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 selected topics: IFUs, tools to monitor cleaning, sterilization updates.
- Implications for Medical Consumers
AAMI: Association for Advancement of Medical Instrumentation

An alliance of:

Manufacturers
Clinicians
Biomedical technicians
Researchers
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 design to full scope of 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 decontamination / instrument processing and sterilization

Primary standard for medical accreditation agencies
AAMI ST79

- Most likely to be 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 including sterile storage
- Staff qualifications & education
- Reprocessing procedures step by step
- Installation, care, maintenance of steam sterilizers
- Quality control and process improvement
AAMI ST79 2010 consolidates:

- ST 46 – steam sterilization
- ST 42 – table top sterilizers
- ST 37 – “flash sterilization” (now referred to as immediate use)
- ST 35 – Safe handling and biological decontamination of medical devices
- ST 33 – Guide for reusable rigid container systems
FAQ: Do I need both the 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.
AAMI & Dentistry . . .

Common factors between dental settings and ASC (ambulatory surgery centers)

- Fast turn-overs
- Low inventory of expensive devices and instruments
- Instrument processing often assigned to least trained, lowest paid
- Limited regulatory/technical resources
Direct applications for AAMI ST79 in dental care settings?

- Large dental clinics / equipment
- Centralized instrument processing
- Medical model large capacity washers and large capacity pre-vac sterilizers
Direct applications for AAMI ST79 in dental care settings?

- Dental clinics within hospitals and ASCs
- Tracers: cases and instruments tracked throughout a facility by Joint Commission Survey or CMS review
  (CMS: Centers for Medicare and Medicaid)
- VA, military, government dental clinics
FAQ:

- How do I justify the need to update or remodel our sterilization area?
Direct applications for AAMI ST79 in dental care settings?

- Document provides excellent guide for task analysis, training, budgetary back-up
- Trouble shooting reference for process failures
Direct applications for AAMI ST79 in dental care settings?

Oral Maxillofacial surgery

- Single standard of care all settings
- Increased risks with invasive procedures
- Issues with reprocessed implants
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
- Reprocessing single use items – ie. 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, training documented
- Use of device
- Cleaning/disinfection/sterilization
- Lasers ? Implants ? Handpieces ?
- Curing lights, power scaling devices, intra-oral cameras, etc.
- Chemicals, dental materials
FAQs
How did this happen?
How will it impact patient safety?
Load recall?

Brown stains – Rust or bio soils???
Achieving “clean”

Increased focus in ST79 for:

- More guidance on cleaning agents and directions from device manufacturers
- More specific information on effect of cleaning chemicals on removal of blood
- New research on residuals (lint, micro-particles, and subsequent infection)
Monitoring “clean”

- At a minimum, “visually clean”
- All processes should be verified including manual
- How to monitor ultrasonics and washers and verify efficacy
- Verification versus validation
ST79 – Annex D
User Verification of cleaning process

- Protein is most common marker
- Benchmark acceptable levels not established
- Is the “Visual” standard adequate?
- Table D.1 & D.2 tests for soils and washer efficacy
ST79 – Annex D
User Verification of cleaning process

ProFormance™
CLEANING VERIFICATION
AAMI and AORN recommend at least weekly testing of the cleaning process. Comply with these standards by utilizing ProFormance™ monitoring tools. Individually and as part of complete kits, the ProFormance™ line of products provide an objective test of cleaning methods that are clearly visible and easy to interpret.
Rinsing

- The Rodney Dangerfield of decontamination...
Sterilization Monitoring

- Physical, Chemical, Biological
- Chemical indicators Class I through VI
- Newest Class VI emulator to release implant loads while waiting for biological spore test
FAQ:
Do we really need internal indicators?

- Most common gravity type sterilizers do not “pull vacuum”, may have cold spots
- Increased load mass with cassettes
- Monitors needed due to operator errors including overloading & peel pouches loaded paper to paper
“An internal CI should be used within each package, tray or rigid sterilization container system . . .”

“This internal indicator may be a single-variable CI 3, multi-variable CI 4, or integrating indicator CI 5 . . .”

“The CI should be placed in that area of the package . . . least accessible to steam penetration . . .”
Internal Indicators & Placement

Figure 2: Chemical internal indicator strip placed prior to sterilization.
Internal Indicators & Placement

- Placement of internal indicators according to container manufacturer instructions.

- “The Cl is retrieved at the time of use and is interpreted by the user.”
Class IV & V indicators

- CI IV multi-variable indicators designed to react to two or more of the critical variables.

- CI V integrators are the medical standard for internal CI & designed to emulate the performance requirements for biological spore test indicators.
Do we need to do Bowie-Dick (Cl II) process checks for our tabletop pre-vac vac sterilizer?
Small package vs. total load mass

Large pack AND total load mass

Package, Load, Daily, Weekly
FAQ:
I am sterilizing a dental implant. Where do I put the BI for this load?
What about the “dummy” package?
The Challenge Pack or PCD

- Process Challenge Device

- Uses Class IV or Class V CI and BI (Biological Spore Test) inside a pack/wrapped cassette simulating the largest or most dense package that will be processed.

- Follow IFU for sterilizing dental implants.
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.
FAQ

• I have sterilization instructions from the handpiece manufacturer and from my sterilizer company. Which do I follow?
Order of precedence in IFUs - Instructions for Use:

- Device manufacturer validated process
- Sterilizer manufacturer directions
- Packaging manufacturer
AAMI ST42 and ST55

- ST42 - Steam Sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care and dental facilities, included in ST79.

- ST55 - design & performance of table top sterilizers.
ANSI / AAMI Standard 55

From the ADA News Nov. 2011:

“Steam Sterilizer Standard Project Set”

- ADA Standards Committee approves work project.
- Volunteers review the standard already written by AAMI.
Alerts for medical consumers – that’s US!

- FDA/AAMI summit Oct. 2011
- Create standardized usable instructions for sterile processing of devices.
- Address the inability to disassemble some devices.
Alerts for medical consumers – that’s US!

- Elevate the training and education of central sterile personnel.

- Better define what is “clean” including validation and test soils.
Did You Know ... 

- Only one state in the nation requires hospital central sterile technicians to have formal training and certification.
- Many central sterile techs are recruited from the environmental services (housekeeping dept.) and are trained on the job.
- The average SPD processes thousands of instruments during just one shift.
From the FDA Medical Devices Oct. 2011 FDA/AAMI summit:

7. Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing.
AAMI Resources

- To view AAMI resources and purchase publications: (membership is not required to order publications but will yield reduced price)

www.aami.org/publications/standards/st79.html

  “Water for the reprocessing of medical devices”

- ST40:2004 reaffirmed 2010 FDA
  “Table top dry heat sterilization and sterility assurance in health care facilities, 2nd ed.”
Resources, cont.

- Sterilization Equipment Design and Use
  pub. May 2010, order code STBK10-2

- Table top steam sterilizers, 3rd Ed.
  pub. March 2011
  “Minimum construction and performance requirements for small table top steam sterilizers”
Remember: You make a difference in patient health and safety!

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