Cleaning & Care of Ophthalmic Instruments

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Intraoperative Steps

- Remove excess debris immediately after use
- Keep instruments wet to prevent surgical debris from drying
- Transport dirty instruments within an enclosed container

Pre-cleaning

- 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 by the manufacturer. The instruments should be maintained in a moist state before cleaning in order to prevent the drying of surgical debris onto or within them. In particular, OVDs can dry onto instruments very quickly following use and resist removal during subsequent cleaning.

Cannulated Instruments

- Phaco and I/A hand pieces should be thoroughly rinsed at the conclusion of each case with at least 120 mL of sterile water through both their irrigation and aspiration ports.

Decontamination Process

- Decontamination room should be setup up for efficient & effective cleaning while at the same time minimize potential environment contamination
- Never put ophthalmology surgical instruments through a mechanical washer
- Cleaning should be performed immediately after use prior to decontamination
- Always wear proper PPE when cleaning instruments
- Utilize neutral pH detergent for decontamination

Decontamination Process (cont.)

- Once initial cleaning to remove excess debris has been completed, decontamination process may begin
- If an ultrasonic cleaner is available, may be used for handheld instruments (not including phaco hand pieces)
- If a quick rinse is available, should be used to flush phaco hand pieces and all lumens
- Dispose of single use items
- Setup decontamination area with 1 disposable wash basin with detergent, followed by 3 sterile water wash basins

Decontamination Process (cont.)

- In 1st wash basin utilize disposable brush to scrub all instruments and disposable syringe to flush lumens and phaco hand pieces (120mL)
- After efficient decontamination utilize the 3 sterile wash basins to rinse all instruments individually
- Flush all lumens and phaco hand pieces with sterile water (120mL)
- Flush all lumens and phaco hand pieces with dry air prior to sterilization
- All brushes and syringes must be discarded after every use
- Place all instruments in proper sterilization containers

Ultrasonic cleaner

- Ensure that gross soil has been removed prior to placement in the ultrasonic cleaner.
- Check the manufacturer's DFU of instruments to identify instruments that should not be subjected to ultrasonic cleaning.
- An ultrasonic unit designated for cleaning medical instruments should be used.
- 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.

Rinsing

- Inappropriate use and incomplete rinsing of enzymatic detergents have been associated with outbreaks of TASS
- 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.
- 2 step rinse process
- Use of tap water for rinsing and for removal of detergent.
- The final rinse should be with sterile distilled or sterile deionized water.
- The water used to clean or rinse instruments should be discarded after each use.
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Cleaning agents

- Intraocular surgical instruments should be cleaned with neutral ph detergent.
- 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.
- 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.
- Cleaning tools such as syringes and brushes should be discarded after each use.
- Whenever possible, single-use brushes and other cleaning implements should be used and then disposed of afterwards.

Manufacturer's instructions

- The manufacturer's written instructions for the cleaning and sterilization of a particular intraocular surgical instrument should be read, understood, and followed by those responsible for processing the instrument; personnel training in the cleaning and sterilization procedure should be documented. All instructions should be readily accessible and periodically reviewed to ensure that they reflect the manufacturer's current recommendations.
- The cleaning process should be audited to ensure that the procedures being used comply with the manufacturer's instructions and that the personnel performing cleaning procedures have received documented training and have demonstrated competency in the cleaning process.

The DO's and Don'ts

- Never use metal brushes to clean instruments
- Use lubricating solution only on hinges
- Use soft nylon brushes, disposable soft toothbrushes
- Always double rinse to remove cleaner residue
- Discard all cleaning mixture and rinse water between cases
- Always flush phaco hand pieces & I/A tips to remove viscoelastic material

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Compliance Director

As Compliance Director, she works to design, develop, and prepare Ambulatory Surgery Centers for initial accreditation, reaccreditations, and licensure of new and existing centers.

Tina has effectively and successfully assisted over 30 ASC's in obtaining licensure, CMS accreditation and/or CMS deemed status (JC, AAAHC), and reaccreditations.

Sterilization

Understanding the Alphabet Soup

Terms Used in the Industry

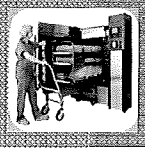
- Flash sterilization
- Immediate Use Steam Sterilization (IUSS)
- Short Cycle
- End of day processing
- Terminal Cycle

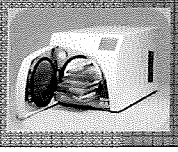
STERILIZATION – is the process by which all living micro-organisms both pathogenic and non-pathogenic including spores are killed.

STEAM STERILIZATION

Steam sterilizers are Class II medical devices subject to FDA approval per a 510(k) clearance letter.

The are available in a wide variety of shapes and sizes for sterilization of heat-stable **instruments**.





CMS DEFINITION OF IUSS

- The new term, IUSS, is still used to describe the process for steam sterilizing an instrument that is needed immediately, not intended to be stored for later use, and which allows for minimal or no drying after the sterilization cycle.
- IUSS is now the preferred term, because "flash" does not adequately convey the fact that sufficient time and a number of steps and safeguards are required to accomplish pre-cleaning procedures that are necessary to ensure sterilization. The old terminology is also not necessarily consistent with current recommendations for the length of cycles needed for IUSS and/or the need to use rigid sterilization containers designed specifically for IUSS.

Immediate-Use Steam Sterilization

•Multi-Society Statement (AAMI, AORN, APIC, IAHCSMM, ASC Quality Collaboration, Accreditation Association for Ambulatory Health Care, Inc)

• Flash sterilization now referred to as immediate-use sterilization
• "Immediate-use sterilization" is broadly defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field."

• Not to be stored for future use

• Not held from one case to another

Ref: http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf

Short Cycle

- It should be noted that IUSS is *not* equivalent to "short cycle" sterilization. Regardless of the cycle duration, correct use of a sterilization cycle for a wrapped/contained load that meets the device manufacturer's instructions for use (IFU) is the equivalent of terminal sterilization and is *not* IUSS if it includes use of a dry time and is packaged in a wrap or rigid sterilization container intended to be stored for later use.

CMS DEFINITION OF TERMINAL STERILIZATION

Surgical instruments must ordinarily be sterilized using terminal sterilization cycles within rigid sterilization containers, wrappers, or primary packaging designed to maintain the instruments' sterility and which allow the devices to be stored for later use ("terminal sterilization").

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- All instructions should be readily accessible and periodically reviewed to ensure that they reflect the manufacturer's current recommendations.
- The cleaning process should be audited to ensure that the procedures being used comply with the manufacturer's instructions and that the personnel performing cleaning procedures have received documented training and have demonstrated competency in the cleaning process.

Instrument inventory

- An adequate inventory of the necessary intraocular surgical instruments should be maintained to allow for the timely processing of instruments between cases. Adequate time must be allowed for processing instruments according to the manufacturer's written instructions; otherwise, the cleaning and sterilization of the instruments will be ineffective.
- Instrument sets should be identified per case and documented on the OR record.

TASS

WHAT DO WE DO ?

Toxic Anterior Segment Syndrome (TASS)

- The introduction of foreign material into the anterior chamber of the eye, which could result in an acute inflammatory response known as toxic anterior segment syndrome (TASS). This inflammatory response could lead to severe visual impairment if it is not recognized and treated in a timely manner.

Disease Entity

- TASS causes severe intraocular inflammation accompanied by diffuse corneal edema within 1-2 days of an anterior segment surgery.
- Symptoms
  - Deceased or blurry vision after surgery
  - Pain
  - Photophobia
  - Intraocular Pressure increase

The induction of TASS is thought to be associated with;

- contaminated balanced salt solution, endotoxins or particulate
- detergent residues
- denatured ophthalmic viscoelastic devices (OVDs),
- preservatives
- foreign matter
- Topical ointments

Primary Prevention

- Use proper balanced salt solution (BSS) with the correct pH, osmolality, and ionic composition.
- Avoid any kind of preservatives in intraocular solutions, intracameral medications or irrigating solutions
- Adequate sterilization of instruments
  - Double rinse
  - No wet instruments
  - Flush all cannula's

Identify Trends

- Patient order
- Staff
- Rooms
- Instrument set
- Medications-lot numbers
- Changes in supplies
  - Packs
  - Prep
  - Swabs/cotton balls

Environmental Audit

- Air handling system
  - Last time filters changed?
  - Are air return ducts dirty/dusty?

Water Filtration System
Water testing annually ?
Build up in sterilizer?

Instruments

- Identify if same sets were used for identified cases
- Cannulated instruments are flushed with 120-150 ml
- Instruments wiped immediately after exposure to viscoelastic
- Ocular instruments are rinsed 2X's, final rinse distilled water
- Cannula flushed with 120-150ml

Possible other contributing factors

- Powder gloves
- Kleenex-lint sources
- Medications, gels, & ointments with preservatives

Containment

- Remove all eye drops, ointments & preps
- Reprocess all instruments
- Avoid use of any lint producing items
- Change all phaco & I/A tips

QUALITY ASESSMENT & PERFORMANCE IMPROVEMENT

QAPI

Basic's of QAPI

- Implement an ongoing effective QAPI plan
- Must include all departments and services, including those furnished under contract.
- Focus on indicators to improve health outcomes
- Prevention of medical Errors
- Identify Quality Projects, ASC's must have an annual project

- Ensure safety and welfare of patients and employees with the monitoring of risk occurrences and potential risks for trend analysis.
- Collect and analyze information to identify and assess problem patterns.
- Assess patient care problems in terms of performance criteria that reflect clinically sound, achievable patient care practices.
- Develop problem correction and monitoring methods to assure identified problems do not recur.
- Provide the Governing Body/Board of Directors with identified issues and trends at least quarterly.
- Evaluate the Quality Assurance program annually and submit a written report to the Governing Body/Board of Directors to review and revise the program as needed.

What should we be monitoring?

- Patient Care Process (pre-admissions, admission, treatment, discharge planning, post discharge follow up)
- Contract Services Quality of Care (radiology, laboratory, pharmacy)
- Patient Medical Record
- Utilization Review
- Infection Control
- Safety and Disaster
- Clinical Privileges
- Patient Satisfaction
- Personnel Services
- Staff Education

- Staff education.
- Review and revision of policies and procedures.
- Monitoring and investigation of patient grievances.
- Investigate, and take immediate action for patient & employee safety, if necessary, on all unusual occurrence/variance reports.
- Providing recommendations to the Governing Body/Board of Directors on additional equipment, staff or funding based on identified facility needs according to findings from the QAPI projects.

Annual Requirements

- Year end summary to the Board with Performance Improvement project(s) outlined
- Contract services evaluation for services being provided
- Review/Changes to the QAPI Plan and adoption by the board
- Disaster Plan review and evaluation of a disaster drill