

Since the release of the "Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments" the Joint Commission, the Federal Drug Administration, Centers for Disease Control, and Center for Medicare and Medicaid Services have updated their position on the use of Steam Sterilization. Please see the Press Release below and relevant documents regarding this change prior to reading the Sterilization Guidelines.



AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
AMERICAN SOCIETY OF OPHTHALMIC ADMINISTRATORS

PRESS RELEASE

Reviewed: September 2013
Released: June 15, 2009

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STATEMENT FROM THE ACADEMY AND ASCRS REGARDING THE JOINT COMMISSION'S CLARIFICATION OF ITS POSITION ON STERILIZATION PRACTICES

FAIRFAX, VA – Recently, there has been concern and confusion about the interpretation of standards and survey process regarding sterilization in ophthalmic facilities. Over the past year, the American Academy of Ophthalmology (Academy) and the American Society of Cataract and Refractive Surgery (ASCRS), along with the Outpatient Ophthalmic Surgical Society, have discussed the concerns of ophthalmic surgery centers with the Joint Commission. The [new position statement](#), released by the Joint Commission on June 15, 2009, clarifies the interpretation of standards regarding steam sterilization.

Summary of Position Statement

The Joint Commission announced a refocusing of its survey efforts on all of the critical processes involved in sterilization, not just the selection of the sterilization cycle or method. If the process is considered complete and performed well, then the Joint Commission will consider it effective. Thus, the use of a shorter steam sterilization process for unwrapped instruments will no longer be considered "ineffective," without considering all of the aspects of the sterilization process. Joint Commission surveyors will observe processes of cleaning, sterilization, and transportation of instruments, and ask for manufacturers' instructions.

Recommendations for Ophthalmic Surgery Centers

Ophthalmic surgery centers under the purview of the Joint Commission should be familiar with the Position Statement on Steam Sterilization as well as the [Centers for Disease Control/Hospital Infection Control Practices Advisory Committee Guideline for Disinfection and Sterilization in Healthcare Facilities](#).

In addition, it is recommended that attention be paid to the following:

- Avoid using the antiquated term, "flash sterilization."
- Clean and rinse all surgical instruments appropriately after each case, as per the manufacturer's instructions.
- Follow the manufacturers' instructions for instrument sterilization, both the sterilizer and the instrument manufacturer.
- Protect instruments from recontamination during the transport to the sterile field.
- Have a written policy in place for protocols for what happens (cleaning, handling, sterilization procedure) to the instruments prior to each surgical case and after each case in accordance to the manufacturers' instructions.

Recommended practices for cleaning and sterilizing intraocular surgical instruments

From the American Society of Cataract and Refractive Surgery
and the American Society of Ophthalmic Registered Nurses

Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber, or segment, of the eye following cataract surgery. A variety of substances have been implicated as causes of TASS. These substances can be divided into extraocular substances that inadvertently enter the anterior chamber during or after surgery (topical anti-septic agents,^{1,2} talc from surgical gloves,^{3,4} topical ophthalmic ointment⁵), products that are introduced into the anterior chamber as a part of the surgical procedure (anesthetic agents,^{6,7} preservatives,⁸⁻¹¹ inappropriately reconstituted intraocular preparations,¹² mitomycin-C,¹³ intraocular lens¹⁴), and irritants on the surfaces of intraocular surgical instruments that have accumulated as a consequence of inadequate or inappropriate instrument cleaning (denatured ophthalmic viscosurgical devices [OVDs] [Sutphin JE, Papadinos TJ. IOVS 1989; 30:165 ARVO Abstract 8],¹⁵ detergents,¹⁶ heat stable endotoxin from overgrowth of gram-negative bacilli in water baths of ultrasonic cleaners,^{17,18} degradation of brass containing surgical instruments from plasma gas sterilization,¹⁹ and impurities of autoclave steam²⁰).

Whereas opportunities exist to prevent TASS resulting from extraocularly or intraocularly applied products by product withdrawals, product communications, and compounding alerts, preventing TASS by appropriate management of intraocular surgical instruments is a challenge that must be repeated with each cycle of cleaning and sterilization of cataract

surgical instruments at every cataract surgical facility. In fact, this challenge is not always satisfactorily addressed, resulting in single-facility outbreaks of TASS that frequently subside when the cleaning and sterilization steps are improved (N. Mamalis, MD, H. Edelhauser, PhD, personal communication, September 2006). Careful review of a number of facilities reporting cases of TASS to the Intermountain Ocular Research Center at the University of Utah in the spring of 2006 identified many opportunities to lower the risk for TASS through improving the steps of the cleaning and sterilization process.²¹

The goal of these recommended practices for cleaning and sterilizing intraocular surgical instruments is to prevent single-facility outbreaks of TASS related to contaminated or degraded instruments. It is also hoped that the availability of recommended practices could facilitate the identification of causes of TASS and resolution of single-facility outbreaks of TASS when they occur. The recommendations have been written to be generic enough to enable appropriate application at all facilities performing cataract surgery, recognizing that differences in procedures and activities exist between surgical facilities.

The recommended practices are derived largely from existing, evidence-based general recommendations for cleaning and sterilizing all surgical instruments,²²⁻²⁴ from evidence derived from published reports of single-facility outbreaks of TASS,^{3,4,15-20} and from directions for management of equipment provided by manufacturers. The challenge of preventing TASS is multifaceted. Relevant factors include the minute amounts of irritants needed to cause clinically significant postoperative inflammation of the anterior chamber, the frequency with which cataract surgery is performed on a daily basis across the country, the variety of instruments used, and the various requirements for cleaning different types of instruments. Consequently, these recommendations for cleaning and sterilization were developed by representatives of professional societies for cataract surgeons, ophthalmic and operating room nurses, and infection control, in collaboration

Prepared February 16, 2007, by the American Society of Cataract and Refractive Surgery Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Instruments.

Guidance provided by the Association of periOperative Registered Nurses, the Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, the Centers for Disease Control and Prevention, and the U.S. Food and Drug Administration.

Editor's Note: These guidelines were distributed with the March issue of JCRS. We are reprinting them in this issue so they can be cited and made available to all ophthalmic personnel.

with manufacturers of intraocular cataract surgical instruments. Guidance was also provided by the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration.

These recommended practices are not intended to address all requirements for sterilization and quality assurance of the sterilization process. They should be used in conjunction with current consensus guidelines from the Association for the Advancement of Medical Instrumentation (AAMI), the American Society of Ophthalmic Registered Nurses (ASORN) and the Association of periOperative Registered Nurses (AORN).^{22-24,30} The recommendations are believed to be relevant for instruments used in all intraocular surgical procedures, most of which are cataract surgical procedures; therefore, to expedite consistent and optimal instrument management, the recommendations are intended to apply to all intraocular surgical instruments. When recommendations for instrument management include cleaning without disinfection prior to sterilization, unsterilized instruments should be considered contaminated and therefore unsafe for handling unless appropriate barriers and precautions are used (eg, gloves and separation from environments in which disinfected items are handled).

The recommendations are divided into 2 sections. The first establishes general principles of cleaning and sterilization that must be addressed to prevent TASS. The second provides specific recommendations for cleaning and sterilizing intraocular surgical instruments.

GENERAL PRINCIPLES OF CLEANING AND STERILIZING INTRAOCULAR SURGICAL INSTRUMENTS

The instruments should be kept moist until the cleaning process begins to avoid drying of debris and OVD.^{23,25,26}

All debris inclusive of OVD should be removed.^{15,25,27}

Quality and volumes of water should be used as specified by manufacturer's directions for use (DFU) for suspension of detergents and for cleaning and rinsing instruments.^{22,23,28} The DFU for many intraocular instruments require or recommend sterile distilled or sterile deionized water for most cleaning steps. Sterile distilled or sterile deionized water are required for final rinsing.²⁵

Follow detergent and instrument manufacturers' DFU to ensure proper use of the detergent and to ensure compatibility with the instruments.^{22,23,28}

Rinsing should remove all cleaning agents as well as all debris loosened during the cleaning process.^{25,26,29}

The method of sterilization applied to instruments should be approved by both the manufacturer of the

sterilizer and the manufacturer of the surgical instruments. Sterilizers should be maintained in accordance with the manufacturer's recommendations.²²⁻²⁴

Procedures for instrument cleaning and sterilization should be developed and written for each healthcare facility.^{22,23}

Adequate time should be provided to allow completion of all steps of cleaning and sterilization.^{22,23}

Staff training, competency validation, and periodic performance review should be implemented for each healthcare facility.^{22,23,30}

RECOMMENDATIONS FOR CLEANING AND STERILIZING INTRAOCULAR SURGICAL INSTRUMENTS

1. Adequate time for thorough cleaning and sterilization of instrumentation should be established.
 - a. Rigorous adherence to recommended procedures for cleaning and sterilizing surgical instruments should never be circumvented to save time or money.^{30,31}
 - b. Inventory of instruments should be sufficient to meet surgical volumes and to provide adequate time for completion of cleaning and sterilization.^{22,23}
 - c. Flash sterilization is designed to manage unanticipated, urgent needs for instruments. Flash sterilization should not be used to save time or as a substitute for sufficient instrument inventory.²²
2. For each piece of equipment, the manufacturer's DFU pertaining to cleaning and sterilization should be followed.²²⁻²⁴
3. Ophthalmic viscosurgical device solution, which can dry and harden within minutes, should not be allowed to dry on the instruments.²⁵
 - a. Instruments should be wiped with a dampened lint-free cloth and flushed and/or immersed in sterile water in the operating room (OR) immediately following use, in strict accordance with manufacturer's DFU for each instrument.^{23,24} Sterile water baths used for cleaning or soaking soiled instruments should be kept in areas removed from the operative field and removed from sites that maintain instruments needed to complete the surgical procedure.
 - b. The DFU for some reused cannulated instrument specify the solution, volumes, and frequency for flushing of each lumen. Flushing should be completed as specified in the OR or in the decontamination area.^{23,24}
4. Whether they are used, instruments opened for a procedure should be transported from the OR in a closed container to the decontamination

- area, where cleaning should be completed immediately.^{23,24}
5. Disposable cannulas and tubing should be used whenever possible, and they should be discarded after each use. These devices are sold without DFU for cleaning, and thorough cleaning is difficult to achieve and to validate.²⁵
 6. Devices labeled for single use only should not be reused; single-use devices do not include instructions for reuse or reprocessing. The FDA actively regulates third-party and hospital reproducers of single-use devices according to FDA guidance.³²
 7. To avoid contamination with bioburden and cleaning chemicals, intraocular instruments should be cleaned separately from nonophthalmologic surgical instruments.
 8. The importance of enzymatic detergents for the cleaning of soiled intraocular instruments has not been established. Inappropriate use and incomplete rinsing of enzymatic detergents have been associated with outbreaks of TASS.¹⁶ If the DFU does not prohibit the use of a detergent and if a detergent is used
 - a. Care should be taken to ensure instructions for proper dilution, outdate, and disposal are followed. The cleaning solution should be mixed with measured amounts of water and detergent (ie, not mixed with estimated volumes), according to the detergent's DFU.^{23,24,28}
 - b. Following cleaning with detergents, with or without the use of an ultrasonic cleaner, instruments should be thoroughly rinsed with copious volumes of water to ensure removal of all detergent. If rinse volumes are specified by the detergent manufacturer's DFU or by the equipment manufacturer's DFU, they should be considered minimum volumes. Use of tap water for rinsing and for removal of detergent should be compatible with the manufacturer's DFU for the detergent and for the equipment. The final rinse should be with sterile distilled or sterile deionized water.^{25,29,30}
 9. If an ultrasonic cleaner is used
 - a. Ensure that gross soil has been removed prior to placement in the ultrasonic cleaner.
 - b. Check the manufacturer's DFU of instruments to identify instruments that should not be subjected to ultrasonic cleaning.
 - c. An ultrasonic unit designated for cleaning of medical instruments should be used.²⁴
 - d. Validation of functioning, degassing, and preventive maintenance should be performed as recommended in the ultrasonic cleaner's DFU.^{23,24}
 - e. Ultrasonic machines must be emptied, cleaned, disinfected, rinsed, and dried at least daily and preferably after each use.^{17,18,33} Unless specified otherwise by the manufacturer, cleaning should be performed with an EPA-registered, facility-approved disinfectant and followed by sterile or tap water rinse sufficient to fully remove the cleaning agent. If not contraindicated by the ultrasonic cleaner's manufacturer, final rinse with 70% to 90% ethyl or isopropyl alcohol is recommended when feasible and unassociated with risk for fire. The machine should be dried completely with a lint free cloth.³⁴⁻³⁶
 - f. Refilling should occur immediately prior to use.
10. Manual cleaning processes
 - a. Brushes should be designed for cleaning medical instruments.²⁴
 - b. Cleaning tools such as syringes and brushes should be discarded after each use. If brushes are reused, they should be designed for reuse and they should be cleaned and high-level disinfected or sterilized, preferably after each use, or at least once daily.^{24,34}
 - c. Cleaning solutions should be discarded after each use.²⁴
 - d. When flushing is used as part of a cleaning technique, the effluent should be discharged into a sink or separate basin so the fluid is not reused. Discharge of the effluent should be completed to minimize splash and aerosolization.
 11. Rinsing
 - a. Follow the manufacturer's DFU for selecting the appropriate type of rinse water for equipment.
 - b. Unless otherwise specified by the manufacturer's DFU, sterile distilled or sterile deionized water should be used for the final rinse of instruments.²⁵
 - c. Rinsing should provide flow of water through and/or over instruments, with effluent discarded as it is used, so only debris-free water is used for rinsing.
 - d. Agitation in a basin of water should not be used as a final rinse.
 12. Following thorough rinsing, instruments with lumens should be dried with forced or compressed air.
 - a. Compressed air should be filtered and free of oil and water.
 - b. Instruments with lumens should be fully dried.²³
 13. Specific instruments: phacoemulsifier handpiece, irrigator/aspirator, irrigator/aspirator tips, and inserters

- a. Flush phacoemulsifier handpiece with balanced saline solution prior to removing from the operative field.
 - b. Wipe each instrument with a lint-free cloth and place immediately in a bath of sterile water. Remove from the operative field and remove from sites that maintain instruments needed for completion of the surgical procedure, in strict accordance with the manufacturer's DFU for each piece of equipment. To avoid introduction of water or reintroduction of gross soil to the operative field, the sterile water bath should be clearly separated from the operative field.²³
 - c. Clean and flush each item in accordance with the manufacturer's DFU and verify removal of all debris inclusive of OVD.²³
 - d. Inspect irrigator/aspirator tips, preferably under magnification, before sterilization.^{23,25}
14. If reusable woven materials are used for draping the sterile field, to absorb condensate in steam-sterilized instrument trays or to wipe instruments, they should be laundered and rinsed thoroughly between each use to eliminate surgical compounds, debris, and cleaning agents.
- a. Inadequate rinsing of high pH detergents used in institutional laundering can leave chemical residues that could be transferred to intraocular instruments.³⁰ Laundry procedures should be reviewed and monitored to ensure delivery of residue-free, reused woven materials; otherwise disposable, chemical, and lint-free materials should be used.
 - b. All woven materials used in intraocular surgery or instrument management should be lint free.
15. Cleanliness and integrity of instruments should be verified.^{23,24}
- a. Instruments should be visually inspected for debris and damage, preferably under magnification, immediately after cleaning and before packaging for sterilization to ensure removal of visible debris.^{24,25,30,37}
 - b. Additional or repeated cleaning and rinsing steps may be required on a case-by-case basis to ensure removal of all debris and OVD.
 - c. Surgeons should examine instruments under the microscope prior to each use and reject any instrument that shows signs of residual debris or defects.³⁸
16. Sterilization
- a. The method for sterilizing intraocular surgical instruments should be in accordance with the DFU of the instruments and with the DFU of the sterilizer manufacturer.^{22,24}
 - b. Steam sterilization should be completed in accordance with published guidelines.^{22,24}
 - c. Glutaraldehyde is not recommended for sterilizing intraocular instruments because of the toxicity of glutaraldehyde residues resulting from inadequate rinsing or contamination during post-sterilization handling. Other low temperature methods of sterilization should not be used unless the ophthalmic instrument manufacturer and the sterilizer manufacturer have validated the method for the specific instruments with respect to efficacy of sterilization, potential ocular toxicity (eg, from oxidation of metals), and instrument functionality.¹⁹
 - d. Verification of sterilizer function should be completed at least weekly, preferably daily, in accordance with the sterilizer manufacturer's instructions for use and with published guidelines, and documented in the facility log.^{22,24}
 - e. Measures should be taken to ensure that preventive maintenance, cleaning, and inspection of sterilizers are performed on a scheduled basis, according to the sterilizer manufacturer's written instructions.^{22,24} All preventive maintenance should be documented.
 - f. Maintenance of boilers, of the water filtration systems, and of the quality of water supplying the steam-sterilizing system should be verified at least yearly. Healthcare organizations may find consultation with companies specializing in boiler maintenance and water quality helpful.^{20,22,24}
17. Administrative controls should be implemented.
- a. Policies and procedures regarding cleaning and sterilizing intraocular surgical instruments should be written, reviewed periodically (at least annually), and kept readily available within the practice setting.^{22,23}
 - b. A sufficient number of instrument sets, phacoemulsifier handpieces, irrigator/aspirators, and inserters should be purchased to allow adequate time for cleaning and sterilization between procedures.
 - c. Personnel involved in handling and cleaning and/or sterilizing intraocular surgical instruments should
 - i. Be educated about TASS and its causes at hire and updated regularly thereafter.²⁵
 - ii. Receive initial education, training, and validation of competency in the cleaning, inspection, preparation, packaging, sterilization, storage, and distribution of all intraocular surgical instruments. Education, training and validation of competency should be updated at least annually and prior to introduction of any new devices or procedures.^{22,23}

- iii. Be educated and trained in cleaning and sterilization procedures as well as related tasks (eg, equipment operation, preventive maintenance) via a formal, standardized training program administered by qualified personnel.^{22,23}
- iv. Undergo competency validations by direct observation of performance, using a competency checklist to ensure uniform evaluation of all personnel.^{22,23}
- d. Records of instrument use, of medication use, and of sterilization should be maintained in accordance with facility policy.^{22,24,25} Complete and detailed records will aid in the investigation of any occurrence of TASS.
- e. A surveillance system for detecting TASS should be implemented. Cases of TASS should prompt re-evaluation of cleaning and sterilization procedures.²¹

APPENDIX

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