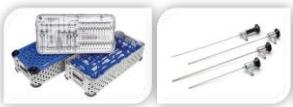


Reprocessing Complex Instruments

Are they STERILE or did they just get HOT?



Presented at
Excellentia Infection Prevention Conference
Las Vegas, NV · October 5, 2016

Speaker Disclaimer



Chuck Hughes
VP, Infection Prevention Consulting Services
SPSmedical Supply Corp. now part of Crosstex International
6789 W. Henrietta Road · Rush, NY 14543 USA
(800) 722-1529 · E-mail: chughes@spsmmedical.com

Certified as a Health Education teacher, Chuck has worked for over 25 years in the manufacturing industry in areas of Regulatory Affairs, R&D, Marketing, Microbiology and Sterilization Training. He is a corporate member AORN, AST, IAHCSMM, SGNA and numerous other organizations, including AAMI and CSA where he contributes to sterilization standards. A popular speaker at regional, national and international healthcare conferences, Chuck has visited thousands of healthcare facilities during his career providing sterilization consulting services that include fee based and complementary audits of instrument reprocessing areas.

Objectives

Upon completion, participants will be able to...

1. Discuss the recent CDC Health Advisory regarding reprocessing best practices,
2. Explain best practice steps for reprocessing surgical instruments and the critical role manufacturer's IFUs play,
3. Identify common errors with the reprocessing of complex surgical instruments.

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 Decontamination area
- inspect & assemble in Prep & Pack area
- package & sterilize in Sterilization area
- maintain sterility in Sterile Storage area

Quality Assurance

- document, document, document!!!

Sterilization Best Practices

(Point of Use)

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.

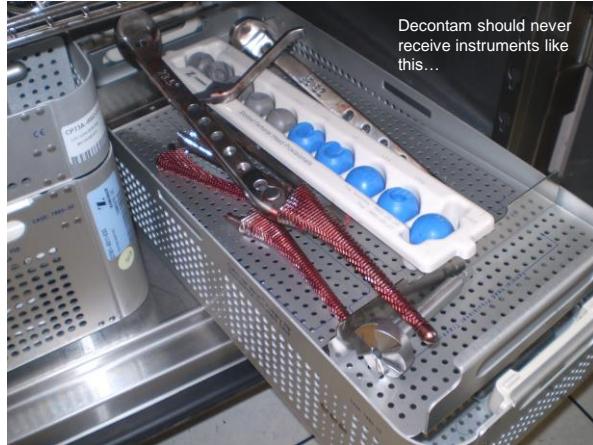


Sterilization Best Practices (Transport)

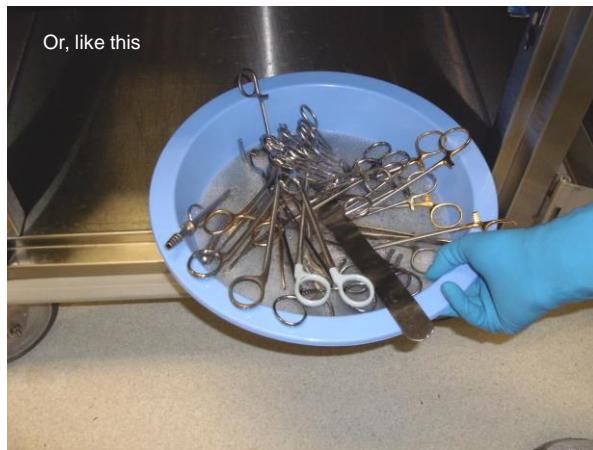
- Hand carried items may be contained using a plastic bag or container with a lid.
- Large quantities of instruments may be contained within a transport cart with doors or plastic cover. Items placed on top of a transport cart must be contained.
- Sharps must be carried in a puncture-resistant container 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...



Or, like this



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.



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.

Best Practices for Sterilization & HLD of Reusable Medical Devices

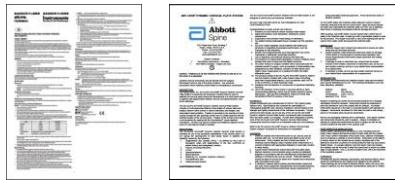






Sterilization Best Practices (Decontamination)

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.



(Decontamination)

- 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.



EXAMPLE - MFR's Cleaning IFU **SYMMETRY** Orthopedic Instruments



1. Submerge in enzymatic detergent.
2. Flush port with 50 ml enzymatic detergent.
3. Soak for 10 min in protein soluble 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.

EXAMPLE - MFR's Cleaning IFU **SYMMETRY** Orthopedic Instruments

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).

EXAMPLE MFR's Cleaning IFU

Zimmer Orthopedic Surgical Instruments



1. Completely submerge instruments in enzyme solution and allow to soak for 20 min.
2. Rinse in tap water for minimum of 3 min.
3. Ultrasonic clean for 10 min.
4. Rinse in purified water for at least 3 min.
5. Repeat **sonication** and rinse steps.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

EXAMPLE - MFR's Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

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.

EXAMPLE - MFR's Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic 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.

EXAMPLE - MFR's Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

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.

EXAMPLE - MFR's Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

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.

EXAMPLE - MFR's Cleaning IFU

BAUSCH + LOMB Storz Ophthalmic Instruments

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

13. Immers 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

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.

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?

What if you cannot comply?

If this is an issue, you must secure the proper resources, or you must contact the device manufacturer and ask them to revalidate to your standard reprocessing procedures.

Not complying with device MFR' IFU is a patient safety issue and could cause you to lose accreditation.



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

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)

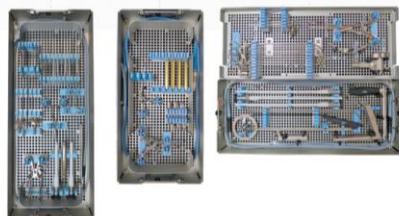
- Visually inspect each instrument for cleanliness and function. Use a lighted-magnifying lens for detailed inspection of small or complex instruments.
- Return any dirty instruments to the decontamination area for re-cleaning. Do not attempt to clean at the prep table or a sink.
- Remove excess moisture 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.



Anything wrong here?

(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.

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.

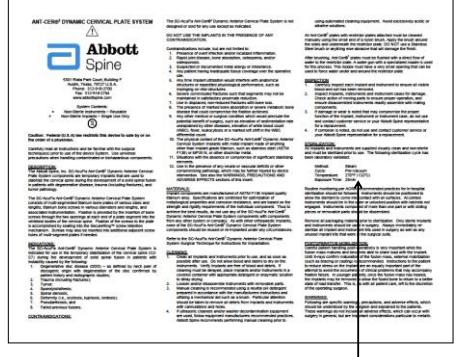
Sterilization Best Practices (Steam Sterilization)

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.*



25 min @ 270°F (132°C) Pre-vacuum

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
- Eliman
- 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
- Inuity
- 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
- Viays
- Vilex
- Wallach
- Welch-Allyn
- Wells-Johnson
- Wexler
- Zimmer

Dental Handpieces?

Device MFG.	Device Description	Process	Time/Temperature/Dry
ADEC W&H	Synea Lighted HS Handpieces	Steam Pre-vacuum	4 min @ 134°C/273°F
		Steam Gravity	6 min @ 121°C/250°F
W&H	TREND LS Straight Handpiece and Contra-angle Handpieces	Steam Pre-vacuum	3 min @ 134°C/274°F
		Steam Gravity	4 min @ 134°C/274°F
Anthogyr	NI Ti Control Endo Handpiece	Steam	18 min @ 135°C
Kavo Dental	MULTIflex HS Handpieces	Steam or C-Vapor	up to max 135°C/275°F
Piezosurgery Inc.	Dental Handpiece	Autoclave	4 min @ 134°C/273°F
*In accordance with ANSI/AAMI ST24:1998			16 min @ 121°C/250°F
Sabra	Dental Handpieces	Autoclave	15 min @ 132°C 20 min @ 121°C

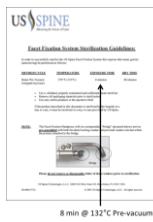
None of these common dental handpieces are validated to a Standard steam cycle

Steam Dynamic Air Removal*	4 min @ 132°C/270°F
*Pre-vacuum or SFPP	3 min @ 135°C/275°F
Steam Gravity Displacement	10 min @ 132°C/270°F
	30 min @ 121°C/250°F

What if you cannot comply?

Again, if this is an issue, you must secure the proper resources, or you must contact the device manufacturer and ask them to revalidate to your standard sterilization cycle.

Not complying with device MFR's IFU is a patient safety issue and could cause you to lose your accreditation.



(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.



Room Temperature?

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.



Storage & Delivery

Open shelving may be used, but should be:

- 2" from outside walls
- 8 to 10" from floor
- 18" from ceiling fixture
- not crunched, bent

not crushed, bent, compressed, punctured or near any location that could become wet. Wrapped trays should not be stacked as this causes compression; whereas, rigid containers are designed to be stacked.

Common errors in the reprocessing of Surgical instruments

Sterilization & Storage

- 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 allowing steam sterilized items time to cool to room temperature (24°C/75°F),
- Not storing sterile items in a separate, controlled area,
- Stacking wrapped trays which causes compression.

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.

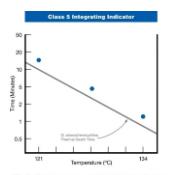
(Quality Assurance)

- 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.



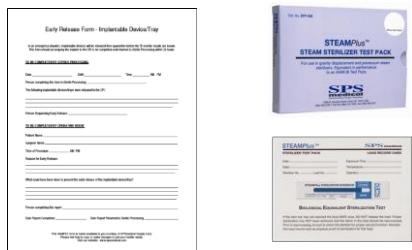
How do you monitor extended cycles?

It's important to document the BI you are using is validated for use with extended cycles. Ask your 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.



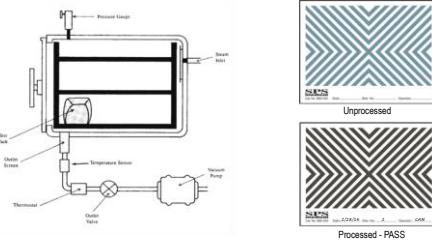
(Quality Assurance)

- **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 Assurance)

- 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.



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)

- **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.

Conclusion

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

We hope this presentation and our complimentary [Pocket Guides](#) referencing best practices, will assist you in achieving your infection prevention goals!



To request a complimentary set of our *Sterilization Best Practices* pocket guides and wall posters, call 1-800-722-1529 or e-mail info@SPSmedical.com

Thank You!



Chuck Hughes

VP, Infection Prevention Consulting Services
SPSmedical Supply Corp. now part of Crosstex International
6789 W. Henrietta Road · Rush, NY 14543 USA
(800) 722-1529 · E-mail: chughes@SPSmedical.com

Certified as a Health Education teacher, Chuck has worked for over 25 years in the manufacturing industry in areas of Regulatory Affairs, R&D, Marketing, Microbiology and Sterilization Training. He is a corporate member AORN, AST, CAMDR, OSAP, IAHCSMM, SGNA and numerous other organizations, including AAMI and CSA where he contributes to sterilization standards. A popular speaker at regional, national and international healthcare conferences, Chuck has visited thousands of healthcare facilities during his career providing sterilization consulting services that include fee based and complementary audits of medical device reprocessing areas.

References & Resources

Association for the Advancement of Medical Instrumentation. (2013). *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79). Arlington, VA.

Association for the Advancement of Medical Instrumentation. (2015). Comprehensive guide to flexible and semi-rigid endoscope reprocessing in health care facilities (ANSI/AAMI ST79). Arlington, VA.

Association of periOperative Registered Nurses. (2015 Edition). Recommended Practices for High-Level Disinfection.

Society of Gastroenterology Nurses and Association, Inc. (2015) Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes. SGNA

Society of Gastroenterology Nurses and Association, Inc. (2015) Standards of Infection Control in Gastroenterology Setting. SGNA

Occupational Health and Safety Administration (OSHA). (2006). *Best Practices for the Safe Use of* Rutala, W. A., Weber, D. J., & the Healthcare Infection Control Practices Advisory Committee (HICPAC). (2008). *Guideline for Disinfection and Sterilization in Healthcare Facilities*.