Best Practices for Processing Ophthalmic Instruments

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****This in-service has been Approved by the CBSPD, Inc. for 1.5 CEUs.**

Objectives

- To identify AAMI recommended cleaning protocols
- To review the AAMI preparation recommendations for instruments and sets
- To review the recommended procedures to prevent Toxic Anterior Segment Syndrome (TASS)

Background

Over the past 15 years, the time to perform a cataract procedure has decreased from 2.5 hours to 15-20 minutes. The cost for a set of cataract instruments can range from $6,000 to $8,000 or more. Due to the short amount of time between cases, there is an urgency to turn the instruments around for the next case.

Ophthalmic (eye) Instruments come in contact with the eye and thus body fluids. They are considered contaminated and **must receive the entire cleaning and sterilization process between patients.**

Manufacturer's Instructions

The surgical Instrument manufacturer should:

- specify the pH of detergent (e.g. neutral pH)
- may recommend a pre-soak in an enzymatic cleaner to help remove protein soils (e.g. body fluids)
- specify if any special cleaning implements are needed (e.g. to clean out lumens)
- specify water quality for cleaning and rinsing

However, as a sterile processing professional, you need to reconcile this information with standards from the Association for the Advancement of Medical Instrumentation (AAMI), the American Society of Ophthalmic Registered Nurses (ASORN), the Association of peri-Operative Registered Nurses (AORN),

the American Society of Cataract and Refractive Surgeons (ASCRS) and the Centers for Disease Control (CDC).

Manufacturer's Instructions are also known as Instructions for Use (IFUs). A copy should be kept on file and readily available to processing personnel. It is important to make sure that the IFUs are followed each and every time instruments are processed. Furthermore, the IFUs should be updated every two years.

Training and Competencies

Employee training should complement the AAMI guidelines as well as manufacturers' instructions. Eye instrumentation is extremely delicate and as such requires very special handling and processing to prevent damage. All personnel handling eye instrumentation should ensure careful handling. Employee competencies should be verified in the processing protocols for processing ophthalmic instruments. These competencies should be verified initially and annually. It is recommended to use resources such as ophthalmic instrument company's educational materials and AAMI standards for reference.

Cleaning

According to AAMI, cleaning is the removal of contamination from an item to the extent necessary for further processing or for the intended use. It involves the use of detergent and water for the removal of adherent visible soil (i.e. blood, pus, protein) from the surfaces, crevices, serrations, jaws and lumens of instruments, devices and equipment, by a manual or mechanical process.

Due to their design, eye instruments are challenging to clean. They can have very small lumens. Their very delicate tips can easily break or be damaged by improper handling.

Decontamination

OSHA defines decontamination as, "the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." [29 CFR 1910.1030]. Decontamination is generally used in health care facilities to refer to all pathogenic organisms, not just those transmitted by blood. It is the first and most critical step in breaking the chain of disease transmission.

Cleaning is important because the process of disinfection or sterilization is totally dependent upon direct contact of the sterilant or disinfectant with the surface of the item. Any protein left on items can be "baked on" in the sterilizer.

Both AAMI and AORN have a major focus on Toxic Anterior Segment Syndrome also known as TASS. This condition is an acute inflammatory response of the anterior chamber of the eye. If not recognized and treated in a timely manner, TASS can lead to severe visual impairment. There are many causes of

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TASS including detergents, water quality, steam quality, instruments, etc. The American Society of Cataract and Refractive Surgeons (ASCRS) have identified the following as major causes of TASS:

- Detergent residues (in general)
- Preservatives
- Residues from sterilization processing
- Residues of detergents inside a reusable cannula or instrument
- Cement sealant on bags of irrigating solution which has leached out

All of these can induce TASS and cause severe damage to ocular tissue. Particular care must be taken in the processing of intraocular surgical instruments to help ensure that foreign substances or materials associated with the instruments will not be introduced into the anterior chamber of the eye during surgery. Outbreaks of TASS have often been linked to the failure to follow the processing procedures recommended by the instrument manufacturer. Specific instrument cleaning and sterilization recommendations intended to diminish the risk of TASS associated with intraocular surgical instruments have been published by the American Society for Cataract and Refractive Surgery (ASCRS, 2006). These recommendations have also been published in AAMI ST-79 as an Annex.

Some of the major recommendations include:

- An adequate inventory of the necessary intraocular surgical instruments should be maintained in order to allow for the timely processing of instruments between cases. This can be a major issue in surgery centers.
- Insufficient inventory of instruments leads to short cuts in cleaning
- Adequate time must be allowed for processing instruments according to the manufacturer's instructions; otherwise, the cleaning and sterilization of the instruments **will be ineffective.**
- A designated cleaning area and equipment specific to the cleaning of intraocular surgical instruments should be identified.
- Whenever possible, intraocular surgical instruments should be processed separately from general surgical instruments and equipment in order to reduce the potential for cross-contamination by material or residue from the general surgical instruments
- Instruments should be pre-cleaned immediately following use. Gross debris should be removed, and **instrument lumens should be flushed with sterile distilled water or another suitable agent as recommended in the room at the end of the procedure**
- Only cleaning agents that have been recommended by the manufacturer should be used.
- Particular attention should be paid to the specified concentration of the cleaning agent and to the recommended water quality.
- Final rinsing of the instrument should be performed with sterile, distilled, or deionized water, unless otherwise specified by the manufacturer.
- The water used to clean or rinse instruments should be discarded after each use.
- If an ultrasonic cleaner is used to process the instruments, it should be emptied, cleaned, rinsed, and dried at least daily or, preferably, after each use.
- Brushes and other cleaning tools should be cleaned and sterilized as recommended by the manufacturer at least daily or, preferably, after each use.

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- Cleaning and sterilization equipment should be properly maintained.
- Foreign materials such as endotoxin or heavy metals may be deposited onto the instruments during processing and induce TASS
- Water used for the final rinse of the device should have a low endotoxin content to avoid pyrogens on processed devices.
- Adequate cleaning and rinsing should result in low bioburden. Cleaning is essential to the effectiveness of terminal sterilization and to the protection of patients from pyrogens.

The Decontamination area should be a separate area that is dedicated to cleaning of ophthalmic instruments. The cleaning of ophthalmic instruments should take place away from the area where any other types of surgical instruments are cleaned. For example, in a separate tote bin not in the same sink. The temperature of the area should be 60-65°F and the humidity 30-60%. There should be 10 air exchanges per hour under negative pressure. The temperature and humidity should be monitored daily and documented.

You must have manufacturer's instructions for cleaning of all devices, including the recommended method (i.e. manual, mechanical), cleaning implements and chemicals recommended (e.g. detergents).

The steps in the cleaning process include:

- Contain contaminated items at the point of use
- Transport to Decontamination
- Sort
- Soak
- Wash
- Rinse/Dry

Pre-cleaning/Transport - Instruments should be pre-cleaned in the OR immediately following use. Gross soil and debris should be removed and lumens flushed with sterile distilled water (or other agent as recommended by the instrument manufacture). Keep instruments moist to avoid drying of soils. This can be accomplished by placing a towel, moistened with water, over the instruments then placing in a closed plastic bag. Some instrument manufacturers are now recommending cleaning immediately or within 30 minutes of use.

Transport of used instruments should be in closed containers to confine and contain them. The container should be labeled as biohazard (OSHA). A biohazard bag can be used but only if the instruments cannot puncture through the bag.

Soaking of instruments helps to remove soils. Soaking can be performed using a detergent. However, the use of enzyme detergents is preferred – but only if recommended by the instrument manufacturer. Do NOT soak instruments in fluids for prolonged periods of time because biofilms can form. Biofilms generally form on any surface that is exposed to non-sterile water or other liquids and is consistently found in many environments including industrial and medical systems.

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Cleaning – You need to take special precautions with eye instruments due to their delicate nature and design. Due to the sensitivity of eye tissue, cleaning becomes a challenge. Manual cleaning may be the only validated method. Yet, manual cleaning is not as controlled (standardized) as mechanical cleaning. Some eye instrument manufacturers do not recommend ANY detergent. This causes confusion for the end user. We cannot effectively clean unless we use a detergent and water!

Enzymatic Cleaners are organic substances which assist in the breakdown of soils. They facilitate the removal of blood and protein soils and are excellent for devices with lumens. Their effectiveness is dependent upon concentration, use temperature and contact time. They are sold as liquid concentrates or powder. Generally, they are more effective in warm water. Enzyme activity can be inactivated above certain maximum temperatures (140°F). You should have a thermometer to monitor the water temperature to make sure you do not exceed the detergent manufacturer's recommendations.

Principles of Cleaning - You must have manufacturer's written instructions for cleaning of all the devices you process. All items must be in the open position. Multi-part items should be disassembled, if possible. You must wear personal protective equipment (PPE) including an impervious gown, head cover, shoe covers, cuffed gloves, face shield and fluid resistant mask. (NOTE: The head cover is not part of PPE but keeps fallout from the head and hair from getting into sets).

Manual cleaning may be the only cleaning process available. Items should be completely submerged (if immersible). It is preferable to use the 3-sink method; one to wash, to rinse, and for the final rinse. Manual cleaning can also be used to remove deposits which were not removed during the pre-soak. Manual cleaning detergents are usually used for manual cleaning and as a pre-soak. They range from low foam to high foam products. Generally they have a neutral pH of 7 to 9. They are sold as concentrates so they must be diluted correctly. Always measure and dilute the detergent as specified by the detergent manufacturer. Make sure your sink or container used for cleaning is marked with the water level to make sure the detergent gets diluted properly. The water used to clean instruments should be discarded **after each use.**

Manual Cleaning Implements - You can use soft bristle brushes (of various sizes and lengths (avoid metal brushes)) or soft cloths. Do not use any abrasive items, sponges or cleaning implements with wood handles (permeable). Implements used to clean instruments should be cleaned according to the manufacturer or **at least daily, preferably after each use.**

Specialty Cleaners – There are specialty cleaning and rinsing system for lumened devices such as Phaco and OZIL handpieces. These are excellent to clean and rinse lumens. However, you must disinfect and clean the device and tubings according to the manufacturer's IFUs and document the cleaning.

Diamond Blade Knives - Follow the instructions for use for the diamond blade you are processing. Generally, it is recommended that immediately after using a diamond knife, the blade should be rinsed with demineralized water, preventing cell particles or viscoelastic materials from sticking to the blade. Ultrasonically clean holding the knife and suspending only the blade into the fluid. The blade should not touch any other instruments or the sides of the cleaner. Never completely submerge a diamond knife in an ultrasonic cleaner. At all times, (except cleaning) the blade should be in the retracted position to

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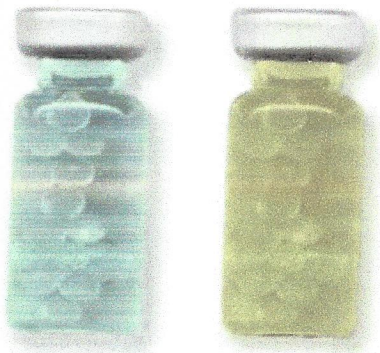
prevent damage. Inspect the blade using a microscope. Again, always follow the instructions for cleaning provided by the manufacturer.

Ultrasonic Cleaning uses sound waves transmitted through a solution. The sound waves produce tiny bubbles which implode which results in a scouring action that cleans. This mechanical process is known as cavitation. Ultrasonic cleaning is very effective to remove soils in hard-to-reach areas (box locks, mouth teeth, etc.). Generally, you can only use detergents specifically formulated for ultrasonic cleaners which are low foaming. The water temperature in the sonic cleaner is usually 100 - 140 ° F. Sonic cleaning can follow manual cleaning. The detergent solution should be changed at least daily, **preferably after each use. Outbreaks of TASS have been associated with contaminated sonic baths.** The unit should have a cover to contain aerosols. Items should not be stacked inside the sonic machine. Follow the sonic cleaner manufacturer's instructions regarding degassing cycles. Generally, each time the water is changed, a "de-gas" cycle should be run to remove the air from the water. The sonic should be run with the basket ONLY inside.

Containers/baskets should have perforations; they should be all metal mesh. Plastic baskets are not recommended because they absorb the sound waves. The sonic cleaner should be located in Decontamination Area. The sonic cleaning process is much more efficient than manual cleaning process alone.

According to AAMI ST-79, all cleaning processing equipment should be tested for efficacy weekly and the results documented. There are several methods; a tune containing a fluid which changes color from blue to yellow when cavitation is detected. This is a more objective test. However, you can also use aluminum foil.



TESTS FOR SONIC CLANERS
Aluminum foil test **Sonocheck Test**

Rinsing Is the most important part of the cleaning process. It is essential to remove loosened debris and remove all detergent residues (important to reduce the incidence of TASS). Rinsing should be performed with the volume and quality (sterile, distilled, or deionized water (if manual cleaning) of

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water recommended by the instrument manufacturer). The water used to rinse instruments should be discarded **after each use.** High purity water (e.g. sterile or reverse osmosis) is recommended for final rinse to prevent mineral deposits and TASS.

Lubrication - The use of instrument milk is beneficial to instruments to prevent corrosion and to keep moving parts from getting stiff. However, ***not all instruments should be lubricated.*** The instrument manufacturer will indicate if this process is recommended.

Inspection - Look for defects:

- Rusting common (especially if IUSS frequently used)
- Corrosion
- Damage to tips/ teeth
- Cords
- Lumens (e.g. Phaco handpieces)
- Stiffness
- Sharpness
- Spotting – Staining - Rust

Instruments should be inspected using lighted magnification. For best results, ophthalmic instruments can best be inspected using a microscope.

Delicate tips require protection. You can use small containers with silicone mats for individual instruments to provide ultimate protection. When handling eye instruments, place instruments in the tray so that they do not touch each other. Locate each instrument in the tray to prevent movement and possible damage during handling. Always keep delicate tips protected with a tip guard when the instrument is not in use. If using tip guards (protectors), you must obtain the manufacturer's instructions for use. Some protectors can "catch" onto the instruments which can result in damage. You can use any tip protector that has been approved for use in a sterilization system; foam sleeves, plastic; paper/plastic. Make sure the device can be held open with the protector on (e.g. scissors, clamps). You must have the manufacturer's data that the sterilant will penetrate through the tip protector.

Sterilization – Whether you are sterilizing the instruments in a conventional steam sterilizer or a table top (a table top sterilizer is defined by AAMI as a sterilizer having an internal chamber size of 2 cubic feet or less) you must read the IFUs for exposure time, temperature and cycle time. Some eye instrument manufacturers have European temperatures only (e.g. 273°F). In the US, we are not permitted to use this temperature. You must reconcile the IFU information with your sterilizer's IFUs. You may have to separate sets to meet IFUs (e.g. some instruments require 10 minutes exposure; you cannot sterilize all instruments for 10 minutes; only those whose manufacturer recommends this time).

Summary - Best practices for processing ophthalmic instruments requires knowledge of the standards and recommendations to prevent TASS. You must have the current manufacturers IFUs for the instruments, sterilizer, cleaning agents, packaging materials, etc. It all starts with the IFUs then follows with effective cleaning and rinsing. We must have the correct packaging methods and materials. The processing equipment should be maintained in good condition. We must properly handle items after

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sterilization. It is also important to monitor staff compliance with all stated policies and manufacturers' instructions. Make sure staff is properly trained with competencies verified annually.

Successful outcomes require we develop effective policies, train staff and monitor for compliance. We must be proactive in our practice, not reactive!

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Quiz – Processing of Ophthalmic Instruments

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/processing_ophthalmic_instruments_quiz.htm

Good Luck!

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