Reprocessing Ophthalmic Instruments



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Speaker Disclaimer

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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.

Objectives

Upon completion, participants will be able to...

1. Discuss the importance of complying with best practices and where to find them for reprocessing ophthalmic instruments,
2. Explain reprocessing steps and the importance of having the instrument manufacturer's instructions for use (IFU),
3. Identify ways to reduce immediate-use steam sterilization (IUSS) for increased compliance with best practices.

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 instrument reprocessing best practices ensures patient safety, as one of our greatest threats is healthcare associated infections (HAIs).

In the U.S., it is estimated that 5,000 patients acquire HAIs and nearly 300 patients die – each day!

Healthcare Associated Infections

While improperly reprocessed instruments is certainly not the leading cause of HAIs, it has been documented by the CDC as one of the causes.

We 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!

Best Practices

Surgical instrument reprocessing "best practices" are detailed in **AAMI** Standards, **AORN** Guidelines for Perioperative Practice, along with other documents, such as **ASORN** publications which focus specifically on ophthalmic instruments.

Instrument Reprocessing
Best Practices

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.

ASORN
Caring and Handling
of Ophthalmic Microsurgical Instruments

Properly cared for ophthalmic instruments will prevent infections and inflammations, and thus promote safe patient care.

Instrument life will also be increased and reduce costs for repairs and replacement. In addition, properly cared for instruments will function properly and safely.

Bottom line, proper care and handling of instruments will affect your patient outcomes.

ASORN
Caring and Handling
of Ophthalmic Microsurgical Instruments

Improper care of ophthalmic 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.

Cleaning delicate Ophthalmic Instruments

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 some MFRs, specific times may be recommended for soaking, ultrasonic cleaning and rinsing.

EXAMPLE - 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 - 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 - 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 - 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 - 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 - 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.

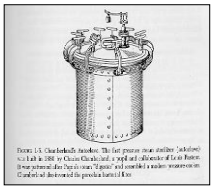
Sterilizing delicate Ophthalmic Instruments

There's a variety of FDA cleared sterilization methods (Steam, Chemical vapor, Dry heat, EO gas, Gas plasma, Ozone and Peracetic acid); however, it is the instrument manufacturer who decides which process and at what parameters the instruments must be sterilized based on their validated IFU.

Most instrument MFRs have validated Steam!

Saturated steam under pressure is one of the oldest methods used to sterilize surgical instruments.

The CDC recommends steam sterilization as the *process of choice*, because it is efficient, fast, and inexpensive.



Chamberland autoclave built in 1880

Steam Sterilization

There are two (2) types of steam sterilizers approved to run these standard cycles:

- **Gravity displacement** (250°F/121°C for 30 mins exposure, plus drying **or** 270°F/132°C for 15 mins exposure, plus drying)
- **Dynamic air removal*** (270°F/132°C for 4 mins exposure, plus drying **or** 275°F/135°C for 3 mins exposure, plus drying).

* Pre-vacuum is the most common DAR method. Steam-flush-pressure-pulse is another method.

Steam Sterilization

To assist sterilization and aid drying, place pouches facing each other and on edge using a pouch divider.

Place wrapped trays/cassettes on the bottom shelf, pouches on the top shelf.

Steam Sterilization

Loading heavier items on the bottom shelf and lighter items on the top, enables condensate to drain out without wetting other items in the load.

To maintain sterility, packages should be visibly dry before transporting to a sterile storage area

Steam Sterilization
(Rigid Sterilization Container Systems)

Some can be used in…

- Steam gravity
- Steam pre-vacuum
- IUSS, aka *FLASH*
- EO Gas
- Hydrogen Peroxide
- Ozone

Check with your rigid sterilization container manufacturer to confirm the sterilization process(s) and cycle parameters.

FLASHING
Ophthalmic Instruments

Flashing, which has been renamed immediate-use steam sterilization (**IUSS**), is when the sterilizer or instrument manufacturer's validated exposure or dry times are shortened. Because the instruments come out of the sterilizer hot and wet, they must be used immediately.

IUSS is not recommended for routine use and as stated, instruments must be used immediately, rather being stored for future use.

Tips on how to reduce Immediate-Use Steam Sterilization (IUSS)

1. Update Policy & Procedures to reflect national standards.
2. Clearly define "emergency situation" that justify IUSS.
3. Educate all personnel as to risks associated with IUSS.
4. Review sterilizer logs to identify what is being IUSS. Review each MFR's IFU to understand validated reprocessing steps. Use this info to justify need for terminal sterilization.
5. Purchase additional instruments for back - back case schedules.
6. Adjust steam sterilizers to terminal cycles with full dry time.
7. Hold all personnel AND loaner instrument vendors accountable to comply with Policy & Procedures.

Sterilizer Monitoring

Assuring that instruments are being properly sterilized, is a critical aspect of all healthcare facilities.

A quality control program should be established to verify sterilization of instruments in accordance with the MFR's IFUs, sterilizer maintenance and personnel competency.

Sterilizer Monitoring

Steam sterilizers
should be monitored with physical, chemical and biological indicators.

Physical Indicators – *chart/print out of each cycle,*
Chemical Indicators – *outside/inside of each package,*
Biological Indicators – *at least week, preferable daily and every load that contains an implant.*



Sterilizer Monitoring

Biological Indicators are more than just a pretty vial and should be selected based on three (3) criteria:

1) Accuracy for sterilization cycle being tested,

2) Reduced incubation time (RIT), and

3) Cost (BI, incubator and supplies).

Do not confuse the order of these criteria as faster or less expensive BIs that provide inaccurate test results, are not only invalid, but also a danger to patient safety!

Sterilizer Records

Make sure all of your sterilizer records are kept together and are…

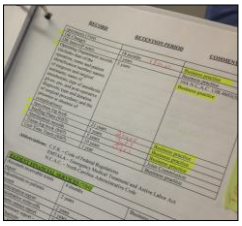
COMPLETE,
ACCURATE,
PRESENTABLE!

Keeping them together is the easiest way for a Surveyor to observe you are in compliance!

How long should you keep your sterilizer records?

Standards do not say, as this varies from State to State in the U.S.

Your Risk Manager should be able to tell you how long and you should keep your records for that length of time.



CONCLUSION

While the delivery of non-sterile instruments may not be a leading cause of surgical site infections, it has been documented by the CDC as one of the problems. 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 all of the time.

I hope the information I have shared today, helps you in this important goal!

Questions?

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References & Resources

Accreditation Association for Ambulatory Healthcare (AAAHC)
5250 Old Orchard Road, Suite 200 · Skokie, IL 60077
www.aaahc.org

American Society of Ophthalmic Registered Nurses (ASORN)
655 Beach Street · San Francisco, CA
www.asorn.org

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

Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard · Baltimore, MD 21244
www.cms.gov

The Joint Commission (TJC)
One Renaissance Boulevard · Oakbrook Terrace, IL 60181
www.jointcommission.org