The AAMI Impact: What Dentistry Can Learn from AAMI ST79

Best Practices for device and instrument reprocessing

Learning goals:

- Purpose and goals of AAMI organization & overview of ST79.
- Review regulatory network based on clinical settings & accrediting bodies.
- Focus: IFUs, Tools to monitor cleaning, Sterilization monitoring.
- Review practical compliance steps.

AAMI:
Association for Advancement of Medical Instrumentation

An alliance of:

Manufacturers
Clinicians
Biomedical technicians
Researchers

AAMI
Advancing Safety in Medical Technology

AAMI:
Association for Advancement of Medical Instrumentation

Leadership for ***safe*** medical instrumentation

Leading Source of consensus standards for using technology in medical care

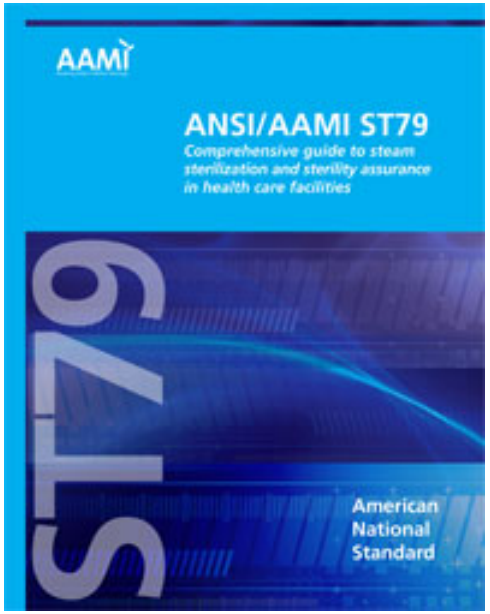
AAMI Standards
References and benchmarks

- Organized mid 1960s as medical devices and sterilizers became more complex.
- Broad scope today includes dialysis equipment, design of cardiac devices, training of biomedical technicians.

AAMI ST79

- Comprehensive Guide to Steam Sterilization and Sterility Practice in **Health Care Facilities**

- Evolution from focus on sterilizer equipment to full scope of instrument decontamination.



CDC Guidelines

More comprehensive guide to overall infection prevention best practices.

Primary standard for most state dental statutes.

AAMI ST79

Most complete reference standard for instrument processing and sterilization.

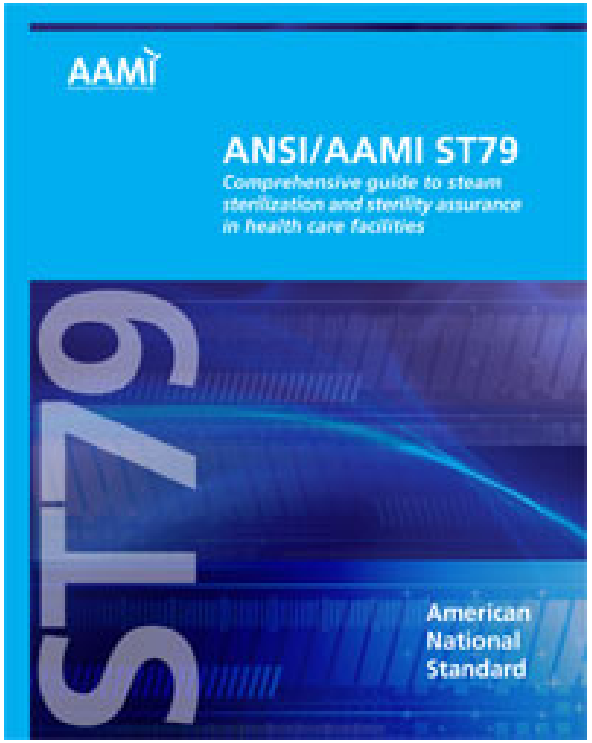
Primary standard for medical accreditation agencies.

AAMI ST79

Source standard

for Joint Commission
& Federal agencies:
FDA, OSHA, CMS, VA

State public health depts.



AAMI ST79 includes . . .

- Functional criteria for steam sterilization.
- Physical standards for instrument processing areas & sterile storage.
- Staff qualifications & education.
- Reprocessing procedures step by step.
- Installation, care of steam sterilizers.
- Quality control and process improvement.

Framework of ST79

1. Lowering and limiting bioburden before sterilization.
2. Properly preparing items for sterilization.
3. Selecting correct sterilization parameters.
4. Maintaining sterility of items until used.

Focus Issues from ST79

- IFUs – Instructions for Use.
- Achieving “clean” and tools to monitor.
- Packaging and sterilization monitoring.

FAQ:
Do I need **CDC guidelines** AND
AAMI ST79 as references for my dental clinic?

AAMI & Dentistry . . .

- “comprehensive guideline for all steam sterilization activities *in healthcare facilities, regardless of size* . . . “
- “ . . . and provides a resource for all healthcare personnel who use steam for sterilization.”
- Specific guidelines for tabletop sterilizers and dental settings.

What dental settings & ambulatory surgery centers have in common:

- Physician / dentist ownership.
- Fast turn-overs.
- Low inventory costly devices & instruments.
- Instrument processing often assigned to least trained, lowest paid.
- Limited regulatory/technical resources.
- Dedicated infection preventionist ???

Direct applications for AAMI ST79 in dental care settings?

- Dental clinics within hospitals and ASCs
- Tracers: cases / instruments tracked throughout a facility by Joint Commission Survey or CMS review.

  (CMS: Centers for Medicare and Medicaid)
- VA, military, government dental clinics.

Direct applications for AAMI ST79 in dental care settings?

Hospital based dental care.

Federally Qualified Health Centers.

Large dental clinics & multi site clinics.

Dental Schools.

Increasing use of large capacity medical washers, large pre-vac sterilizers.

Direct applications for AAMI ST79 in dental care settings?

- Any update or remodel of instrument processing facilities.
- Guide for task analysis, training.
- Budget and equipment requests.
- Trouble shooting reference for process failures.

Direct applications for AAMI ST79 in dental care settings?

Oral Maxillofacial surgery

A single standard of care all settings

- Increased risks with invasive procedures
- Issues with reprocessed implants

IFUs – Instructions for Use

- “The written recommendations of the device manufacturer should always be followed.”
- “The reusable medical device manufacturer is responsible for ensuring that the device can be . . . cleaned and sterilized.”
- Single Use dental implant packaging.

Manufacturer's IFU

- Must be available.
- Staff trained & documentation.
- Cleaning/disinfection/sterilization & the correct equipment to follow IFU.
- Lasers ? Implants ? Handpieces ?
- Curing lights, power scaling devices, intra-oral cameras, etc.
- Chemicals, dental materials.

Order of precedence in IFUs - Instructions for Use:

1. Device or instrument. (manufacturer validated process).

2. Equipment – ultrasonic, sterilizer, etc.

3. Detergents, pouch or cassette manufacturer.

Dental Handpiece IFU

How did this happen?

How will it impact patient safety?

Load recall?

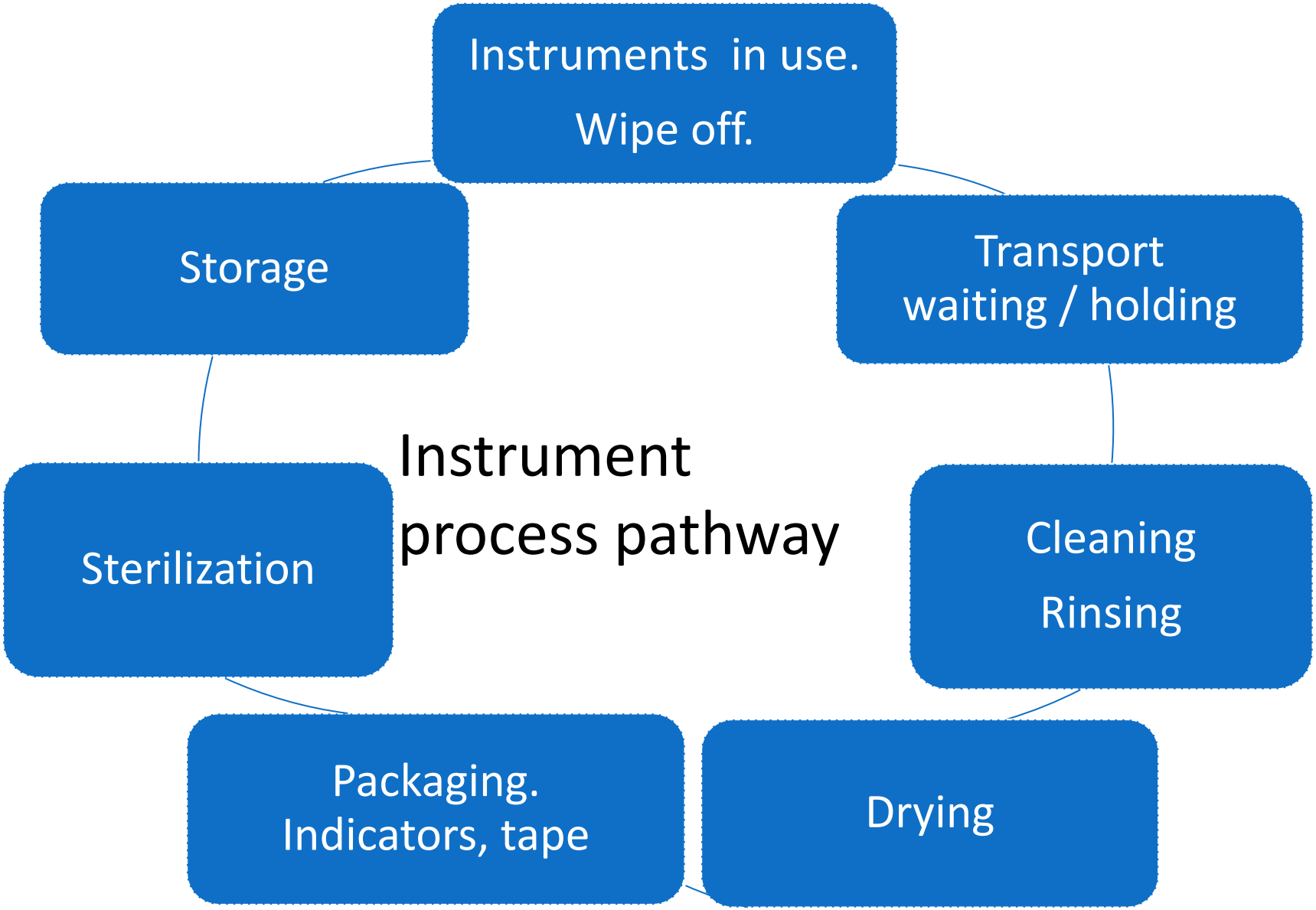
Brown stains – Rust or bio soils???

What causes rust & stains?

- “Stainless” steel can rust, corrode.
- Dried blood, chemicals during use.
  (acid etch, bleach)
- Prolonged or delayed soaking.
- Cleaning chemicals & pH.
- Mixed metals.
- Poor water quality cleaning & rinsing.
- Use rubber eraser to check if rust.

Cleaning:
"the removal of bio-burden & contaminants from surfaces and items to the extent necessary for further processing or intended safe use" (AAMI ST79)

"If the item is not clean, sterilization cannot be successful."


Instruments in use.
Wipe off.
Transport
waiting / holding
Cleaning
Rinsing
Drying
Packaging.
Indicators, tape
Sterilization
Storage
Instrument
process pathway

Design / Efficiency of instrument processing area

- **Must have Dirty to Clean pattern** with sufficient separation.
- Based on # of treatment rooms, staff, volume.
- Sufficient instruments and hand pieces.
- Instrument Processing efficiency = $$$ saved.
- Multi Dr. offices – instrument process tech.
- Storage of supplies vs sterile goods.

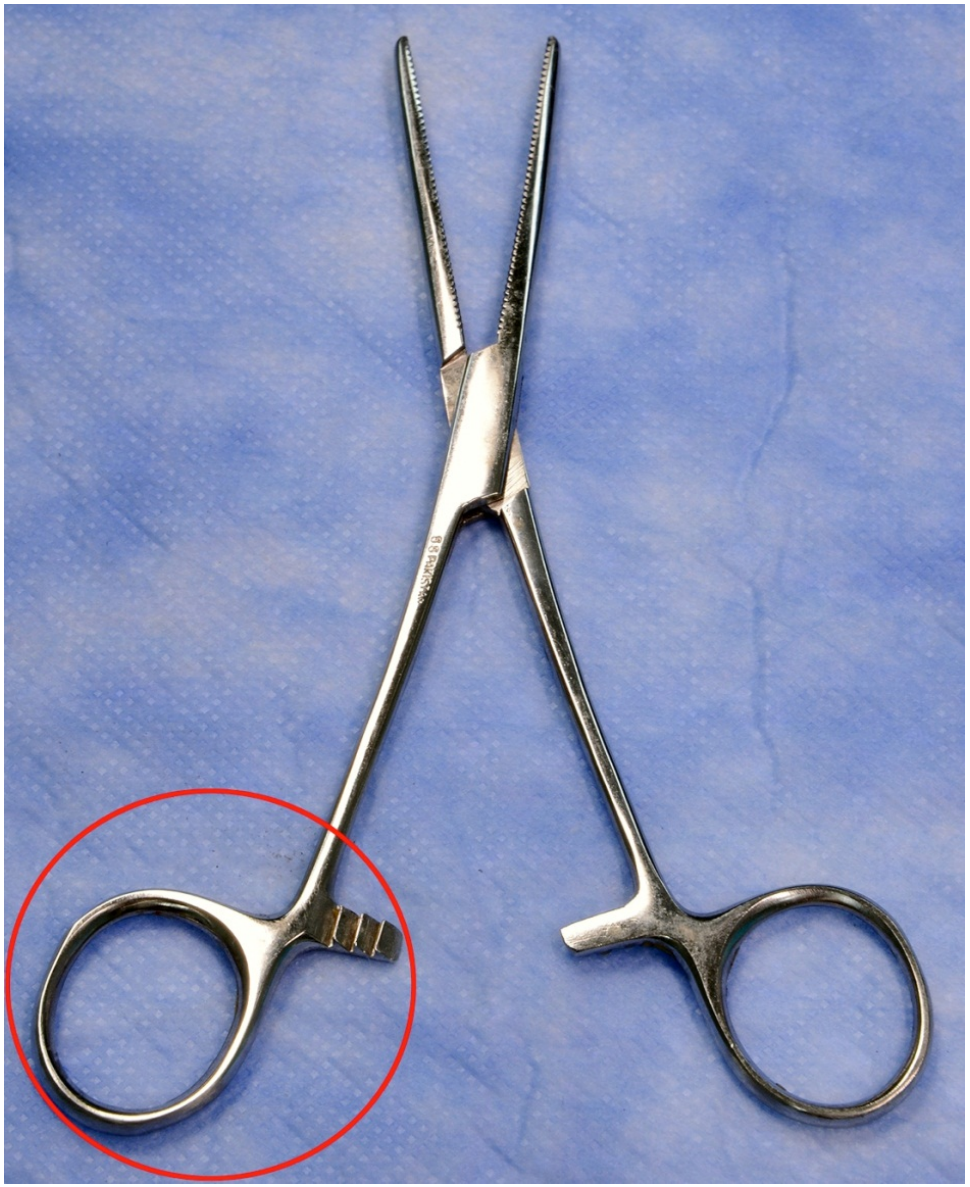
Increased focus in ST79 on tools to monitor cleaning

- Measuring effectiveness of equipment / chemicals / human factors.
- Specific measures for blood & protein removal.
- Residuals (lint, micro-particles).

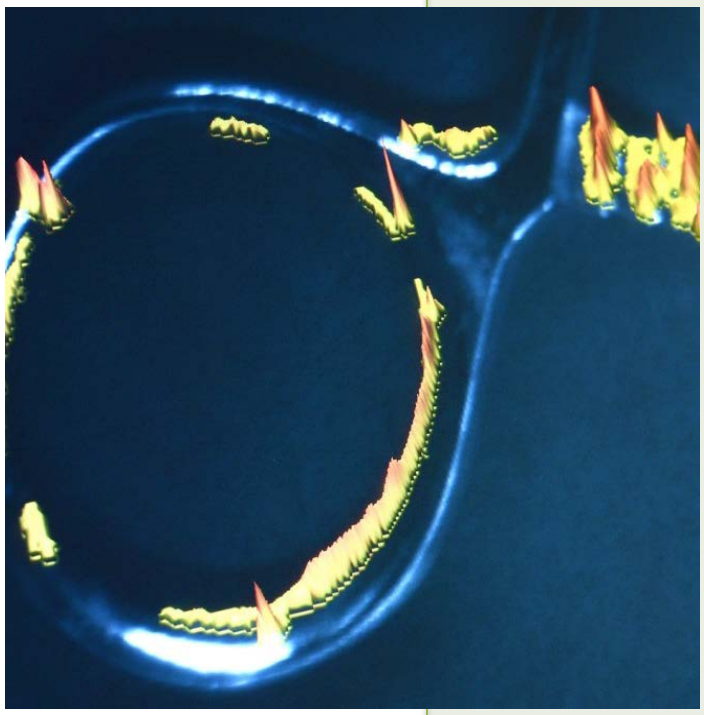
Monitoring Clean - Visual Assessment

- Minimum level of cleaning assessment.
- Have a policy in Exposure Control manual.
- Training.
- Use tools such as magnification and lighting.

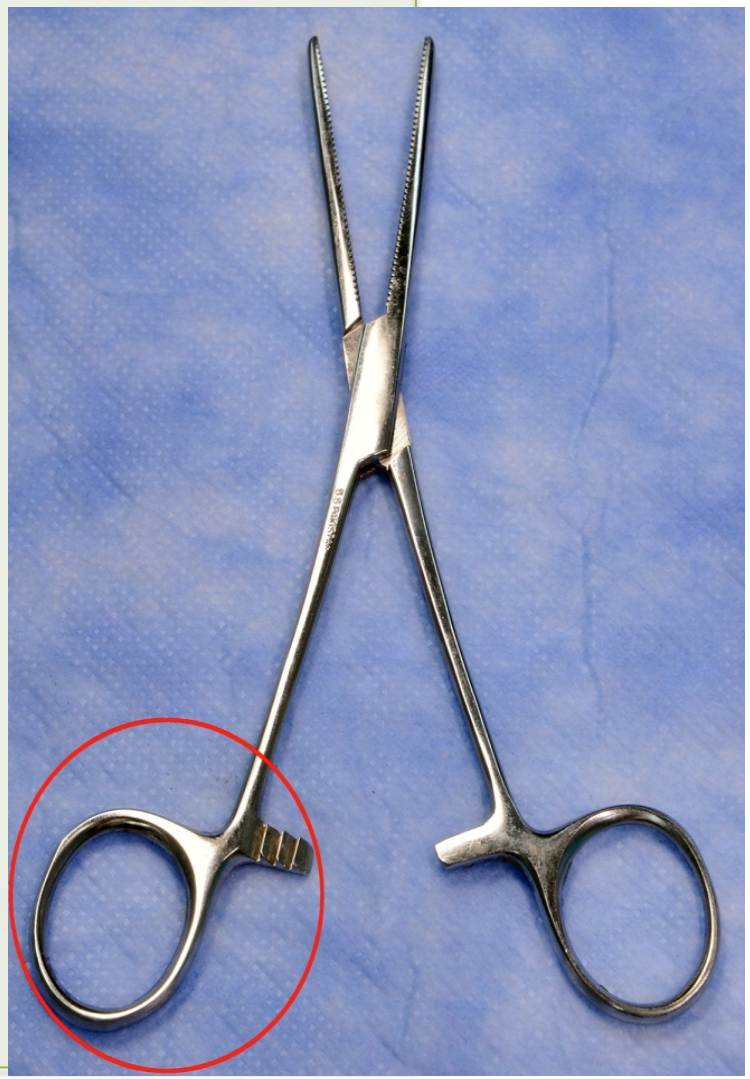
Is this item clean?



The 3D image, (left), shows residual protein detected by fluorescent detection system.



The same pair of forceps were photographed following the test and shows no apparent protein visually.



Random testing of “clean” items ready for sterilization:

141018163523

Dataset ID	141018163523
Site ID	01000
Capture Time	18/10/2014 16:35:23
Type	Measurement
Contamination Limit	Signal Mass (µg)
Contamination Measurement	21.493 µg
Calibration XY Time	16/04/2013 14:33:03
Calibration Quantity Time	16/04/2013 15:49:17

Cleaning failures impact patients

- Known transmission Hep. B & C through surfaces and / or instrumentation in dental settings.
- Documentation of cleaning failures with various scope devices.
- Surgical site infections traced to inorganic residuals, lint, etc.
- What causes “dry socket” ??

Dental Soils on instruments & in equipment:

- **Blood soils with potential of viable viral pathogens (Hep B, C, etc.).**
- **Biofilm.**
- **Endotoxin.**
- Inorganic cements, restorative residue.
- Fibers and lint.

What gets measured, gets done. How to measure “clean”

- Quality assurance for cleaning process.
- Use manufacturer IFUs.
- Human factors, task analysis, training.
- Verify equipment performance.

- **Use objective tools to measure results.**

User Verification of Cleaning – Tools to measure results:

Measure ***surface soil / contaminants*** using test markers such as protein, ATP, presence of hemoglobin, etc.

Measure ***functionality*** of cleaning equipment such as washers and ultrasonic instrument cleaning devices.

Ideal Cleaning Tests . . .

- Test materials, reagents will not damage instruments or surfaces.
- Surface markers have low toxicity and easy to remove.
- Rapid and easy within clinical settings.
- Inexpensive supplies and equipment.
- Data available to support test marker & benchmark standard for “clean”.

Are they seeing what you missed?

Surface soil test products

- 2 % Hydrogen Peroxide reacts with blood catalase.
- Protein detection swab with reagent.
- Hemoglobin swab test is more sensitive.
- ATP luminescence tests use swabs & device.

Fluorescent Markers

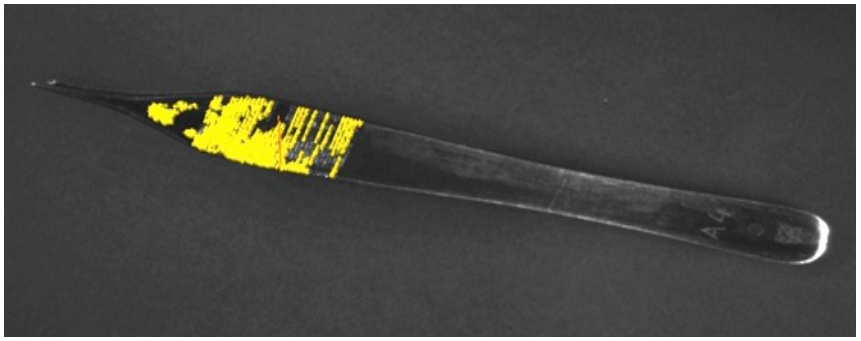
- Clear gel used as marker.
- High touch areas are marked before cleaning.
- Assess removal using UV / black light.
- Monitoring and training tool.
- Primarily for surfaces.

Fluorescent Protein Detection System:

- Extensive research in England due to more widespread risk of prions. (CJD)
- Extreme difficulty to clean or inactivate prions (hydrophobic protein strands).
- Requires greater sensitivity for protein detection.
- Test process for instruments.
- Cost factor.

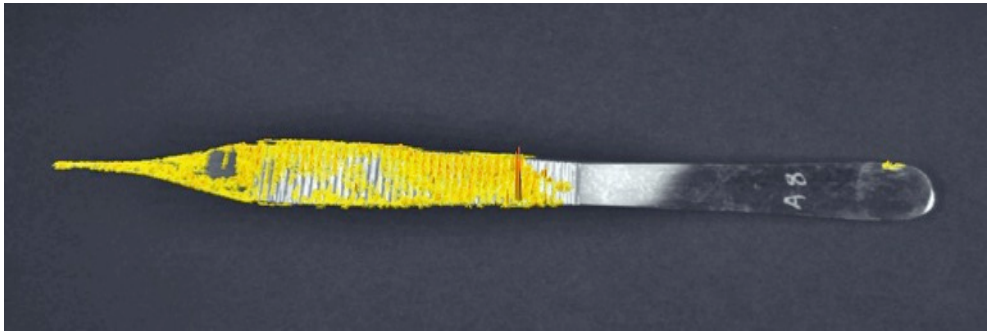
Randomly chosen images of washed identical instruments

Alkali washed forceps 4A



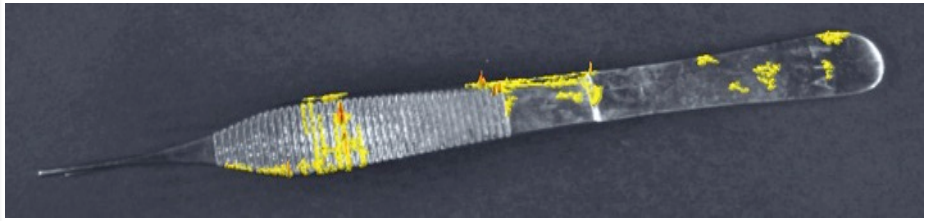
2.8 µg total residual protein

Non-ionic washed forceps 8A



5.4 µg total residual protein

Enzyme washed forceps 17A



0.9 µg total residual protein

Water-only washed forceps 22A

11.8 µg total residual protein

Equipment Functionality Testing:

Noise does not = cleaning activity!

Aluminum foil test:

Fresh sheet foil suspended across tank full of solution.

Check for even pattern dents and small holes.

Foil residue may contaminate cleaning solution.

Foil test for ultrasonics

Equipment Functionality Testing:

Alternative test for ultrasonic uses small capsules which react to cavitation energy and change color if sufficient cavitation energy.

ST79 – Annex D
User Verification of cleaning process

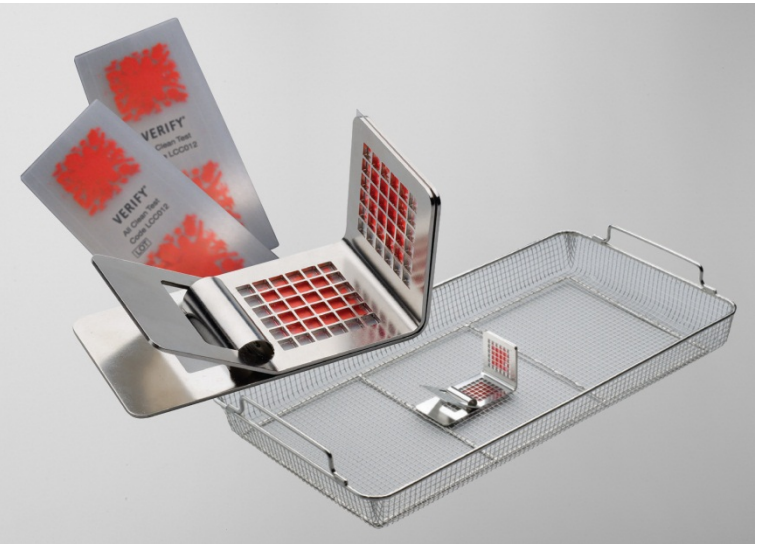
Washer Functionality Test Coupons:

Coupons use simple color markers or more discriminating test soil simulating blood and fibrin.

Holders or plastic covers emulate crevices and box locks.

Measures spray arm action & detergent activity.

Washer function tests



Cleaning & IFUs

- Manufacturer's Instructions for Use.
- Cleaning instructions should be followed.
- May be inappropriate. Contact the manufacturer of device for clarification.
- Device instructions take precedence. Then incorporate directions for cleaning equipment and cleaning chemicals.

How to improve cleaning . . .

- Wipe off cements, soils at point of use.
- Avoid dried blood soil. Soak or spray.
- Avoid soaking over 1 hour.
- Use medical grade detergents.
- Do not overload ultrasonic.
- Change solution based on volume. Minimum change daily.
- Rinse thoroughly with good water.
- DRY items before packaging.

How Does Sterilization Work?

Condensation of saturated steam on instrument surfaces transfers energy.

Steam must circulate and contact all packages & instruments.

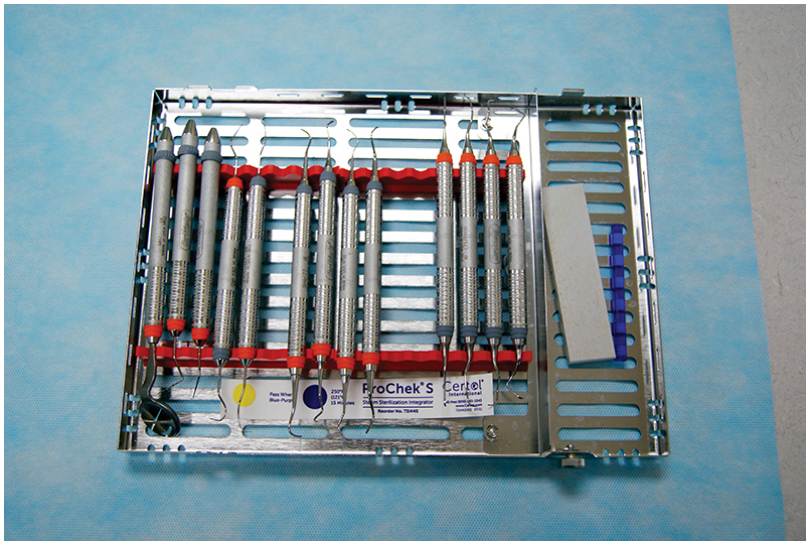
Sterilization Monitoring
Physical, Chemical, Biological

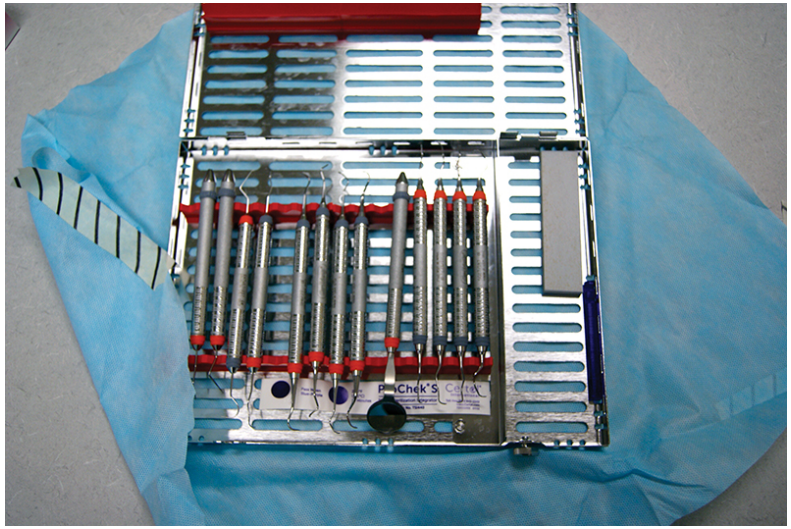
- Physical – readouts temp, pressure. Printouts helpful to monitor, record.
- Chemical – tape, indicator strips and pouch inks, Class I through VI.
- Biological Spore tests – self incubate or third party.

Do we really need internal indicators?

- Gravity sterilizers prone to cold spots.
- Increased load mass with cassettes.
- Operator error - overloading &
  peel pouches loaded paper to paper.
- Need external if internal not visible.
- Pouch ink indicators ??
- Cl V integrators for oral surgery packs.

External / Internal Chemical Indicators





Packaging & Loading

Avoid over-fill peel pouches.

Mark date & sterilizer ID on every package on plastic side or tape; use non-toxic markers.

Load paper – plastic pouches on edges, always paper side next to plastic side.

Place heavy thick packs on lowest rack.

Make space for steam between packages!

Sterilizer Loading & Best Practices

What does your sterilizer look like?

Spore Testing:

Use spore tests weekly.

Self incubate or third party.

Check expiration dates.

Process a control matching each lot #.

Place spore test inside pouch or cassette. (challenge pack)

Keep records of testing.

Quality Checks for Sterilization:

- Scheduled maintenance all sterilizers.
- Package all items for sterilization.
- Label packages date & sterilizer.
- Biological spore tests min. weekly.
- Watch expiration dates; use controls.
- Train & monitor instrument processing.
- Keep sterile items in clean closed areas.
- Keep records.

Have a Sterilization Failure Policy

80 % of Sterilizer & Spore Test Failures are Human Error.

If spore test failure all items must be reprocessed back to last passing spore test.

Check mechanical controls, print-outs, chemical indicators, loading conditions.

Check door gasket, sufficient water or solution in sterilizer, possible clogged relief valves.

Use CDC Guidelines. Re - run spore test.

This is why hospitals spore test daily.

Small package vs. total load mass

Large pack AND total load mass

Package, Load, Daily, Weekly

Dental implant reprocessing

- The device/implant manufacturer's IFU "instructions for use" take precedence.
- If item is designed for single use and no reprocessing instructions available –
  it is not advisable to reprocess yourself.

- **Reprocessing of single use items creates manufacturer status and places liability on the clinic / dentist / surgeon.**

CDC & AAMI Resources:

2003 Guidelines Dental:
www.cdc.gov/mmwr/pdf/rr/rr5217.pdf

2008 Guidelines for Healthcare Facilities:
www.cdc.gov/hicpac/Disinfection_Sterilization/13_11sterilizingPractices.html

2016 Summary Guidelines Dental:
http://www.cdc.gov/oralhealth/infectioncontrol/pdf/safe-care.pdf

AAMI website: www.aami.org/index.aspx

Link to ST79 (how to order document, prices):
www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=1383

Sites and links accurate as of Oct. 2016

Remember: You make a difference in patient health and safety !

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