this program, participants will be able to…

- identify the various accreditation organizations that survey healthcare facilities in the US,
- explain three (3) key areas of instrument reprocessing being emphasized during Joint Commission surveys,
- understand how to respond to Surveyor's questions regarding instrument reprocessing.

It is important to know…

That national survey organizations and some Department of Health (DOH) agencies now audit healthcare facilities for strict compliance with standards, guidelines, and MFG's instructions for use (IFU).

The Centers for Medicare & Medicaid Services (CMS) has recently revised their Survey and Certification document to include more **stringent audits** in the areas of infection control and sterilization.

Areas of emphasis include:

- Compliance with nationally recognized standards/documents.
- Formal training in areas of infection control and sterilization.
- Compliant cleaning, sterilization and monitoring procedures.
- Established criteria for flash sterilization.

Reference:
CMS Infection Control Surveyor Worksheet, Exhibit 351, 2015.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

ACCREDITATION ASSOCIATION *for* AMBULATORY HEALTH CARE

The Accreditation Association for Ambulatory Healthcare (AAAHC) added an infection control chapter to their standards handbook.

Infection control **highlights** included:

"Adhering to standards, guidelines, and manufacturer's instructions for cleaning, disinfection, and sterilization of instruments, equipment, supplies, and implants."

Reference:
OR Manager Magazine, Volume 26, Number 2, **2010**.

The Joint Commission

Beginning in 2010, surveyors have spent additional time during surveys evaluating what they have identified as three (3) key areas of instrument reprocessing – **Cleaning**, **Sterilization** and **Storage**.

In 2011, The Joint Commission surveyors received **in-depth training** on sterilization processes. This education was provided in collaboration with AAMI and included a review of all aspects of the AAMI ST79 guideline on steam sterilization.

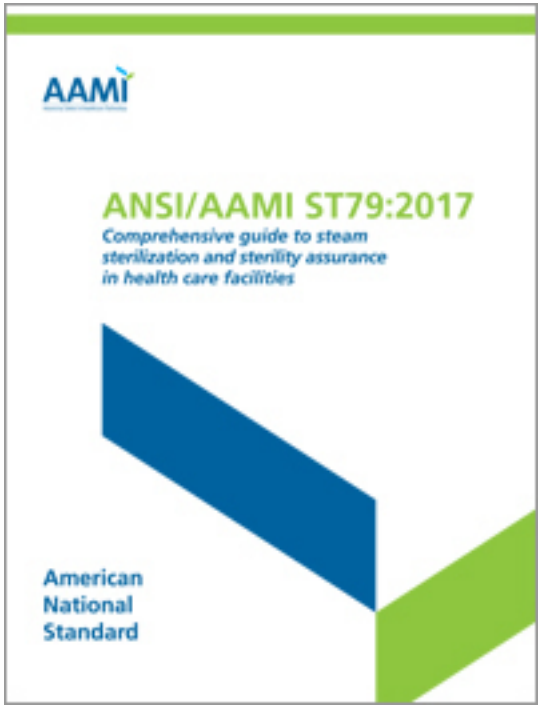
ANSI/AAMI ST79:2017

Considered the bible of sterilization, this comprehensive guide to steam sterilization in healthcare facilities covers all aspects of facility design, personnel and reprocessing procedures.

ORDER CODE: AAMI ST79

List Price: $396.00 plus shipping

Member Price: $346.00 plus shipping



The Joint Commission

- **Top Non-Compliance Item**
- The No. 1 standard found out of compliance is *IC.02.02.01, EP 2: The organization implements infection prevention and control activities when doing the following:* ***Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.***
- Specific infection control-related breaches recently identified by our survey teams in medical and dental sterilization processes tend to follow certain themes.

The Joint Commission

1. Poor Training
2. Overlooking Evidence
3. Ignoring Indicators
4. Non-Compliant Use of Instruments
5. Broken Processes

The Joint Commission

1. Poor Training

- lack of documented frontline staff competency and training specific to the sterilization processes specific to infection control
- lack of trained, documented managerial/supervisory oversight specific to the sterilization process

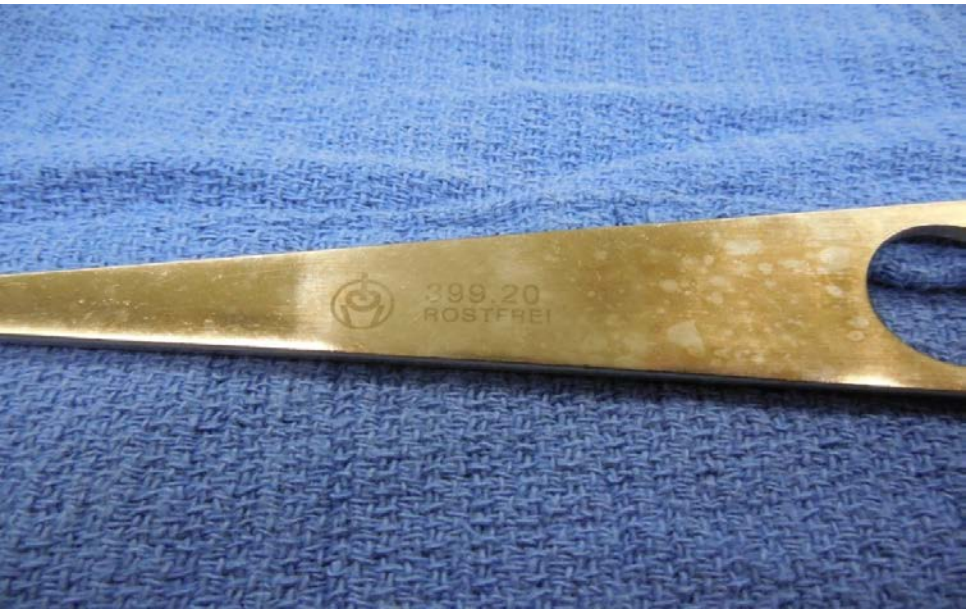
The Joint Commission

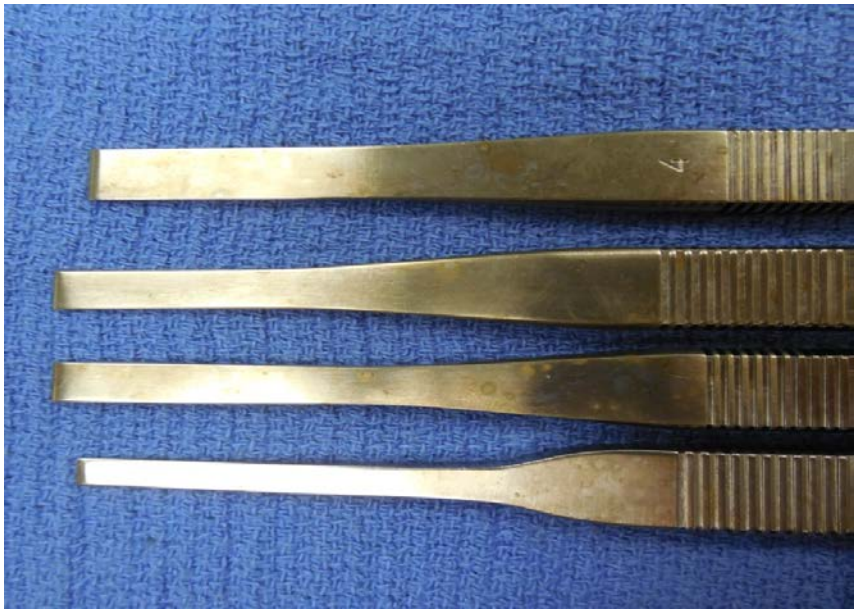
Overlooking Evidence

- little use or adherence to any sterilization Evidence Based Guidelines (EBGs); use of chemical indicator for ultrasound probes expired
- poor adherence to manufacturers' Instructions for Use (IFU) for medical and dental instruments and supplies lack of leadership oversight and accountability regarding evidence-based, manufacturer supported reprocessing of surgical instruments
- no accurate means of measurement for pre-cleaning detergent and enzymatic

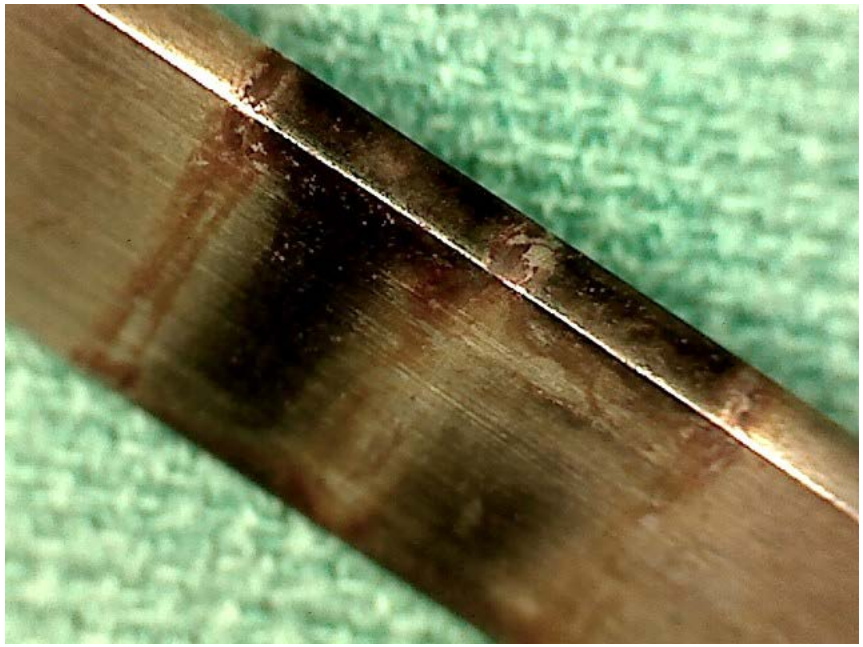
Instrument Inspection

Silicate Staining





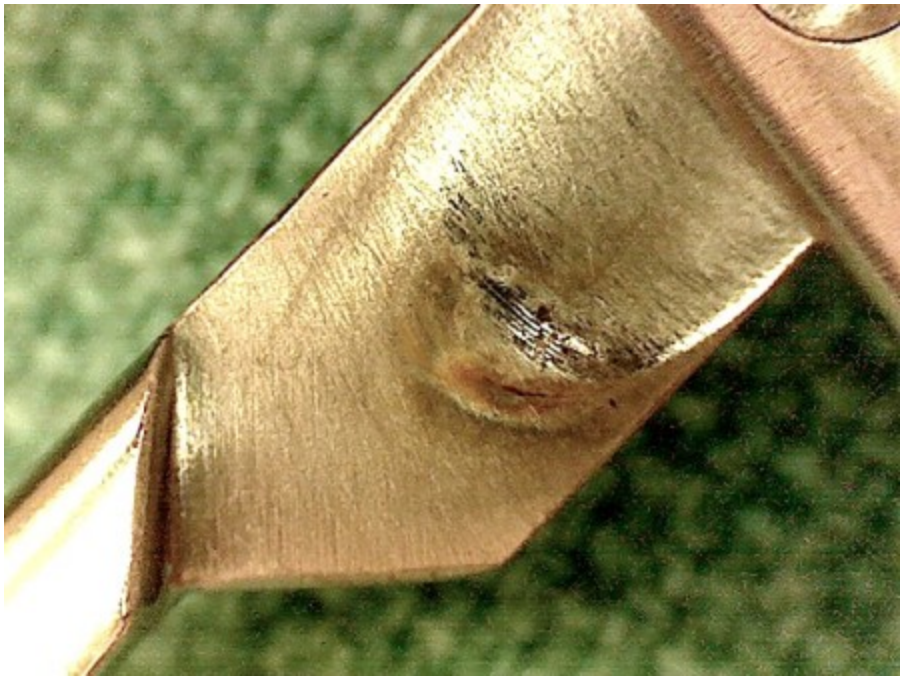
Surface Corrosion

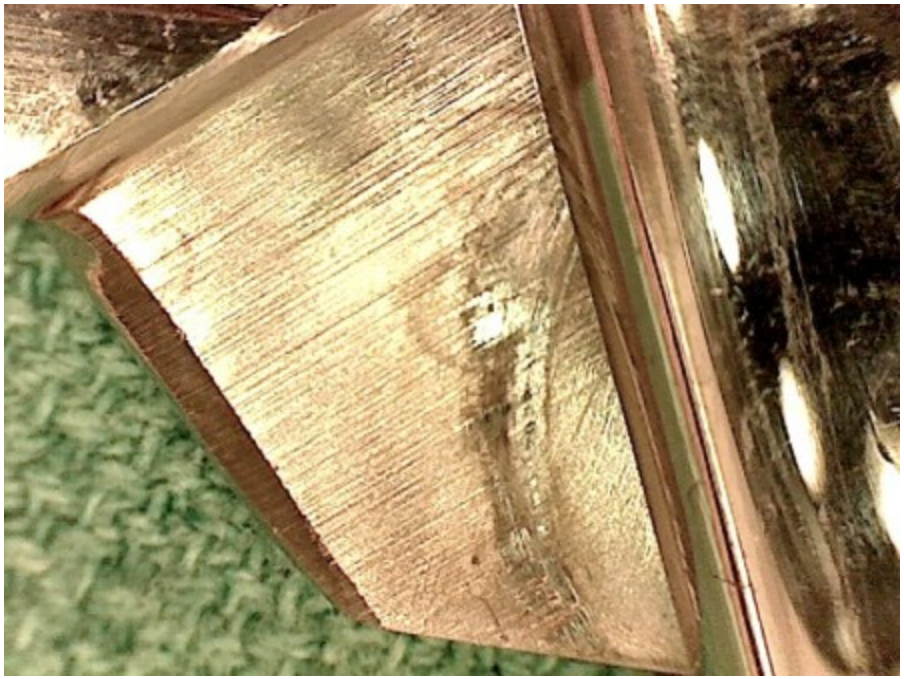


Surface Corrosion

Cause
• Disinfection, poor quality steam and water, rusty surfaces (instruments & machinery) in reprocessing cycle • Biological material residue
Consequences
• Risk of cross contamination for other instruments • Change to pitting corrosion • Corrosion of machinery
Prevention
• Remove corroded instruments from the reprocessing cycle
Recommended Action
• Send instruments for refurbishment • Replace corroded machinery

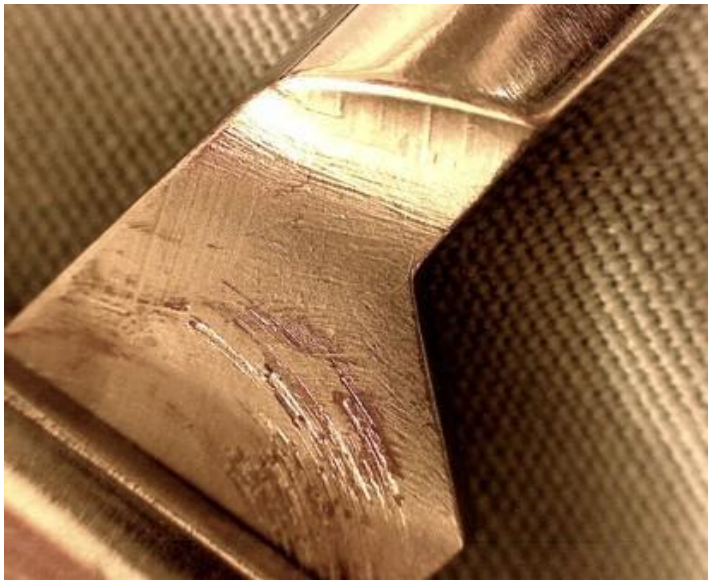
Friction Corrosion



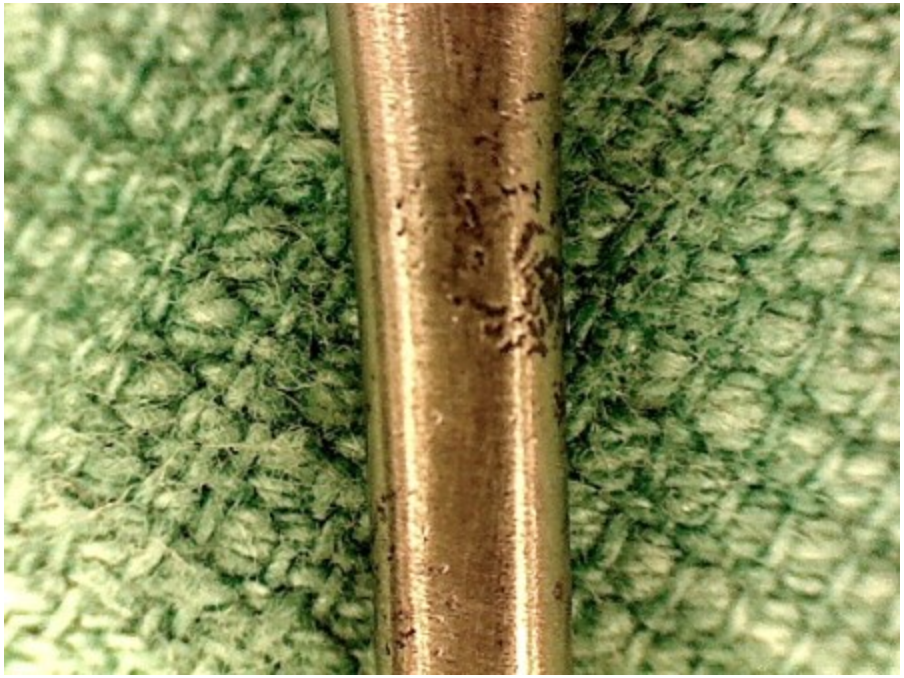


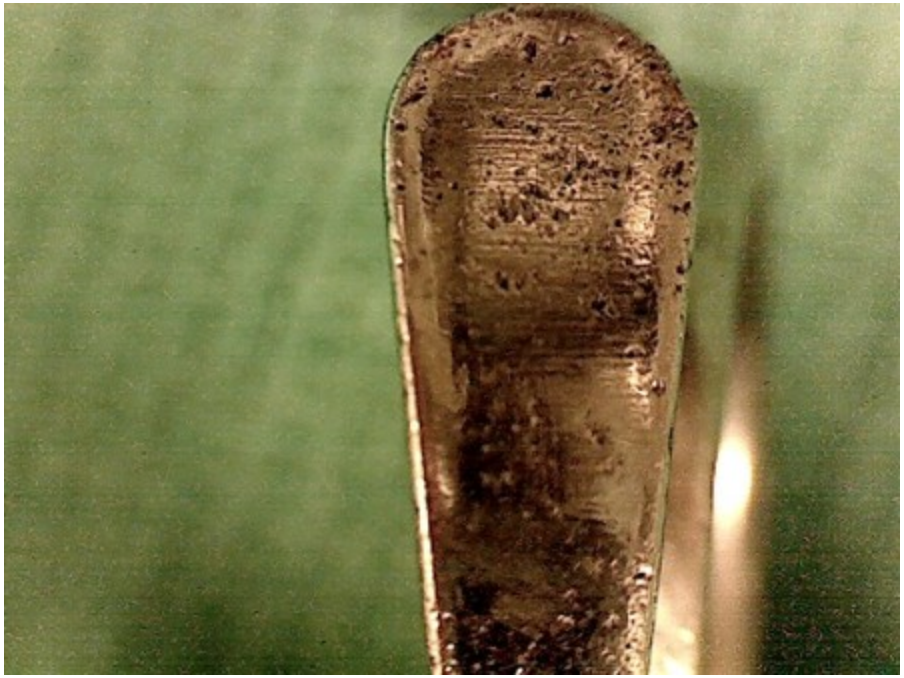
Friction Corrosion

Cause
• Friction in the joints of hinged instruments
Consequences
• Risk of cross contamination of other instruments • Development of pitting corrosion • Corrosion of machinery
Prevention
• Manual lubrication of all joints during reprocessing
Recommended Action
• Send instruments for refurbishment

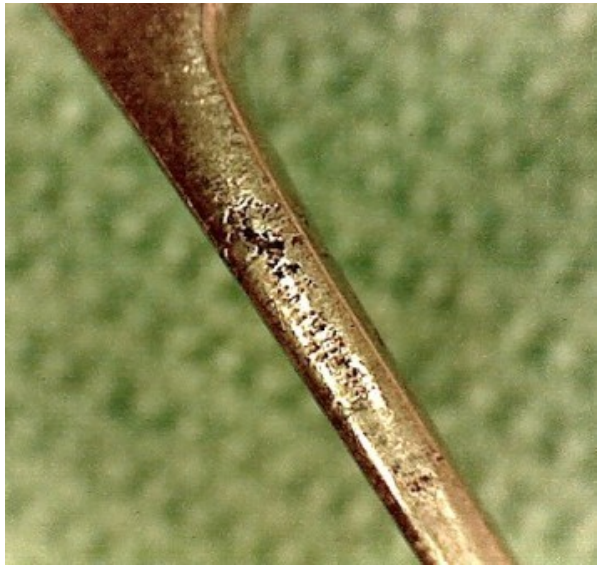


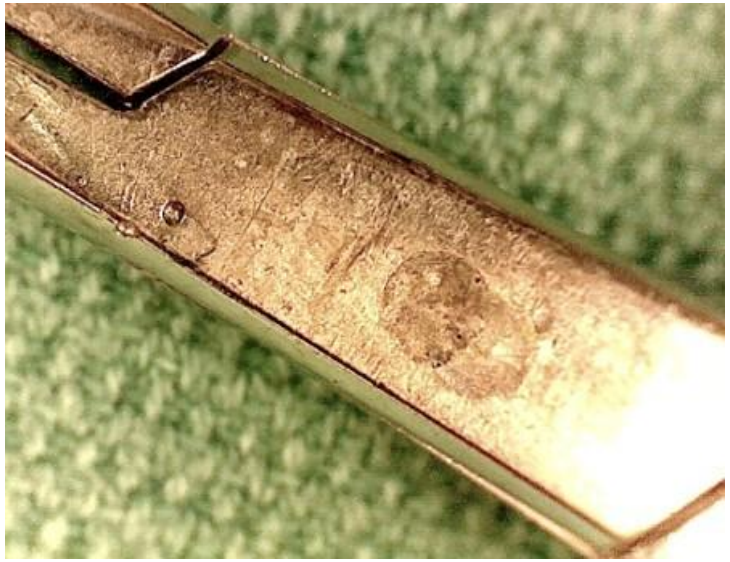
Pitting Corrosion

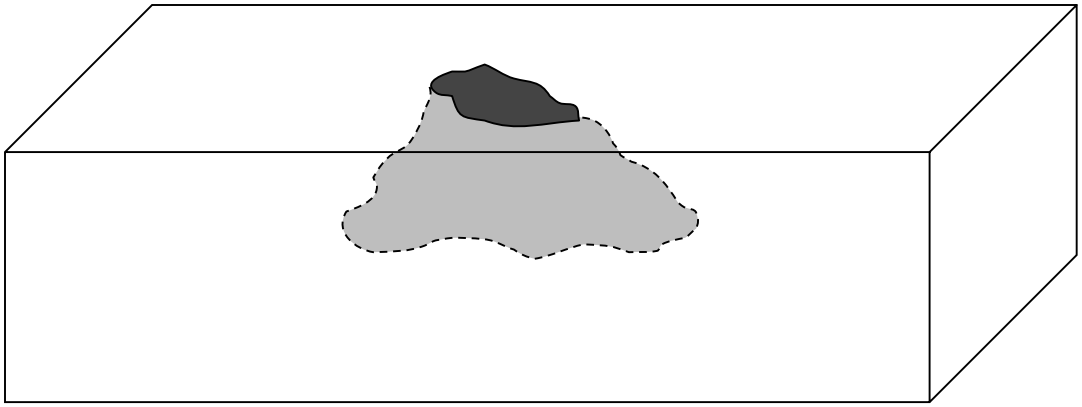


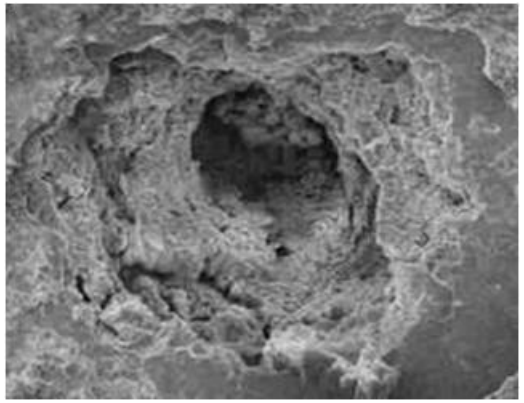


Pitting Corrosion







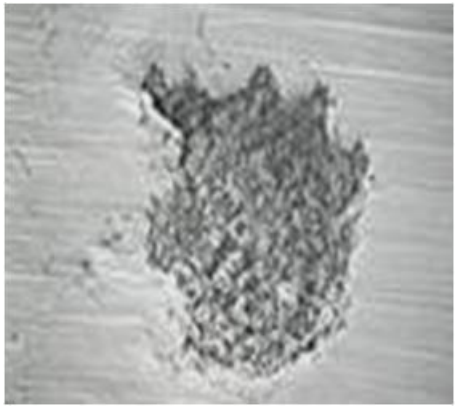


Pitting Corrosion:

Stereo microscope

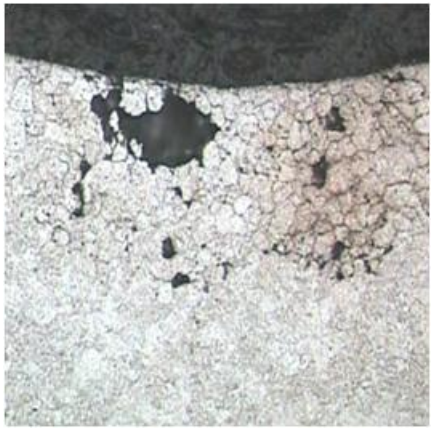
m = 20:1

Electron microscope



m = 500:1

Light microscope



m = 100:1

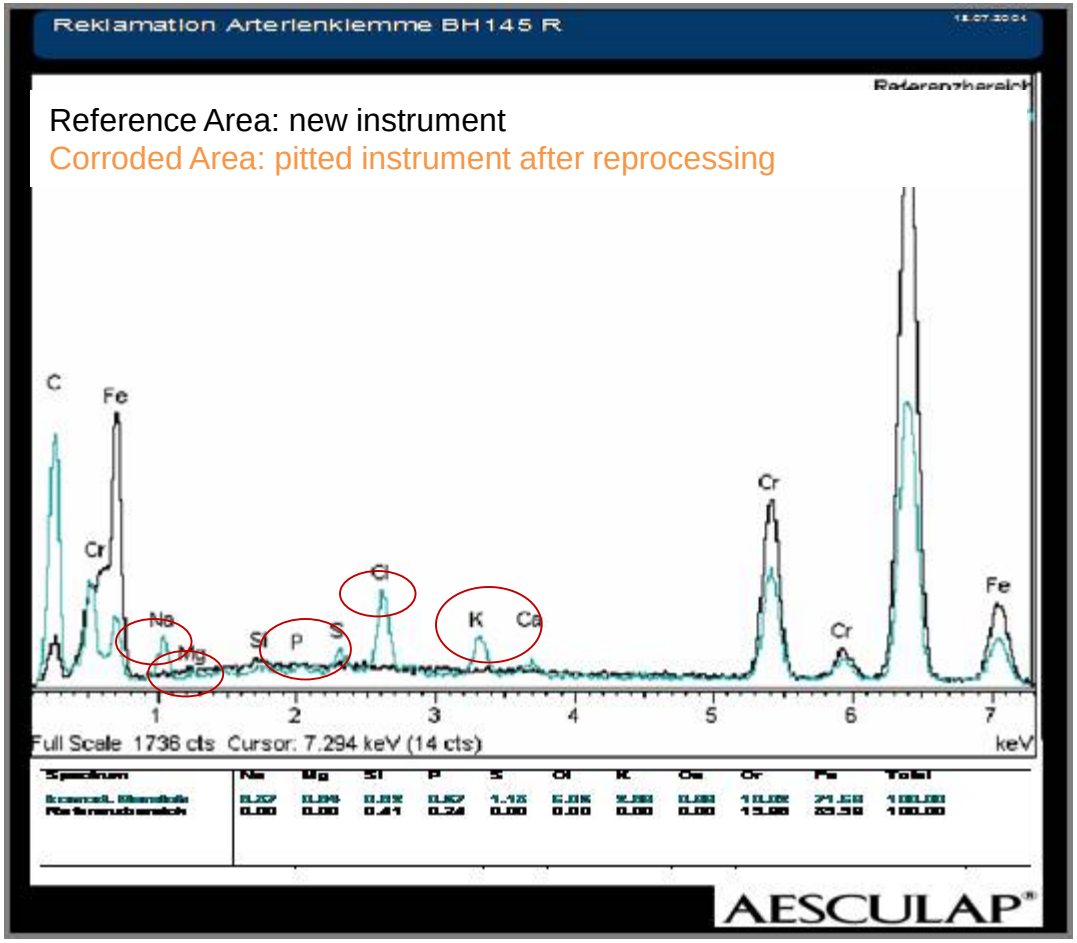
Results of pitting:

- enlargement of instrument surface
- formation of cavities
- change of grain structure

Insufficient cleaning

Risk of cracking

Pitting Corrosion – Hygienic Risks



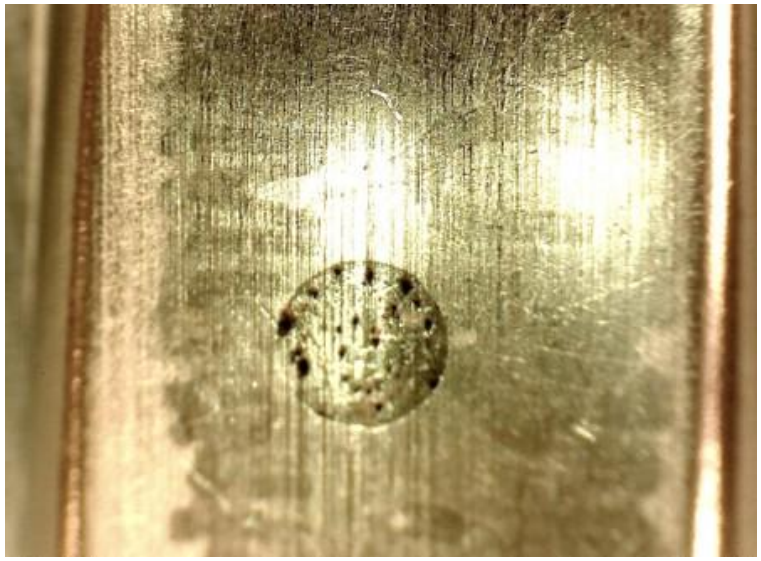
Elements of blood / body liquids:

- Na – Sodium
- Mg – Magnesium
- P – Phosphor
- S – Sulfur
- Cl - Chlorides
- K – Potassium
- Ca - Calcium

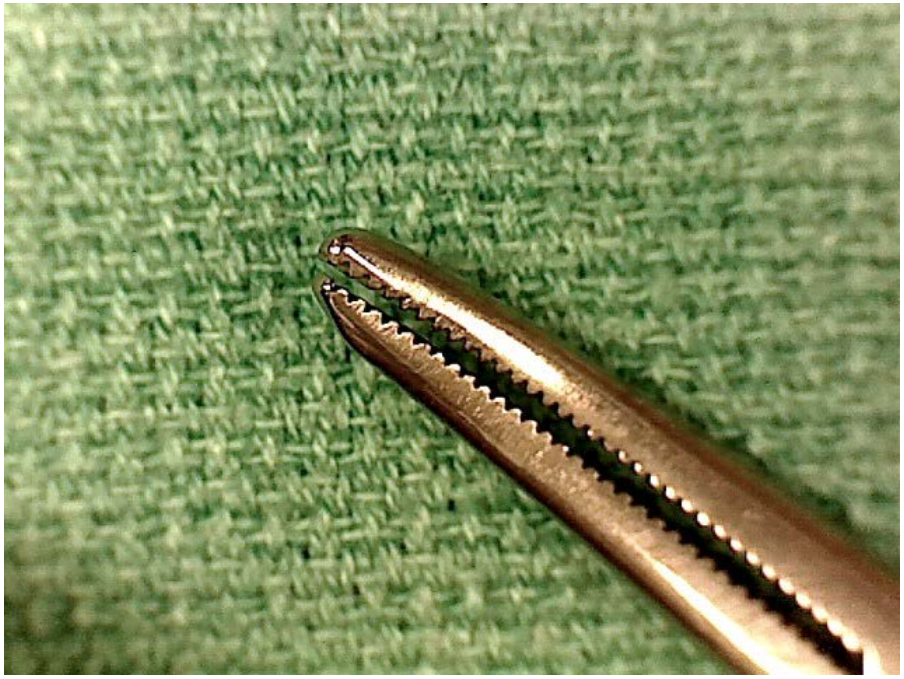
Safety Concern

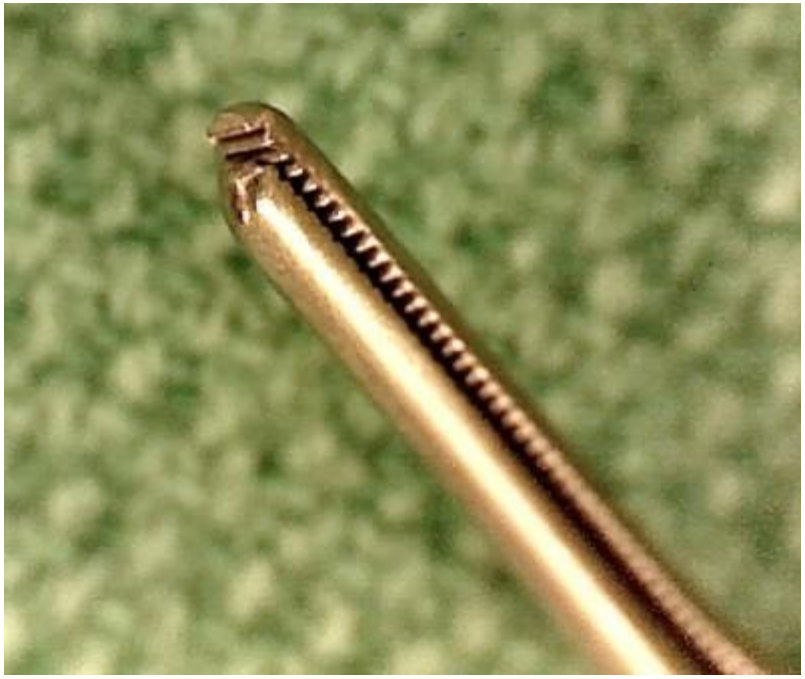
Pitting Corrosion

Cause
• Surface or Friction corrosion • High chloride content in final rinse Water or autoclave steam
Consequences
• Hygienic risk • Risk of cross contamination (instruments and machinery)
Prevention
• Improvement of water and/or steam quality
Recommended Action
• Corroded instruments should be withdrawn from service and replaced • Training for Staff on how to identify early indicators of pitting corrosion

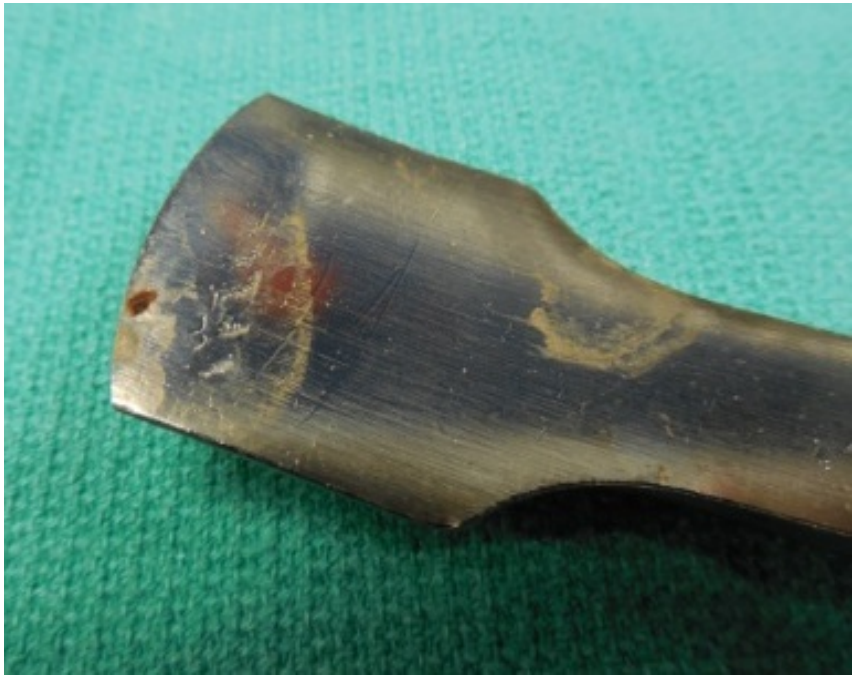


Damaged Instruments

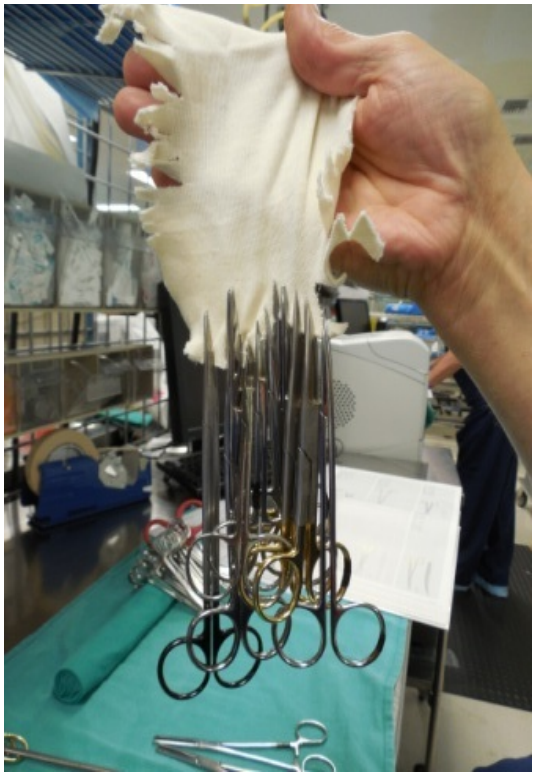




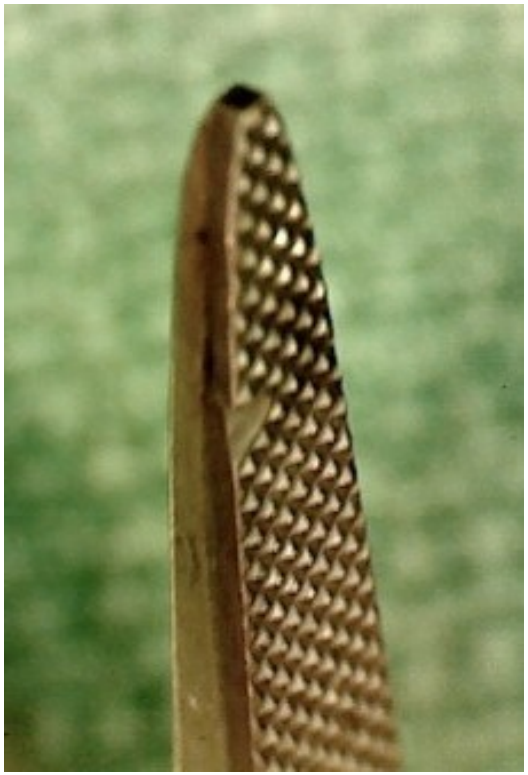
Other Findings - Residue



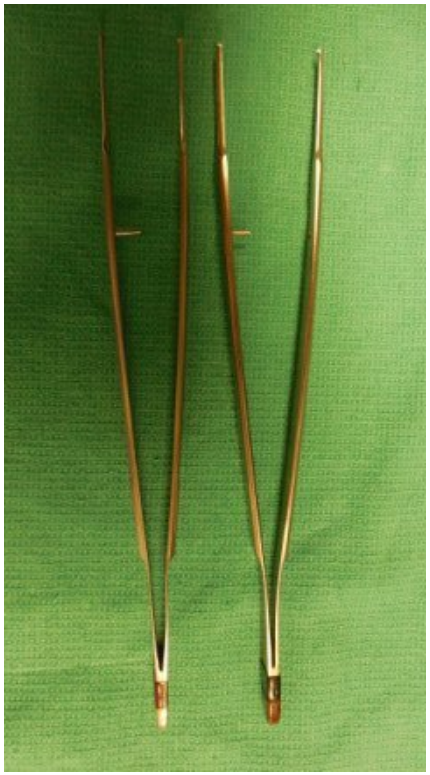
Other Findings



Dull Scissors

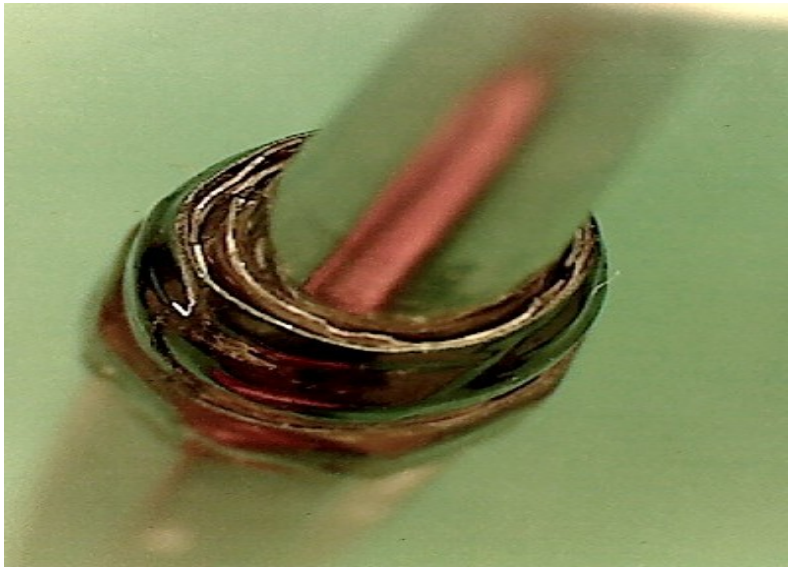


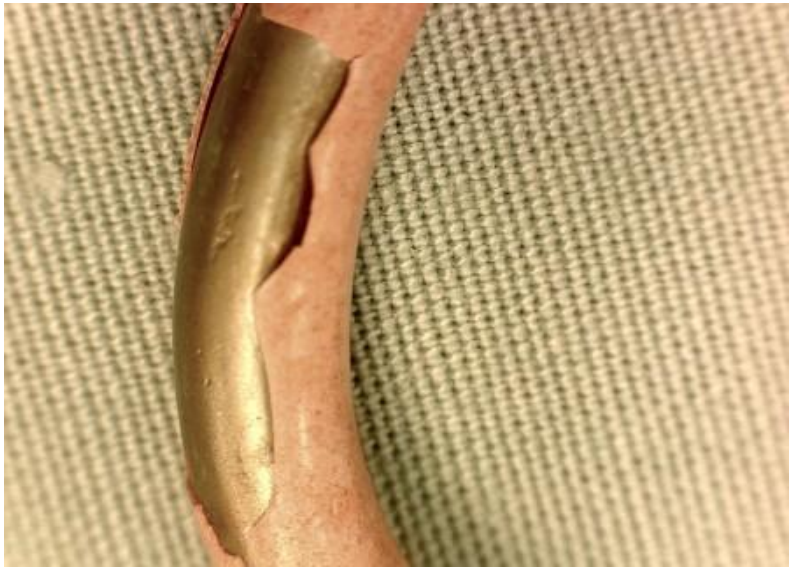
Damaged Needle Holders

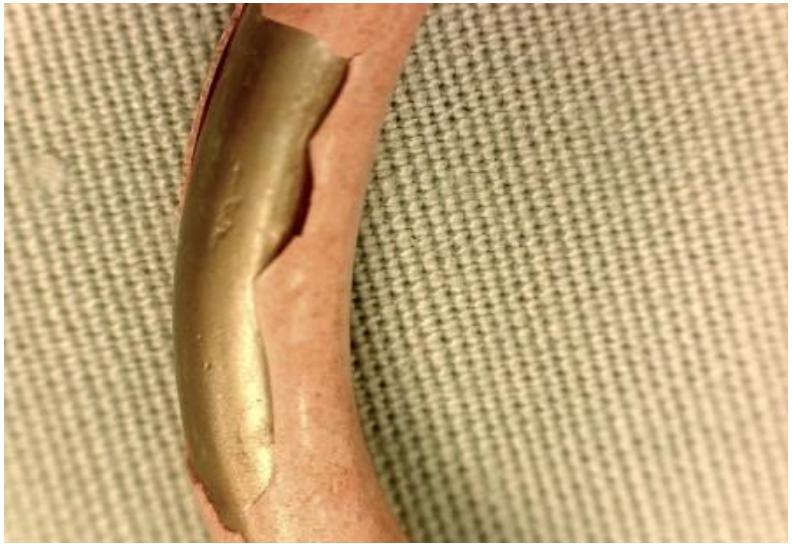


Sprung Forceps

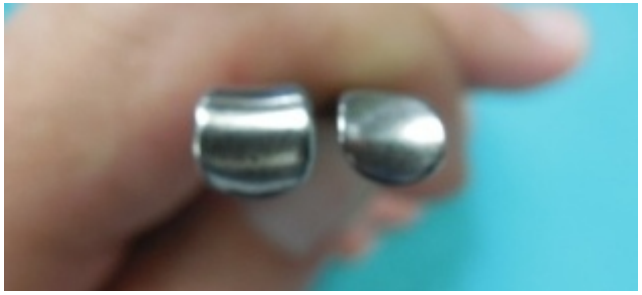
Other Findings – Improper Marking



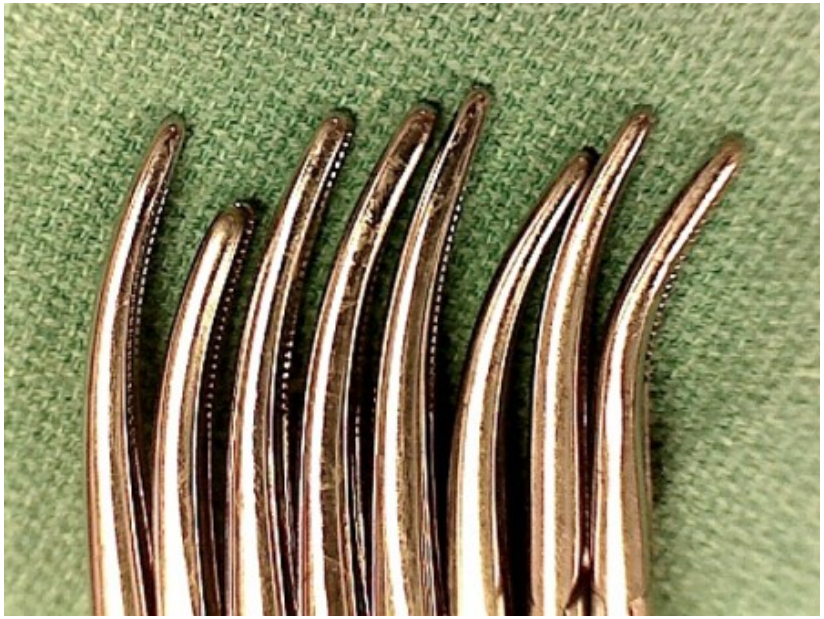




Manufacturer Variety

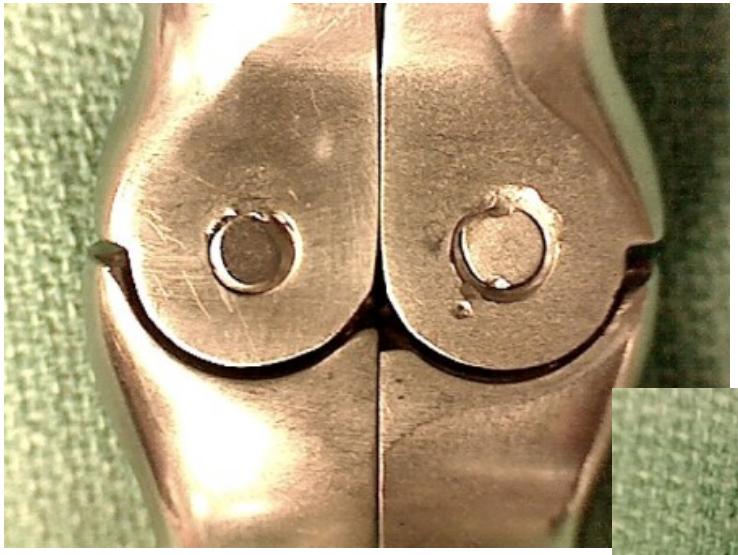


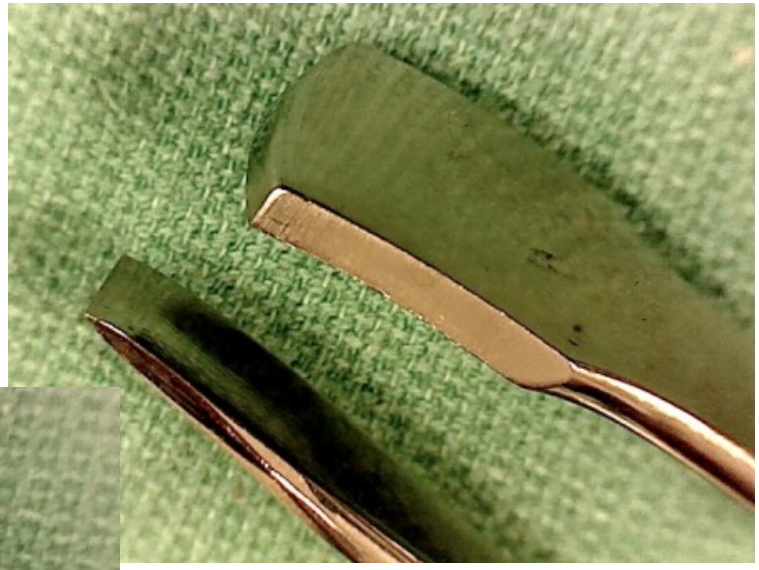
Same manufacturer, same article code, different shape

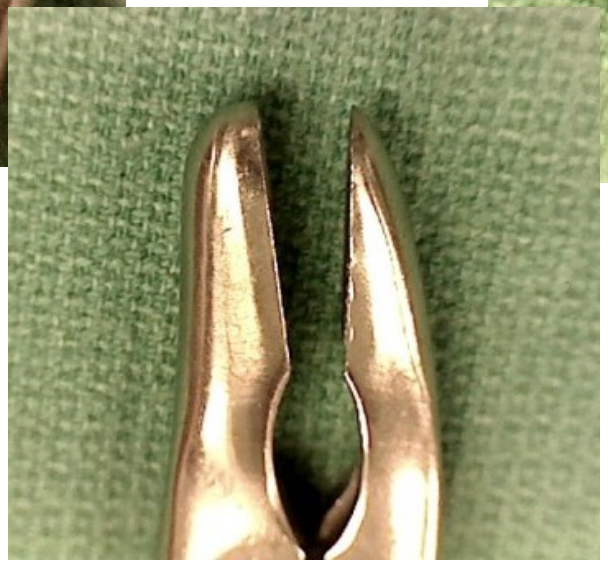


8 Hemostats, 4 Manufacturers

Findings – Repair Quality

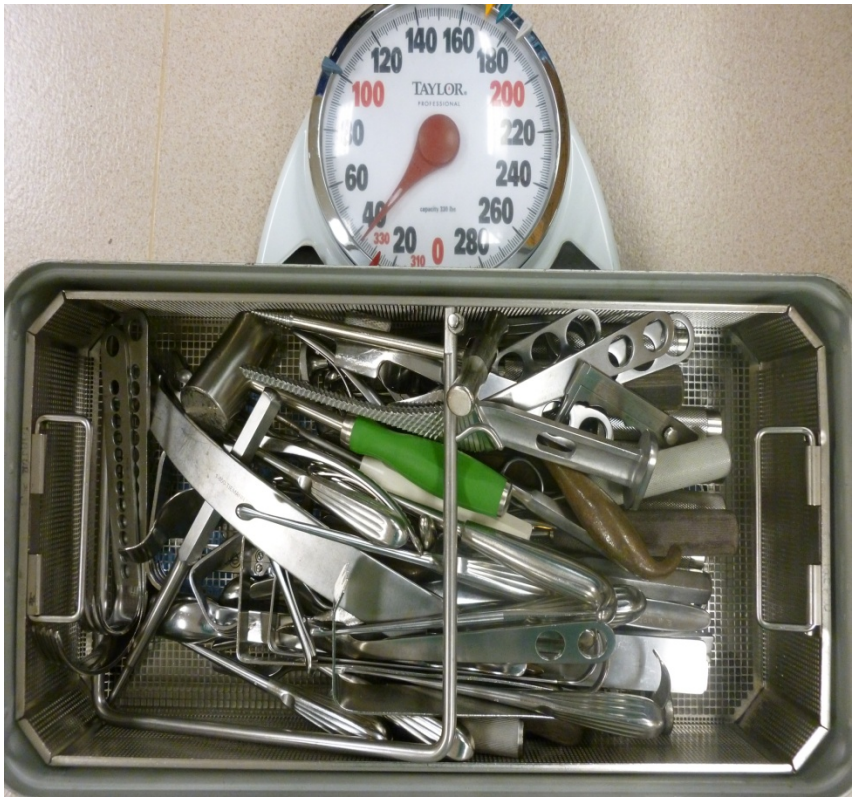






Professional & Continuous Repair Management is Imperative.

Set Weights & IFU's



Weight should not exceed 25 lbs

Impact to Efficiency:
Heavy Sets potential for staff injury
Time wasted looking for IFU /
Potentially not following IFU

IFU's

Mechanical Equipment

The Joint Commission

Ignoring Indicators

- premature release of instruments prior to the 24-hour read time of biological indicator result as required per the manufacturer's IFUs
- inconsistent use of chemical indicators in paper-plastic peel pouches
- inadequate documentation of physical/mechanical monitoring that sterilization parameters were met (time, temperature, pressure)

The Joint Commission

Non-Compliant Use of Instruments

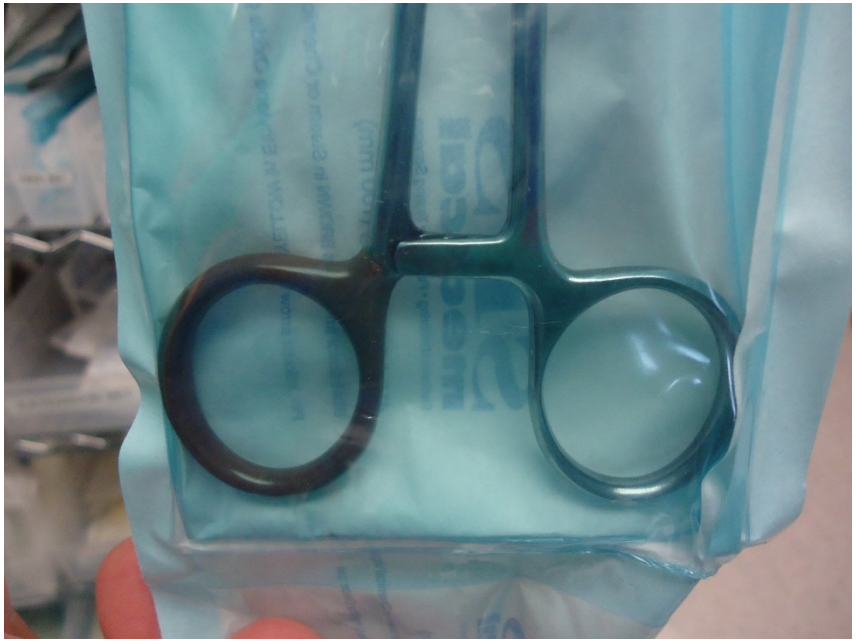
- hinged instruments observed to be in closed position in peel packs
- failure to use personal protective equipment (PPE) including protective gowns or eye shields during decontamination activities
- instruments being cleaned, decontaminated and left to dry in the only sink available in the procedure room. No clean sink available for hand hygiene
- lack of physical or defined separation of contaminated and clean instruments within the dental procedure areas where decontamination activities occur

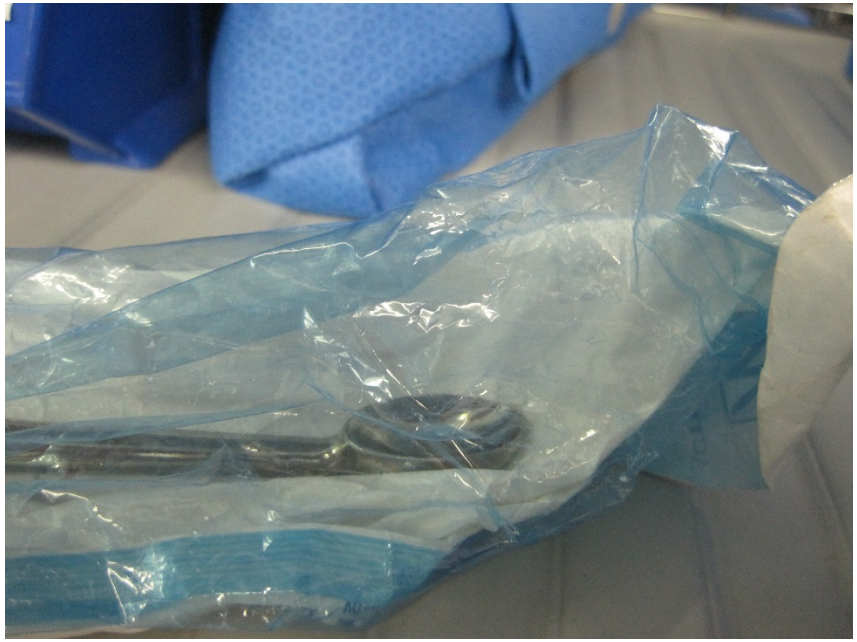
Pouches

Pouches

Pouches

Pouches





The Joint Commission

Broken Processes

- lack of documentation of monthly sterilizer preventative maintenance and cleaning as required per manufacturer instructions for use
- insufficient process to ensure that brushes used in the decontamination area were cleaned when soiled
- unsatisfactory tracking of sterilizer maintenance (blanks on logs)
- inadequate tracking/monitoring parameters for cycles

The Joint Commission

1. Cleaning and decontamination. All visible soil must be removed prior to sterilization because steam and other sterilants cannot penetrate soil, particularly organic matter. Manufacturers' instructions are available for all instruments; these include directions for the cleaning and decontamination process.

   Some smooth metal instruments may be easily brushed clean, while complex products may require disassembly and special cleaning techniques. Many manufacturers specify that an enzymatic soak be used as well.

The Joint Commission

2. Sterilization.

   Most sterilization is accomplished via steam, but other methods are also available. Steam sterilization of all types, including flashing (IUSS), must meet parameters (time, temperature and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument. In addition to these instructions, parametric, chemical and biological controls must be used as designed and directed by their manufacturers.

The Joint Commission

3. Storage or return to the sterile field.

   Each newly sterilized instrument must be carefully protected to ensure that it is not recontaminated. For full steam sterilization cycles, packs of instruments are wrapped and sealed. Instruments subjected to steam sterilization using methods other than full cycle sterilization may be transported in “flash pans” or other devices specifically designed for the prevention of contamination during and after the steam process.

The Joint Commission

JC surveyors will, among other activities:

- Observe instruments from the time they leave one OR to when they are returned to the next.
- Ask HCWs to provide the Mfg's' instructions for instrument sterilization, and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.
- Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.

The Joint Commission

- Verify that staff members are wearing appropriate personal protective equipment.
- Observe the sterilization process. The surveyor will ask for the manufacturer's instructions for the following items: the sterilizer, wrapping or packing, and the instruments.
- Review sterilization logs. Surveyors will ask about physical, chemical and biological indicators.
- Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.

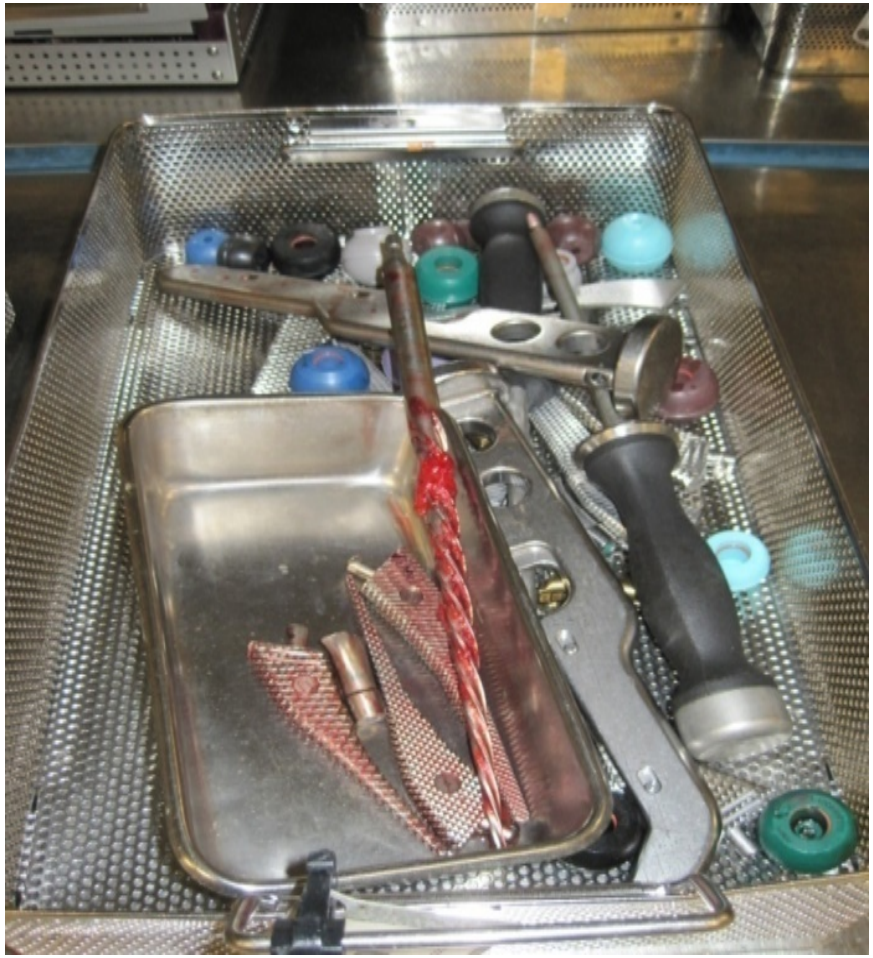
Point of Use Preparation
(Soiled Items)

AORN RP: Care of Instruments

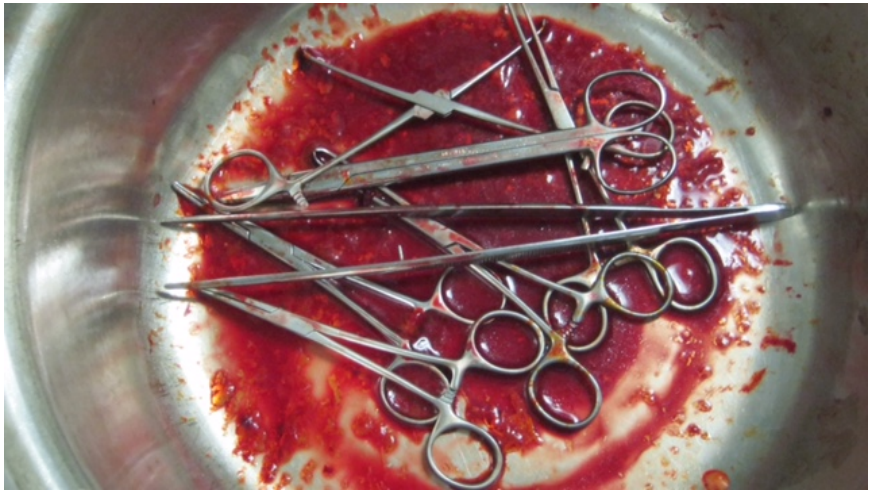
Instruments should be wiped as needed with sterile surgical sponges moistened with sterile water during the procedure to remove gross soil.

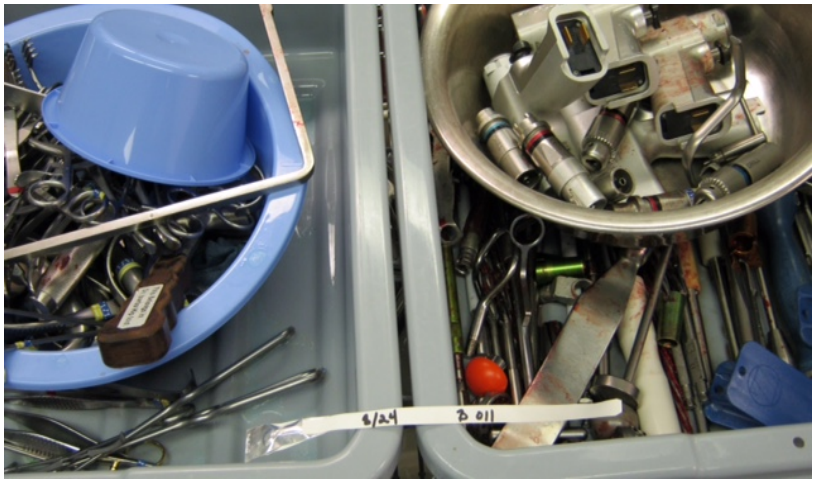
Instruments with lumens should be irrigated with sterile water as needed throughout the surgical procedure.

End of Use to Decontamination Receipt



Current Situation





Point of Use Preparation
(Soiled Items)

AORN RP: Care of Instruments

Blood and body fluids, as well as saline, are highly corrosive. Corrosion, rusting, and pitting occur when saline, blood, and debris are allowed to dry in or on surgical instruments.

Dried blood and debris can be difficult, if not impossible to remove from all surfaces during the decontamination process; therefore, subsequent disinfection or sterilization may not be achieved.

Other Key Factors for Point of Use

Biofilm

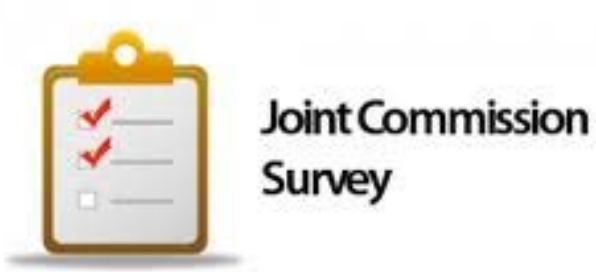
Biofilm consists of an accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily. Biofilm has the effect of protecting microorganisms from attempts to remove them by ordinary cleaning methods used in the sterile processing department.

These materials can be difficult to remove from all surfaces during the cleaning and decontamination process, reducing the efficacy of the subsequent sterilization process.

Note: Consider the complex geometric shapes, curves, lumens, and hinge points of modern devices.

So, let's discuss...

The types of questions and possible findings, that you can now expect from TJC as well as other surveyors regarding instrument reprocessing when a strict CS audit is performed.



Joint Commission
Survey

Using what is called a Tracer Method, TJC surveyors will among other activities:

- Follow a case cart from an OR suite to the decontamination area.

Joint Commission
Survey

- Are contaminated instruments transported in a timely manner?

- Are they contained in leak a proof container and labeled with a biohazard symbol?

OSHA requirement

Joint Commission Survey

- How does the OR Technician or Nurse deliver the case cart to decontamination? Does he/she cross the line into decontamination? If so, is there appropriate PPE to change into prior to entering decontamination?

- When entering decontamination, does the staff instruct you to put on appropriate PPE?

Expect your Surveyor…

- To verify that personnel are wearing correct PPE?
- To ask who is certified and who trains new staff?
- To ask to see your competency checklist?
- Do you have the AAMI Standards?

CERTIFICATION

AAMI ST79 Section 4.2.2

It is recommended that all personnel performing sterile processing activities be certified as a condition of employment. At a minimum, all such personnel should successfully complete a central service certification examination within two years of employment and should maintain that certification throughout their employment.

Facility Design

Temperature and humidity control is important for staff comfort and the containment of microbial growth, especially mold. A daily record should be kept.

Commercial fans and reservoir type water humidifiers should <u>not</u> be used.

Facility Design

(Environmental Control: Temperature)

3.3.5.5 Heating, ventilation, and air conditioning (HVAC) operating parameters

ANSI/ASHRAE/ASHE 170

- Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the sterile processing areas. Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log.

Facility Design

(Decontamination Area)

Should be separate from other areas with floors, walls, ceiling and work surfaces made of nonporous materials to withstand frequent cleanings and wet conditions.

Decontamination area should have a minimum of 10 air exchanges, negative air flow and be exhausted outdoors without re-circulation.

Teach your staff to perform the "tissue test"

Facility Design

(Decontamination Area)

Should be separate from other areas

Teach your staff to perform the "tissue test"

Joint Commission Survey

- Is the eye wash station checked and how often?
- Are the eyepieces clean and free of debris?
- Does the eye wash station have lukewarm water running through it?

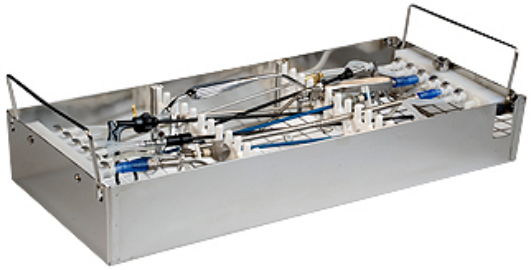
Eyewash stations should be run for 3-5 minutes when checking them weekly (every 7 days). The water should be turned on and allowed to push the eyepieces off without manually removing them.

Facility Design

With the use of cleaning and disinfection solutions, or EO, emergency eye wash units must be available, with unobstructed access.

They must be “hands free” and able to flush both eyes simultaneously for 15 minutes.

The Joint Commission



Joint Commission surveyors will, among other activities:

- Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.

EXAMPLE MFG's Cleaning IFU

Zimmer Orthopedic Surgical Instruments

1. Completely submerge instruments in enzyme solution and allow to soak for 20 min.
2. Rinse in tap water for minimum of 3 min.
3. Ultrasonic clean for 10 min.
4. Rinse in purified water for at least 3 min.
5. Repeat sonication and rinse steps.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

50 minutes?

Joint Commission
Survey

- What sink is used for soaking and which is used for rinsing?
- Are they labeled as such?
- How many minutes does the instrument manufacturer require for a soak? Do you time the process?
- Are instruments rinsed with cold water before cleaning?

Joint Commission Survey

- How much enzymatic cleaner is used per gallon of water?
- How do you know how much to use?
- Do you measure when adding?
- Is there a closed system for feeding mechanical washers? If not, is there a cap to ensure debris does not enter the detergent bottle?

Joint Commission Survey

- Do you have an ultrasonic cleaner?
- How often do you change the solution?
- What is the daily routine maintenance required for the ultrasonic and mechanical washers?
- Who is responsible for routine maintenance?
- Are you performing cleaning tests on mechanical washers? If not, how do you ensure your instruments are clean?

The Joint Commission

Joint Commission surveyors will, among other activities:

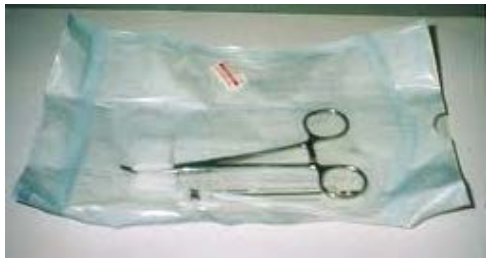
- Ask health care workers to provide the MFG's instructions and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.

Joint Commission
Survey

- Is HLD used in decontamination?
- If so, how long is the solution good for?
- Are any opened bottles labeled?
- How long is the soak time?
- How long are the quality test strips good for?
- Are the MRC strips dated?
- When a new bottle is opened, what is the process?

Surveyors have been reported to have asked…

- Why are your hinged instruments not fully open?
- Why are they in contact with other instruments inside the same set?



The Joint Commission

Joint Commission surveyors will, among other activities:

- Observe the sterilization process. The surveyor will ask for the manufacturer's instructions for the following items: the sterilizer, wrapping or packing, and the instruments.

The Joint Commission

The Joint Commission

Joint Commission surveyors will, among other activities:

- Review sterilization logs.
- Surveyors will ask about physical, chemical and biological indicators.

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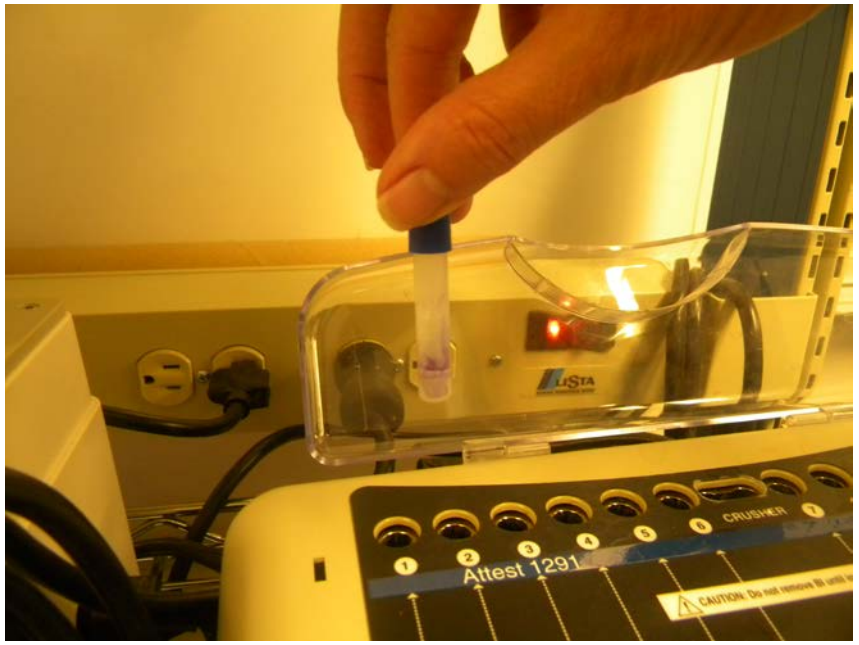

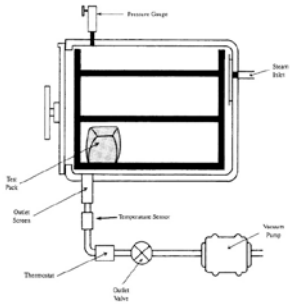

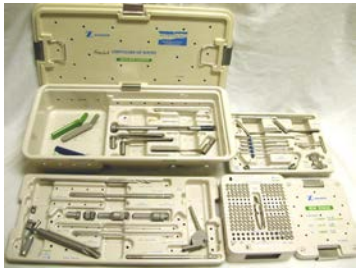

- How often do you run a Bowie-Dick?
- Where do you place your test pack(s)?
- What is your process for sterilizing implants?
- Do you flash implants? Not likely to say “IUSS”
- What is your flashing rate?
- What have you done to decrease flashing?
- How do you track instrument sets?
- What do you do when you have a wet pack?

The Joint Commission

Surveyors will, among other activities:

- Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.

Let’s Review

Surviving Your Next Survey!

Surveyors will, among other activities:

- Observe instruments from the time they leave one OR to when they are returned to the next.
- Ask HCWs to provide the MFG's' instructions for instrument sterilization, and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.
- Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.

Surviving Your Next Survey!

- Verify that staff members are wearing appropriate personal protective equipment.
- Observe the sterilization process. The surveyor will ask for the manufacturer's instructions for the following items: the sterilizer, wrapping or packing, and the instruments.
- Review sterilization logs. Surveyors will ask about physical, chemical and biological indicators.
- Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.

Conclusion

While accreditation organizations will be looking for strict compliance with national standards during their survey, your goal should be compliance every day.

Even though you see thousands of instruments each and every day, you must never forget that behind every instrument, is a **PATIENT**!

Questions?