The variety of equipment available and the complexity of devices make it essential to consult and follow the manufacturer's IFU to achieve optimal cleaning effectiveness.

IX.f.3. The operator of the mechanical washer should consult with the mechanical washer manufacturer's written IFU to determine
- the level of decontamination that is achieved (eg, low-level, intermediate) and
- how to monitor the cycle to determine that the parameters necessary to render the processed items safe to handle are met (see Recommendation XVI).

[4: Benefits Balanced with Harms]

Recommendation X

Surgical instruments should be inspected and evaluated for cleanliness and correct working order after decontamination and if soiled or defective, should be removed from service until they are cleaned or repaired.[1]

Items that are not clean or do not function correctly can put a patient at risk for injury or SSI. Inspection and evaluation provide an opportunity to identify soiled or damaged instruments and to remove these items from service until they are cleaned or repaired.

X.a. Items should be inspected and evaluated for
- cleanliness;
- correct alignment;
- corrosion, pitting, burrs, nicks, cracks;
- sharpness of cutting edges;
- wear and chipping of inserts and plated surfaces;
- missing parts;
- integrity of insulation on insulated devices;
- integrity of cords and cables;
- clarity of lenses;
- integrity of seals and gaskets;
- presence of moisture;
- correct functioning; and
- other defects.

[2: Moderate Evidence]

Use of instruments that are not thoroughly cleaned, are damaged, or do not function correctly poses a risk to patient safety.

X.a.1. Powered equipment should be checked before use to verify that power ceases when the device is turned off and that the device is functioning as intended. Instruments that require power to operate should be attached to the power source for testing as specified in the manufacturer's written IFU. *[3: Limited Evidence]*

Power that does not cease when a powered device is turned off can cause harm to personnel or patients. Verifying that instruments requiring a power source are functioning as intended may help to prevent injury to patients and personnel.

X.a.2. Instruments that require assembly or that work with an accessory instrument should be assembled to confirm correct fit and that locking mechanisms work as intended. After inspection, these instruments should be disassembled before packaging for sterilization. *[3: Limited Evidence]*

Attachments and accessory items not designed to the instrument manufacturer's specifications may not fit or seal correctly and may be ejected with force and pose a risk to patients and personnel. Disassembling items before sterilization helps ensure that the sterilant contacts all surfaces of the item being sterilized.

X.a.3. Lighted magnification should be used to inspect hard-to-clean areas of devices for cleanliness. *[2: Moderate Evidence]*

An instrument that appears clean to the naked eye may harbor debris that cannot be seen without magnification.

Lipscomb et al compared the results of 202 cleaned and decontaminated instruments by first visually examining them and then examining them using microscopic analysis (ie, episcopic differential interference contrast microscopy). Visual inspection by the researchers showed that 37% of the instruments (75 of 202) had a low level of contamination, and 4% (eight of 202) had a high level of contamination. The microscopic assessment showed 66% (133 of 202) were severely contaminated and 27% (55 of 202) were moderately contaminated.

X.a.4. The internal channels of reusable arthroscopic shavers should be inspected using an endoscopic camera or borescope. *[2: Moderate Evidence]*

It is not possible to visually inspect lumens without a device that can penetrate the lumen. Retained organic material or debris in lumens can lead to patient injury.

In a 2007 case-control study, Tosh et al reported on an outbreak of *Pseudomonas aeruginosa* SSI in seven patients on whom the same arthroscopic shaver was used. Upon investigation, the researchers found debris in a lumen of the shaver although the shaver had undergone repeated decontamination and sterilization procedures. The researchers concluded that the retained surgical debris allowed the bacteria to survive the sterilization process, and the subsequent use of the shaver was likely related to the SSI outbreak.

The FDA recommends that the inside of the device be inspected and that consideration be given to using a 3-mm videoscope

to inspect the channels of the shaver hand piece.

X.a.5. Insulated devices should be visually examined and tested using equipment designed to detect insulation failure. *[2: Moderate Evidence]*

Electrode insulation damage caused during use or processing may create an alternate pathway for the electrical current to leave the active electrode and cause patient injury. Some insulation failures are not visible. Damage to insulation may not be seen during visual inspection.

In a two-part study, Espada et al tested 78 robotic and 298 insulated laparoscopic instruments for insulation failure using a porosity detector. The researchers found that 25 of 78 robotic instruments (32%) had an insulation defect, but only seven of 25 defects (28%) were visible to the naked eye. Thirty-nine of the 298 laparoscopic instruments (13%) had an insulation defect, but only 27 of the 39 defects (69%) were visible to the naked eye.

In a nonexperimental study that examined insulated instruments from four hospitals, Montero et al used a porosity detector to detect insulation failure. The researchers found that 33 of 226 insulated instruments (15%) had an insulation failure. There was no significant difference in insulation failure between hospitals that routinely checked for failure and those that did not.

Serious patient injury, such as thermal bowel injury, can occur when instruments with insulation defects are used.

X.b. Defective instruments should be identified, removed from service, and repaired or discarded. *[3: Limited Evidence]*

Identification of defective instruments and removal from service facilitates segregation of these instruments from instruments to be used when assembling sets. Removing defective instruments from service reduces the risk that defective instruments will be used.

X.c. Instruments should be thoroughly dried before they are assembled in packaging systems in preparation for sterilization. *[3: Limited Evidence]*

Moisture can interfere with sterilization processes. Excess moisture on instrument surfaces can alter the content of steam and can pose a challenge for effective heating of the instrument during steam sterilization. Hydrogen peroxide vapor and hydrogen peroxide gas plasma sterilization cycles may abort in the presence of excess moisture. Ethylene oxide combines with water to form ethylene glycol (ie, antifreeze), which is toxic and is not removed during aeration.

Recommendation XI

Prevention of toxic anterior segment syndrome (TASS), an acute inflammation of the anterior segment of the eye, requires thorough cleaning and rinsing of intraocular instruments and strict adherence to the manufacturer's written IFU and to professional guidelines.

Toxic anterior segment syndrome is a complication of anterior segment eye surgery and is most commonly associated with cataract surgery. According to the FDA, hundreds of surgical centers in North America reported outbreaks of TASS between 2000 and 2011.

Most instances of TASS appear to be related to instrument processing. Factors associated with TASS include

- contaminated instruments,
- contaminated ultrasonic cleaners,
- detergent residues (eg, soaps, enzymatic cleaners) remaining on instruments,
- insufficient rinsing of instruments,
- endotoxin residues on instruments,
- steam impurities during steam sterilization,
- use of glutaraldehyde during processing,
- dried debris and residues of ophthalmic viscoelastic (OV) material remaining on instruments,
- use of reusable cannulated instruments, and
- insufficiently dried lumens.

Further research is warranted to determine the multifactorial risk factors for TASS.

In response to a number of TASS outbreaks, the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses issued recommended practices for processing ophthalmic instruments. The ASCRS formed a task force composed of members of industry and the ASCRS to educate surgeons who perform anterior segment eye surgery on the causes, symptoms, and treatment of TASS, and to help investigate outbreaks of TASS. The task force posted a questionnaire on the ASCRS web site to allow surgeons to self-report cases of TASS and provide information about instrument cleaning and processing practices; surgical protocols; substances and techniques used for cleaning phacoemulsification and irrigation/aspiration hand pieces; and products used during the perioperative period, including medications, irrigation fluids, cannulas, and instrument tips. The questionnaire has been maintained on the ASCRS web site since June 2007. In addition, members of the TASS task force made site visits at the request of personnel from the facilities reporting TASS cases.

Cutler Peck et al conducted a retrospective analysis of 77 questionnaires submitted to the ASCRS web site from June 1, 2007, through May 31, 2009, and evaluated the findings from 54 TASS task force site visits conducted between October 1, 2005, and May 31, 2009. The researchers found there were common practices associated with TASS that included

- inadequately flushing phacoemulsification and irrigation/aspiration hand pieces,

- using enzymatic cleaners,
- using detergents at the wrong concentration,
- using contaminated fluids in ultrasonic cleaners,
- adding antibiotics to balanced salt solutions,
- using epinephrine with preservatives,
- using preoperative skin antiseptics incorrectly,
- using powdered gloves,
- reusing single-use products, and
- failing to maintain instruments correctly.

The researchers concluded that changing these practices could help prevent TASS.

Bodnar et al conducted a retrospective analysis of 130 questionnaires submitted to the ASCRS web site from June 1, 2007, through March 1, 2012, and of information from 71 site visits conducted by the TASS task force between October 1, 2005, and December 31, 2011. The researchers noted several trends when comparing their data with the data previously analyzed by Cutler Peck et al. When analyzing data obtained from the questionnaires, the researchers found a 26% reduction in sites reporting inadequate flushing of hand pieces and a 27% increase in sites reporting the use of deionized or distilled water for the final rinse. When analyzing data from the site visits, the researchers found a 36% reduction in the use of epinephrine with preservatives and a 36% reduction in the use of enzymatic detergents; however, they found a 21% increase in the handling of intraocular lenses and instrument tips with gloved hands, a 47% increase in poor instrument maintenance, and a 34% increase in use of contaminated fluids in ultrasonic cleaners. The researchers concluded that education had improved some practices but had not improved others.

The findings from these studies indicate a need to improve education of personnel who use or process ophthalmic instruments regarding best practices for care and processing of ophthalmic instruments to prevent TASS.

XI.a. Immediately after use during the procedure, ophthalmic instruments should be wiped clean with sterile water and a lint-free sponge and flushed or immersed in sterile water according to the manufacturer's written IFU. *[1: Strong Evidence]*

Ophthalmic viscoelastic material can harden and dry within minutes, making subsequent removal difficult. Keeping OV or other organic material moist can prevent drying and hardening of such material on ophthalmic devices.

Biofilm adheres to the surfaces of instruments and is very difficult to remove. Keeping the OV and organic material moist helps facilitate removal and prevent biofilm formation.

XI.b. The instrument manufacturer's written instructions for cleaning should be reviewed and followed. *[2: Moderate Evidence]*

The method of cleaning and the compatibility of cleaning products may vary among instrument manufacturers. Instructions for cannulated instruments indicate the type and volume of solution to be used for rinsing and cleaning and the number of times and for how long the cannula should be flushed.

XI.c. Adequate time, an adequate number of personnel, and sufficient instrument inventory should be provided to permit thorough instrument cleaning and sterilization. *[2: Moderate Evidence]*

Time constraints may create a disincentive for personnel to adhere to recommended cleaning and disinfection procedures.

In a retrospective analysis of 77 questionnaires and 54 site visits to identify risk factors associated with TASS, an ASCRS task force reported that 23 of the sites (43%) were noted to have an insufficient number of instrument sets or of personnel to provide adequate time to process ophthalmic instruments. Personnel at six sites (11%) did not follow the manufacturer's written IFU, and four individuals were observed to perform inadequate flushing of phacoemulsification and irrigation/aspiration hand pieces.

XI.c.1. An inventory of ophthalmic instruments sufficient to meet the anticipated demand should be maintained. *[2: Moderate Evidence]*

An adequate instrument inventory provides sufficient time for personnel to follow correct cleaning, decontamination, and terminal sterilization procedures and helps eliminate or reduce the need for immediate-use steam sterilization (IUSS).

XI.d. Intraocular instruments should be cleaned in a designated cleaning area. Intraocular instruments should be cleaned separately from general surgical instruments. *[2: Moderate Evidence]*

Procedures for processing ophthalmic instruments differ from those for general surgery instruments. Cleaning intraocular instruments separately from general surgery instruments can help prevent cross-contamination with bioburden from heavily soiled nonophthalmic surgical instruments.

XI.e. Single-use disposable cannulae should be used whenever possible. *[1: Strong Evidence]*

Thorough cleaning of these devices is difficult because the lumens are exceptionally small. Use of reusable cannulae has been associated with TASS.

In a 2006 review of the literature to identify possible causes of TASS, Mamalis et al identified detergent residues and denatured OV material on reusable intraocular instruments as possible causes.

XI.f. The scrub person should flush the irrigation and aspiration ports of phacoemulsification and irrigation/aspiration hand pieces and accessory reusable tips and tubing with sterile water according to the manufacturer's written IFU

before disconnecting the hand piece from the unit. *[2: Moderate Evidence]*

Inadequate flushing of phacoemulsification hand pieces has been associated with TASS. When OV material is allowed to dry on phacoemulsification hand pieces, it is difficult to remove. Flushing immediately after the procedure can help prevent OV material from drying. Flushing the hand piece prevents buildup of OV material inside the hand piece, which is difficult to remove during cleaning.

XI.g. Cleaning products used to clean intraocular instruments should be selected and used in accordance with the instrument manufacturer's written IFU. · *[2: Moderate Evidence]*

Some IFU for ophthalmic instruments recommend against the use of enzymatic detergents.

In a retrospective analysis of questionnaires and site visits to examine instrument cleaning and processing of extraocular and intraocular products used during cataract surgery, Culter-Peck et al identified common practices associated with TASS. They analyzed 77 questionnaires and 54 site visits; 909 cases of TASS were reported. Use of enzymatic cleaners was reported in 36 questionnaires (47%) and observed at 48 sites (89%). The researchers concluded that the benefit of using enzymatic cleaners to clean ophthalmic instruments had not been established and, in fact, was prohibited in some manufacturers' instructions for specific-use products.

In a randomized controlled trial (RCT) to determine whether enzymatic detergents used to clean ophthalmic instruments could cause TASS, Leder et al randomly assigned rabbits into seven treatment groups to receive intracameral injection of three different doses of enzymatic detergent. Although the enzymatic detergent caused a severe inflammatory response, the response did not include TASS. The researchers concluded that given that patient exposure to an enzymatic detergent would be significantly less than the lowest dose used in the experiment, enzymatic detergent on ophthalmic instruments was not a cause of TASS.

Mamalis and Edelhauser raised concerns about the validity and generalizability of the study conducted by Leder et al in a letter to the editor and stated "there are significant differences in the inflammatory reaction of the rabbit, as well as their response to toxic insults, that make it difficult to extrapolate findings from the rabbit to the human." They noted that the conclusions of the researchers were inconsistent with the results presented in the study and contended that the results of the study actually provided additional support for the role of enzymatic detergents as a potential cause of TASS.

Following the instrument manufacturer's IFU helps ensure compatibility of the cleaning product with the device. Incorrect selection and incorrect detergent dilution has been associated with TASS.

XI.g.1. After cleaning, ophthalmic instruments should be rinsed with a copious amount of water. *[2: Moderate Evidence]*

Thorough rinsing helps remove residual cleaning product. Detergent residue has been identified as a possible cause of TASS, although studies performed on rabbits have not supported enzymatic detergent residues alone as a cause of TASS. ·

In a review of the literature, Ozcelik et al identified detergent residues/soaps, enzymatic cleaners, inappropriate rinsing, and dried debris and OV material residues as potential causes or risk factors for TASS. However, in an RCT to investigate whether enzymatic detergents used to clean ophthalmic instruments could cause TASS, Leder et al concluded that enzymatic detergent residues alone did not cause TASS. The researchers randomly assigned 35 rabbits into seven treatment groups (ie, low, medium, and high detergent concentration of three detergents, plus a control group of untreated rabbits) and injected their eyes with detergent accordingly. The enzymatic detergents caused a severe but unusual response; however, this response has not been reported in humans.

When the instructions for cleaning are strictly followed, it is possible to remove all detergent. ·

XI.g.2. A final rinse should be performed with sterile distilled or sterile deionized water. · · *[2: Moderate Evidence]*

Untreated water may contain endotoxins, which are heat stable and as such will remain biologically active after sterilization and which have been implicated in occurrences of TASS. · · ·

Residual enzymes and detergents not rinsed from instruments have been associated with TASS. · · ·

XI.g.3. After cleaning, lumens should be rinsed with sterile deionized or distilled water. The rinse fluid should be expelled from the lumen into a drain and not back into the rinse water. Lumens should be dried with medical-grade compressed air. · *[2: Moderate Evidence]*

Rinsing removes detergent and other residue from the lumens. Expelling the lumen rinse into a drain prevents reuse of the rinse water and prevents recontamination of the lumen with debris that has been rinsed out of the lumen. Compressed air forced through the lumen eliminates moisture that can serve as a medium for microbial growth.