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Cleaning Monitoring: Process, Products, & Results

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Healthmark, A Getinge company

Disclosures

- Presenter is an employee of Healthmark, A Getinge company – a manufacturer and distributor of medical products to healthcare facilities and healthcare professionals.
- No compensation has been received for this presentation
- All opinions are those of the presenter.
- This presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

Healthmark Policy

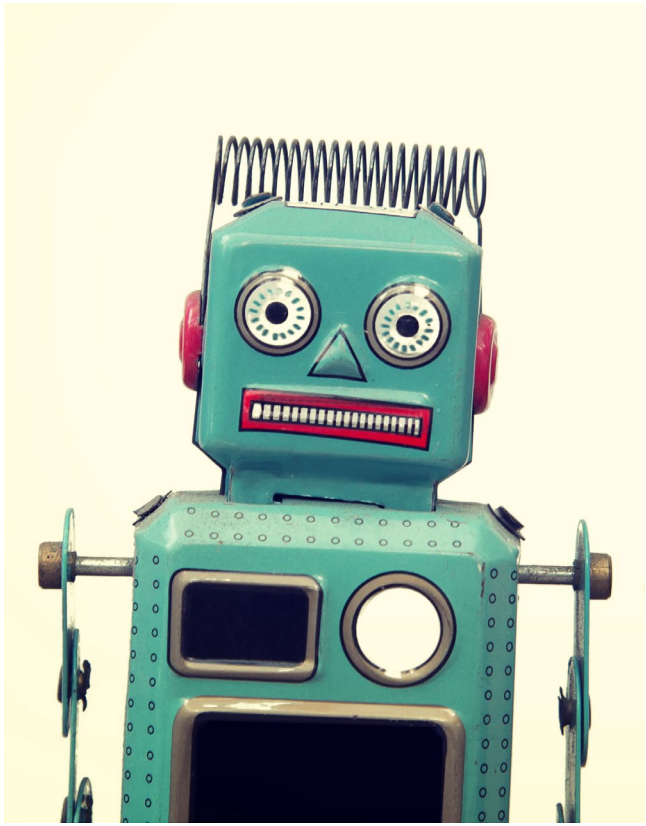
- Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

- This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

Objectives

- Understand the 10 Factors that affect the cleaning process
- Understand the Manual vs Mechanical Cleaning Processes
- Take a closer look at Instrument Washers, Ultrasonics, & Cart Washers
- Assess cleaning verification
  - Recommendations
  - Products

Why do we Need Cleaning Verification Testing?



Did you know?

- Hospitals were not required to challenge their automated cleaning equipment until the year 2000?

The Ten Factors of Clean

- Time
- Water Quality
- Temperature
- Chemical Activity
  - Dilution/Concentration
- Mechanical Action
- Item to be cleaned (Substrate)
- Type of Soil
- Instructions for Use (IFU)
- Human Factors
- Quality Management System (QMS)

Adherence to these 10 factors will determine how clean your devices will be.

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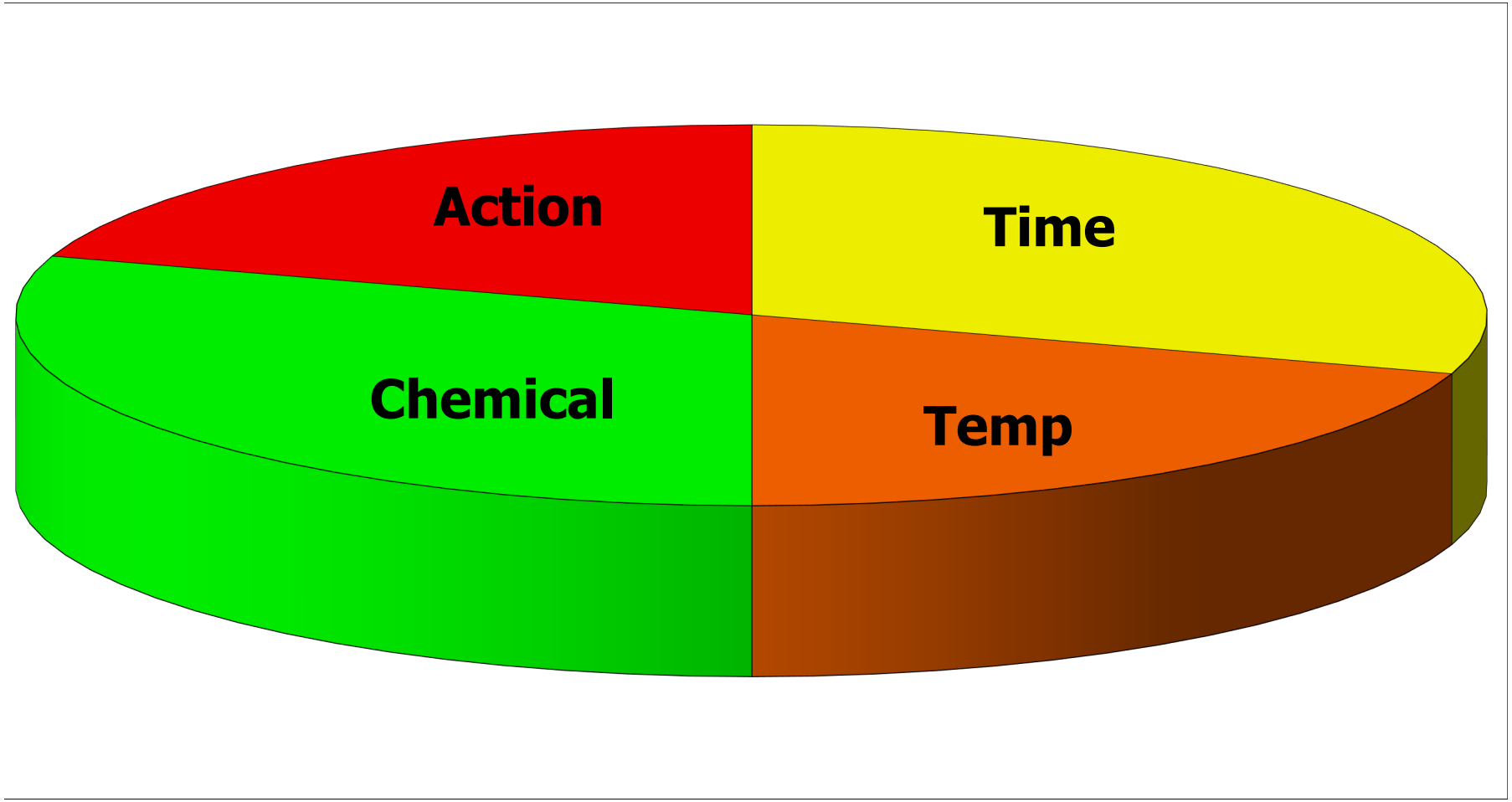
Four Factors of Cleaning



These factors are interdependent.

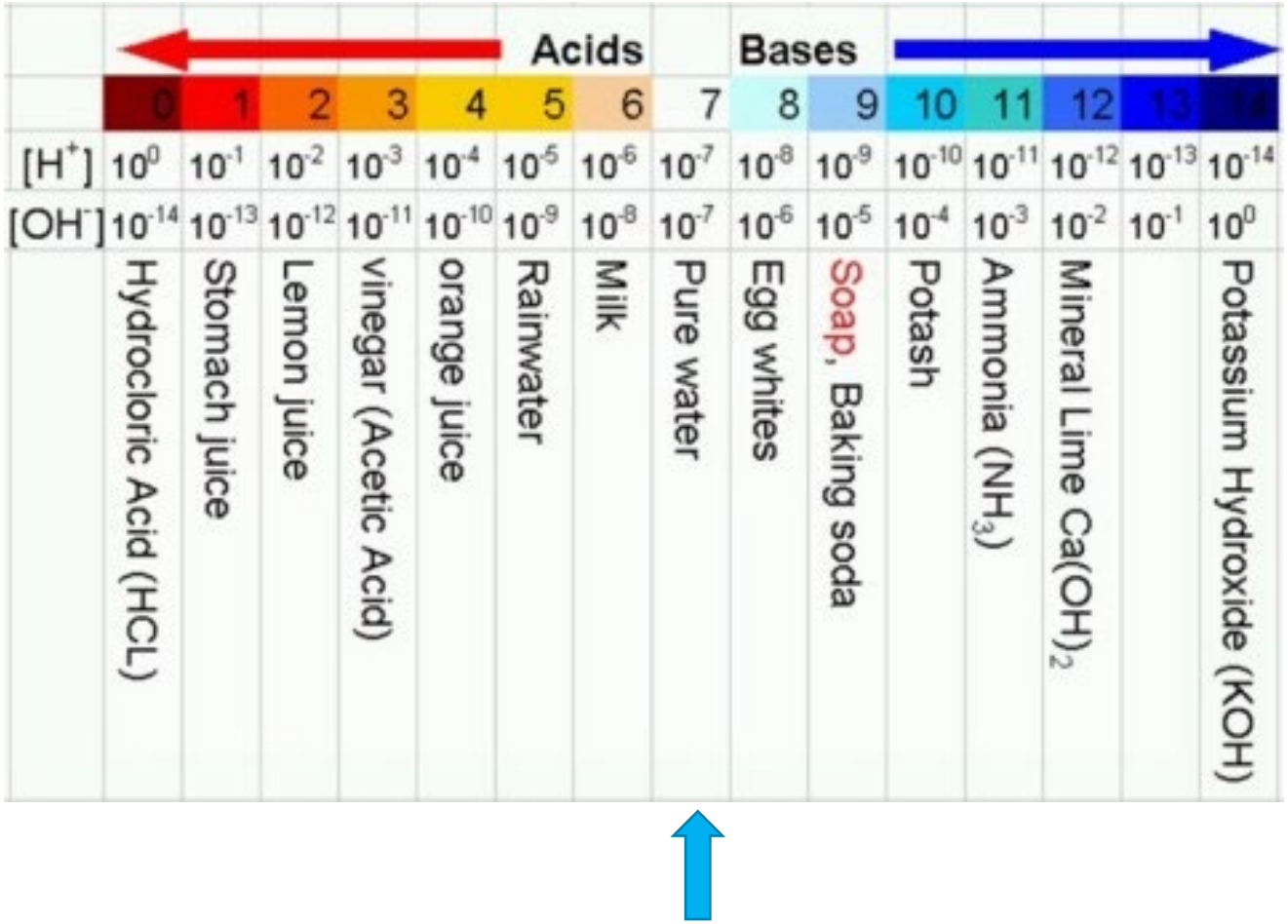

Water Quality

Water Quality

- Water quality is a broad concept covering several key characteristics of the water used
- The relevant measurable characteristics are pH level, Hardness, and Alkalinity
- Greatly impacts the performance capabilities of the chemistry being used.

What is pH?

- The pH scale measures the acidity or alkalinity of a liquid
- The diagram shows that the scale ranges from 1 which is acid to 14 which is alkaline, with the mid-point between the two being 7, which is neutral



As a guide, water would fall around 7

How does water hardness effect cleaning

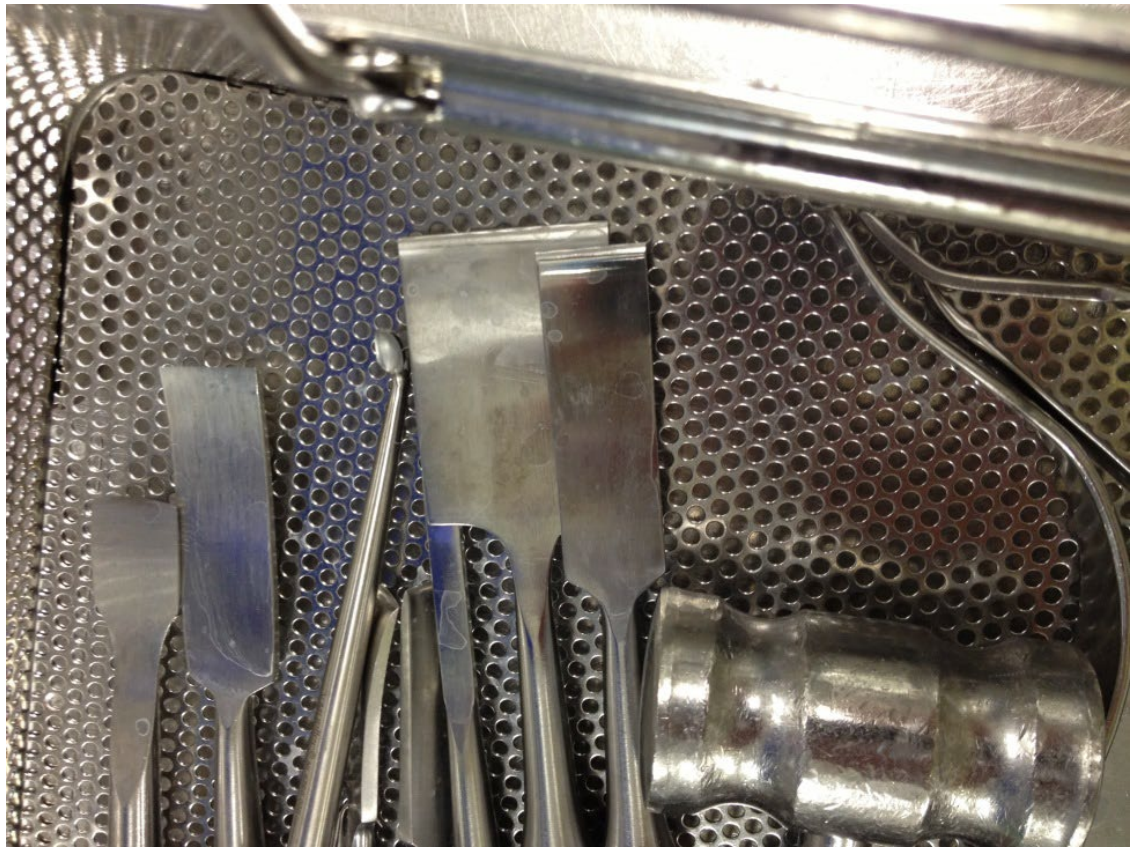
When chemistry does not rinse away easily, It can remain behind and results in visible deposits

Some of chemistry is tied up managing the hard water minerals. This reduces the amount of chemistry available to perform cleaning

The harder the water, the more chemistry that is needed effectively clean

Detergents used in automated washers should be low-foaming. If foaming is excessive, wash action is greatly reduced effecting the efficiency of the cleaning process

What are those spots on my medical devices?*



Water constituents and their influence in reprocessing

While any natural water contains dissolved salts, The nature and concentrations present in drinking water vay depending on the source of the water and how it is collected.

The water constituents may cause the following problems:

Minerals causing water hardness (calcium and magnesium salts)	Scaling, lime deposits due to calcium and magnesium salts, corrosion potential
Heavy and nonferrous metals, e.g. iron, manganese, copper	Brown-red deposits, secondary rust
Silicates, silicic acid	White-grey, colored appearance, thin scaling
Chlorides	Pitting
Evaporation residue	Spotting and scaling

Apart from its natural constituents, drinking water sometimes contains rust, generally flushed from corroded pipework. During the reprocessing cycle this rust tends to adhere to instruments, causing rust spots (extraneous rust) and subsequent corrosion.

* Reprocessing of Instruments RED BOOK, 11th edition 2017, www.a-k-i.org

Temperature

Temperature

- Plays a major role in cleaning
- You need the right temperature at the right stage of the process
- Blood denatures at temperatures above 45°C (110°F)
- When blood denatures, it becomes highly insolvent
  - It bonds strongly to the substrate (e.g., the surface of instruments) and it dries out, becoming very resistant to the action of solvents


Chemical Activity

Cleaning Activity: Enzymes

- Enzymes speed up cleaning action
- Enzymes are like living cells which attack and breakdown organic soils
- ***Each*** enzyme acts on a particular kind of substance, which is called substrate
- In short, an enzyme is thought to fit its substrate like a key fits a particular lock

Chemical Activity: Detergents

- A detergent for medical use must be able to remove all organic and inorganic materials without damaging the device.

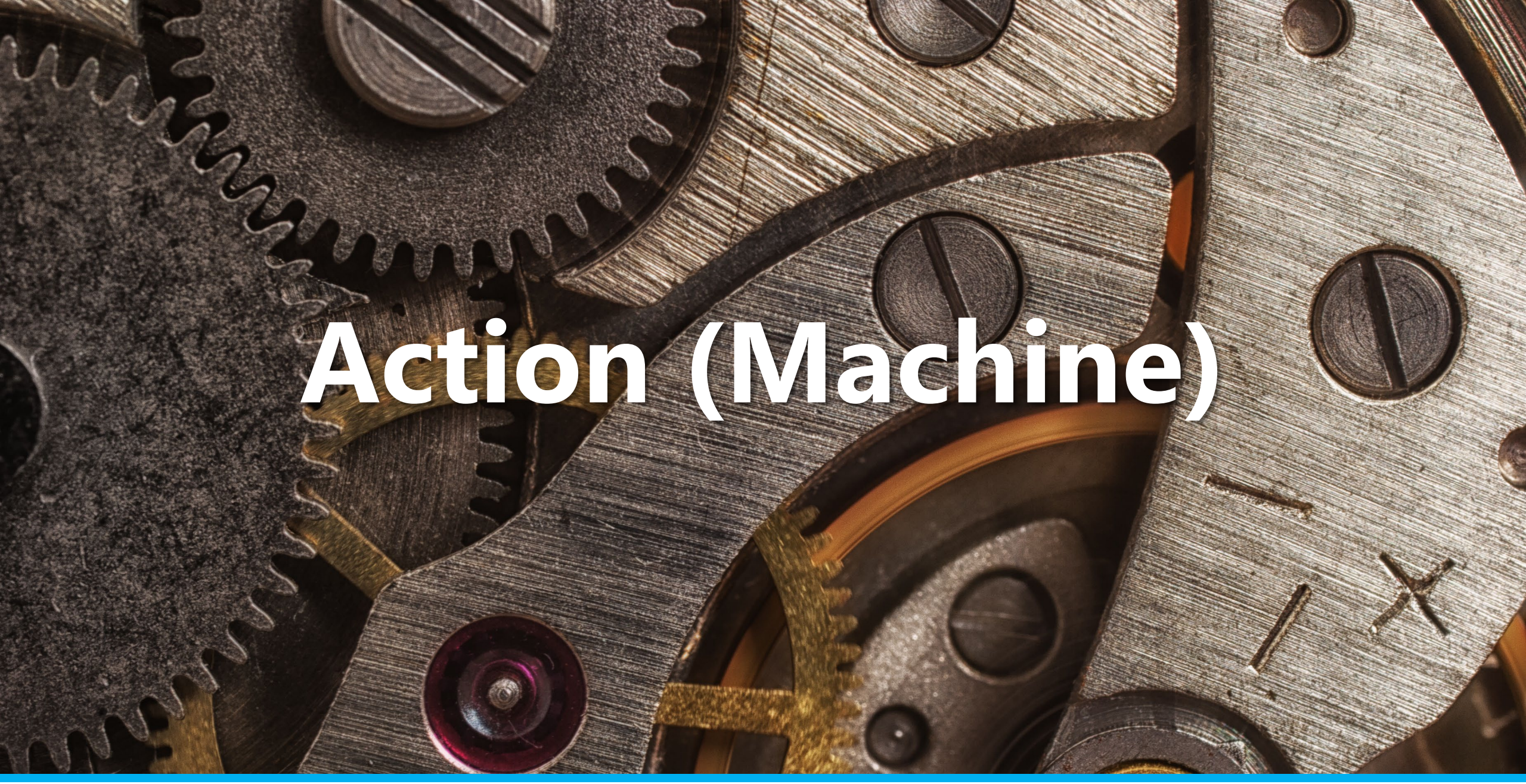
- Temperature of water and the storage environment can affect detergent efficacy.

Dilution & Concentration

- Precise concentration and dilution is dependent on water quality, soil load, and temperature
- Needs to fall into a range based on expectation of cleaning

<u>More Is Not Better – Residuals and or sudsing</u>

Chemistry Manufacturers


Action (Machine)

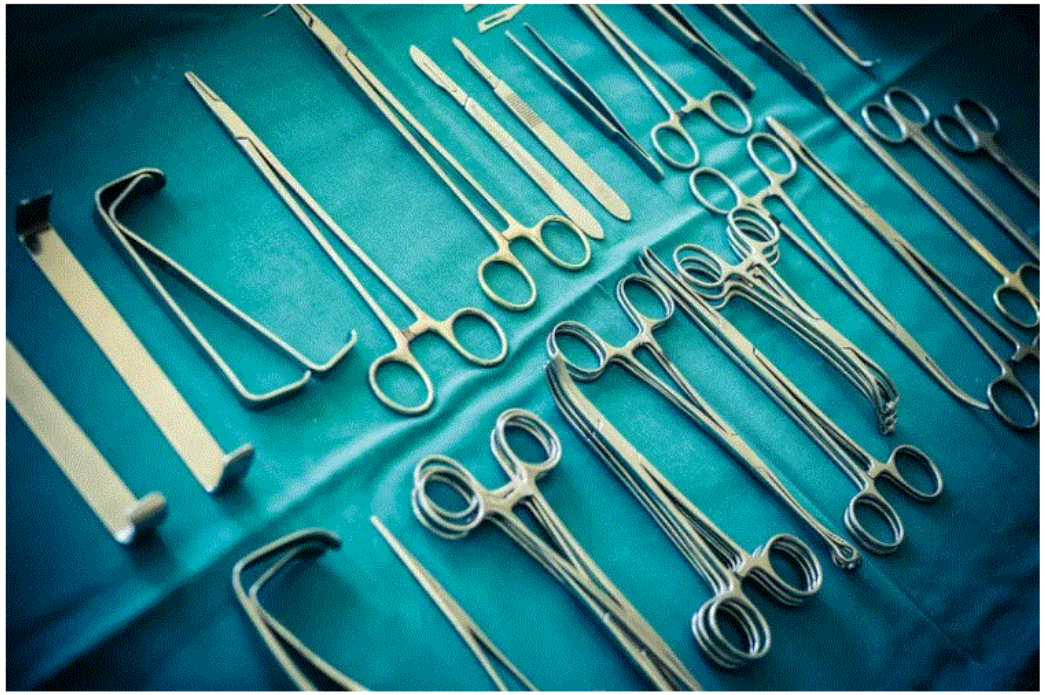
Mechanical Cleaning Equipment

- Instrument Washers
- Ultrasonic Washer
  - Lumen Washing
- Cart Washers

Why are Cleaning Verification Tests performed?

Dirty Surgical Instruments Tied to Hundreds of Infections at Colorado Hospital, Lawsuit Alleges

By Rachael Rettner published June 20, 2019



CALGARY HERALD

Local News

Surgeries scrapped after residue found on instruments

Matt McClure • Calgary Herald
Nov 20, 2014 • November 20, 2014 • 2 minute read • Join the conversation

Dozens of procedures at one of the Alberta's largest hospitals were postponed this week after a "fine dark residue" was found on surgical instruments.

The issues at Lethbridge's hospital are coming to light a year after the auditor general identified critical and lingering concerns in the reprocessing of medical devices at the province's health facilities.

Why are Cleaning Verification Tests performed?

- Many automated washer challenges can be identified using a Cleaning Verification test, before the medical devices are processed.
- Sterile is not Sterile unless Clean is Clean
- Human beings are imperfect
- Recommendations and guidelines regarding cleaning verification have been established.
- In the next slides, we will review guidance that is offered.

Quality Management System

AAMI ST90:2017

QMS foundation for equipment verification is performed utilizing three processes:

Installation Qualification (IQ)

- Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

Operational Qualification (OQ)

- Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

Performance Qualification (PQ)

- Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

FDA, AAMI, & Other Standards State…

- Simulated testing should be done with a surrogate device that closely approximates the actual types of soil the instrument is exposed to in clinical use
- Further the surrogate device should be made of the same type of material as the medical device

Washer/Disinfector

- Automated washers work on the principle of “impingement”
- Because of their spray force & thermal action, they are an effective means of cleaning.

Washer/Disinfector

- To clean effectively, items must be properly positioned and prepared in a way that facilitates the mechanical cleaning process

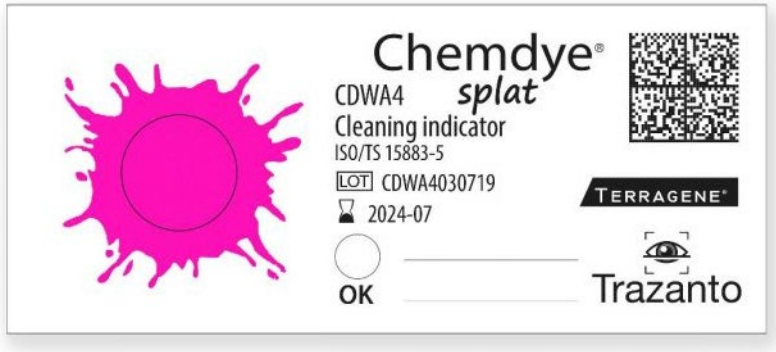
In Europe:

In the US:

ANSI/AAMI ST79:2017

- Annex D:
- **Verification test for mechanical washers**
- **Test for soil removal:** Indication is visual assessment or absence of marker on a coupon placed in the washer.

Cleaning Verification Products



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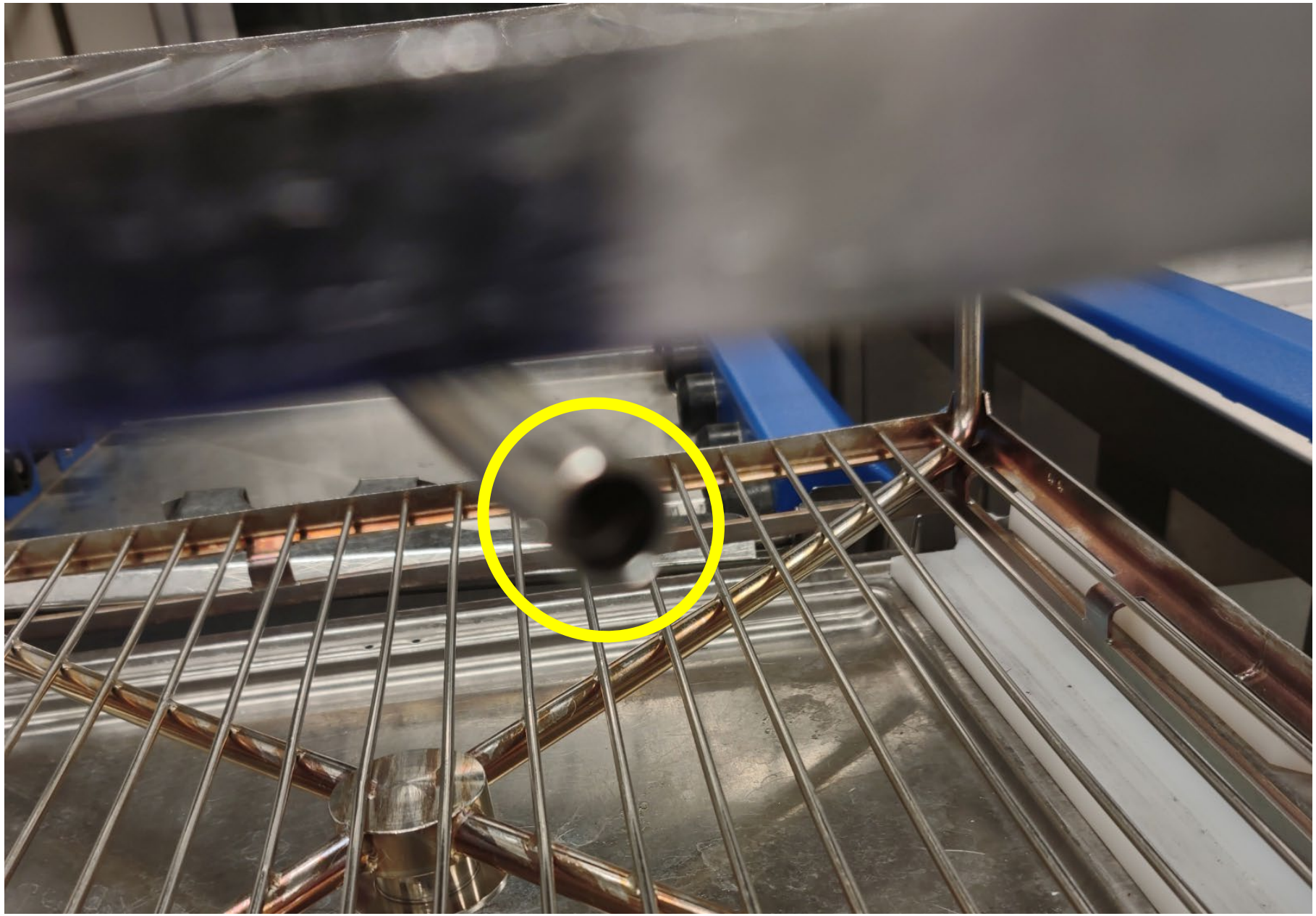
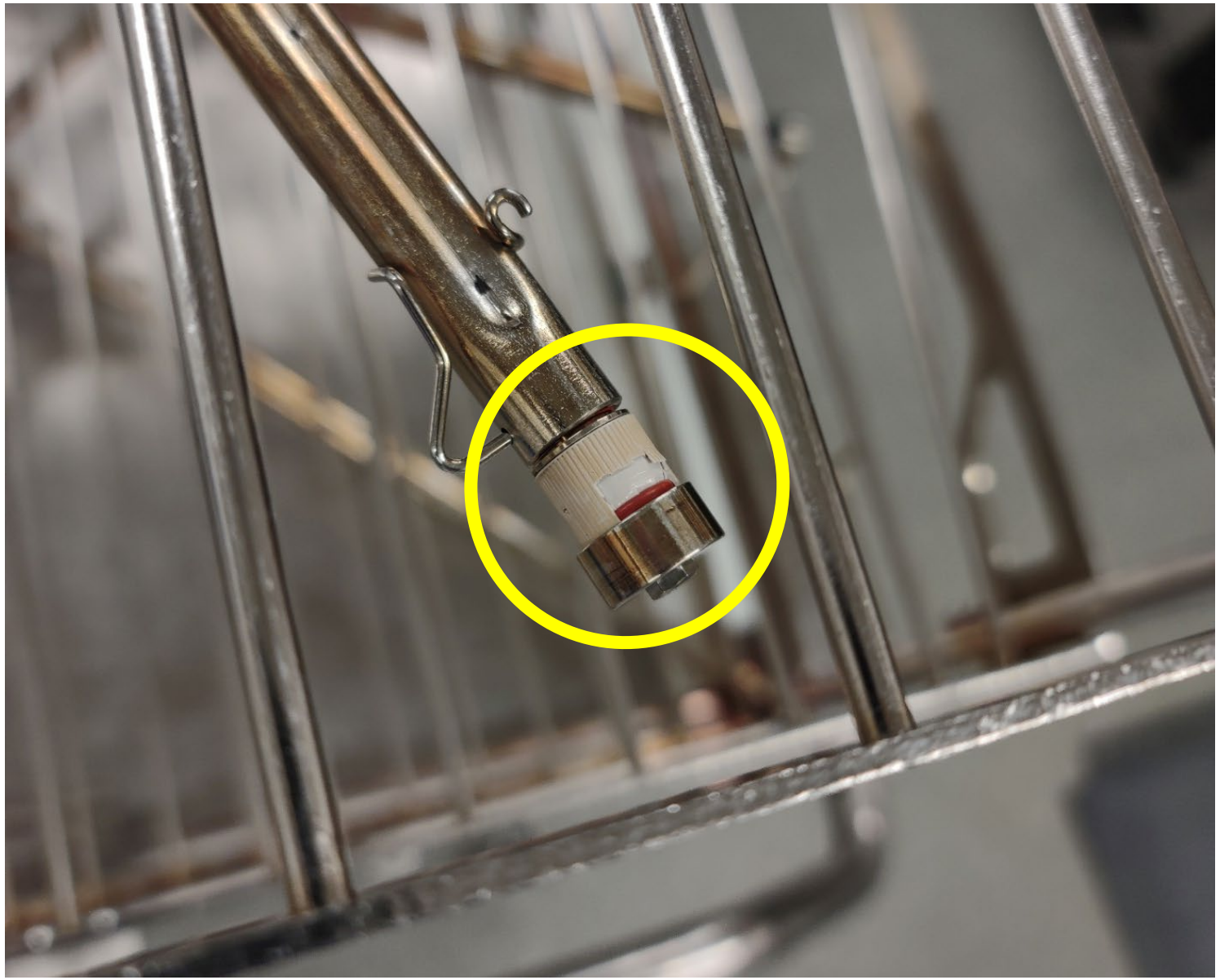
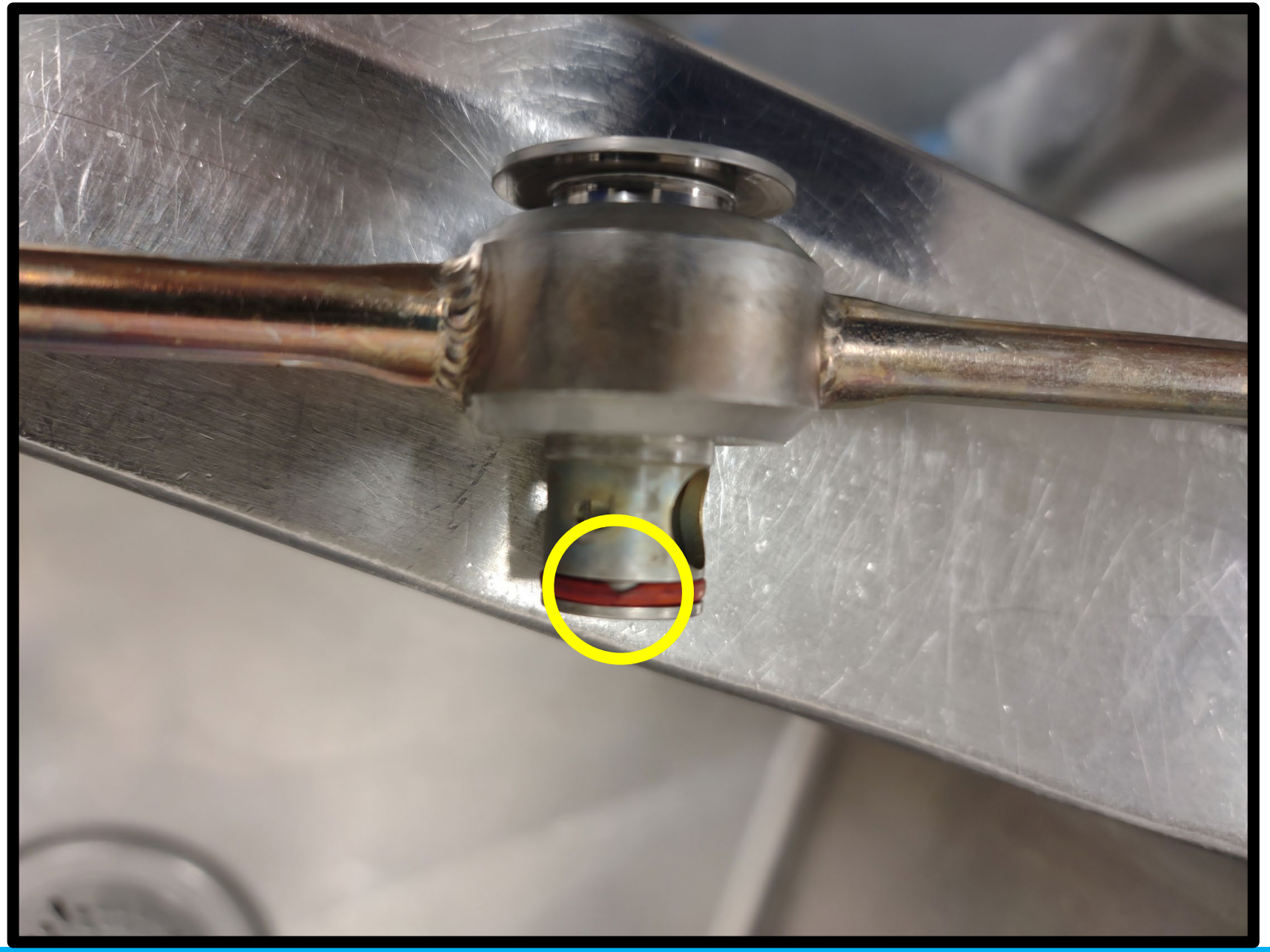
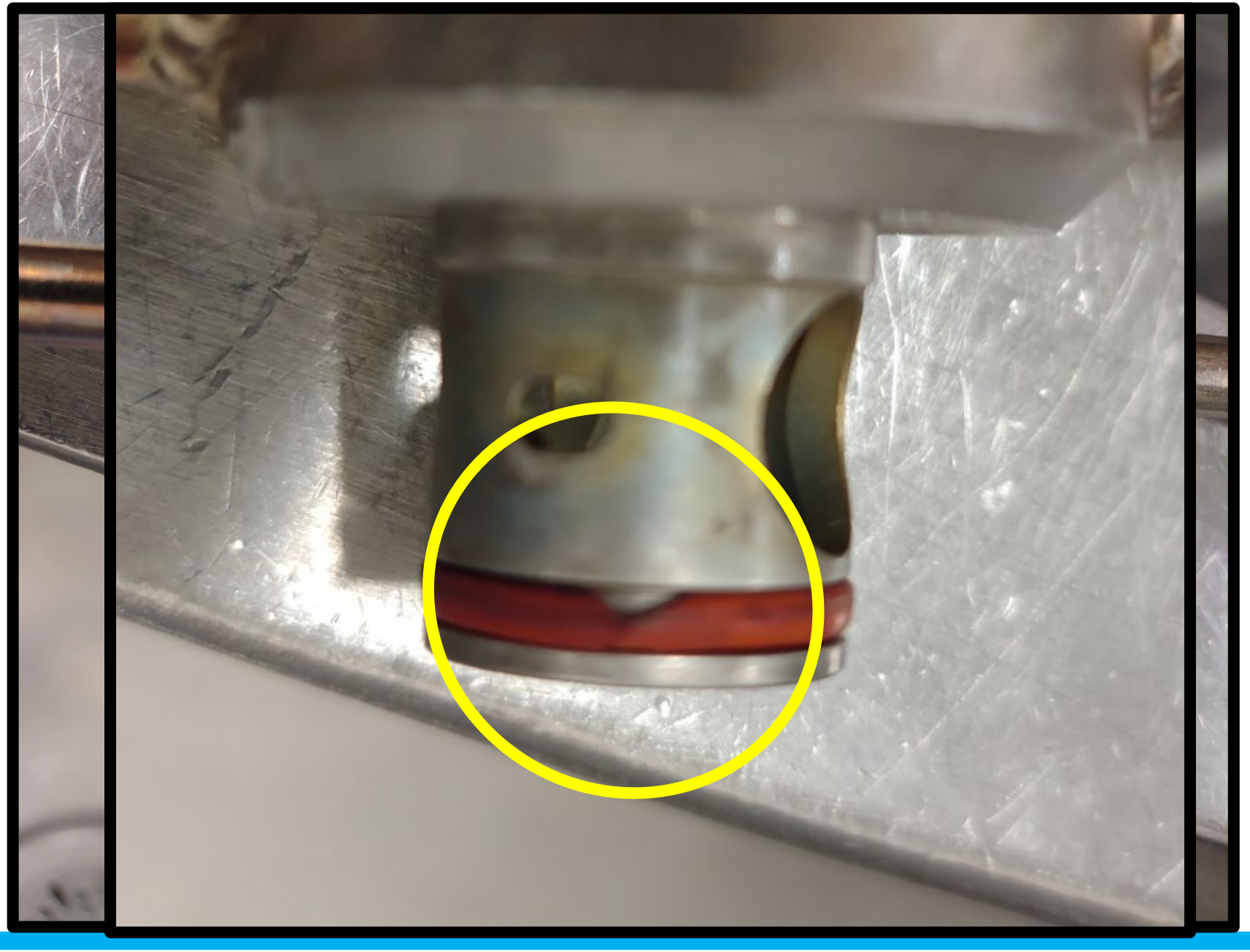
Case Study

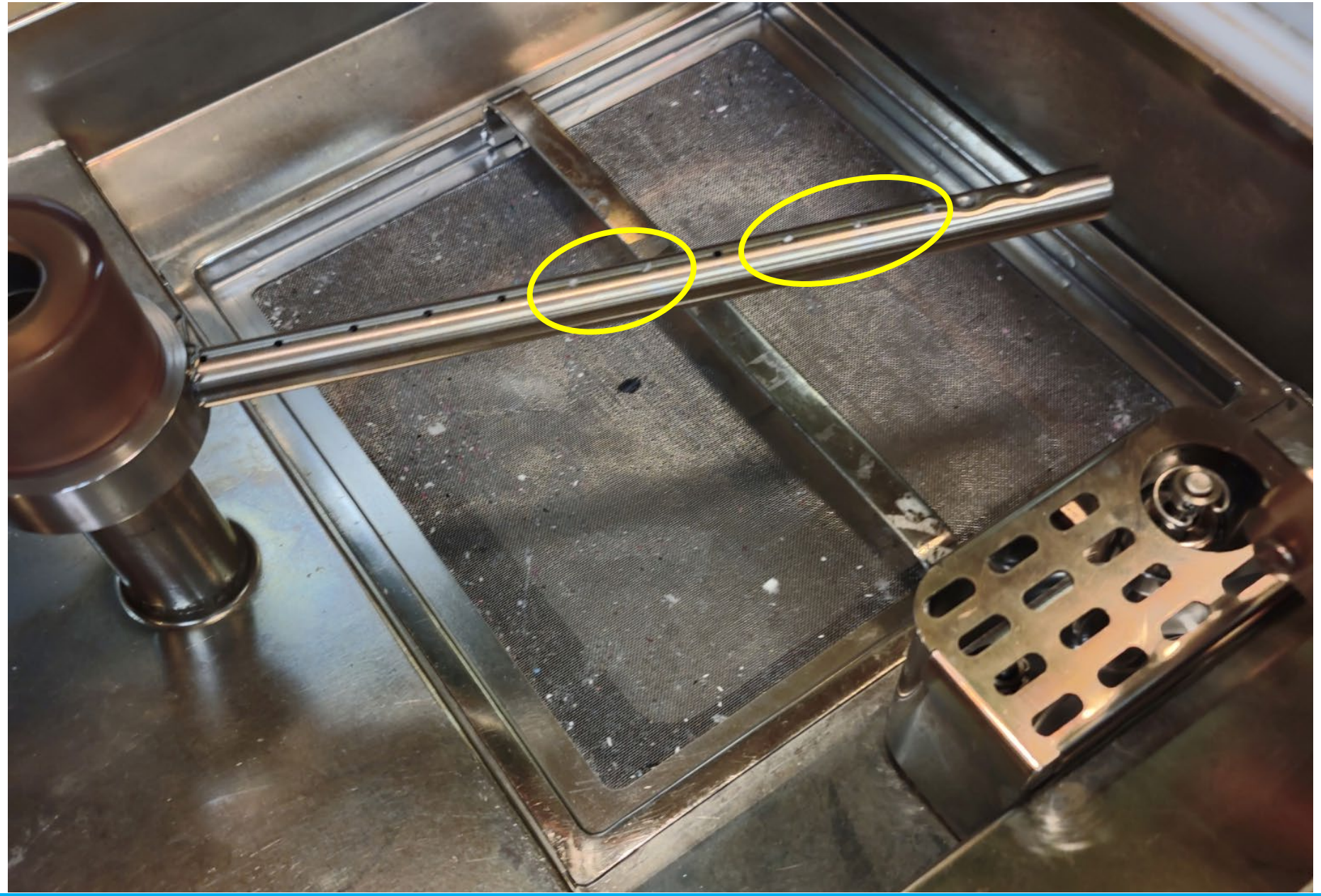
- Auditing a department that was performing nightly “soil removal” testing
- In over 2 years of record keeping their “soil removal” tests passed every night
- During the audit, TOSI testing was run on the same washer and all 3 tests failed

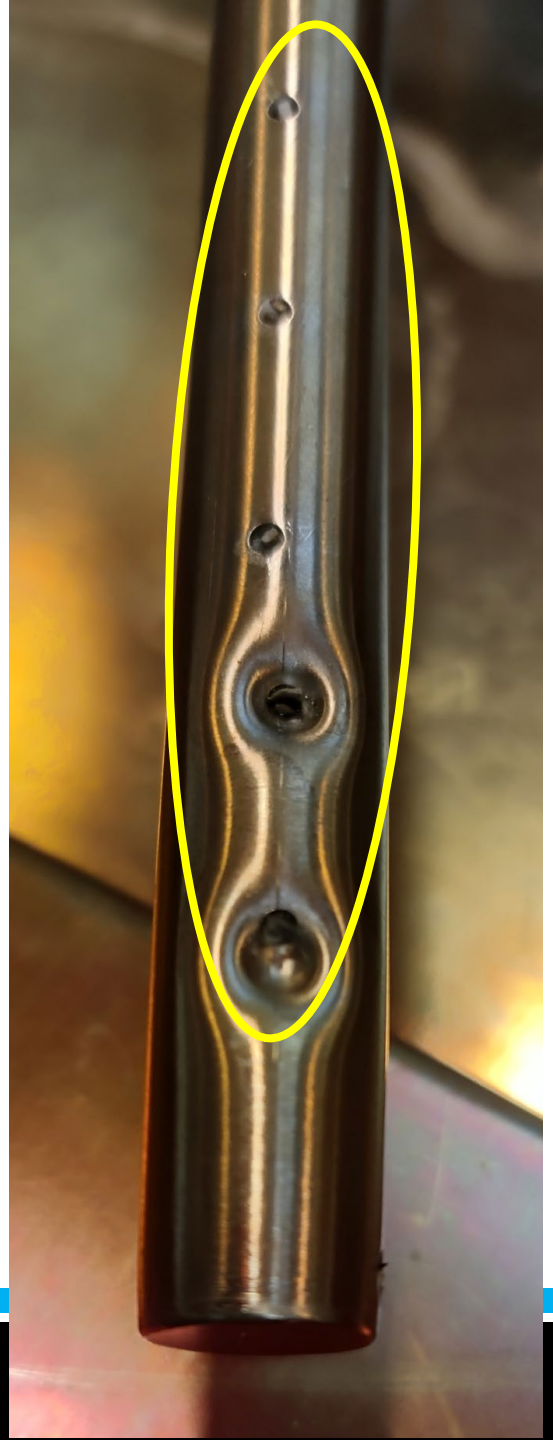












Are you looking for a test that passes every time?

Or do you want to know if your washer is actually working?

Ultrasonic

- Ultrasonic units have 2 primary functions:
  - Cavitation
  - Soil Removal

Irrigating Ultrasonic

- Irrigating Ultrasonic units have 3 primary functions:
  - Cavitation
  - Soil Removal
  - Soil Removal through Lumens

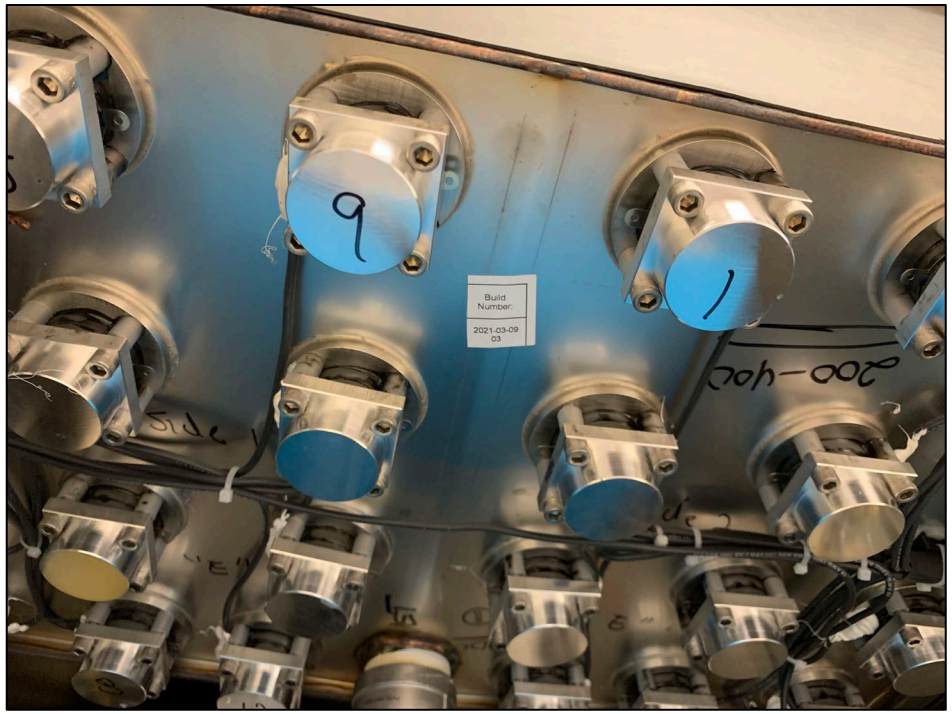
Ultrasonic

- When the sonic wave passes through liquid it makes the liquid vibrate
- Hospital cleaners produce from 20,000 to 38,000 vibrations per second
- The vibrations cause a process called “Cavitation”

Basic Function #1

- **Cavitation**
  - Produced by:

Generator(s)



Transducers

ANSI/AAMI ST79:2017

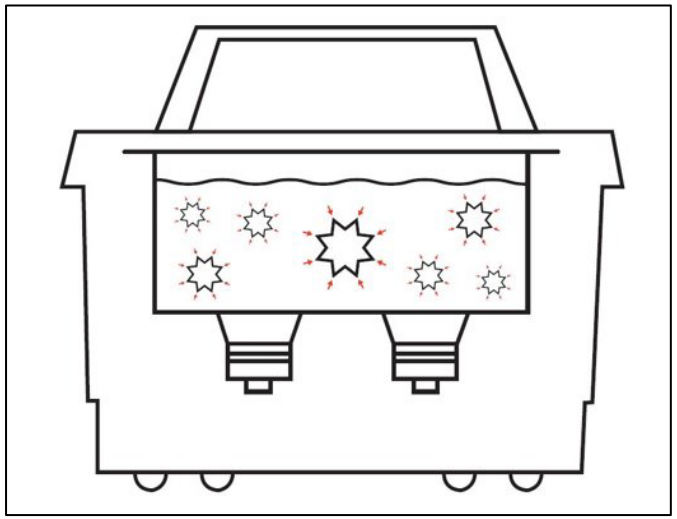
- 7.6.4.4.1
  - Perform cavitation testing daily whenever the ultrasonic cleaner equipment is in use.

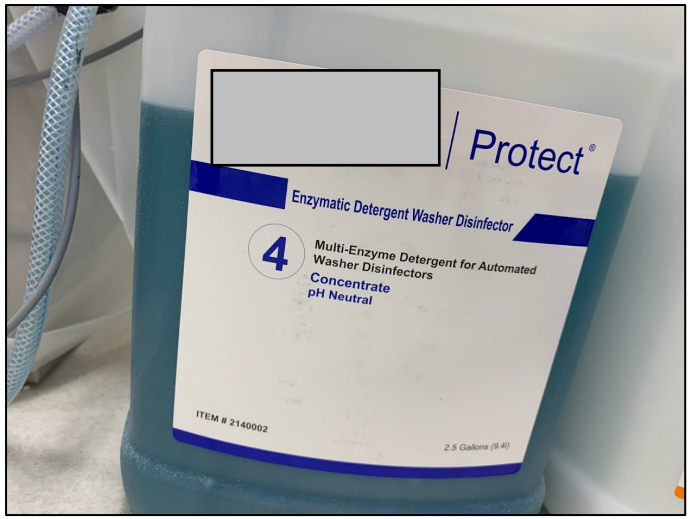
Basic Function #2

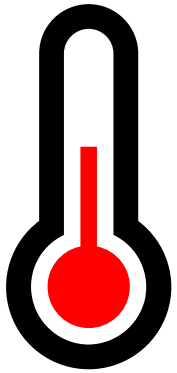
- **Cleaning**
  - Removal of surgical soils

Basic Function #2

- **Soil removal**
  - Cavitation
  - Detergent
  - Temperature
  - Time







Basic Function #3

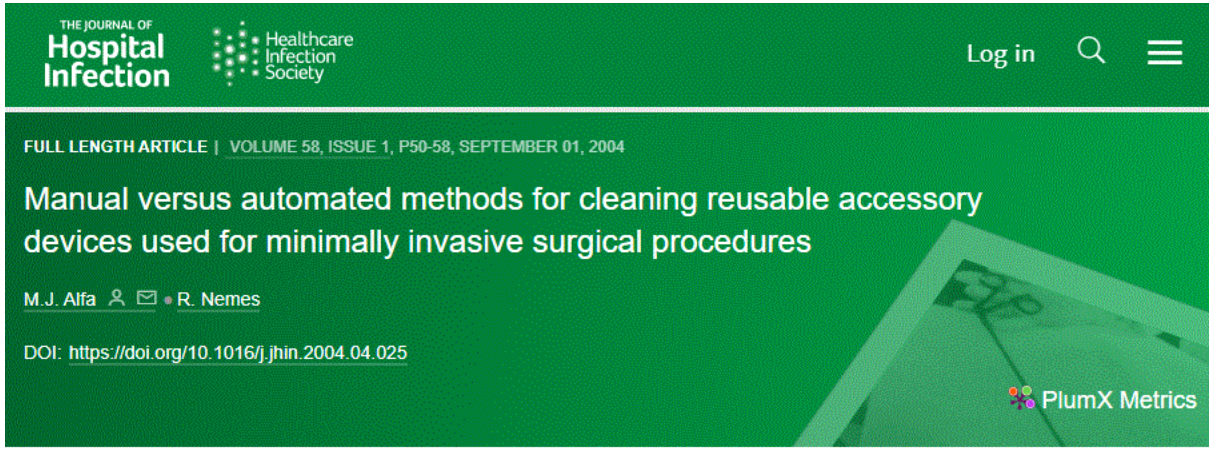
- Soil removal from channels

Basic Function #3

- **Soil removal from channels**
  - Dr. Alfa study – Manual vs automated methods

Manual cleaning left 2 to 50-fold MORE SOIL residuals!

Automated cleaning **achieved > 99% reduction** in soil parameters.

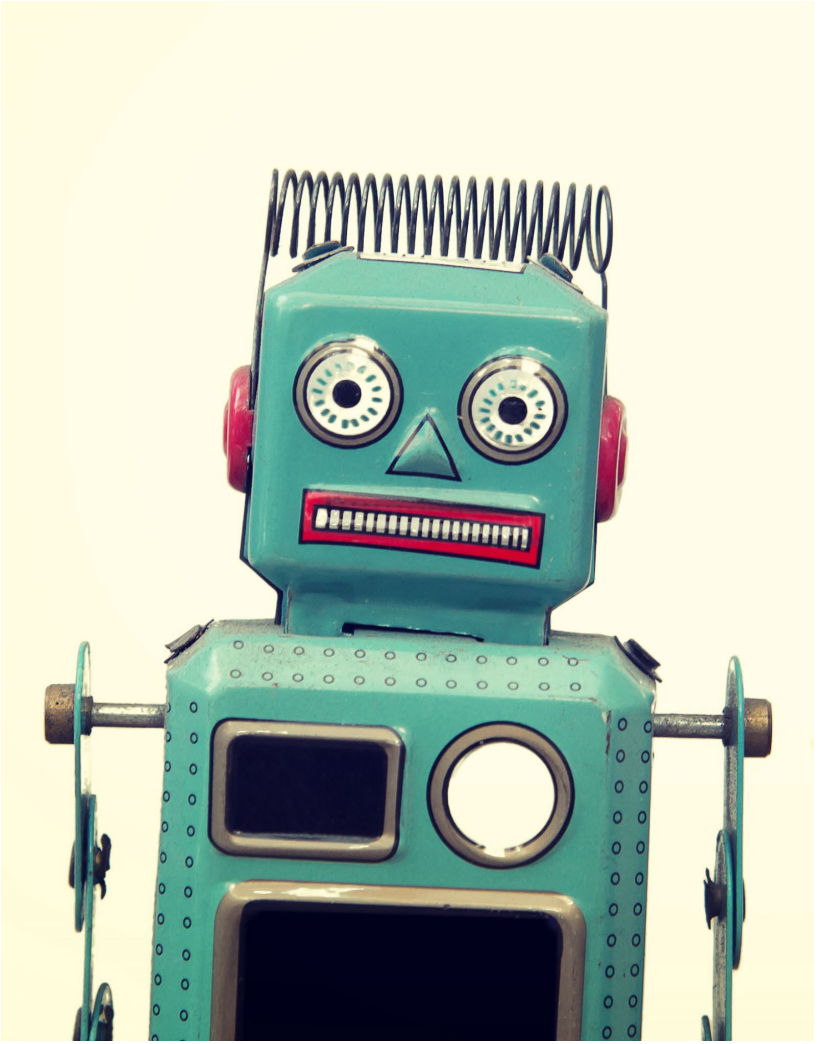


Abstract

We undertook a simulated-use study using quantitative methods to evaluate the cleaning efficacy of ported and non-ported accessory devices used in minimally invasive surgery. We chose laparoscopic scissors and forceps to represent worst-case devices which were inoculated with artificial test soil containing 10^6 cfu/mL *Enterococcus faecalis* and *Geobacillus stearothermophilus* and allowed to dry for 1 h. Cleaning was performed manually, as well as by the automated SI-Auto Narrow lumen cleaner. Manual cleaning left two- to 50-fold more soil residuals (protein, haemoglobin and carbohydrate) inside the lumen of non-ported versus ported laparoscopic accessory devices. The SI-Auto Narrow lumen cleaner was more efficient than manual cleaning and achieved >99% reduction in soil parameters in both non-ported (using retro-flushing) and ported laparoscopic devices. Only the automated cleaning of ported devices achieved 10^3–10^4–fold reduction in bacterial numbers. Sonication alone (no flushing of inner channel) did not effectively remove soil or organisms from the inner channel. Our findings indicate that non-ported accessory devices cannot be as reliably cleaned as ported devices regardless of the cleaning method used. If non-ported accessory devices are reprocessed, they should be cleaned using retro-flushing in an automated narrow lumen cleaner.

https://www.journalofhospitalinfection.com/article/S0195-6701(04)00210-5/fulltext#relatedArticles

Handsome Man

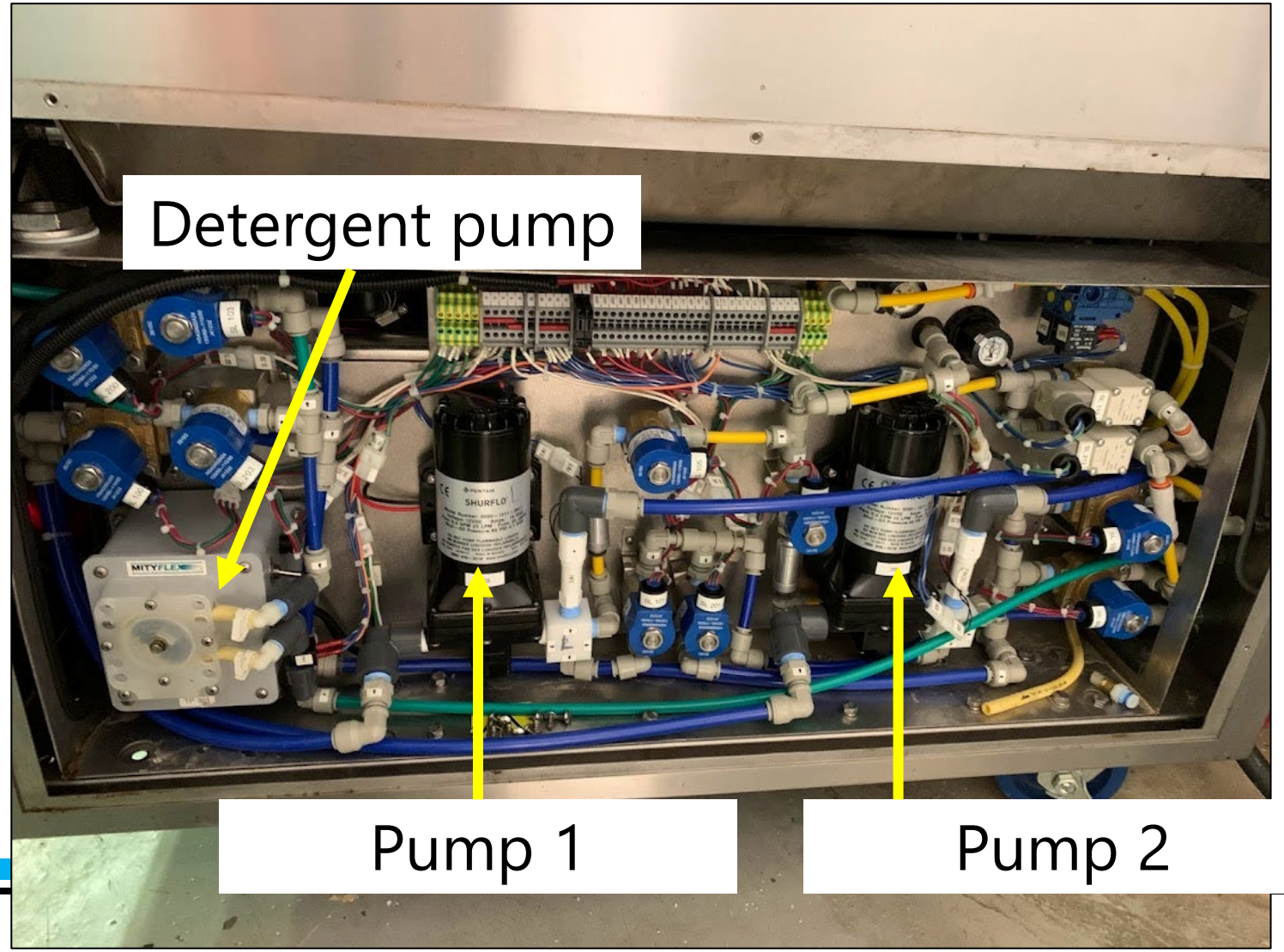


Machine

ANSI/AAMI ST79:2017

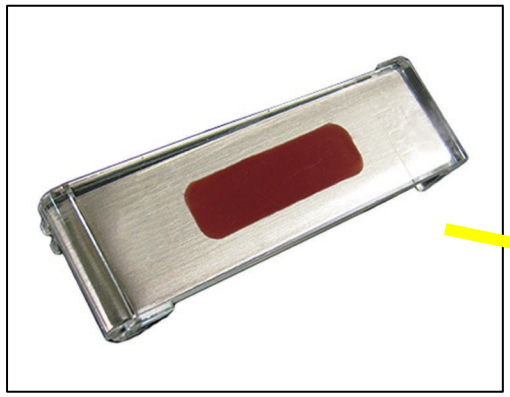
- Annex D
  - Test for cavitation
  - Test for **soil removal**
  - Test for **soil removal** within **lumens**

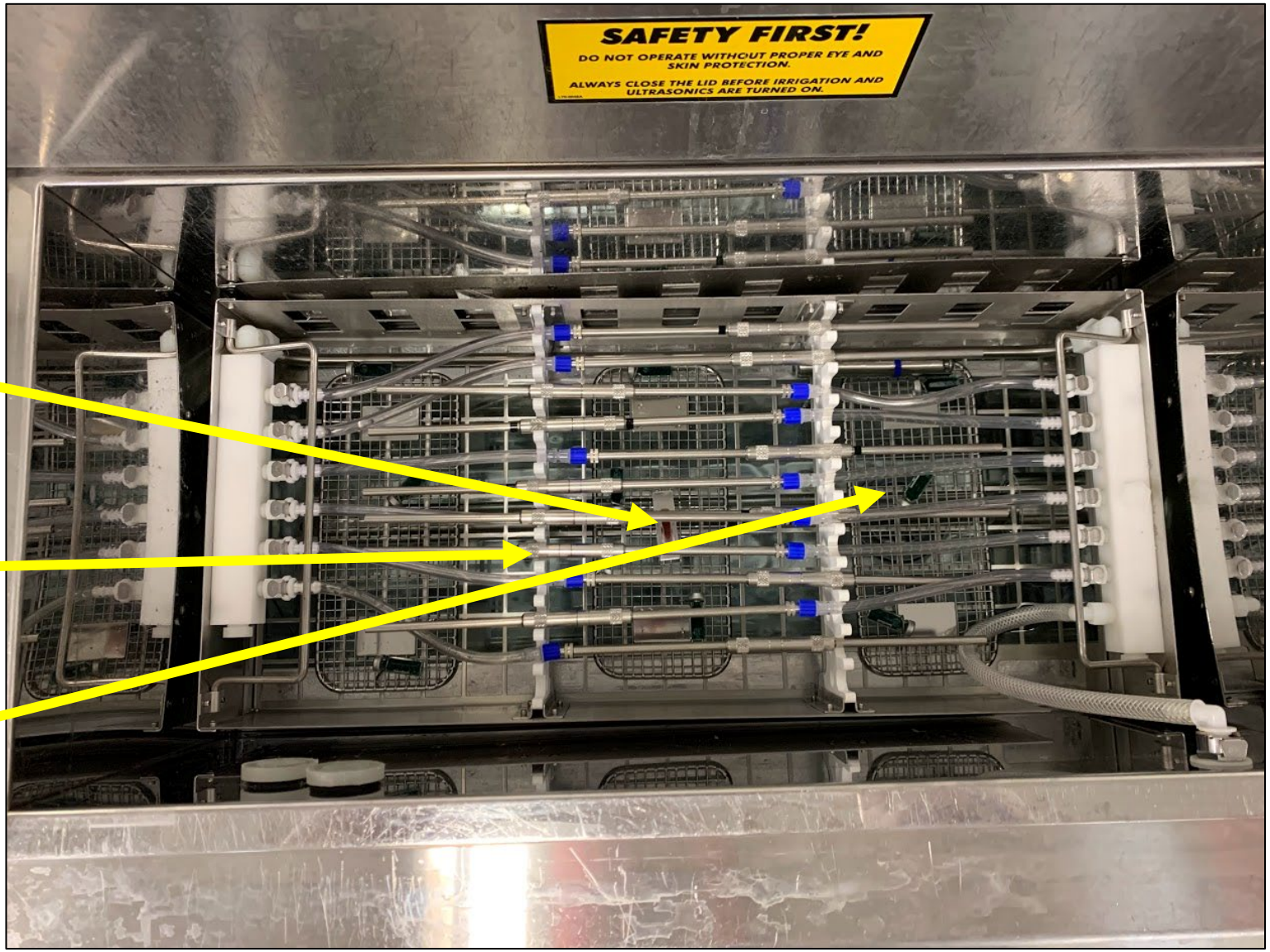
Basic Function #3 – Soil removal from channels

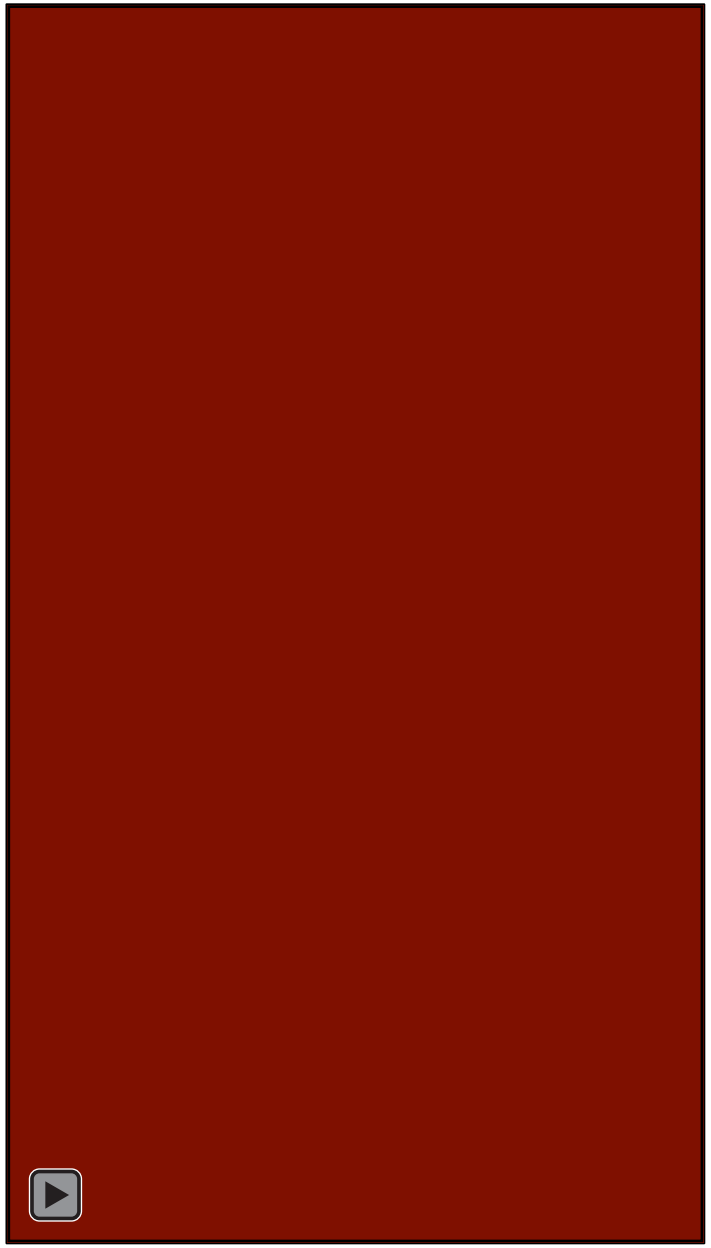


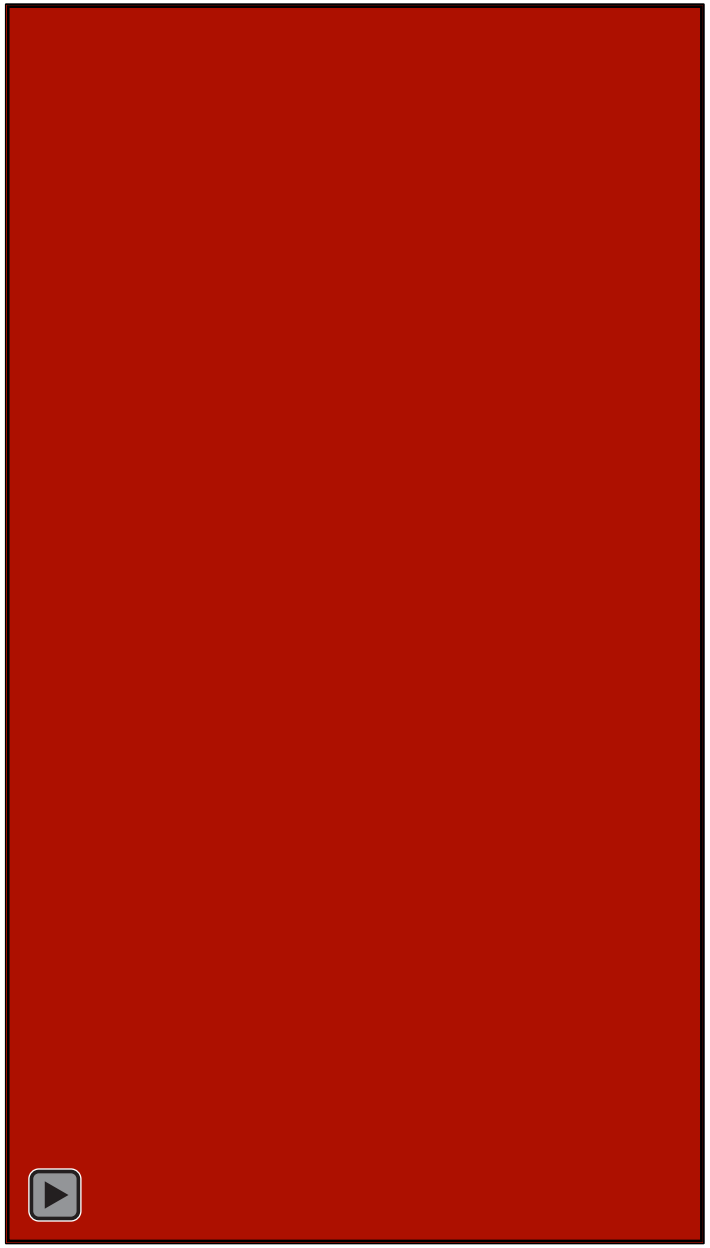
How do you know that your ultrasonic is working?

Case Study

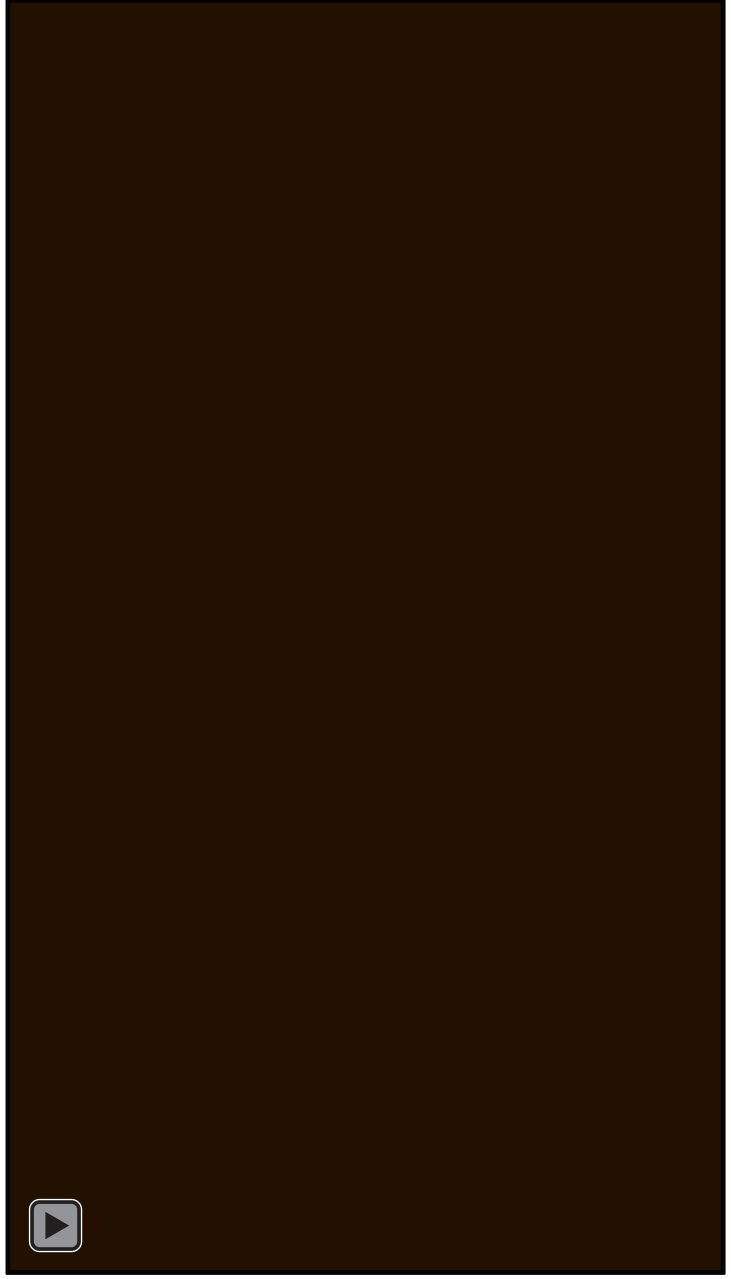


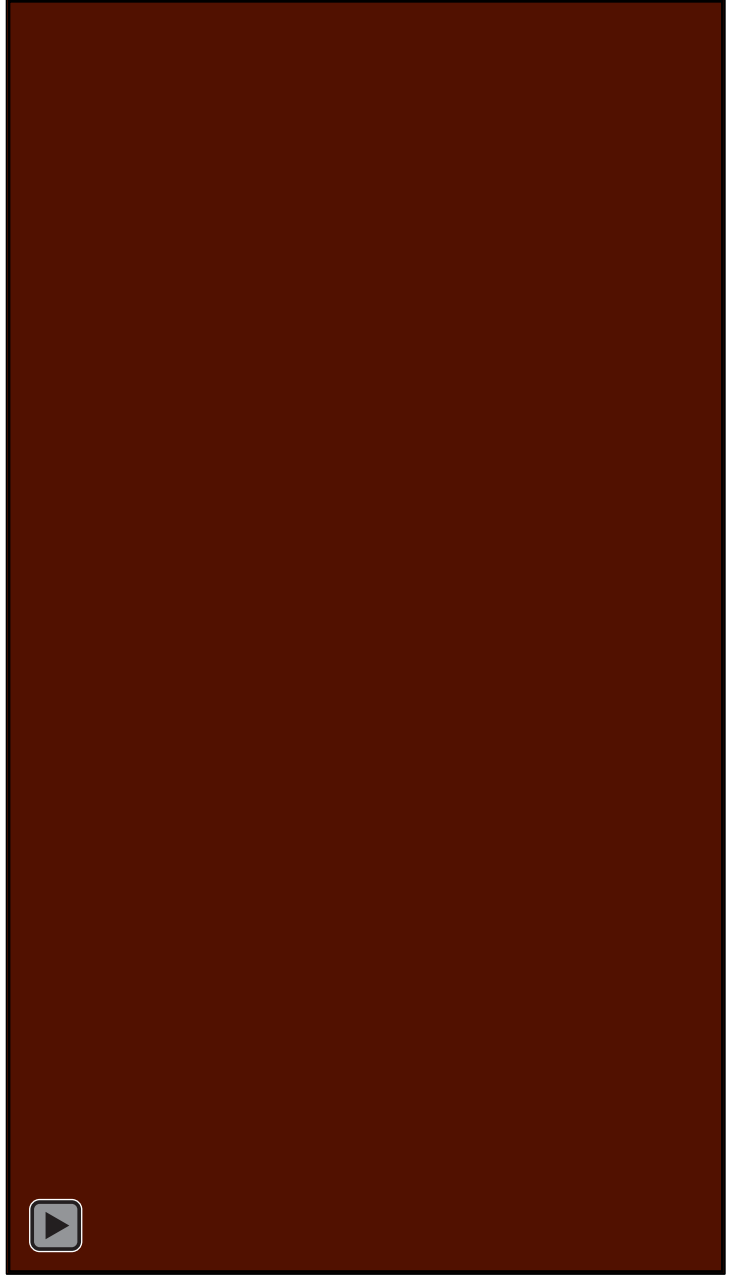

SAFETY FIRST!
DO NOT OPERATE WITHOUT PROPER EYE AND SKIN PROTECTION.
ALWAYS CLOSE THE LID BEFORE IRRIGATION AND ULTRASONICS ARE TURNED ON.



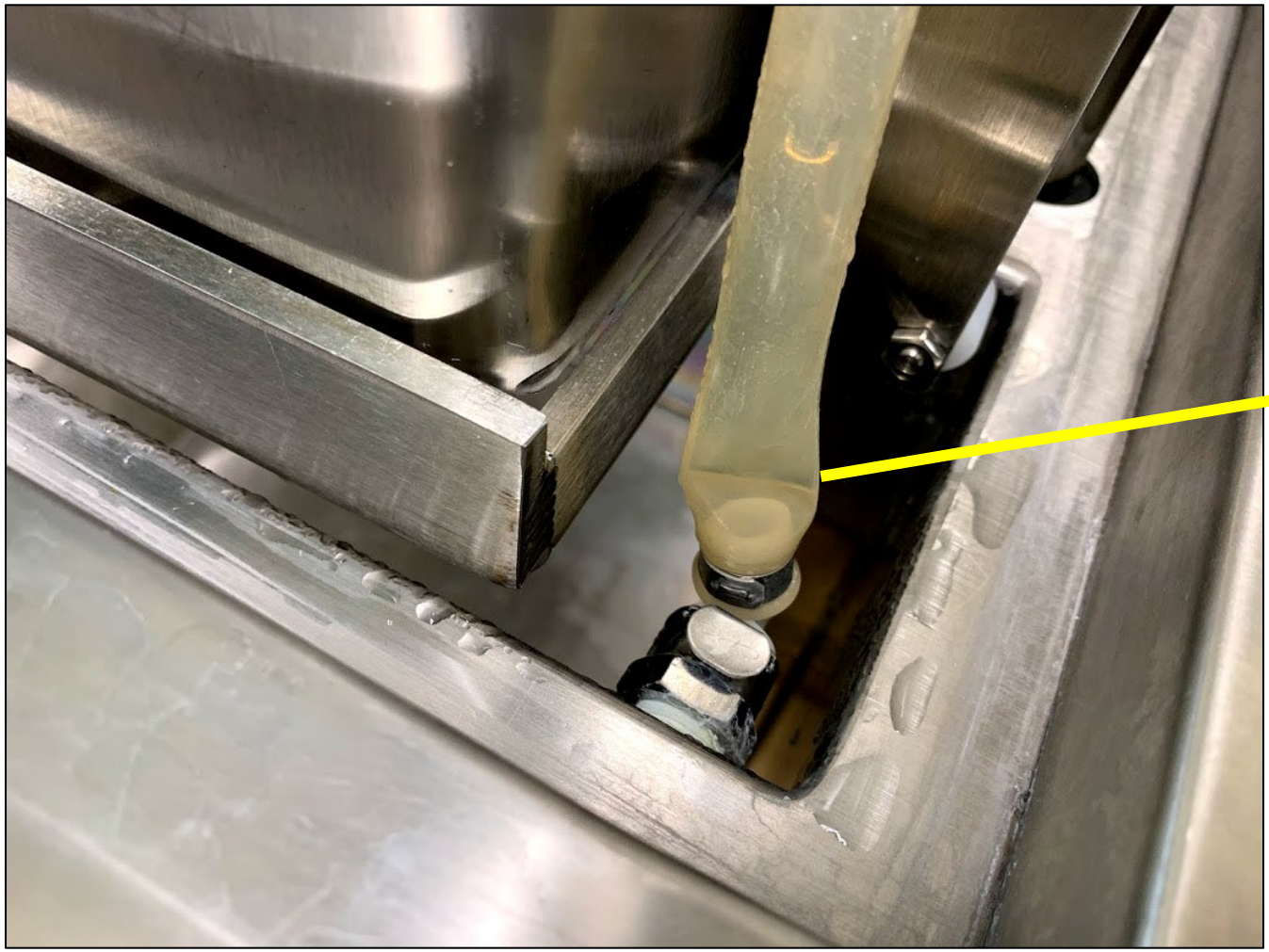


We've seen what a **broken O ring** can do to our **lumen flushing**. What's another potential problem?

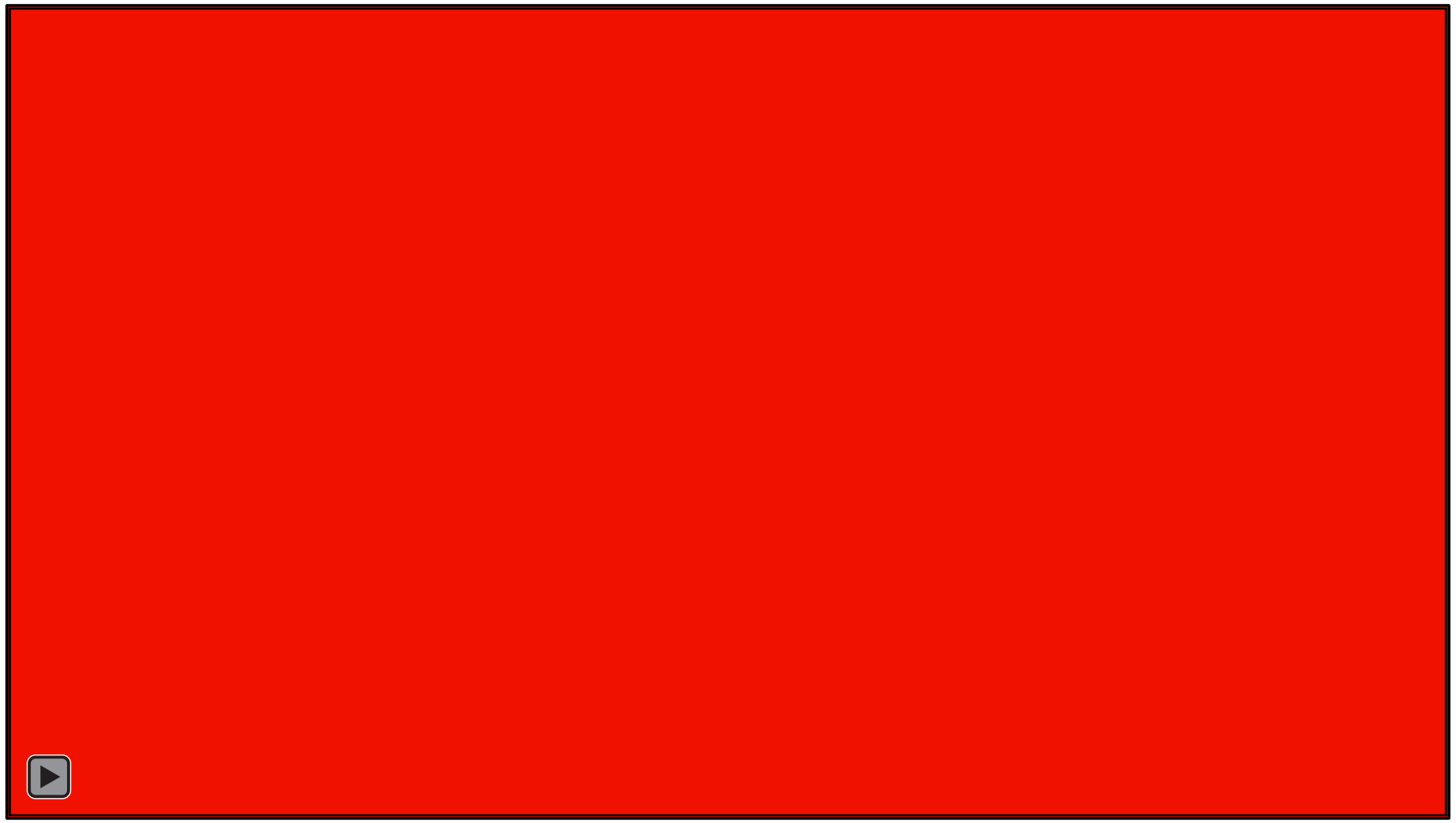




Case Study 2



Another potential problem…



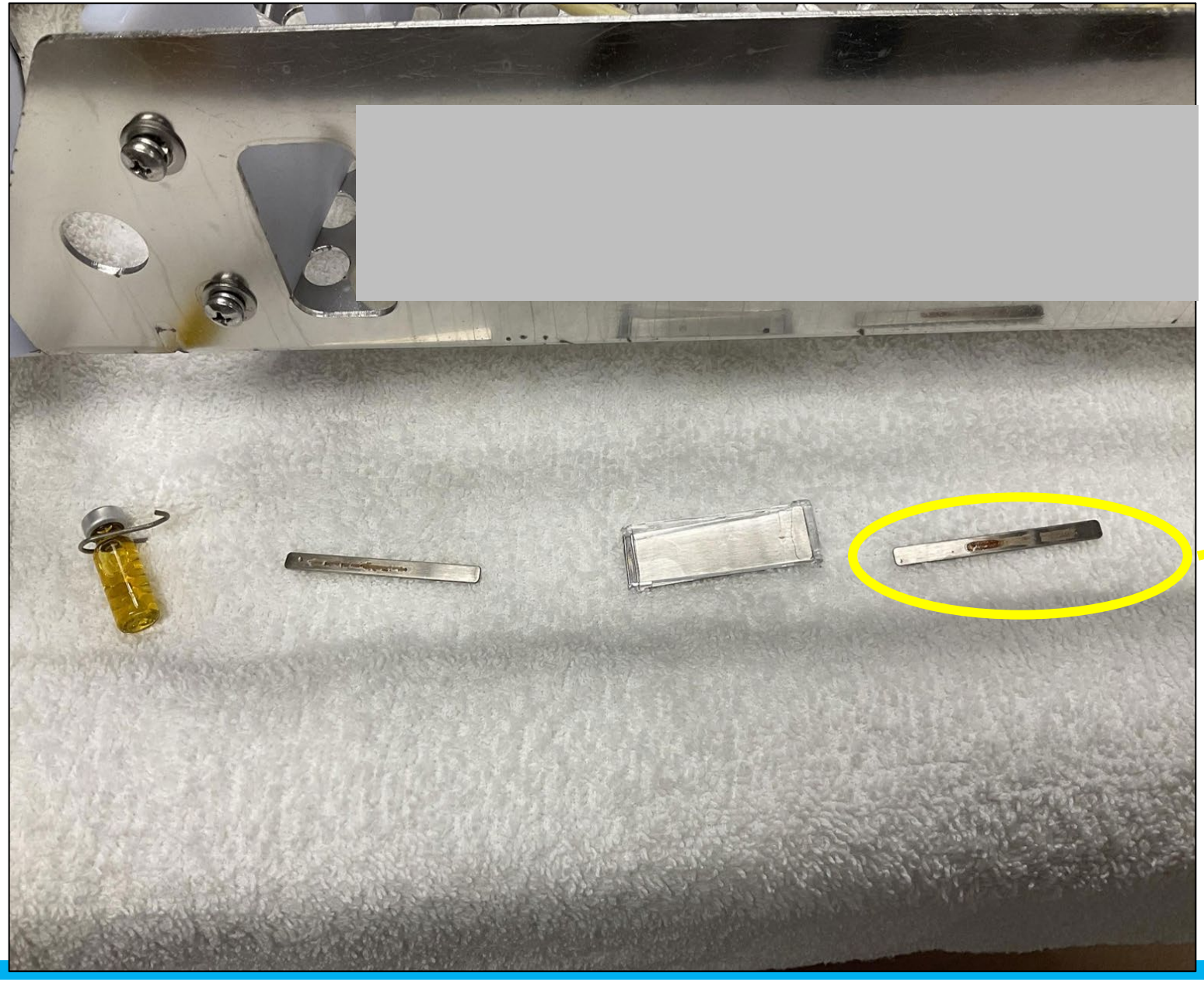

MITYFLEX
SHURFLO


PENTAIR
SHURFLO
Model Number: 5050 – 1311 – D011
Voltage: 12VDC Amps: 18 MAX
Flow: 5.3 GPM 20 LPM Fuse: 25 AMP
Shut – Off Pressure: 60 PSI 4.1 BAR
DO NOT PUMP FLAMMABLE LIQUIDS
NO BOMBEE LIQUIDOS INFLAMMABLES
NE POMPER PAS DES LIQUIDES INFLAMMABLES
MADE IN MEXICO
(800) 845 – 3218 WWW.SHURFLO.COM
IP100

None of these malfunctions shown for the ultrasonic machines resulted in an alarm

How do you know that your ultrasonic is working?

Ever wonder what happens in your lumened items when they are not connected to the lumen flushing mechanism in your sonic?



Current State

- Most facilities test their ultrasonics.

Ultrasonic Cleaning Verification Testing

- Use the AAMI ST79 guidelines to build your quality assurance procedure for ultrasonic equipment.

Upon installation	Cavitation
Each day it’s used	Soil removal
After major repairs	Soil removal - lumen

Cart Washers

- Cart washers are important tools in the overall effort to reduce cross contamination
- They are often used to clean not just surgical case carts, but also basins, instrument trays, wheelchairs, patient transport equipment and other supplies.
- Many now have instrument wash cycles available.

How a Cart Washer is Perceived

An Internet Survey showed that:

- 12% of the respondents felt a cart washer gave high level disinfection
  - They do not. They provide thermal disinfection that are low level to intermediate level disinfection
- 26% had processed orthopedic trays through a cart washer
  - Which should only be done on an instrument rack on the instrument cycle. Does you cart washer have these?
- 65% did not receive yearly in-service on the cart washer
  - Yearly training and demonstrated competence should be performed on loading, unloading, use, and safety related to the cart washer.
- Items processed beside surgical case cart
  - Wheelchairs, bins, beds, walkers, wire racks, surgical containers, commodes,…

Confusion like this, is why we are talking about Cart Washers today

What can I put in my Cart Washer?

That depends on the cart washer.

- Does it have multiple cycles?
- Are the items you want to process validated for a cart washer

As always, you must follow the IFU from

- The medical device manufacturer
- The cart washer manufacturer

Also understand the Spaulding Classification

- Items that only require low level disinfection
  - Crutches
  - Case carts
  - IV Poles
  - Wheelchairs

Safety & Cleaning Verification Review

- Because there are so many different cart washer models, this is a general overview
  - Always refer to the Cart Washer IFU
    - Staff demonstrate where the emergency shut offs are inside the washer (all modern cart washer have them)
      - Note: When entering the Cart Washer, make sure power is off and all safety features are activated.

Safety & Cleaning Verification Review

- Daily and weekly inspection
  - Documented
  - Review how to verify process of the cart washer
    - Non-instrument cycle
      - Temperature and Spray Arm Coverage
    - Instrument cycle (if the cart washer has this specific cycle)
      - Soil Removal and Temperature

Training

We all know poorly trained staff can cause concerns. What should you do?

Provide at least yearly in-services that include:

- Review of hospital guidelines on using the Cart Washer
- Review of the Cart Washer manual
- Depending on the type and age of the Cart Washer, review of the various cycles, when to use them and on what equipment
- Loading of equipment (all types that can be processed and cleaned)
- Preventive maintenance (daily/weekly) as needed
- Chemical safety- cleaning solutions
- Cleaning Verification tests used on the Cart Washer
- Safety systems (internal and external emergency shut offs)

Perform at least yearly competencies

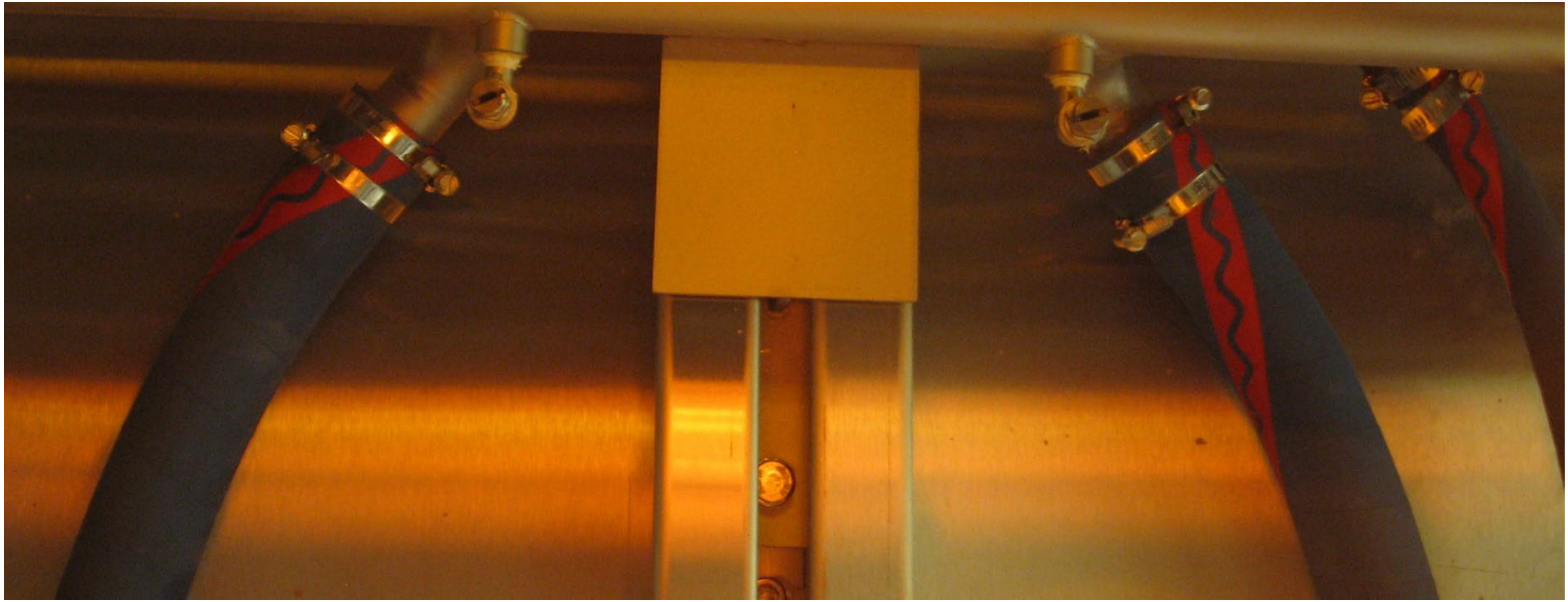
- Practical return demonstration of the important skills
- Demonstrated ability to interpret and record cleaning verification tests

Daily Inspection

Should be done at least once a day; preferably each shift.

- Look at various debris screen (different models have different locations and may have more than one) are they clear of debris?
- If the Cart Washer has water jets, are they clean of debris (clogged)?
- If Cart Washer has moving spray arms, are they present and turning?
- Is there staining/scaling on the inside chamber walls?
- Is there a sufficient level of cleaning solution in the container?
- Are all the door seals/gaskets intact?

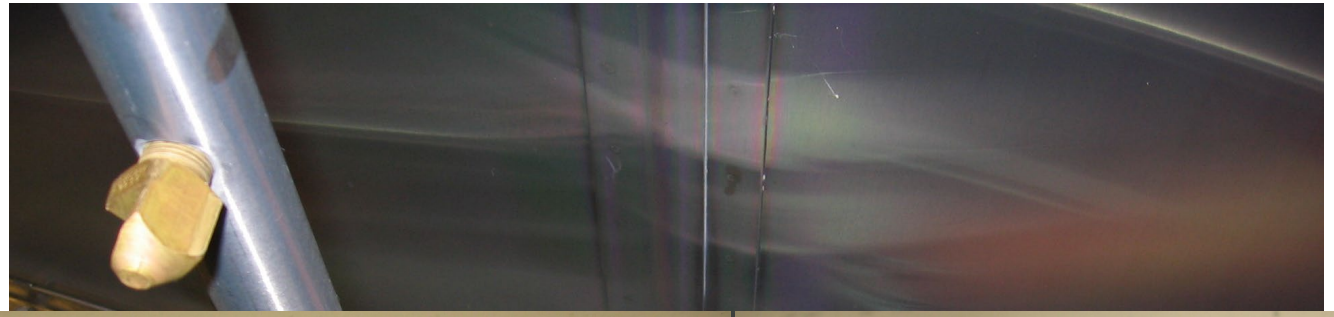
Much better

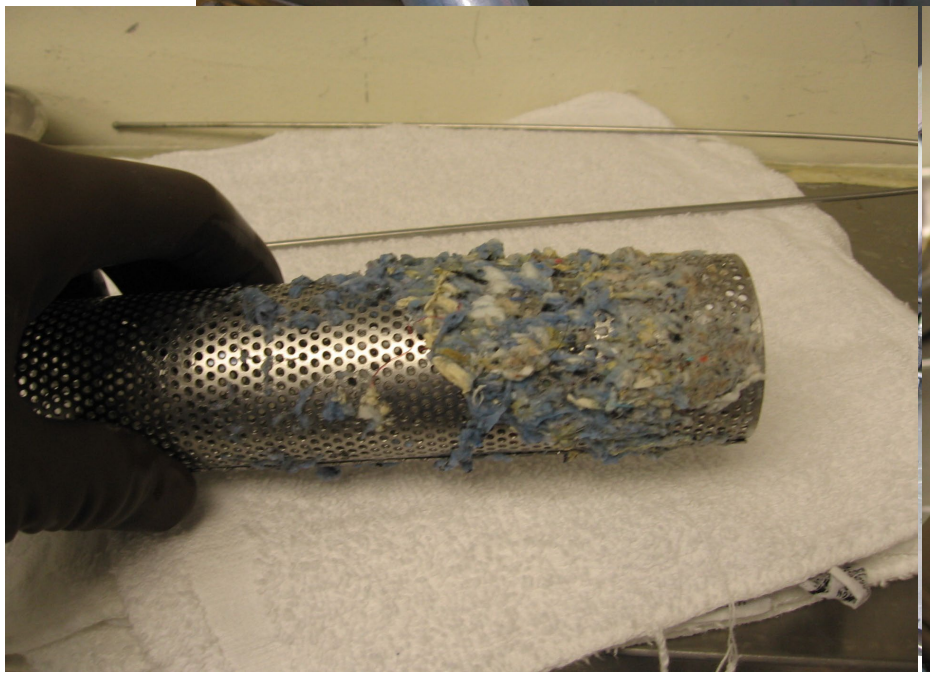


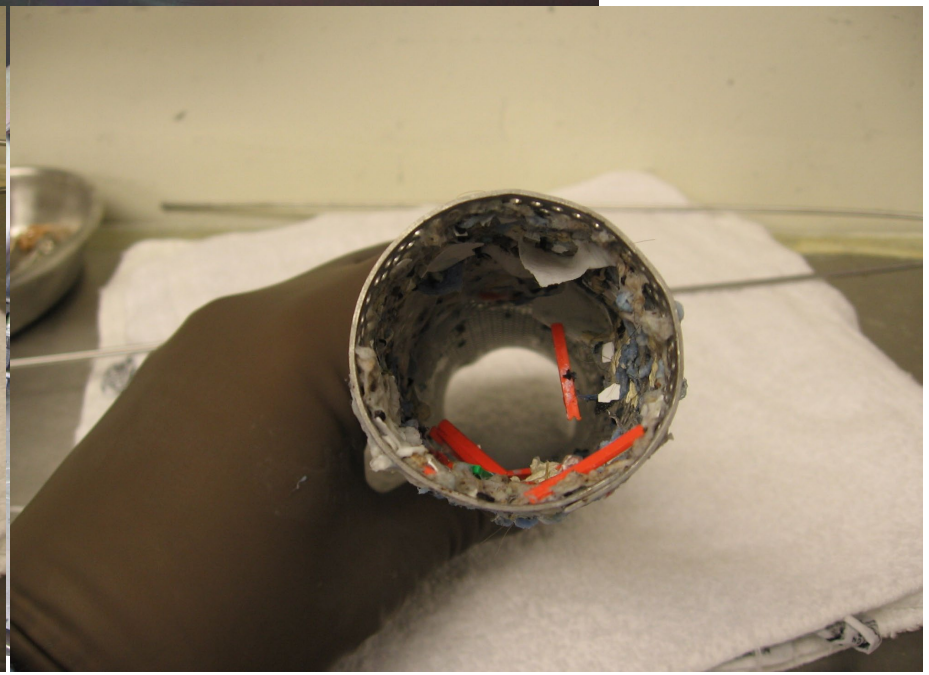
Do you see the issue?

A closer look

What do you think we will find in here?







Daily filter cleaning is important

Weekly Inspection

Should be done same time each week.

- Note: Perform all daily inspection duties plus:

Minimum temperature checked by independent means and temperature is recorded.

A Mechanical function test of spray jets and arms has been performed. (Pass or Fail)

If the Cart Washer has an instrument cycle, it must be tested with a TOSI on each level and the results recorded.

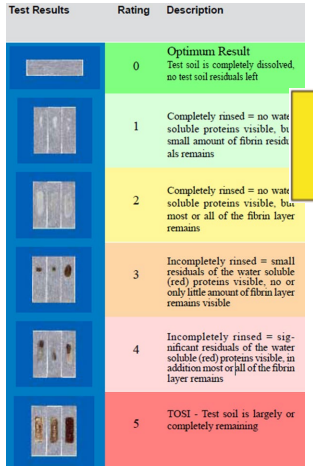
Verification Questions to Ask Yourself

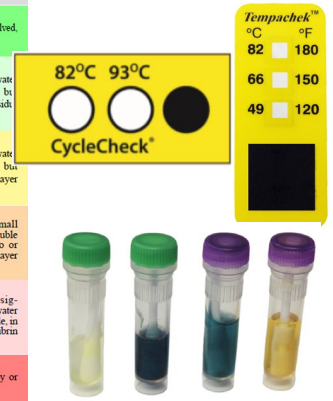
Is it important to know that I reached the proper temperature during my cycle?

Is it important to know that I am getting adequate spray coverage over my equipment (case carts) inside the cart washer?

If I am processing instruments in my cart washer, is that cycle performing properly?

Wrap-Up





- Over the course of this program we have discussed:
- How the 10 factors of cleaning affect the cleaning process.
- Explored the similarities and differences between Manual Cleaning and the Mechanical Cleaning Processes
- Identified the different manufacturers and models of automated washers (Washer Disinfectors, Ultrasonics, Cart Washers)
- Learned ways to assess the cleaning process through daily equipment operation inspection and cleaning verification testing
- We also examined the external factors that can also impact the cleaning process like water quality, chemistry and concentration, IFU's and Human factors.
- Discussed which products should be used to help us be compliant to the standards and help ensure best practices are being employed to achieve optimal results that impact positive patient outcomes.

Action Steps – Take Aways

- Are you using a surrogate device to simulate blood on stainless steel for soil removal?
- Are you performing testing of the 3 basic functions of the irrigating ultrasonic?
- Are you doing any testing on your cart washer?
- Very important to understand what the test is telling you both when it passes, but more importantly how to find the solution when it fails. A failure is the “Canary in the Coal Mine”. The cause of the failure must be found and corrected because our patients rely on us for safe instrumentation.
- Examine your testing methods. Think about whether you want your testing to pass every time, or do you want it to tell you if your machine is working properly?

QUESTIONS?