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LEARNING OBJECTIVES

1. *Explain the potential consequences of improper ophthalmic instrument reprocessing*
2. *List three IFU changes that may impact ophthalmic instrument reprocessing*
3. *Identify common pitfalls when reprocessing ophthalmic instruments*

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SELF-STUDY SERIES

Eye spy: Changes in ophthalmic reprocessing

by Delores O'Connell

When sterile processing managers request information about best practices, evidence-based procedures, or the location of specific reprocessing information within standards, I always ask them, "Do you perform eye cases?" The most frequent answer: "We don't do cataract cases, so eye instrumentation isn't a concern for us." While cataract surgery is the bulk of eye surgeries performed in the U.S., it is not the only surgery performed on those beautiful windows to the soul, so I revise my question; "Do you perform eye trauma, glaucoma, macular degeneration or pediatric corrective surgeries?" The answer is typically a resounding "yes!" and a look of surprise.

Managers now realize that they must identify the instruments used in their facility for both routine and uncommon eye surgeries they perform. Why? Because ophthalmic instrumentation may require special handling, may have new recommendations, or may require sterile processing managers to rethink their ophthalmic instrument reprocessing protocols.

Why all the concern for eye instruments?

While the ANSI/AAMI ST79:2017 "*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*" is the universal guidance for all surgical instrument reprocessing, eye instruments require additional special considerations. Improperly processed eye instruments have led to a condition called Toxic Anterior Segment Syndrome (TASS), a preventable acute inflammation of the eye that if not caught quickly may result in diminished eyesight or blindness in the affected eye.

While often attributed to cataract surgeries, TASS can occur from any ocular surgery where the anterior segment is exposed. TASS is not an infection but a reaction to foreign material carried into the eye. Incomplete cleaning processes that leave residual cleaning chemistries, mineral deposits from steam sterilizers, and/or powder from sterile gloves have contributed to cases of TASS. Though ophthalmic instruments have the same materials of construction and require similar reprocessing steps (point-of-use treatment, cleaning, rinsing and sterilization), vigilance against the causative elements of TASS requires enhanced methods that are key for any ocular program.

Furthermore, TASS is not the only concern. Surgical site infections can cause complications that can also lead to impaired vision or blindness. Considering these serious risks, it's easy to understand the critical importance of thoroughly cleaning, rinsing and sterilizing ophthalmic instruments.

The specifics of ophthalmic instrument reprocessing

Technicians need an eye for detail when reviewing their ophthalmic instrument reprocessing procedures. Every step, whether it's during point-of-use pretreatment, cleaning, rinsing, or sterilization, requires exact implementation of the instrument manufacturer's instructions for use (IFU). It's also important to be aware of recent changes in the IFU that may have a large impact on the sterile processing department's handling of ophthalmic instruments.

Attention to reprocessing needs starts in the procedure room. Point-of-use treatment to remove bioburden is a continuous part of every procedure, not just ophthalmic surgeries. Following best practices and guidelines for pre-treatment will ensure that soils do not dry on the instruments or within the lumens. Typically, this is accomplished with sterile water and a lint-free surgical sponge. Eye tissue is very delicate and is easily torn or damaged, but ironically, when eye tissue dries on or in the instruments ,it can be very difficult to remove and can result in instrument damage.

Post-procedure, the instruments should be transported as instructed by relevant IFU and following facility policy and OSHA recommendations. If using a commercial pre-treatment product, it's important to use a non-enzymatic wetting agent. This product must also be free-rinsing and must align with the instrument IFU.

A gentler cycle

If an instrument is not clean, it cannot be successfully sterilized. However, many ophthalmic instruments are very delicate and easily damaged, so they require special handling during cleaning. Recent revisions to ophthalmic instrument IFU include added details about mechanical washing, with some going so far as to specify exact processing parameters. The standard cycles of mechanical washers may not be safe for delicate ophthalmic instruments.

Not all washers are created equal. Managers should assure that they are using a cycle specifically designed to handle ophthalmic instrumentation. They should verify that the department's mechanical washer can meet their ocular instruments' IFU parameters. This is as important as any other step in reprocessing. A call to the original equipment manufacturer of the mechanical washer can determine if and how specific cycle requirements can be added to a unit. If the recommended cycle parameters can't be added, manual processing instructions should be followed.

Changing ultrasonic requirements

Ultrasonic cleaning systems are equally integral to the successful cleaning of eye instruments. In years past, ophthalmic IFU required that an ultrasonic system be dedicated solely to a department's ophthalmic instruments; now instructions may require *two* ultrasonic cleaners. The first dedicated unit provides static soaking and ultrasonic cleaning, and the second unit delivers critical water ultrasonic rinsing. This is an example of why it's important to review an instrument's IFU periodically for updates; they may have changed significantly.

Disinfection dilemma

Disinfection makes instruments safe to handle on the clean side of SPD. However, since residual disinfectant chemicals can injure eyes, many ophthalmic instrument IFU caution against chemical disinfectants. So, how can you disinfect without chemical disinfectants? Thermal disinfection solves this dilemma. This process uses heat and not chemicals to kill microorganisms. Consider using washers and ultrasonic units capable of thermal disinfection temperatures ≥180°F in their final rinse.

Focus on details and big picture

The days of departments having only one or two instrument sets for a potential eye case may be over. As they become more aware of specific processing needs for each ophthalmic instrument, sterile processing managers are grouping instruments into sets identified for their special processing requirements. In addition, some departments are choosing to have a specific location within the decontamination area that's devoted strictly to eye instrumentation.

Providing readily accessible key information, tools and supplies for technicians and not comingling with other specialties increases control of the ophthalmic reprocessing function. It is also helpful to review the quality system in place for ophthalmic reprocessing protocols and apply Lean principles to optimize these procedures in all settings, including the hospital central sterile department, the outpatient surgery department, and the reprocessing areas in freestanding surgery centers.

Sterile processing departments often focus on big changes and lose sight of specific processes and procedures they should already have implemented. It's crucial to review all instruments' IFU regularly, including but not limited to instructions for ophthalmic instruments, other procedural instruments, washers, ultrasonic units, brushes, cleaning chemistries, sterilizers, and supporting tools and accessories, to assure up-to-date compliance. In addition, watching the sterile processing department in action may help managers identify some common processing problems.

Don't be shortsighted about mats

While silicone instrument mats are ideal for protecting delicate tools inside an automated system, mats can also inhibit cleaning. For example, mats can over-absorb the cavitation action of ultrasonic systems and decrease the cleaning ability of their cycles. Developing an ultrasonic process for ophthalmic instruments without mats will help ensure effective cleaning the first time and eliminate the need for rework.

Watch out for water contaminants

Water quality is vital in all phases of reprocessing and is especially important when reprocessing ophthalmic instruments. Utility/tap water is not of the same quality in all areas of the country, and some regions may have additional issues with heavy mineral deposits and pH levels that are not conducive to instrument reprocessing. The Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force noted in 2018 that utility/tap water may contain heat-stable endotoxins and gram-negative bacteria in municipal water supplies and recommended critical water for the final rinse.

Help is available to tackle any water quality questions that may arise, first from the AAMI Technical Bulletin TIR 34:2014 *Water for the reprocessing of medical devices*, and then from the washer and ultrasonic manufacturers. They can typically direct sterile processing departments to water testing resources. These professionals understand the needs specific to instrument reprocessing. Proper water quality will ensure a long life for the surgical instruments and for the mechanical washers and ultrasonic cleaners.

Avoid cleaning chemistry blind spots

The proper selection and use of cleaning chemistries is very important for effective reprocessing. Poor cleaning chemistry choices can lead to damaged instruments, incomplete soil removal, and interference with mechanical cleaning equipment. Inappropriate rinsing of chemistries may also leave residues that can lead to TASS.

The chosen cleaning chemistry must be compatible with each instrument. For example, if an instrument's IFU calls for a neutral pH detergent, this is a strong indication that high pH solutions will damage the instrument finish. Therefore, alkaline cleaning chemistries would not be appropriate for this device. The cleaning chemistry must also be compatible with the equipment or process. Ultrasonic cleaners have different requirements from automated washers, for example.

It is critical to review all cleaning chemistry claims. If doubt or confusion exists, contact the product's manufacturer to request a technical data monograph (TDM). TDMs provide detailed

Self-Study Test Answers: 1. B, 2. B, 3. B, 4. A, 5. C, 6. B, 7. A, 8. D, 9. B, 10. C

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information about the product itself and frequently include results of product testing that illustrate how the manufacturer arrived at the claims for the cleaning chemistry.

Getting soap in your eye may sting but getting residual enzymes in your eye from a poorly processed instrument may blind you. Many ophthalmic instrument IFU have limited or discontinued the use of enzymatic chemistries for this reason.

One more caution: selecting a chemistry based on cost, convenience, or a shorter cycle or soak time, rather than choosing one that complies with your instrument's IFU, is shortsighted. Not aligning with the IFU may represent an off-label use of the chemistry, which could put a facility in the difficult position of defending their practice to a reviewer during a survey.

Another change: single-use brushes

Ophthalmic instrument IFU revised in the last three years may now include a restriction to single-use brushes for cleaning. Departments must define what 'single use' means. Additionally, departments with mixed inventory (some instruments' IFUs that allow brush reuse and some that don't) must have a means to segregate instruments to ensure proper brush use. These requirements may impact brush inventories (and waste management procedures) to account for increased disposal of some reusable brushes.

Optimize inspection

While lighted and magnified visual inspection is now a standard, it may not be enough for today's intricate instruments. Lumens, cracks, and fine details make enhanced magnification tools a necessity. Using a borescope or video enlarger allows a full assessment of the entire instrument, including the internal surfaces of lumens.

Burrs, cracks, or breaks trap foreign material and residual soils and chemistries that may be transferred to the eye during the procedure. If any of these flaws are identified at any time, follow facility protocols for repair or return to the manufacturer for further evaluation.

Instrument staining is more than cosmetic – it's a serious concern. Staining has many causes. The most troublesome are stains from residual chemical, hard water or other foreign substances that can cause TASS if transferred to the eye. If instrument staining is noted, a full review of the entire reprocessing workflow from decontamination through sterilization should be done to determine the exact cause of the staining and how to resolve it.

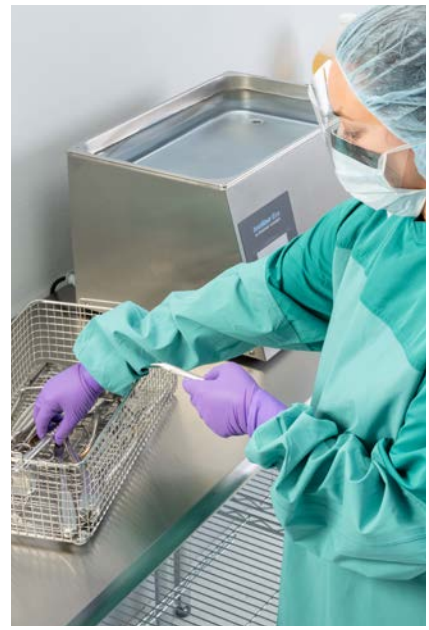
Making the invisible visible

Eyes are sensitive organs, but they can't see everything, even with magnification. Yet even a microscopic amount of powder from a glove or residual debris can induce catastrophic reactions in the eye. Using powderless gloves solves one problem, but how can reprocessing technicians see other contaminants that can't be seen?

A quality procedure for soil testing needs to be in place before the instruments are prepared for sterilization, to verify that instruments are clean beyond what can be visualized. ANSI/AAMI ST79:2017, Annex D lists eight soil markers that are appropriate for use to identify residual soils. Protein is listed first because protein is present in all human soils. Checking for protein-based residuals will reliably identify instruments that are not clean and that need to be returned to the decontamination area to restart the process.

Appropriate streamlining

Reducing unnecessary complexity in reprocessing is valuable. It helps to reduce errors and makes work easier for staff members. However, some streamlining efforts may be detrimental. For example, special cycles may be required to sterilize some ophthalmic instruments, but not all. One set of instructions may call for a 10-minute 270°F prevacuum steam sterilization cycle, while other IFU call for a four-minute exposure. Standardizing on the 10-minute exposure cycle streamlines the process, but then the four-minute instruments are not being processed per their IFU. Moreover, the extra exposure may have a negative effect on these delicate instruments. Longer exposures could increase repair/sharpening frequency and shorten the useful life of the instruments. Always consult the relevant instrument manufacturers before determining whether or not to standardize a cycle and consider all potential consequences of a streamlining change before it is made.



Set your sights on the future

Because of documented patient injury risks, reusable ophthalmic instruments must be processed with great attention to detail and to each instrument's IFU. The increasing complexity of ophthalmic instruments and their reprocessing requirements will require ongoing attention by everyone involved in their handling. As they continue to evolve, so will their IFU, so it's important to check periodically for updated requirements. Any workflow improvements should also take the IFU into account, including automated equipment needs, the appropriate use of cleaning chemistries, single-use accessory requirements, and proper inspection tools. By keeping an eye on ophthalmic reprocessing in your facility, you will help prevent TASS and infections and thereby improve patient safety. HPN

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CONTINUING EDUCATION TEST • MARCH 2021

Eye spy: Changes in ophthalmic reprocessing

Circle the one correct answer:

1. **What can cause Toxic Anterior Segment Syndrome?**
   a. Bacteria
   b. Foreign material
   c. Dry eye
   d. Infection
2. **Which set might have ophthalmic instruments?**
   a. Labor and Delivery set
   b. Trauma sets
   c. Total hip replacement set
   d. Bronchoscopy set
3. **Why do ophthalmic instruments require special washer cycle parameters?**
   a. They are harder to clean
   b. They are delicate and easily damaged
   c. They can only be cleaned one at a time
   d. They do not require manual cleaning
4. **Silicone mats should not be included with instruments in the ultrasonic cleaner because they can inhibit cleaning.**
   a. True
   b. False
5. **When selecting a type of cleaning chemistry, it should be approved for use per the _____.**
   a. Instrument IFU
   b. Washer or ultrasonic IFU
   c. A and B
   d. None of the above
6. **If water is safe to drink it is guaranteed safe for instrument reprocessing.**
   a. True
   b. False
7. **Soil tests help to find residual soils that may be invisible to the naked eye.**
   a. True
   b. False
8. **Why is instrument staining a concern?**
   a. Staining is cosmetic and nothing to worry about
   b. Doctors don't like it
   c. It shows instrument color tape is bleeding
   d. It could be foreign material that could transfer to the eye
9. **Residual soils that are not visible to the unaided eye are of no concern since the item will be sterilized.**
   a. True
   b. False
10. **What should be done when several instruments within a single set have different sterilization exposure times?**
    a. Sterilize at the longest exposure time of the instruments in the set
    b. Sterilize at the shortest exposure time of the instruments in the set
    c. Create separate sets based on sterilization needs
    d. Standardize on one sterilization time

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