

# Guidelines for the cleaning and sterilization of intraocular surgical instruments



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These Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments were written by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force, comprised of representatives of the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, and the Outpatient Ophthalmic Surgery Society. These consensus subspecialty guidelines include evidence-based recommendations regarding issues that may be unique to the cleaning and sterilization of intraocular instrumentation. A newly published OICS Task Force study supports the safety of common short-cycle instrument processing

practices for sequential same-day anterior segment surgery. Other studies substantiate the risk of toxic anterior segment syndrome from routine use of enzymatic detergent, whose microscopic residues are difficult to eliminate from intraocular instrumentation. Finally, based on published international outcomes and endophthalmitis rates, future studies should critically evaluate a variety of operating room protocols that may increase cost, waste, and carbon footprint, without any actual safety benefit.

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**P**ostoperative infectious endophthalmitis and toxic anterior segment syndrome (TASS) are rare, but potentially sight-threatening, complications of cataract and other intraocular surgery. The small volume of the eye and its sensitivity to minute amounts of chemical or microbial contaminants means that improper instrument cleaning or sterilization practices might pose a significant risk to patients. The Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force is made up of representatives of the American Society of Cataract and Refractive Surgery (ASCRS), the American Academy of Ophthalmology (AAO), and the Outpatient Ophthalmic Surgery Society (OOSS). These professional societies represent ophthalmologists and the clinical staff of ophthalmic outpatient surgery centers, including surgeons, nurses, and technicians. The OICS Task Force includes experts on TASS and endophthalmitis and has written this document to provide specialty-specific, evidence-based guidelines for the cleaning and sterilization of intraocular surgical instruments. This document is an update of original recommended practices for cleaning and sterilizing intraocular surgical instruments published in 2007.<sup>1</sup>

Most of the recommended practices are derived from existing evidence-based recommendations for cleaning and sterilizing all surgical instruments in general,<sup>2–4</sup> from published analyses of TASS outbreaks,<sup>5–12</sup> and from manufacturers' instructions for use (IFU) for surgical instruments and equipment. In addition, task force members have collaborated in performing new research that supports certain recommendations, which is referenced in this document.

This specialty-specific document seeks to outline minimum standards for intraocular instrument cleaning and sterilization based on a consensus of experts representing the 3 sponsoring societies. Although developed specifically for cataract surgery, the recommendations in this document are also relevant for instruments used in other intraocular surgical procedures. It is not intended to be a comprehensive list of every requirement for sterilization and quality assurance of the sterilization process. Individual centers might elect to incorporate additional measures beyond what is outlined in this document.

Appropriate consideration should also be given to guidelines from other relevant organizations.<sup>2–4,13</sup>

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However, many recommendations from these published guidelines are made with respect to all surgical procedures and are not specific to ophthalmic instrumentation and surgery. Therefore, those recommendations often do not take into account the unique conditions of intraocular surgery and special requirements for cleaning and sterilizing ophthalmic instrumentation. As a result, all-inclusive, broad guidelines attempting to cover surgery from head to toe could sometimes include inappropriate, or even risky, practices for ophthalmic cases. For example, cataract surgeries are shorter than many general surgical procedures and are often performed with higher daily volumes. Intraocular surgical instruments are among the smallest in size and generally do not become heavily soiled from tissue or bacterial contamination. On the other hand, minute amounts of detergent or chemical contaminants that would be well tolerated in other body cavities can cause severe intraocular inflammation (TASS) when introduced into the eye.<sup>14,15</sup> These characteristics might differentiate optimum cleaning and sterilization procedures for cataract surgery from those required for many other types of surgery.

### TOXIC ANTERIOR SEGMENT SYNDROME

Toxic anterior segment syndrome is an acute severe inflammatory reaction to a toxic contaminant introduced into the anterior chamber during intraocular surgery. In addition to severe anterior chamber cell and flare, it might be associated with fibrin, hypopyon, diffuse limbus-to-limbus corneal edema, atonic pupil, secondary glaucoma, and in some cases, vitreous cells.<sup>16</sup> Because of these signs, TASS might be misdiagnosed and mistreated as infectious endophthalmitis. Even if TASS resolves with treatment and without permanent sequelae, the patient often suffers the emotional trauma of believing he or she might have a potentially blinding infection.

A large outbreak of TASS in 2006 led to the formation of the ASCRS TASS Task Force, whose surveys and site visits have consistently shown that improper instrument cleaning and sterilization is the most commonly identified cause of TASS.<sup>17,18</sup> The TASS Task Force separately analyzed and compared causes of TASS during 2 periods: 2007–2009 and 2009–2012.<sup>17,18</sup> Data from 130 questionnaires and 71 site visits to affected ambulatory surgery centers (ASCs) were incorporated into the final analysis of 1454 cases of TASS from approximately 69 000 concomitant cataract surgeries. The most common risk factors for TASS included inadequate flushing and rinsing of handpieces, use of enzyme detergents, and use of ultrasonic baths.<sup>18</sup>

### 2014 OPHTHALMIC AMBULATORY SURGERY CENTERS SURVEY OF STERILIZATION PRACTICE

In 2014, a survey developed by the OICS Task Force was sent to OOSS member-ASCs regarding cleaning and sterilization of intraocular instruments. The survey was completed by 232 respondent centers representing a variety of ambulatory surgical settings including single-specialty ophthalmology and multispecialty centers. Ownership

models included 100% physician owned, corporate affiliated, hospital affiliated, and hospital outpatient departments (HOPD). For the purposes of analyzing cleaning and sterilization practices for ophthalmic surgery specifically, multispecialty ASCs, hospital-affiliated ASCs and HOPDs were excluded. In total, 182 complete responses were analyzed for this OICS guideline document. During the preceding 12 months, the responding single-specialty ASCs reported performing a total of 608 117 eye surgical procedures. The overall infection rate was 0.02%, with 116 facilities reporting zero cases and 66 facilities reporting 104 cases of endophthalmitis. The overall rate of TASS was 0.01%, with 161 facilities reporting zero cases and 21 facilities reporting a total of 50 cases. Most facilities (97.3%) had been inspected by a regulatory agency during the previous 3-year period. As a result of the inspection, 16.9% of the facilities reported being asked to change cleaning or sterilization protocols.

### GENERAL ADMINISTRATIVE PRINCIPLES

All facilities should establish written protocols for instrument cleaning and sterilization. These “policies and procedures” should be based on industry standards and guidelines with input from the nursing and medical staff. They should be approved by the governing body of the facility and be available to operating room (OR) and instrument processing staff. In addition, these policies and procedures should be reviewed annually and on acquisition of new instrumentation or sterilizing equipment.<sup>2,3</sup> We acknowledge the wide diversity among ophthalmic surgical settings and in the surgical products and instrumentation used. Physician and nursing medical staff directors should be allowed some discretion in developing and reviewing their facility’s written policies and procedures for instrument cleaning and sterilization based on the best available clinical evidence. These should then be approved by the facility governing body.

Personnel involved should be properly trained in handling, cleaning, and sterilizing intraocular surgical instruments and subject to periodic oversight.<sup>2,3,13</sup> In addition to the general principles of asepsis, this training should also include the cleaning, inspection, preparation, packaging, sterilization, storage, and distribution of intraocular surgical instruments. Appropriate staff should also be trained in related tasks, such as equipment operation and preventive maintenance. They should undergo competency validations by direct observation of performance.<sup>2,3</sup> Staff education, training, and the validation of competency should be updated and documented at least annually and coincident with introduction of new surgical equipment, medical devices, or packaging systems.<sup>2,3</sup>

Both infectious endophthalmitis and TASS are rare events, and their incidence should be monitored as a means of confirming the safety and efficacy of the facility’s written protocols. The OR staff should be educated about the causes of both endophthalmitis and TASS. A surveillance system for reporting and documenting infectious endophthalmitis and TASS should be implemented. Any increase in the

frequency of infectious endophthalmitis or TASS should prompt a thorough analysis and documented review of the facility's procedures and protocols for instrument cleaning and sterilization.<sup>17</sup> Records of instrument use, of medication use, and of sterilization procedures should be maintained in accordance with facility policy.<sup>2-4,16</sup> Such records might aid in the investigation of any outbreaks of TASS or infectious endophthalmitis.<sup>2-4,16</sup>

## CLEANING INTRAOCCULAR SURGICAL INSTRUMENTS

Cleaning and decontamination, which include thorough rinsing and flushing, should precede disinfection or sterilization. It is recommended that ophthalmic instrumentation should be cleaned separately from nonophthalmic surgical instruments. Contaminated and soiled instruments should also be cleaned in an area separate from where packaging and sterilization take place.

During decontamination and cleaning, all debris inclusive of ophthalmic viscosurgical device (OVD) should be removed from the instruments.<sup>7,16,19</sup> It might be helpful to keep instruments moist until the cleaning process begins to avoid drying of debris and OVD.<sup>2,3,16,20</sup> A dampened lint-free cloth or soft brush should be used to clean instruments in accordance with the manufacturer's IFU.<sup>3,4</sup> Additional or repeated cleaning and rinsing steps might be required on an instrument-by-instrument basis to ensure removal of all debris and OVD.<sup>21</sup>

The volume and type of water for cleaning and rinsing instruments should follow the manufacturer's IFU.<sup>2,3,22</sup> The IFU for many intraocular instruments recommend or require critical water (sterile distilled, reverse osmosis, or deionized) for most cleaning steps and for final rinsing.<sup>16,23</sup> Flushing instruments with lumens should be initiated in the OR and completed in the decontamination area.<sup>3,4</sup> When sterile water baths are used for cleaning or soaking soiled instruments in the OR, they should be separated from the sterile field and instruments still in use. When flushing is used as part of a cleaning technique, the effluent should be discharged into a sink or separate basin while minimizing splash and aerosolization so that contaminated fluid is not spread.

Facilities might consider discarding cleaning syringes or brushes after each use. If brushes are reused, they should be cleaned and disinfected or sterilized at least once daily.<sup>4,24</sup> Instruments should be visually inspected for debris and damage after cleaning and before packaging for sterilization to ensure removal of debris.<sup>4,13,16,25</sup>

Immediately after use, phacoemulsification and irrigation/aspiration (I/A) handpieces can be placed in a sterile water bath that is separated from the active operative field to avoid drying of the OVD until cleaning.<sup>2,3</sup> Instruments with lumens, such as phaco or I/A handpieces, should be cleaned and flushed in accordance with the manufacturer's IFU. All debris including OVD should be removed promptly.<sup>2,3</sup> Many IFU specify thorough flushing with critical water. Rinsing should provide flow of water through

and over instruments, with effluent discarded so that only debris-free water is used for subsequent rinsing.

## ENZYMATIC DETERGENT

One practice that is controversial is the use of enzymatic detergents for decontaminating intraocular surgical instruments. The manufacturer's IFU that accompany ophthalmic instruments and ultrasound cleaning baths often call for the use of enzymatic cleaners, the omission of which would therefore be considered off-label. However, the necessity of enzymatic detergents for cleaning contaminated intraocular instruments has not been established. Contrary to some manufacturers' IFU for their intraocular instrument, it is our position that enzymatic detergents should not be routinely required for intraocular instruments for several reasons. These detergents typically contain subtilisin or alpha amylase exotoxins, neither of which is denatured by autoclave sterilization. Corneal endothelial toxicity from enzymatic detergents has been documented in both animal and human studies.<sup>15,26,27</sup> Inappropriate use or incomplete rinsing of enzymatic detergent has been associated with outbreaks of TASS.<sup>17,18</sup>

The purpose of enzymatic detergent is to assist in the removal of bulk biomaterial from surgical instruments. However, intraocular instruments acquire minimal bio-burden during eye surgery and the material they do collect is usually completely removed with prompt manual rinsing and cleaning. Studies have shown that while following the manufacturer's IFU, even minute enzyme residue left on intraocular instruments can cause TASS.<sup>14</sup> The small-diameter lumens and fragile nature of intraocular instruments often make complete removal of all traces of enzyme detergent difficult. A recent study from the Moran Eye Center found that detergent residues can be detected by scanning electron microscopy (SEM) and energy dispersive x-ray spectroscopy (EDS) on the surface of phaco tips even after meticulous rinsing with sterile water prior to sterilization following the instrument manufacturer's IFU.<sup>28</sup> Much larger enzyme residues are found if thorough rinsing is not performed.<sup>28</sup>

Rabbit studies performed at the Moran Eye Center analyzed whether enzymatic detergents used to clean ophthalmic instruments can cause TASS-like responses.<sup>14</sup> Different dilutions of enzymatic detergent were injected into the anterior chambers of rabbit eyes, and the animals were evaluated postoperatively for signs of anterior segment inflammation. Severe anterior segment inflammation, including fibrin formation, developed within 72 hours after the injections. There was a dose-related correlation between the enzyme concentration and the severity of the inflammatory response. Post-mortem vital staining showed dose-related toxicity from the enzymatic detergent to the corneal endothelium.

Many ASCs specifically avoid using enzymatic detergent for intraocular instruments that, depending on the instrument, might be an off-label practice. In the 2014 survey of OOSS member ASCs, the majority of facilities (55.5%) did not use an enzymatic cleaner for intraocular instrument

decontamination compared with 44.5% who did. The average self-reported rate of endophthalmitis was 0.021% for non-enzyme-using facilities compared with 0.027% for enzyme-using facilities. We are not aware of any study showing that enzyme detergent for intraocular instruments reduces the rate of endophthalmitis. Lacking proven efficacy for endophthalmitis prevention, enzymatic detergents might unnecessarily elevate the risk for TASS without providing significant benefit to the patient. It is our position that if intraocular surgical instruments are thoroughly rinsed with critical water promptly after each use, the routine use of enzyme detergents is unnecessary and should not be required for routine decontamination of ophthalmic intraocular instruments.

Some instrument IFU, however, specify use of enzymatic detergent, and this has led to surgical centers that are not using enzymatic detergent to be cited by surveyors for the Centers for Medicare and Medicaid Services (CMS) or other regulatory agencies. After meeting with CMS, the U.S. Food and Drug Administration (FDA), and the Association for the Advancement of Medical Instrumentation (AAMI) about the potential risk for TASS from this practice, our OICS Task Force issued an appeal to intraocular surgical instrument manufacturers in 2016 to validate alternate cleaning and decontamination methods that do not require the routine use of enzymatic detergent.

Enzymatic detergent cleaning may be warranted in certain situations. If enzyme detergents are used for any reason, instructions for proper dilution and disposal of cleaning solutions should be 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 IFU.<sup>3,4,22</sup> The instruments should be thoroughly rinsed to ensure removal of all cleaning agents as well as all debris loosened during the cleaning process.<sup>15,16,20</sup> Use of tap water for rinsing and for removal of detergent should be used only if in compliance with the manufacturer's IFU for the detergent and for the equipment. Because tap water can contain heat-stable endotoxin from gram-negative bacteria found in the municipal water supply, critical water is recommended for the final instrument rinse.<sup>16,23</sup>

## ULTRASONIC CLEANING

Ultrasonic cleaning poses another risk factor for TASS according to the TASS Task Force surveys. If an ultrasonic cleaner is used, the technician should remove all visible soil before placing instruments in the ultrasonic cleaner. The ultrasonic unit should be designated for cleaning medical instruments and preferably should only be used for ophthalmic instruments. If a unit is used for other types of surgical instruments, it should be emptied, cleaned, and rinsed before use with ophthalmic instruments to avoid cross contamination.<sup>4</sup>

Ultrasonic machines should be emptied, cleaned, disinfected, rinsed, and dried at least daily.<sup>9,10,29</sup> Unless otherwise specified by the manufacturer, cleaning should be performed with an Environmental Protection Agency-

registered, facility-approved disinfectant and followed by critical water rinsing sufficient to fully remove the cleaning agent. If not contraindicated by the ultrasonic cleaner's IFU, a final rinse with 70% to 90% ethyl or isopropyl alcohol should be considered for the ultrasound cleaning compartment. The machine should be dried completely with a lint-free cloth and then cleaned following the manufacturer's directions before the next use.<sup>24,30</sup>

## REUSE OF PHACO TIPS

When feasible and safe, reuse of some surgical instruments might improve the cost-effectiveness of cataract surgery. In addition to proper cleaning and sterilization to prevent microbial contamination, appropriate reuse requires preserving the structural integrity of the instrument so that it maintains its surgical function. In many international settings, phaco tips are routinely reused to reduce waste and the cost of replacement. At the surgeon's discretion, a used tip can be discarded if any reduced cutting efficiency is noted. We are unaware of convincing evidence to suggest that this potentially off-label practice is dangerous or less effective than using a new phaco tip for every case. Although most phaco tips are made of a comparable titanium alloy,<sup>31</sup> there is wide disparity in the labeling for reuse between manufacturers. One manufacturer (Alcon, Fort Worth, TX) specifies single use only for all its phaco tips. Another manufacturer (MicroSurgical Technology, Redmond, WA) allows 50 reuses of its phaco tips. A third manufacturer (Abbott Medical Optics/Johnson & Johnson Vision, Santa Ana, CA) allows 20 reuses of 1 tip yet only a single use for its other model of phaco tip.

One study performed at the Moran Eye Center assessed 8 phaco tips (both single use and reusable) after 10 autoclave sterilization cycles.<sup>28</sup> None of the tested tips showed any significant morphologic changes on SEM or EDS analysis. A second Moran Eye Center study in conjunction with the Utah Nanofab Laboratory tested 8 phaco tip models from 3 manufacturers using a well-described ex vivo porcine cataract model. SEM and white-light interferometry (WLI) testing of each tip was performed after 5 simulated reuses involving prolonged continuous ultrasound cycles in nuclei of varying density.<sup>32</sup> Regardless of whether they were labeled for single or multiple use, the reused phaco tips in this experimental model did not show significant ultrastructural damage or wear, such as microfracture, deformation, fissures, or breakage. This model was very robust, using the maximum 100% continuous longitudinal phaco power setting that would be equivalent to 10 minutes of continuous phaco at 20% power. Not surprisingly, some superficial surface changes on used tips were found on SEM in this study and a second study evaluating clinically used tips.<sup>33</sup> The theoretical significance or relevance of these microscopic surface changes is debatable, but they should not pose a safety risk. The results in these studies suggest that labeling some titanium phaco tips for single use might be arbitrary, in particular when virtually identical titanium tips are labeled for 20 or 50 uses by different manufacturers. Lacking clinical evidence to the contrary, we suggest that

manufacturers perform validation studies for reusable phaco tips. With respect to the tips tested in this study, we concur with the investigators' suggestion that cataract surgeons be allowed discretion in terms of reusing phaco tips off-label based on their clinical observations and judgment.<sup>32,34</sup>

## STERILIZATION OF INTRAOCULAR SURGICAL INSTRUMENTS

Sterilization process monitoring and management are critical to the ASC infection control program. Adequate time to follow recommended procedures for cleaning and sterilization of instrumentation should be established.<sup>13,35</sup> The method of instrument sterilization should be based on guidelines from the medical device, packaging system, and sterilizer manufacturer. Routine monitoring and verification of sterilizer function with biological indicators should be performed at least weekly, and preferably daily, in accordance with the sterilizer manufacturer's IFU and documented in the facility log.<sup>2-4</sup> Measures should be taken to ensure that preventive maintenance, cleaning, and inspection of sterilizers are performed and documented on a scheduled basis, according to the sterilizer manufacturer's IFU.<sup>2-4</sup>

Strict adherence to every IFU might not always be possible. There might be discrepancies between the individual IFU for the sterilizer, packaging system, and/or medical device. Many surgical trays have instruments from more than one manufacturer, which could have conflicting IFU. Separating instruments by manufacturer and performing different sterilizing procedures for each instrument group is not practical. In these situations, it is appropriate for physicians and nurses to exercise their best clinical judgment in establishing instrument cleaning and sterilization policies that maintain safety while resolving conflicting IFU.

Complete terminal, wrapped sterilization cycles should be used to sterilize ophthalmic surgical instruments that will be stored overnight for future use. Short-cycle steam sterilization is commonly used for what we refer to as *sequential same-day* ophthalmic procedures; that is, subsequent consecutive surgeries occurring on the same day the instruments are sterilized.<sup>36</sup> However, the terminology used by agencies that license and regulate ASCs to describe and differentiate short cycles of steam sterilization has created some confusion among the ophthalmic ASC industry.

The CMS Survey and Certification S&C:14-44-Hospital/CAH/ASC "Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings" was released in August 2014.<sup>37</sup> This defined IUSS as replacement terminology for the outdated term *flash sterilization* and stated that IUSS was not acceptable as a routine method of sterilization. IUSS might be used on an emergent basis to provide instruments to the OR for a surgical case that is already underway. After meetings and discussions with the OICS Task Force, CMS subsequently clarified in 2015 that "IUSS is not the same thing as "short-cycle" sterilization, which is a form of terminal

sterilization that is acceptable for routine use for a wrapped/contained load where pre-cleaning of instruments is performed according to the manufacturers' instructions, and the load meets the device manufacturer's instructions for use (IFU), includes use of a complete dry time and is packaged in a wrap or rigid sterilization container validated for later use. Use of short-cycle sterilization is particularly common in facilities that perform eye surgery and is acceptable when all IFU (ie, sterilizer, device, and container manufacturer's) are followed. However, there appears to be confusion in the field about the differences between IUSS and short cycle sterilization, and misuse of the term IUSS to refer to what is in fact short cycle sterilization. Facilities performing surgery should understand the differences between IUSS and short cycle sterilization in order to ensure that they comply with Medicare infection prevention and control requirements".<sup>38</sup>

## SHORT-CYCLE, SEQUENTIAL, SAME-DAY USE

The importance of complete drying of ophthalmic surgical instruments after steam sterilization depends on how the load is handled and stored on completion of the sterilization cycle. Moisture present after sterilization could provide a vector for microorganisms from the environment or non-sterile hands to enter a closed packaging system and contaminate the contents of the load. Therefore, unless otherwise specified by a packaging system's IFU, wrapped instruments being terminally sterilized before overnight storage should always be completely dry. This is also necessary to ensure integrity of the microbial barrier of any instrument packaging system or wrapping that will be handled by nonsterile hands.

Short-cycle sterilization for a contained wrapped or unwrapped load is appropriate for sequential same-day instrument reuse. Unwrapped sterile instruments should be protected from microbial contamination during transfer from the point of sterilization to the point of use. This might be accomplished with an approved covered containment device. Some sterilizer IFU permit interruption of the drying phase under certain circumstances.<sup>39</sup> The risk for infection resulting from sterile moisture in the container or on the instruments when the undried (wet) and unwrapped instruments are sterilized for sequential same-day use and are brought from the sterilizer directly to the operating room in a covered containment device has not been established.

In the 2014 survey of OOSS member ASCs, short-cycle sterilization was commonly used between sequential same-day cases (52.3% of respondents). The most commonly used sterilizers for sequential same-day cases were the AMSCO (STERIS, Mentor, OH) (42.1%) and the STATIM (SciCan, Canonsburg, PA) (28.4%). Overall, 49.7% of responding facilities had a STERIS AMSCO brand sterilizer and 44.3% had a SciCan STATIM brand sterilizer. The following processing methods for instrument sterilization between sequential same-day cases were commonly used: STATIM cassette (28.2%), closed sterilization containers (26.0%), and wrapped (18.2%).

An OICS Task Force-initiated study funded by OOSS, ASCRS, and AAO evaluated current practices for ophthalmic instrument sterilization using the short cycles of 2 FDA-cleared steam sterilizers that are in common use according to the OOSS ASC survey.<sup>36</sup> The first was a STATIM 2000 sterilizer (SciCan) using the metal cassette provided with the STATIM and the second was an AMSCO Century V116 pre-vacuum sterilizer (STERIS) using a Case Medical SteriTite rigid container (Case Medical, South Hackensack, NJ). The evaluations were performed by an independent medical device validation testing laboratory (Highpower Validation Testing and Lab Services, Rochester, NY) and compared wrapped, contained, and unwrapped instruments with and without interruption of the drying phase. Separate studies were performed to verify the sterilization efficacy of the 2 sterilizers with short cycles as well as the sterility of any moisture present within the 2 instrument-containment devices. Phaco tips and handpieces were chosen for evaluation because they represent the most difficult items on a cataract tray to clean and sterilize. Phaco handpieces from each of the 3 major phaco machine manufacturers in the United States—the Infiniti (Alcon), the Signature (Abbott Medical Optics/Johnson & Johnson Vision), and the Stellaris (Bausch & Lomb)—were tested.

Terminal sterilization was performed on each model of phaco handpiece for overnight storage, and sterilization efficacy was successfully verified for the STATIM and AMSCO sterilizers. These were wrapped (STATIM) or contained (AMSCO) loads that were completely dried and stored for 7 days before sterility testing. Short-cycle sterilization of each handpiece model using unwrapped (STATIM) or contained (AMSCO) loads was also verified when the drying phase was interrupted after 1 minute. This simulated prompt use of sterilized instruments that were still wet for a sequential case on the same day. Finally, a separate series of studies tested the phaco handpieces and containers for moisture sterility after a 3-minute storage/transit period following short-cycle unwrapped or contained sterilization with interruption of the drying phase after 1 minute. A storage/transit time of 3 minutes was used to approximate the upper limit of time needed to transfer a containment device to a nonadjacent operating room. Sterility was verified for each handpiece model and containment device.

Based on these study results and data from the sterilizer manufacturers themselves, it is our position that unwrapped settings and short-cycle sterilization used in accordance with the IFU of FDA-approved sterilizers are appropriate for routine use in between sequential same-day ophthalmic cases.<sup>36</sup> Moist or unwrapped instruments sterilized for sequential same-day use should be promptly transported from the sterilizer to the operating room within a covered containment device to prevent microbial recontamination. The covered instrument-containment device should only be opened in the operating room. If wet, sterile wrapped or unwrapped instruments should only be handled by sterile gloved and gowned staff in a sterile field. Phaco handpieces are immediately primed with a balanced salt solution

and remain wet as they sit on the sterile instrument table. Therefore, the theoretical risk from residual moisture would primarily be in recontamination of a sterile load that was being handled, stored, or transported outside the operating room. Although proximity of the sterilizer to the operating room is preferred for unwrapped sterilization, the OICS Task Force study showed that moisture in the covered containment device did not result in recontamination for at least 3 minutes. It is our position that complete drying is not necessary to maintain the sterility of wrapped or unwrapped ophthalmic instruments that are kept in the covered containment device until retrieved by sterile gloved and gowned staff within the OR for the subsequent case after some short delay.

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.<sup>11</sup> Glutaraldehyde is not recommended for sterilizing laser contact lenses or intraocular instruments because of the toxicity of glutaraldehyde residues resulting from inadequate rinsing or contamination during post-sterilization handling.

### CARBON FOOTPRINT OF CATARACT SURGERY

Climate change, or global warming, is a serious public health concern, and the health care industry is a major source of emissions, responsible for 10% of the total carbon footprint in the United States.<sup>34,40–44</sup> Phacoemulsification in the United Kingdom emits approximately 180 kg of carbon dioxide equivalents (CO<sub>2</sub>-e) per surgery, similar to the emissions from driving an average U.S. car for approximately 430 miles. Over one half of this carbon footprint originates from the procurement of largely single-use supplies. Emissions from phacoemulsification in a high-volume Indian facility are less than 1/10 that in the U.K. with comparable safety outcomes. This is in large part because of their extensive reuse of surgical materials and instruments and their strict surgical and sterilization processes.<sup>43,44</sup>

Most eye surgery centers can reduce their environmental emissions by minimizing material use, reusing or reprocessing surgical materials when applicable, engaging their supply chain in environmentally preferred purchasing, working with facilities management to reduce energy consumption, safely increasing efficiency of OR turnover, and optimizing surgical and central sterile processes. Physician preference cards for surgical trays and disposable custom packs should be reevaluated regularly. For reusable instrumentation, the environmental footprint can be reduced by removing repeated or unnecessary steps in the cleaning and sterilization process, sourcing energy-efficient appliances, properly cleaning and maintaining machines, and removing unnecessary instrumentation from surgical trays. Consideration should be given to using rigid sterilization containers or working with waste management to find a recycling option for blue instrument pack wrapping. For

more information on reducing environmental emissions, visit the websites of Practice GreenHealth<sup>A</sup> or Healthcare Without Harm.<sup>B</sup>

### COST-EFFECTIVENESS OF CATARACT SURGERY

Cataract surgery is the single most common surgical procedure in medicine today. The volume and need for cataract surgery are projected to significantly increase over the next 20 years. We quote and agree with this summary from the *Cataract in the Adult Eye Preferred Practice Pattern* published in 2016 by AAO<sup>45</sup>:

“With large projected increases in the elderly population worldwide, the significant cost burden of cataract surgery will continue to increase for every global healthcare system. Because of the societal imperative that cataract surgery be both safe and cost-effective, it is important to evaluate unproven and potentially unnecessary practices based on carefully monitored studies of surgical outcomes.

In many countries, sterilization and aseptic protocols for ophthalmic surgery have been arbitrarily defined by national regulatory agencies. Many of these measures originated from studies in non-ophthalmic specialties and may not be specifically validated for ophthalmic surgery, where the source of most infections is the patient’s own eyelid and external ocular flora. For example, using infection control protocols based on continuous monitoring of outcomes data, one eye hospital in India reported an endophthalmitis rate of only 0.09% (0.02% of phaco cases) in more than 42,000 consecutive cataract surgeries using short-cycle steam sterilization and continuous reuse of gowns, gloves, surgical tubing, and irrigating solutions.<sup>46</sup> Costlier new infection control measures for ophthalmic surgery should not be arbitrarily imposed by regulatory agencies without evidence based support (III, good quality, strong recommendation).”

More recent studies from 10 regional eye hospitals comprising the Aravind Eye Care System (AECS) in Tamil Nadu, India, document an endophthalmitis rate of 0.02% in 555 550 consecutive cataract surgeries in which all eyes also received topical and intracameral antibiotic prophylaxis.<sup>47–49</sup> Within the AECS, many disposable supplies, such as surgical gloves, gowns, I/A tubing, irrigation bottles, blades, and cannulas, are routinely reused to reduce cost and waste. Multiple patients simultaneously have cataract surgery in a single operating room that contains multiple surgical tables and teams. Operating surgeons and scrub nurses do not rescrub, regown, or reglove between consecutive cases. Despite these numerous practices that would be prohibited in any licensed North American surgical facility, the AECS endophthalmitis rates are outstanding and statistically identical to the pooled self-reported rate of all U.S. ophthalmic ASCs responding to the 2014 OOSS survey.<sup>47</sup> The potential clearly exists that many practices mandated by regulatory and licensing agencies might not have a proven benefit for ocular surgery and therefore might not justify the significantly higher cost and carbon footprint they entail. Further studies could be

performed to evaluate some practices, such as the reuse of disposable instruments. In addition, given the current and historically low rates of post-cataract endophthalmitis, costly new regulations should not be imposed without evidence of benefit.<sup>45</sup>

### DISCLAIMER

These guidelines are intended to assist ASCs in their efforts to adopt appropriate practices for the cleaning and sterilization of intraocular surgical instruments. They are provided for scientific, educational, and informational purposes only. They are not intended to establish the only acceptable or appropriate standards, methods, or practices for cleaning and sterilizing such instruments. Adherence to these guidelines does not guarantee compliance with any legal or regulatory standards, including without limitation the criteria for ASC licensure or certification, or Medicare or other third-party payer reimbursement. In addition, any discussion or recommendation in these guidelines regarding the use of drugs or devices that deviate from the FDA-approved use of such products (ie, an “off-label use”) is made for scientific and educational purposes only and intended to fall within the FDA’s “practice of medicine” exception for off-label uses. Individual physicians must make independent judgments as to whether the off-label use of a particular drug or device is appropriate and in the patient’s best interest based on the facts and circumstances of the particular case.

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