Instructions for Cleaning of Orthopedic Medical Devices

CAMDR – Learning Annex – Talbot 2:30 - Part 1
MDR Leading the Way

DISCLOSURE

- I am an employee of Stryker Corporation.
- I am involved with the manufacture of medical devices.
- No product preferences or names are listed or recommended by this presentation.
- All opinions are those of the presenter.

Upon completion of this activity, the learner should be able to:

- Understand the key areas of responsibility for cleaning orthopedic equipment;
- Know specific requirements met by the device manufacturer and those of accessory products such as washers and cleaning chemical suppliers;
- Understand the rigor applied to the reprocessing of single use devices by regulated third party providers.

Background

- The U.S. Food and Drug Administration (FDA) places the primary responsibility for developing and validating methods for effective reprocessing of a reusable medical device on the manufacturer of the device.
- The manufacturer is expected to validate that the device can be cleaned and disinfected or sterilized adequately to allow the device to be reused.

Two basic components of user verification of cleaning efficacy are:

1.Establishing reasonable benchmarks for the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients; and

2.Developing rapid, easy-to-perform test methods that reliably demonstrate that the cleaning benchmarks have been achieved.

Best practices for cleaning.

Destruction of passivation protection and coatings can happen in as little as a couple of washes with high pH, wrong concentrations, or too long on and exposure to an inappropriate chemical.

Best practices for cleaning.

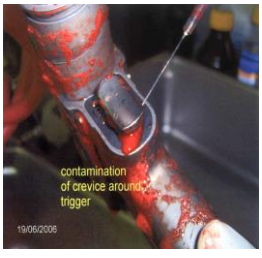
Depending on the products use, the protocol for cleaning must include a chemical marker that can be quantified.

- Spore reduction testing alone can no longer be used as the stand alone endpoint for cleaning.
- A protocol must include a manual and automated method.
- Quantification is not always possible so the best practice is to incorporate:
  - One negative control device
  - One positive control device
  - Minimum of three test devices

Best practices for cleaning.

- Make the device look like it was used.
- Take pictures for the final report

Best practices for cleaning.



What is followed for cleaning on equipment.

- The attached Instructions for Use are validated for function and;
- All steps of the cleaning and sterilization process are validated to the latest requirements of CSA standards (Z314.08);
- Tests used for cleaning validation include assessments for:
  - Bacterial spore reduction – Geobacillus sterothermophilis
  - Vegetative bacteria – E. coli and S. aureus
  - Waterborne bacteria – P. aeroginosa
  - Chemical markers for:
    - Protein
    - Carbohydrate
    - Hemoglobin
    - Total Organic Carbon
- These validation tests are done for initial product, simulated use product and actual aged product for those devices that have reached life as defined by use.

What we know about cleaning needs.

- Timing of cleaning varies from one to several hours.
- Hip Surgery – At the time this picture was taken the equipment had been sitting over thirty minutes (30), the case was still on-going.
- When the surgery finished the equipment had sat after use in the OR for 109 minutes, this is typical surgery time.
- It was picked up by the Processing staff within 20 minutes and was processed through in the Decontamination area in 15 minutes, total time of drying 144 minutes or almost 2 ½ hours.

What we know about cleaning needs.

- Cleaning chemistries are unregulated and variable to the extreme.
  - If it's not specified by the device manufacturer, it is left to the facility to **determine the appropriate detergent – and these are not regulated**
  - An enzyme is only going to loosen the soil, **You still need a detergent to remove soils**
  - **Temperature is also problematic**
  - **Measuring the actual amount of detergent is necessary**
  - **Chemicals are not mixed correctly**
  - 'Are my instruments clean?' If you're paying $5 less a gallon, and I've got dirty instruments, what good is it? You're looking good and my patient is suffering."

(Nancy Chobin, 1995, ICT.)

What we know about cleaning needs.

- Water quality needed is confusing.
  - RO, DI, Tap, Purified, Filtered, Distilled, etc.
- The only "validation' done on the device is by the individual device manufacturer for their product.
  - Standards and guidelines state that only one method needs to be supplied for manual cleaning and one method for automated cleaning on the products instructions.

Best practices for cleaning.

- Validation protocols must also state what solutions were used, brush sizes if needed, step by step processes, such as wash, brush, repeat…
- It is critical that the device manufacturer state a cleaning chemistry requirement or a restriction to preserve your devices.
  - If they do not or you do not follow it, you run the risk of using cleaning chemistries that degrade the equipment.

If generalities are stated, such as "neutral pH detergent" then insure the cleaning chemistries you use are comparable in those terms.

Cleaning Standards

- Unfortunately, standards only go so far and there are no standards for complex equipment.
- i.e. ASTM F1744 – 96: Standard Guide for Care and Handling of Stainless Steel Surgical Instruments.
  - Only uses as examples general equipment categories such as scissors, forceps, needle holders, scapel holders, hinged instruments, microsurgical instruments.
  - This is good for simple instruments, but complex instrumentation needs more instructions.

Processing through Decontamination

- Remove parts from trays and place into wire baskets for ultrasonic soak step (unless the device manufacturer instructs to use their trays)
- Baskets then can be scrubbed then placed into the washer disinfector.
- Trays and inserts are washed separately unless instructions state otherwise. (Usually these parts can be run though cart washer type equipment, but this should be clear from the supplier)
- Inspection for proper rinsing is key to all components. (in both manual and automated processes)
- Movement of articulating hinges or joints critical for cleaning and rinsing.
- High pH cleaners will affect finish overtime.
  - High pH followed by high acid rinsing will affect finish overtime and can be rapid.

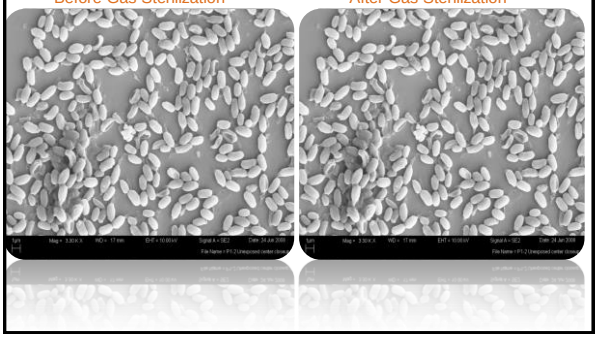
Sterilization

- Sterilizer Type: Pressure Vacuum (Pre-Vac) Sterilizer
- Max Chamber Contents: Nine (9) instrument cases
- Exposure (Holding) Time: Four (4) minutes
- Temperature: 270°F (132°C)
- Pressure: Two to fifteen (2-15) PSIA
- Chamber Drying Time: Thirty to ninety (30-90) minutes

What Clean and Sterile May Look Like.

Before Gas Sterilization

After Gas Sterilization



Reprocessing and Why?

How SUD's are Reprocessed.

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Monitoring the manufacturing process and records maintained.

- Complies with all Quality System Requirements
- Registered as a medical device manufacturer
- Follows the exact regulations as an original equipment manufacturer (OEM)
- No differences or exceptions between OEM and reprocessing firm in respects to safety and efficacy
- Audited by regulatory bodies (i.e.FDA etc.)
- Example of records maintained:
  - Design History Files (including feasibility studies, design inputs, validations, design outputs, and design transfer), Master Files (MAF), Device Master Records, Device History Records, Audits, Corrective Actions (CAPA), Process validations (IQ,OQ,PQ), Sterilization Validations, Cleaning Validations, etc.

Required to report under the U.S. Medical Device Reporting requirements

- Single Use Device reprocessor are considered medical device manufacturers by regulation and are thus subject to all device reporting requirements including adverse event reporting under the Medical Device Reporting (MDR) as well as Reports of Corrections and Removal sections.
- Section of US regulations that apply are FDR 21 part 820.

What specific processer are validated?

- All requirements for cleaning, sterilization and packaging are validated to the extent of a reusable device in the realization of a second use of a single use device.
  - This is often confusing due to the remarking of a reprocessed device as single use again after reprocessing for some devices.
  - This occurs due to the limitations of the functional validation of the reverse engineering principles used to disassemble, clean, and sterilize the device.
- Cleaning is compliant to the current AAMI technical information reports, AAMI/TIR 30 and ISO documents of the used sterilization process.
  - This includes cycle validation for ethylene oxide under 11135-1
- All products marked as "Sterile" must meet 10^{-6} level validation testing to carry this notation on the label.

Do reprocessing procedures tailor to and are validated for specific types of medical devices?

- Yes, all medical devices cleared as able to be placed on the US market through the pre-market notification process must demonstrate validated cleaning, sterilization and packaging tests in compliance to new product.
- Subsequent products in the same classification can be similarly reprocessed. This is listed in the US regulations by product classification.

What routine testing is performed?

- Routine testing required includes:
  - Functional testing including but not limited to: electrical continuity, cutting function, grasping ability, power, and mechanical testing,
  - Sterilization commissioning and certification through supplier control/Quality Assurance personnel requirements or in-house calibration requirements (i.e. for Stryker every 6 months),
  - Biological Indicator monitoring and release
  - Residual sterilant level testing for release
  - All calibration of ancillary support equipment, both in-house and contracted, (i.e. for Stryker every 6 months) and,
  - Sterilization cycle requalification. (i.e. for Stryker annually)

In summary, what have we learned?

- Orthopedic cleaning is validated from the original equipment manufacturer (OEM) and likewise for reprocessed single use devices.
- Validation is necessary for assurance of cleanliness but the levels and standards are not clearly defined.
  - Most manufacturers do "as low as they can test" protocols.
- Cleanliness is subjective to the next clinical use or as further process for medical equipment today.
- Single Use Device reprocessing by registered and regulated third party reprocessors follow the same regulations as the original supplier for the next use.

Questions?

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