BEST PRACTICES
for Sterilization and High-Level Disinfection (HLD) of Reusable Medical Devices
Objectives

Upon completion, participants will be able to...

1. Explain where best practices for reprocessing reusable medical devices are documented,
2. Review best practices steps for reprocessing reusable medical devices, and
3. Discuss common errors when reprocessing reusable medical devices.
In the U.S., instrument reprocessing best practices are detailed in AAMI Standards, AORN Guidelines for Perioperative Practice, along with other documents, such as SGNA which focuses on flexible endoscopes.
Instrument reprocessing is a patient safety issue!

9/11/15, the CDC issued an official Health Advisory to healthcare facilities, such as hospitals, ambulatory surgery centers, clinics and doctors’ offices that utilize reusable medical devices urging them to "immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines."
Sterilization
Best Practices

Point of Use
• pre-clean and spray instruments to prevent soil from drying before transport

Reprocessing Area
• clean & disinfect in Decontam area
• inspect & assemble in Prep & Pack
• package & sterilize in Sterilization
• maintain sterility in Sterile Storage

Quality Assurance
• document, document, document!!!
Sterilization Best Practices
(Point of Use)

Instruments should be kept free of gross soil during surgical procedures as blood, body fluids and saline can damage instruments and if allowed to dry, be difficult to remove during the decontamination process.
Sterilization Best Practices (Point of Use)

• Wipe instruments as needed during the surgical procedure with sterile sponges moistened with sterile water. Do not use saline as saline can be corrosive to instruments.

• Irrigate instruments with lumens as needed with sterile water throughout the surgical procedure. Do not use saline as saline can be corrosive to instruments.

• Separate sharp instruments from other instruments to minimize risk of injury to decontamination personnel. Place disposable sharps into a receptacle that is proper for disposable. Extreme care must be taken in the management and disposal of sharps waste. Place reusable sharp instruments into a separate receptacle that is puncture-proof for transport.
Sterilization Best Practices
(Point of Use)

- Multi-part instruments should be opened, disassembled, and arranged in an orderly fashion within their original set configuration to ensure return as a complete set after processing.

- Hinged instruments should be opened using stringers, racks, or instrument pegs designed to contain instruments.

- Protect delicate instruments from damage by placing light instruments on top of heavier instruments or segregate into separate containers. Microsurgical instruments should always be segregated into separate containers.

- If delay in decontamination is expected, instruments should be moistened with a pre-soak solution or covered with a towel soaked with water to keep blood and debris from drying.
Sterilization Best Practices

(Transport)

All instruments opened during a surgical procedure should be considered contaminated and properly contained for transport to prevent damage as well as exposure or injury to personnel and patients.
Sterilization Best Practices
(Transport)

- Hand carried items may be contained using a plastic bag or container with a lid.

- Large quantities of instruments may be contained within a transport cart with doors or plastic cover. Items placed on top of a transport cart must be contained.

- Sharps must be carried in a puncture-resistant container and liquids must be contained in a spill-proof container.

- Transport containers (plastic bag, container or cart) must be labeled to indicate biohazard contents.

- Contaminated instruments should be transported ASAP.
Decontam should never receive instruments like this…
Sterilization Best Practices

(Decontamination)

Decontamination is the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and are rendered safe for handling, use or disposal.
Sterilization Best Practices
(Decontamination)

• An appropriate emergency eyewash station must be available.

• Three section sink to soak, wash and rinse should be approximately 36” from the floor, 8-10” deep and wide enough to accommodate instrument trays. Sinks should have medical grade faucets or manifold systems available for flushing instruments with lumens. Never clean instruments in a scrub or hand wash sink.

• Personnel must wear appropriate PPE. All head and facial hair should be completely covered. Jewelry, wristwatches and nail polish should not be worn.

• Before leaving the decontamination area, personnel should remove PPE and wash hands. Extreme care must be taken not to contaminate clothing or skin during removal of PPE.
Proper PPE is critical for your safety!
Sterilization Best Practices (Decontamination)

Decontamination should occur immediately after the surgical procedure to prevent soil from drying and the formation of biofilms. The instrument manufacturer’s validated reprocessing instructions for use (IFU) should be available and followed.
Upon arrival, instruments should be removed, sorted and prepared for cleaning. Use care to prevent loss of small parts.

Pre-soaking, detergent type, detergent dilution, water quality, water temperature, cleaning implements (type, size, length) and cleaning should all comply with instrument manufacturer’s IFU.

When manually cleaning, always scrub below the water surface to limit the creation of aerosols. After cleaning, thoroughly rinse all areas to remove debris and detergent residue. Some instruments may require rinsing with treated water. Reusable brushes should be disinfected or sterilized at least daily.

Ultrasonic cleaning should only be used for fine cleaning and set to the instrument manufacturer’s recommended cleaning time.

Test all mechanical cleaners daily and after servicing.
Instructions For Use (IFU)

It is critical to follow the instrument MFR’s instructions for use (IFU) with regards to water temperature, cleaning solution, brush type, and cleaning procedures.

For complex devices, specific times will be validated for the soaking, ultrasonic cleaning and/or rinsing.
1. Submerge in enzymatic detergent.
2. Flush port with 50 ml enzymatic detergent.
4. Scrub with soft bristled brush (agitate instrument while scrubbing).
5. Rinse with warm tap water (38-49°C)
6. Flush port with 50 ml warm tap water.
7. Place in bath of warm water (agitate by hand for at least 1 min). Repeat this process 2 additional times.
8. Ultrasonic for 10 min with neutral pH detergent (flush port with 50 ml prepared detergent before sonication).

9. Flush port with clean tap water (3 times).

10. Rinse for at least 1 min with tap water.

11. Dry with clean, lint free cloth.

12. Inspect.

13. Lubricate tip mechanism and finger slot (do not lubricate flush port).
Bausch + Lomb is pleased to announce the availability of new cleaning instructions for our surgical instruments marketed under the Storz Ophthalmic Instrument and Bausch + Lomb Instrument brands.

Manual Cleaning

1. Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.

2. **Pre-rinse** the instrument by holding it under cold running water for **at least 30 seconds**, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.

3. Place the instrument into a suitable clean basin filled with fresh **neutral pH** cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments.
Ensure that the instrument is fully immersed in the cleaning solution. The following conditions were validated using a neutral pH detergent (Steris ProKlenz NpH) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

4. Using a **soft cleaning brush** gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution for **at least 5 minutes**. Clean the instrument until all visible soil has been removed.

5. **Rinse** the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument and the amount of soil.
6. Place the instrument in an ultrasonic bath filled with fresh neutral pH cleaning solution and sonicate for 5 minutes. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. Do not overload the ultrasonic bath or allow instruments to contact one another during cleaning. Do not process dissimilar metals in the same ultrasonic cleaning cycle.

7. **WARNING:** Do not process powered instruments in an ultrasonic cleaner.

8. The cleaning solution should be changed before it becomes visibly soiled. The ultrasonic bath should be drained and cleaned each day it is in use or more frequently if visible soiling is evident.
Follow the instructions of the manufacturer for the cleaning and draining of the ultrasonic bath.

9. **Repeat steps 4-6** as necessary if visible soil remains on the instrument.

10. **Rinse** the instrument by holding it under warm (27°C – 44°C; 80°F – 100°F) running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument.

11. If the instrument has lumens the **lumens should be flushed** using a syringe filled with 50cc of warm distilled or deionized water using a stopcock as follows:
EXAMPLE - MFR’s Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

a. Place syringe tip into a beaker of warm (30°C – 40°C/85°F – 105°F) **distilled or deionized water** and fill to the 50cc mark.
b. Connect the end of the syringe to the center stopcock fitting.
c. Rotate the stopcock lever to the male Luer fitting (irrigation) or to the female Luer fitting (aspiration) to allow fluid flow to the appropriate Luer fitting.
d. Connect the stopcock to the appropriate Luer connector on the instrument.
e. Push on the syringe plunger to force fluid through the lumen into another beaker for proper disposal. Do not draw flushing fluid back through the lumen. Disconnect the syringe. Disconnect the syringe/stopcock from the instrument.
f. Repeat steps A-E at least three times, for each lumen.
g. Fill the syringe with 50cc of air, reattach the stopcock, and push on the plunger to force air through each lumen. Disconnect the syringe/stopcock from the instrument.

**NOTE:** The CX7120 Universal Maintenance Kit contains a syringe and stopcock suitable for cleaning instrument lumens.

12. Immerse the instrument in clean basin containing fresh deionized or distilled water and **soak for at least three minutes**.
13. Immerse the instrument in **second** clean basin containing fresh deionized or distilled water and **soak for at least 3 minutes**.
14. Perform a **final rinse** of the instrument with sterile distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.
- Do you have an ultrasonic cleaner?
- Is it being used?
- For how long?
Do you know how many devices require ultrasonic cleaning? Do not forget loaners!

Knowing this information, will tell you if you have the right type and right amount of equipment?
Chemical Disinfection

Cleaning alone is not adequate for soiled medical devices that present a high risk of disease transmission to workers or patients. Such medical devices should be subjected to a microbicidal process, per their MFR’s IFU.

Microbicidal processes include disinfection and sterilization by thermal or chemical means. AAMI ST79 provides a flow chart illustrating the use of microbicidal processes to help ensure devices are safe for personnel to handle and indicating the processing stages at which PPE is required.
Chemical Disinfection

Chemical disinfection can be performed by manually soaking a device in a basin of liquid chemical germicide solution or by means of an automated equipment such as washer-disinfectors.

After chemical disinfection, medical devices should be thoroughly rinsed of all chemicals and then dried before undergoing further processing.
Chemical Disinfection

Disinfectants intended for general purpose use, i.e. on environmental surfaces, are regulated by the EPA.

Chemical disinfectants intended for use as the terminal step in processing reusable critical and semi-critical medical devices are regulated by the FDA and require premarket clearance.
Glutaraldehyde has been widely used for a long time in health care facilities for manual high-level disinfection. Most solutions are acidic and must be activated to become sporicidal. There are a variety of brand names available in a variety of concentrations, with and without surfactants.
Ortho-phthalaldehyde (OPA) has demonstrated superior mycobactericidal activity compared to glutaraldehyde and requires no mixing or activation. OPA has been shown to last longer before reaching its MRC and the concentration of the active ingredient, does not decrease with age alone.
Chemical HLD

Other solutions FDA-cleared for HLD include hydrogen peroxide, peracetic acid and sodium hypochlorite in a variety of concentrations and combinations. The FDA website has a listing of manufacturers, active ingredients and contact conditions for each cleared solution.
Chemical HLD

HLD requires appropriate temperature, contact time, and length of use following solution activation. MFR’s IFU must be followed when preparing disinfectant solutions, calculating expirations dates and labeling all containers.

12 min manual contact time
14 day reuse

10 minutes manual contact time
28 day reuse
Sterilization Best Practices
(Prep & Pack)

It is important to carefully inspect and assemble surgical instruments prior to packaging. A dirty or non-functioning instrument is a patient safety issue and should never be used.
Sterilization Best Practices  
(Prep & Pack)

• Visually inspect each instrument for cleanliness and function. Use a lighted-magnifying lens for detailed inspection of small or complex instruments.

• Return any dirty instruments to the decontamination area for re-cleaning. Do not attempt to clean at the prep table or a sink.

• Remove excess moisture from instruments using filtered, medical grade, compressed air.

• Assemble instrument sets in an appropriate tray. Be sure to inspect wire mesh bottom trays for any sharp edges or loose mesh-wire that could cause damage when wrapped.
(Prep & Pack)

• Arrange instruments in manner that does not restrict air removal or sterilant penetration (e.g. assemble all hinged instruments in the open and unlocked position, disassemble multi-part instruments per the manufacturer’s IFU and remove any stylets or plugs from instruments with lumens).
(Prep & Pack)

• Arrange instruments in manner that does not restrict air removal or sterilant penetration (e.g. assemble all hinged instruments in the open and unlocked position, disassemble multi-part instruments per the manufacturer’s IFU and remove any stylets or plugs from instruments with lumens).

• Non-linting, absorbent material (e.g. towel) may be placed in the tray to facilitate drying. For adequate drying, it may be necessary to wrap dense instruments with absorbent material. Plastic organizing trays and cassettes are known to require longer drying times.

• Some lumen instruments require flushing with treated water just prior to packaging.

• Instruments should **not** be held together with tape or rubber bands.
Sterilization Best Practices
(Prep & Pack)

Packaging systems must be validated for the intended sterilization process and used according to the manufacturer’s IFU. Some instruments may require a specific packaging method.
(Prep & Pack)

• Paper-plastic pouches should only be used for small, light-weight instruments. Be sure to remove excess air before sealing pouch. Double pouching is not required, but may facilitate aseptic transfer to the sterile field. Paper-plastic pouches should not be used inside wrapped trays or rigid sterilization containers.

• Reusable wrappers should be laundered between uses and inspected prior to each use. Disposable wrappers should be inspected prior to each use and are for single-use only. Typically, two layers of wrap are required per the manufacturer’s validated IFU.

• Rigid container systems should be decontaminated and inspected between each use. Filters, valves and other components must be used according to the manufacturer’s validated IFU.

• Trays should not exceed 25 lbs. and labeled prior to loading.
Steam sterilization is considered the process of choice over all other sterilization processes. The instrument manufacturer’s validated IFU must be followed when selecting the method of steam sterilization and cycle parameters.
(Steam Sterilization)

• Steam sterilization is possible using one of three (3) methods – gravity displacement, pre-vacuum or steam-flush pressure pulse (SFPP). Pre-vacuum and SFPP sterilizers are referred to as “dynamic air removal” processes.

• Steam sterilizer parameters can be adjusted; however, standard cycles are recommended and should be used unless otherwise stated in the instrument manufacturer’s IFU.

• Gravity displacement steam sterilizers can sterilize routine instruments at 121°C/250°F with 30 minutes exposure time, plus drying time. At 132°C/270°F the exposure time is 15 minutes, plus drying time. Note: Some devices may require extended cycles.

• Dynamic air removal steam sterilizers can sterilize routine instruments at 132°C/270°F with 4 minutes exposure or 135°C/275°F with 3 minutes exposure, plus drying time. Note: Some devices may require extended cycles.
The SC-AcuFix® Ant-Cer® Dynamic Anterior Cervical Plate System is not designed or sold for any use except as indicated.

DO NOT USE THE IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

Contraindications include, but are not limited to:

1. Presence of overt infection and/or localized inflammation.
2. Previous anterior cervical discectomy, laminectomy, or diskectomy.
3. Expected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implantation would interfere with anatomical structures or expected physiological performance, such as impinging on vital structures.
6. Severe comminuted fractures such that segments may not be maintained in satisfactory approximate reduction.
7. Use in displaced, non-reduced fractures with bone loss.
8. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
9. Any other medical or surgical condition which would preclude the potential benefit of surgery, such as elevation or sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), fever, leukocytosis or a marked left shift in the WBC differential count.
10. The physical contact of the SC-AcuFix® Ant-Cer® Dynamic Anterior Cervical Plate System implants with metal implant made of anything other than implant grade titanium, such as stainless steel (ASTM F138) or MP35 N, or other dissimilar metal.

11. Situations with the absence or compromise of significant stabilizing elements.

12. Use in the presence of any neural or vascular deficits or other compromising pathology which may be further impaired by device intervention. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS section of this insert.

MATERIALS:

Implant components are manufactured of ASTM F136 implant quality titanium alloy. Specific set of metallurgical properties and corrosion resistance, and are based on the strength and fatigue characteristics. Thus to achieve the best results, do not use any of the SC-AcuFix® Ant-Cer® Dynamic Anterior Cervical Plate System components with components from any other system or company. As with other orthopedic implants, none of the SC-AcuFix® Ant-Cer® Dynamic Anterior Cervical Plate System components should be impacted or reinserted under any circumstance.

Ref to the SC-AcuFix® Ant-Cer® Dynamic Anterior Cervical Plate System Surgical Technique for instructions on implantation.

CLEANING:

1. Clean all implants and instruments prior to use, and as soon as possible after use. Do not allow blood and debris dry on the instruments. Wash implants in a covered container with appropriate detergent or enzymatic solution confirmed by patient history and radiographic studies.
2. Tumor.
5. Deformity (e.g., scoliosis, kyphosis, lordosis).
6. Pseudarthrosis.
7. Failed fusions.

CONTRAINDICATIONS:

All Ant-Cer® plates with restrictor plates attached must be cleaned manually using the small end of a nylon brush. Apply the brush around the sides and underneath the restrictor plate. DO NOT USE a stainless steel brush or anything else abrasive that will damage the finish.

After brushing, Ant-Cer® plates must be flushed with a directed flow of water to the restrictor plate. A water gun with a specialized nozzle is used for this. This nozzle must have a very small opening that can be used to force water under and around the restrictor plate.

INSPECTION:

1. Carefully inspect each implant and instrument to ensure all visible blood and soil has been removed.
2. Check action of moving parts to ensure proper operation, and ensure disassemble assemblies readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the implant, instrument or instrument case, do not use and contact your Abbott Spine representative or your Abbott Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Abbott Spine representative for a replacement.

STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been laboratory validated.

Method: Steam
Cycle: Pre-vacuum
Temperature: 270°F (132°C)
Exposure Time: 30 min
Routine monitoring per AAMI recommended practices for in-hospital sterilization should be followed. Instruments should be positioned to allow the sterilant to come in contact with all surfaces. All jointed instruments should be in the open or unconnected position with resects not engaged. Instruments components with more than one part or with splitting pieces or removable parts should be disassembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-stereilize all implants and instruments kits used in surgery with any unused implant kits that were with the surgical suite.

POSTOPERATIVE MONITORING:

Central patient handling postoperatively is very important while the fusion mass matures and begins to share load with the implant. Until postoperative monitoring monitoring (such as hemoglobin or other) is recommended to the patient to reduce stress on the implant and allow an equally important part of the patient's recovery. All patients should be followed by a surgeon who is not only skilled in the proper care of the Cervical plate system but also in the care of patients with spinal fusions. These warnings do not include all adverse effects, which may occur with surgery in general, but are important considerations particular to metallic devices.
Examples of MFR’s that have at least one device requiring an “extended cycle”

- Abbott Spine
- Acclarent
- Acumed
- Biomet
- Blackstone
- Boss
- Boston Scientific
- CR Bard
- CarboMedics
- Cochlear
- D.O.R.C.
- DePuy Mitek
- DePuy Orthopedics
- DePuy Spine
- Drager
- Elekta
- Eilman
- Elmed
- EMS
- Encision
- Encore
- Estech
- Ethicon
- FCI
- FH Orthopedics
- FlashPak
- Genesis Biologics
- Globus
Examples of MFR’s that have at least one device requiring an “extended cycle”

- Gore
- Greenwald
- Hand Innovations
- Heine
- Hitachi Medical Systems
- Hu-Friedy
- Hydrocision
- Innovasis
- Insight
- Integra
- Invuity
- Jardon
- K2M
- Kapp

- Lanx
- LDR Spine USA
- Medacta
- Medartis
- Mednext
- Metronic
- Microline
- Missonix
- Nuvasive
- On-X
- Ortho Development
- Orthofix
- Osteomed
- Pega Medical
Examples of MFR’s that have at least one device requiring an “extended cycle”

- Respironics
- Rhein Medical
- Richard Wolf
- Ruggles
- SeaSpine
- Small Bone Innovations
- Spinal Elements
- Spine Weave
- Stryker
- Suprasson
- Surgipro
- Synthes
- The Electrode Store
- Thompson Surgical
- TriMed
- Unisensor
- US Spine
- Vacumetrics
- Varian
- Thoramet
- Viasys
- Vilex
- Wallach
- Welch-Allyn
- Wells-Johnson
- Wexler
- Zimmer
(Steam Sterilization)

• Immediate-use steam sterilization (IUSS) can be accomplished for routine instruments using validated reduced cycle parameters. *Note: Some devices may require extended cycles and many device manufacturers do not recommend the use of IUSS.*

• Always load steam sterilizers with lighter items on top and heavier items below. Peel pouches, basins and instrument trays with solid bottoms should be placed on edge facing the same direction on the sterilizer shelf or cart. Rigid containers and wrapped instrument trays using perforated bottoms should be placed flat on the sterilizer shelf or cart. Never place items directly on or against the sterilizer chamber.

• After processing, all items should be allowed to cool to room temperature before handling.
Steam processed items should not be touched until they have cooled to 75°F/25°C or less as this is the maximum temperature allowed for sterile storage.

The use of a temperature laser sensor may be helpful to verify pack temperature.
Sterilization Best Practices
(Low Temperature)

For heat and moisture sensitive instruments, a variety of low temperature sterilization processes are available. The instrument manufacturer’s validated IFU must be followed when selecting the method and cycle parameters.
Sterilization Best Practices
(Quality Assurance)

Sterilization quality assurance is documented through the use of physical, chemical and biological indicators. Sterilization records should be maintained in compliance with local, state and federal regulations.
(Quality Assurance)

- Physical indicators (e.g. sterilizer print out) should be recorded and maintained for every cycle. The sterilizer operator should review and **initial the print out** after cycle completion before removing the load.

- For individual pack monitoring, an external and internal chemical indicator (CI) should be used. The external CI verifies the package was processed and the internal CI verifies sterilant penetration inside the package. For steam sterilization, a Class 5 CI should be used to monitor critical loads (e.g. implants and IUSS) cycles. **Note: More than one CI should be used with a rigid sterilization container and/or with wrapped multi-layered trays.**

- For steam sterilizer load monitoring, a biological indicator (BI) should be used daily and with all loads containing an implant. For low temperature processes, a BI should be used with every load.
(Quality Assurance)

- The BI is placed inside an appropriate PCD (process challenge device) and placed as recommended by the sterilizer manufacturer. When processing steam loads containing an implant, the PCD should contain both a BI and a Class 5 CI. Routine items in the load can be released immediately based on the Class 5 CI results; however, implants should wait for the BI results whenever possible.
Eliminate Recalls (Steam)

For steam sterilizers, users can now eliminate recalls of positive BI loads by using a PCD with a BI and a Class 5 integrator. While not a replacement for the BI, Class 5 integrators accurately predict BI grow out.
How do you monitor extended cycles?

It’s important to document the BI you are using is validated for use with extended cycles. Ask you BI supplier for their FDA clearance.
(Quality Assurance)

- Release of implants before the BI incubation time for spore growth should be documented with an **early release form**. Steam loads **not** containing implants can be monitored with a Class 5 or Class 6 chemical indicator PCD for immediate load release.
(Quality Assurance)

- **Each day** the sterilizer is BI tested, an *unprocessed* BI from the same lot should be incubated as a CONTROL in each incubator. BI spore growth verifies the incubator is working and the BI was viable when used.
Quality Control
(Vaporized Hydrogen Peroxide)

BI monitoring of VH$_2$O$_2$ low temperature type sterilizers should be:
• at least daily, preferably with every load.
Pre-vacuum steam sterilizers should be tested daily for proper air removal. This test is called a Bowie-Dick type test and is run by itself on the lowest shelf over the drain at 134°C for 3.5 or 4 minutes with dry time optional.

Unprocessed

Processed - PASS
Sterilization Best Practices
(Sterilizer Failure)

Sterilizers that fail any of the quality assurance tests should be reported immediately to a Supervisor and all test procedures reviewed. The load should be reprocessed and the sterilizer retested.

• If the sterilizer fails again, it is considered a malfunction and should be taken out of service. After servicing, retest with three (3) consecutive BI PCDs before using again. Steam pre-vacuum sterilizers should also pass three (3) consecutive Bowie-Dick type tests.
Sterilization Best Practices (Sterilizer Failure)

- **Positive BI test results** should be sent to Microbiology Laboratory for confirmation of actual spore growth and not a false positive reported by the person viewing the BI or a malfunctioning auto-reader. *Note: Confirmation of a positive BI requires incubation for visible spore growth (not enzyme early-readout).*

![Image of a person looking through a microscope with spore-forming bacteria in the background.](image)

*Geobacillus stearothermophilus*
Sterilization Best Practices
(Sterilizer Failure)

- **Operator error** is the leading cause of sterilizer failures, reported to be as high as 85%. Examples include: incorrect use and/or interpretation of BI, incorrect cycle for load contents, use of inappropriate packaging materials or packaging technique and incorrect loading of sterilizer. Proper in-servicing can eliminate sterilizer failures caused by operator error.

- Examples of **sterilizer malfunction**, include:
  - poor steam quality or quantity,
  - incomplete air removal,
  - inadequate cycle temperature,
  - insufficient time at required temperature.
Common errors in the reprocessing of Surgical instruments

Point of Use and Transport

- Failure to wipe off gross soil and/or flush lumens with sterile water,
- Delay in transporting soiled (and opened) items to the decontamination area,
- Failure to use a pre-soak solution on soiled items prior to transport,
- Transporting items without using a closed container and/or without a biohazard symbol.
Common errors in the sterilization of Surgical instruments

Reprocessing area (Decontamination)

- Not donning and/or doffing PPE properly
- Not having enough sinks to soak-wash-rinse
- Not having all the MFR’s written IFUs
- Not following all the MFR’s written IFUs
- Not using ultrasonic cleaner(s) properly
- Testing some, but not all mechanical cleaners
Common errors in the reprocessing of Surgical instruments

Reprocessing area (Prep & Pack)

- Not inspecting 100% of instruments,
- Not using inspection lamps and/or lens,
- Cleaning instruments and/or rigid containers,
- Assembling hinged instruments in the closed position,
- Using improper materials (i.e. marking pens, sterilization tape and/or wrap inside trays, sterilization tape on rigid containers, peel pouches and/or count sheets inside trays).
- Trays exceeding 25 lbs. weight limit.
Common errors in the reprocessing of Surgical instruments

Sterilization, Storage & QA

• Improper loading of sterilizers and/or PCD,
• Incorrect sterilization mode and/or parameters,
• Not enough dry time for type of load,
• Placing steam sterilized carts near an AC vent,
• Not storing sterile items in a separate, controlled area,
• Stacking wrapped trays which causes compression,
• Placing BI test pack improperly on the sterilizer cart,
• Not incubating BI properly.
Conclusion

You can expect TJC and other Accreditation agencies to inspect your facilities for compliance with these “best practices” for both routine and complex medical devices, as instrument reprocessing is a patient safety issue.

We hope this Seminar and the complimentary Pocket Guides referencing best practices, will assist you in achieving this important goal.
Is there room for improvement at your facility?

How should you proceed?

We recommend you update your Policies & Procedures referencing national Standards. Next, in-service all affected personnel regarding the updates and establish an implementation date.
References & Resources


