OR TO CSD BEST PRACTICES

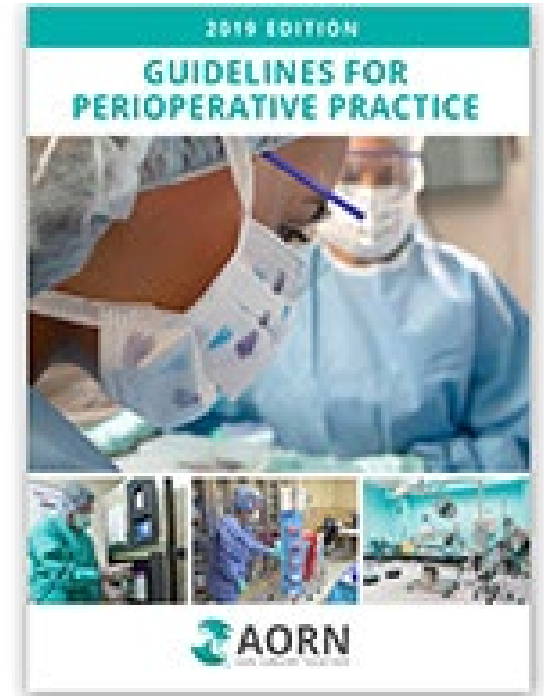
for Sterilization in Health Care Facilities

Objectives

- Review reprocessing best practice work-flow related to: point of use cleaning, receipt, decontamination, assembly, sterilization, storage and distribution
- Discuss how utilizing best practice can impact infection control
- Identify key best practice ideas utilizing the most current national standards and recommended practices
- Describe how to implement best practice in your department

BEST PRACTICES

In the U.S., instrument reprocessing best practices are detailed in **AAMI** Standards and **AORN** Guideline for Perioperative Practice.



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

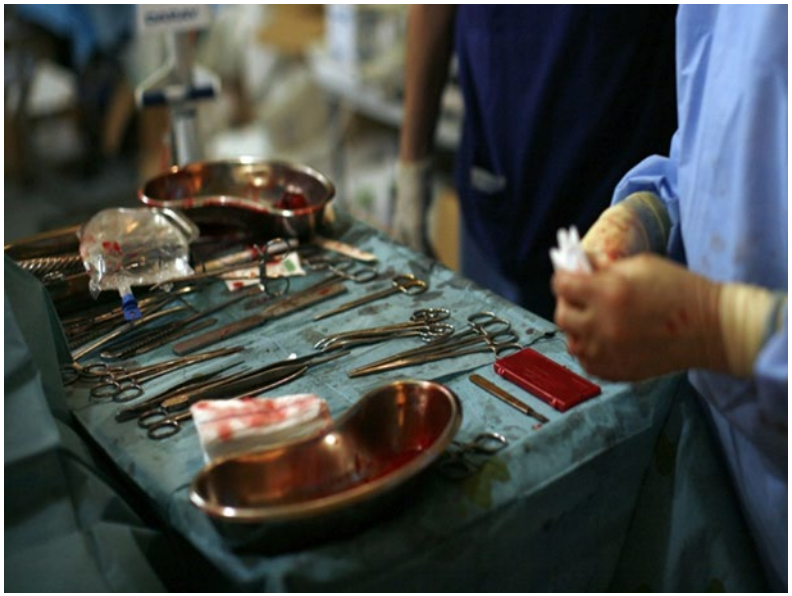
- pre-clean and spray surgical instruments to prevent soil from drying prior to transport

Reprocessing Area

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

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.




Gross soil should be removed
from all instruments at POU

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 of segregate into separate containers. Microsurgical instruments should always be segregated into separate containers.

- If any delay in decontamination is expected, instruments should be moistened with an enzymatic pre-soak solution to keep blood and any 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.

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)

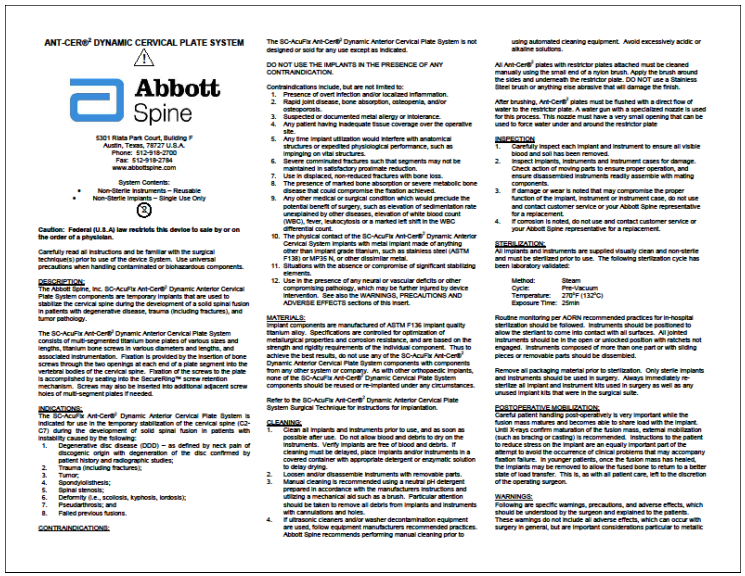
- An appropriate emergency eyewash station should be available.
- Three section sinks to soak, wash, and rinse should be approximately 36” from the floor, 8-10” deep and wide enough to accommodate instrument trays. Never clean instruments in a scrub or hand wash sink.
- Personnel must wear appropriate PPE. All head and facial hair should be completely covered. Jewelry, wristwatches and nail polish should not be worn. **Personal electronic devices should not be brought into the processing area…**
- 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.

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.

BAUSCH+LOMB
Storz
Ophthalmics

BAUSCH+LOMB
Instruments



ANT-CER® DYNAMIC CERVICAL PLATE SYSTEM

Abbott
Spine

5301 Riata Park Court, Building F
Austin, Texas, 78727 U.S.A.
Phone: 512-918-2700
Fax: 512-918-2794
www.abbottspine.com

System Contents:
- Non-Sterile Instruments – Reusable
- Non-Sterile Implants – Single Use Only

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to use of the device System. Use universal precautions when handling contaminated or biohazardous components.

DESCRIPTION:
The Abbott Spine, Inc. SC-AcuFix Ant-Cer® Dynamic Anterior Cervical Plate System components are temporary implants that are used to stabilize the cervical spine during the development of a solid spinal fusion in patients with degenerative disease, trauma (including fractures), and tumor pathology.

The SC-AcuFix Ant-Cer® Dynamic Anterior Cervical Plate System consists of multi-segmented titanium bone plates of various sizes and lengths, titanium bone screws in various diameters and lengths, and associated instrumentation. Fixation is provided by the insertion of bone screws through the two openings at each end of a plate segment into the vertebral bodies of the cervical spine. Fixation of the screws to the plate is accomplished by seating into the SecureRing™ screw retention mechanism. Screws may also be inserted into additional adjacent screw holes of multi-segment plates if needed.

INDICATIONS:
The SC-AcuFix Ant-Cer® Dynamic Anterior Cervical Plate System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:
1. Degenerative disc disease (DDD) – as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
2. Trauma (including fractures);
3. Tumor;
4. Spondylolisthesis;
5. Spinal stenosis;
6. Deformity (i.e., scoliosis, kyphosis, lordosis);
7. Pseudarthrosis; and
8. Failed previous fusions.

CONTRAINDICATIONS:
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. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
3. Suspected or documented metal allergy or intolerance.
4. Any patient having inadequate tissue coverage over the operative site.
5. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
6. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate 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 of 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 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 injured by device intervention. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

MATERIALS:
Implant components are manufactured of ASTM F136 implant quality titanium alloy. Specifications are controlled for optimization of metallurgical properties and corrosion resistance, and are based on the strength and rigidity requirements of the individual component. 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 orthopaedic implants, none of the SC-AcuFix Ant-Cer® Dynamic Cervical Plate System components should be reused or re-implanted under any circumstances.

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

CLEANING:
1. Clean all implants and instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. Verify implants are free of blood and debris. If cleaning must be delayed, place implants and/or instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.
3. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturers instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from implants and instruments with cannulations and holes.
4. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. Abbott Spine recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.

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 direct flow of water to the restrictor plate. A water gun with a specialized nozzle is used for this process. 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. Inspect implants, instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments 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 customer service 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:	20min

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed. Instruments should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disembled.

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

POSTOPERATIVE MODERATION:
Careful patient handling post-operatively is very important while the fusion mass matures and becomes able to share load with the implant. Until X-rays confirm maturation of the fusion mass, external mobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implant are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with al patient care, left to the discretion of the operating surgeon.

WARNINGS:
Following are specific warnings, precautions, and adverse effects, which should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects, which can occur with surgery in general, but are important considerations particular to metallic

(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.

- 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?
ECOLAB
Asepti-Zyme
ZIMMER CANNULATED SCREW SYSTEM
CREST
SKYTRON

Chemical/Mechanical 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.

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's IFUs is a patient safety issue and could cause you to lose accreditation.

IFU = 20 min ultrasonic

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.


Anything wrong here?

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, instrument 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).

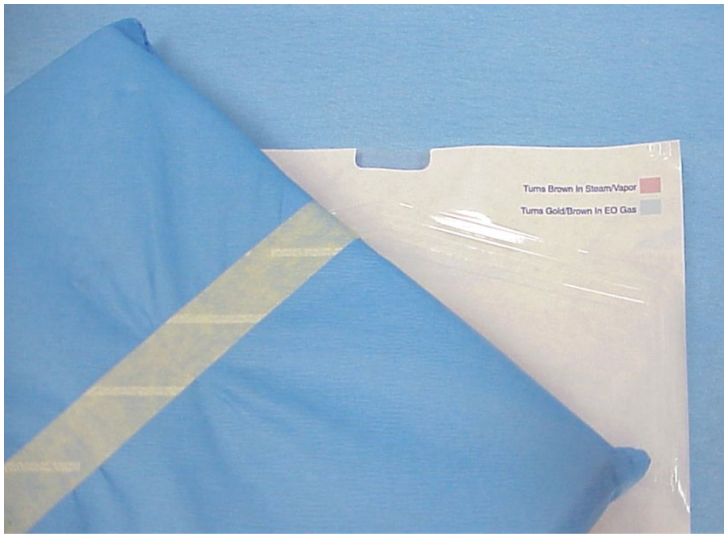
- Non-linting, absorbent material (e.g. towel) may be placed in the tray to facilitate drying. For adequate drying, it may be necessary to wrap dense instruments with absorbent material. Plastic organizing trays and cassettes are known to require longer drying times.

- 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, values and other components must be used according to the manufacturer's validated IFU.

- Trays should not exceed 25 lbs. and labeled prior to loading.

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.

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

INSPECTION

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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:	25min

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed. Instruments should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

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POSTOPERATIVE MOBILIZATION:
Careful patient handling post-operatively is very important while the fusion mass matures and becomes able to share load with the implant. Until X-rays confirm maturation of the fusion mass, external mobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implant are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure. In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon.

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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
- 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

Why Maintain Best Practice?

- 44,000 to 98,000 people die each year from preventable medical errors
- Focus on patient safety and infection prevention is of utmost importance
- Surgical site infections remain problematic

Surgical Site Infections

- Most common and most expensive hospital acquired infection:
  - 2-5% of ALL surgical patients will sustain an SSI
  - Cost is $3.5- $10 billion annually
- Defined by CDC as “an infection that occurs after surgery in the part of the body where the surgery took place.”

Where to get MFR's IFUs?

Some manufacturers post them on their website although many health care facilities rely on Sales Representatives to provide IFUs. Another way is to contact the device manufacturer's Corporate office and ask for Quality Control or Regulatory Affairs.

Quality Control and/or Regulatory Affairs personnel are the ones most familiar with IFUs and should be eager to provide them to you.

Where to get MFR's IFUs?

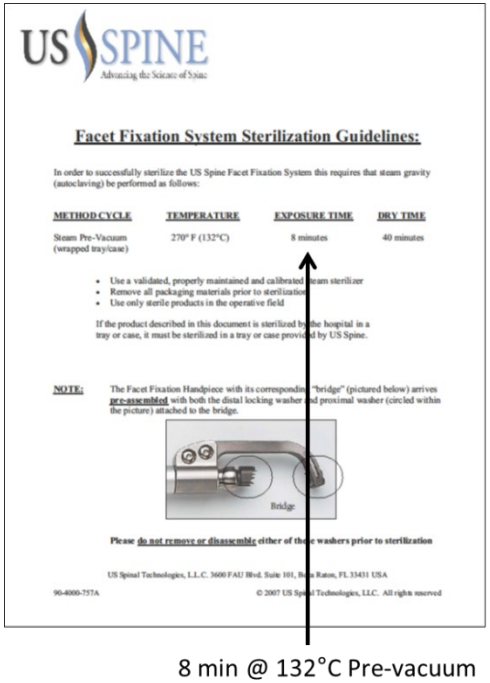
Another option is to hire a Company to do the search for you and to keep the MFR's IFU updated. For an annual fee, they provide you with an internet based library with electronic copies that can be printed out.

oneSourcedocs.com

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 IFUs is a patient safety issue and could cause you to lose your accreditation.


US SPINE
Advancing the Science of Spine

Facet Fixation System Sterilization Guidelines:

In order to successfully sterilize the US Spine Facet Fixation System this requires that steam gravity (autoclaving) be performed as follows:

METHOD CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam Pre-Vacuum (wrapped tray/case)	270° F (132°C)	8 minutes	40 minutes

- Use a validated, properly maintained and calibrated steam sterilizer
- Remove all packaging materials prior to sterilization
- Use only sterile products in the operative field

If the product described in this document is sterilized by the hospital in a tray or case, it must be sterilized in a tray or case provided by US Spine.

NOTE: The Facet Fixation Handpiece with its corresponding "bridge" (pictured below) arrives pre-assembled with both the distal locking washer and proximal washer (circled within the picture) attached to the bridge.

Please do not remove or disassemble either of these washers prior to sterilization

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90-4000-757A

8 min @ 132°C Pre-vacuum

(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 steam processing, items should be allowed to cool to room temperature (75°F) before handling.

When Are Packs Safe to Touch?

Steam processed items should not be touched until they have cooled to 24°C/75°F 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, 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

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 & Quality Assurance

- 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 using a BI and Class 5 CI PCD for implant loads,
- Not placing the PCD correctly in the sterilizer.

Is there room for improvement at your facility?

How should you proceed?

I recommend you assess each of your reprocessing areas and update your Policies & Procedure. Next, in-service all affected personnel regarding the updates and establish implementation dates.

QUESTIONS?

- Point of Use
- Transport
- Decontamination
- Inspection & Assembly
- Steam Sterilization
- Sterile Storage

Conclusion

Medical device reprocessing requires a lot of resources and the future of healthcare is more and more complex devices. HCFs must provide their reprocessing personnel with the enough space, instruments, environmental controls, water quality, supplies, training and **TIME** to comply with each MFR's written IFU.

THANK YOU!

Bob Marrs | VP Organizational Development

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References & Resources

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