Reprocessing Complex Instruments

CAMDR | Canadian Association of Medical Device Reprocessing

Objectives

Upon completion, participants will be able to...

1. Explain why compliance with best practices is important in healthcare,
2. Identify best practice procedures and common errors associated with reprocessing surgical instruments,
3. Discuss best practice procedures and common errors associated with reprocessing flexible endoscopes.

Best Practices

In North America, medical device reprocessing "best practices" are detailed in many documents that are readily available to healthcare facilities.

BEST PRACTICES

Compliance is very important!

Best practices should be adhered to in any profession, because they reflect the values of that profession. In healthcare, adherence to sterilization and HLD best practices ensures patient safety, as one of our greatest threats is healthcare associated infections (HAIs).

More than 200,000 patients get infections every year while receiving healthcare in Canada, and more than 8,000 of these patients die as a result.

Source: www.publichealth.gc.ca

Healthcare Associated Infections

While non-sterile medical devices is certainly not the leading cause of HAIs, it has been documented as one of the causes.

Therefore, as MDRs, you must do everything possible to reduce HAIs, which means compliance with best practices not some of the time, not most of the time, but <u>all</u> of the time!

Reprocessing Complex Instruments

Compliance with best practices requires HCFs to have the proper space, environmental controls, equipment, water quality, supplies, quantity of instruments, personnel and time to follow each manufacturer's validated IFU.



STERILIZATION
Best Practice Procedures

Point of Use
- pre-clean to prevent soil from drying during 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
- documentation & record keeping.

CSA Standards

POINT OF USE
Immediately after use, the user shall clean medical devices of gross soil if present. The devices should be kept moist in a transport container by adding a towel moistened with water (not saline) or a foam, spray, or gel product specifically intended for this use.

Disposable sharps such as needles and blades shall be removed and disposed of by the user. Delicate devices shall be segregated to prevent damage.

Common errors in the reprocessing of surgical instruments

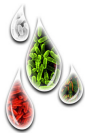
Point of Use (Surgery)
- Failure to wipe off gross soil from instruments and flush lumens with sterile water
- Delay in transporting soiled instruments to the decontamination area
- Failure to spray instruments with pre-clean solution
- Transporting without using a covered, fully enclosed container

Common errors in the sterilization of surgical instruments

Reprocessing area (Decontamination)
- Not wearing proper PPE
- Not having enough sinks to soak-wash-rinse
- Not having sinks of sufficient size for instruments
- No having or not using an ultrasonic cleaner
- Testing some, but not all mechanical cleaners
- Not having MFG's IFUs
- Not following MFG's IFUs

Instructions For Use (IFU)

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



For complex instruments, specific times may be stated for soaking, ultrasonic cleaning and rinsing.

EXAMPLE - MFG'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 - MFG'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).


40 minutes?

EXAMPLE MFG's Cleaning IFU
Zimmer Orthopedic Surgical Instruments

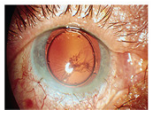
1. Completely submerge instruments in enzyme solution and allow to soak for 20 min.
2. Rinse in tap water for minimum of 3 min.
3. **Ultrasonic** clean for 10 min.
1. Rinse in purified water for at least 3 min.
2. Repeat **sonication** and rinse steps.
3. Remove excess moisture from the instrument with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

50 minutes? 

Ophthalmic Instruments?

Improper cleaning of eye instruments can cause toxic anterior segment syndrome (TASS). TASS is an acute inflammation of the anterior chamber, or segment, of the eye that usually starts within 24 hrs. of cataract surgery.

Patients with TASS complain of blurred vision, mild ocular pain and eye redness. Left untreated, TASS can result in permanent iris damage.



EXAMPLE - MFG'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 - MFG'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 - MFG'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 - MFG'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 - MFG'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 - MFG'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 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.

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).
- Improper location of lot control labels.

Common errors in the reprocessing of surgical instruments

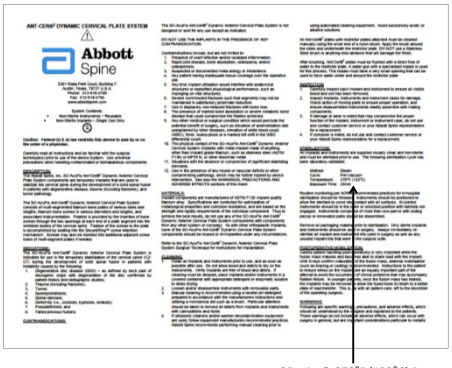
Sterilization

- Improper loading of sterilizers and/or PCD,
- Incorrect sterilization mode and/or parameters,
- Not enough dry time for type of load,
- Wet packs,
- Not allowing sterilized packs to cool to room temperature,
- Placing sterilized items to cool near AC vent.

STEAM Sterilization

If your facility reprocesses complex devices, then you are probably dealing with "extended cycles". As with cleaning, it is important to know which and how many of your devices require extended exposure time and/or temperature settings.





25 min @ 270°F (132°C) Pre-vacuum

Examples of MFG'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 MFG'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 MFG'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

Common errors in the reprocessing of surgical instruments

Storage

- Placing sterile items in a high traffic area,
- Improper ceiling tiles and/or storage shelves,
- Dust on storage shelves,
- Stacking wrapped items on top of each other,
- Putting clean items on top of sterile items,
- Exceeding temperature and/or humidity ranges.

KimGuard® and One-Step® Wraps

(Directions For Use)

Caution: Do not stack trays. Stacking trays can result in damage of the wrap caused by undue pressure from the weight.

Poor storage

® Trademarks of Kimberly-Clark Corp.

Flexible Endoscopes?

Flexible endoscopes are some of the most challenging devices for HCWs to reprocess due to their unique design and complex reprocessing steps.

According to the CDC, "*more healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical device*".

www.cdc.gov

High Level Disinfection Best Practices

Point of Use
- pre-clean to prevent soil from drying.

Reprocessing Area
- perform leak test,
- manual cleaning & rinsing,
- high level disinfection (manual or automated),
- rinsing, drying and storage.

Quality Assurance
- documentation & record keeping.

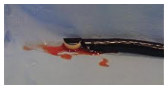
Best Practices

(Similar steps and similar "challenges")

Sterilization	High-Level Disinfection
Point of Use • pre-clean to prevent soil from drying.	**Point of Use** • pre-clean to prevent soil from drying.
Reprocessing Area • clean & disinfect in Decontam, • inspect & assemble in Prep & Pack, • package & sterilize in Sterilization area, • maintain sterility in Sterile Storage.	**Reprocessing Area** • perform leak test, • manual cleaning & rinsing, • high level disinfection (manual or automated), • rinsing, drying and storage.
Quality Assurance • documentation & record keeping.	**Quality Assurance** • documentation & record keeping.

Common errors in the reprocessing of Flexible Endoscopes

Point of Use (Procedure Room)



- Not wearing proper PPE
- Not having MFG's IFUs
- Reprocessing delay (multiple procedures and/or with procedures performed at night or on the weekend)
- Failure to clean all channels (even if unused, fluid and debris can enter channels at the distal tip)
- Transporting without using a closed container and/or not labeled with biohazard id

Common errors in the reprocessing of Flexible Endoscopes

Leak Testing

- Not having the MFG's IFU available
- Use of damaged water resistant cap
- Overlooking pressurization of scope prior to immersion
- Incomplete angulation of the distal tip in all directions during leak test
- Not following the MFG's IFUs for reprocessing a damaged scope

Common errors in the reprocessing of Flexible Endoscopes

Manual Cleaning
- Failure to fully submerge endoscope
- Failure to submerge for the required length of time
- Neglecting to dilute the detergent per the MFG's IFU
- Using worn, damaged or improper brushes
- Failure to use MFG's validated cleaning adapters
- Damaged/improperly reprocessed cleaning adapters
- Failure to thoroughly rinse

Common errors in the reprocessing of Flexible Endoscopes

Manual HLD

- Using a sink or basin of insufficient dimensions
- Using a solution after it's expiration date
- Not MRC testing solution prior to each use

AER

- Failure to manually clean and/or rinse before using the Automated Endoscope Reprocessor (AER)

Common errors in the reprocessing of Flexible Endoscopes

Storage

- Oversight in removing all valves and water resistant cap when storing the endoscope
- Neglecting to ensure that scopes are hung with all locks in the free position
- Crowded and unsecured scope storage areas

Reprocessing Complex Instruments

Do you have enough resources?
Health care facilities must provide reprocessing personnel with proper space, environmental controls, instruments, equipment, water quality, supplies, training and **TIME** to comply with instrument manufacturers' validated IFUs.

Conclusion

It is important to know that accreditation agencies are now looking very closely at instrument reprocessing best practices for **sterilization** and **HLD** when they survey your facility; however, never forget that your patients are looking for strict compliance with best practices at all times.

I hope today's program will assist you in achieving this important goal!

Thank You!

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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.

References & Resources

Association for the Advancement of Medical Instrumentation (AAMI)
1110 North Glebe Road, Suite 220 · Arlington, VA 22201-4795
www.aami.org

Association of periOperative Registered Nurses (AORN)
2170 South Parker Road, Suite 300 · Denver, CO 80231-5711
www.aorn.org

Canadian Standards Association (CSA)
178 Rexdale Blvd. Toronto, OH Canada M9W 1R3 www.csagroup.org

Operating Room Nurses Association of Canada (ORNAC)
66 Leopolds Dr. Ottawa, OH Canada K1V 7E3 www.ornac.ca

Provincial Infectious Diseases Advisory Committee. (PIDAC)
480 University Ave. Suite 300 Toronto, ON Canada M5G 1V2
www.publichealthontario.ca

Society of Gastroenterology Nurses and Associates, Inc. (SGNA)
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