ASCRS ♦ ASOA Symposium & Congress

Technicians & Nurses Program

April 17-21, 2015 – San Diego, California
Instrument Care and Handling

Lori Pacheco, RN, CRNO
Clinical Director
Cape Cod Eye Surgery
and Laser Center
Sandwich, MA

NO FINANCIAL INTEREST

INSTRUMENT CARE AND HANDLING

Instrument processing

How are instruments processed?

INSTRUMENT CARE AND HANDLING

3 Critical Steps...

1. Cleaning and decontamination
2. Sterilization
3. Storage / return to the sterile field
DECONTAMINATION

Why???

Organic material, soil, and debris can block the sterilizing agent from making complete contact with the surface of the instrument.

DECONTAMINATION

Lens matter, visco-elastic agents can permanently block the cannula.

Saline salt crystals cause pitting and deterioration of the surface of instruments.

DECONTAMINATION

Blood and body fluids can cause pitting of instruments and if left to dry, can be difficult to remove.

When and How???
DECONTAMINATION

When?
Decontamination should begin immediately, during the surgical procedure, to prevent drying of blood, soil and debris on the surface and within lumens.

DECONTAMINATION

How?
Critical to follow the manufacturer's guidelines or instructions for use (IFU) for each device.

DECONTAMINATION

Cleaning and rinsing are considered the first and most important steps in decontamination.

DECONTAMINATION

Manual Cleaning

DECONTAMINATION

Instruments should be wiped clean using a sterile, water moistened sponge.

DECONTAMINATION

A soft toothbrush can be used to clean each instrument.
DECONTAMINATION

Instruments with lumens should be flushed with distilled water followed by compressed air.

DECONTAMINATION

Characteristics of a cleaning agent:

- Low sudsing/foaming
- Biodegradable
- Easily rinsed off
- Non-abrasive
- Disperse organic soil
- Non-toxic

DECONTAMINATION

- Detergents: Inappropriate use and incomplete rinsing of enzymatic detergents have been associated with TASS.
- Irritants on the surfaces of ophthalmic instruments accumulate from inadequate or inappropriate instrument cleaning.
- Heat stable endotoxins from overgrowth of gram-negative bacilli in the water of ultrasonic cleaners.

DECONTAMINATION

- The importance of enzymatic detergents for cleaning ophthalmic instruments has not been established.
- Follow instructions for proper use - IFU's.
- Dilution: The cleaning solution should be mixed with measured amounts of water and detergent. Do not guess.

DECONTAMINATION

- Manual cleaning or ultrasonic cleaner. If you are using detergent instruments must be thoroughly rinsed with copious amounts of water for adequate removal of detergent.
- Manufacturer's IFU. If rinse volumes are specified - minimum volumes.
- Manufacturer's IFU. Use of tap water for rinsing should be compatible with the IFU for the detergent and equipment.
- The final rinse should be with distilled water.
Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments

From the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses (ASORN)


DECONTAMINATION

- Completely open or disassemble parts in order to expose all parts of the item.

- Needle holders, forceps and scissors must be completely opened to clean inside the jaws.

DECONTAMINATION

- Warm water not to exceed 140°F / 60°C

DECONTAMINATION

- No Lumens!

DECONTAMINATION

- Lubricants
  - Lubricant is needed for hinged instruments only; scissors, needle holders and forceps.

DECONTAMINATION

- Lubricant prevents the development of stiff joints and inhibits the development of corrosion.
DECONTAMINATION

The instruments are dipped, one by one, into the lubricant; do not soak them.

DECONTAMINATION

Do Not put cannulas in lubricant.

DECONTAMINATION

Dry

Instruments must be dried thoroughly before being stored.

If the instruments are put away wet or damp they will rust.

STERILIZATION

Chemical (liquid, gas)
- Glutaraldehyde
- Ethylene Oxide

Heating (moist heat, dry heat)
- Moist Heat

STERILIZATION

Although heating provides the most reliable way to rid objects of transmittable agents, it is not always appropriate.

STERILIZATION

Heating can cause damage to heat sensitive materials:
- Fiber Optics
- Electronics
- Certain Plastics
STERILIZATION

Liquid sterilants include oxidizing agents i.e. aldehydes...
Glutaraldehyde

STERILIZATION

Glutaraldehyde uses:
• Leather tanning agent
• Fixative for electron microscopy
• Tissue fixative
• Resin or dye intermediate
• Embalming fluid
• Preparation of dental materials
• X-ray film processing
• Surgical grafts and bioprostheses

STERILIZATION

Glutaraldehyde works as a high level disinfectant agent and sterilizing agent.

Advantages...
If infrequent sterilization is required, it is an inexpensive option.
It is safe for lensed instruments.

Disadvantages...
The chemicals used as sterilants in chemical sterilization are designed to destroy a wide range of pathogens. Typically the same properties that make them good sterilants...

Disadvantages...
Glutaraldehyde releases toxic fumes, especially when heated.
The fumes have a pungent odor and are irritating to the eyes, nose, throat and respiratory tract.

makes them harmful to humans
STERILIZATION

Disadvantages...

Residual solution can be extremely toxic to intraocular and extraocular tissue.

It is essential to practice thorough rinsing of all instruments exposed to glutaraldehyde, assuring all solutions are removed from the instruments.

STERILIZATION

Disadvantages...

There is no reliable method of monitoring the sterilization process.

There is potential for contamination of the sterilized items during rinsing and transferring.

STERILIZATION

SDS (SAFETY DATA SHEET)

Glutaraldehyde

Best Practices for the Safe Use of Glutaraldehyde in Health Care

http://www.osha.gov/Publications/glutaraldehyde.pdf

STERILIZATION

Ethylene Oxide (EO) is an organic chemical and a member of the ether group.

http://www.cdc.gov/niosh/topics/glutaraldehyde/
STERILIZATION

EO depends on 4 factors:
1. Gas Concentration
2. Temperature
3. Humidity
4. Time

A typical EO process consists of:
1. Pre-conditioning phase
2. The actual sterilization run
3. A period of post-sterilization
4. Aeration to remove toxic residues

STERILIZATION

Advantages...
- Compatible with packaging material that prolong storage life
- Completely permeates porous materials
- Non corrosive, it doesn’t damage items

Disadvantages...
- EO Equipment is expensive
- Cycles are expensive to run
- Requires aeration
- Harmful to the operator
- Carcinogenic and mutagenic
- Long, slow and complex process
- EO in its pure form is extremely flammable requiring special precautions when determining storage

STERILIZATION

OSHA

Back to Safety and Health Topics
Ethylene Oxide
https://www.osha.gov/SLTC/ethyleneoxide/

International Chemical Safety Card(ICSC)
ETHYLENE OXIDE
http://www.cdc.gov/niosh/ipcsneng/neng0135.html
Moist Heat (saturated steam under pressure)

Steam sterilization is the oldest, cheapest and best understood method of sterilization.

The steam pressure cooker, an early version of the autoclave, was invented by Denis Papin, a physicist and one of the inventors of the steam engine, in 1681. The pressure cooker was used solely for culinary purposes until Chamberlain.

The current design of the autoclave was finalized in the 1880's by Charles Chamberlain.

The first commercial steam sterilizer intended for use on medical products was developed in 1889.

Why is it called an autoclave?

Autoclave

"Auto" Greek word for automatic
"Clvs" Latin for key.
... as in "Lock and Key"

The devise automatically locks shut when pressure rises to avoid steam spraying out if opened by accident.

The autoclave is a large pressure cooker. It operates by using steam under pressure as the sterilizing agent.

High pressures enable the steam to reach high temperatures, increasing its heat content and killing power.
STERILIZATION

Moist heat kills microorganisms by causing coagulation of proteins.

The vibration of every molecule of a microorganism causes splitting of hydrogen bonds between proteins.

Death is caused by irreversible damage to all metabolic functions of the organism.

STERILIZATION

Moist vs. Dry Heat

Steam coagulates a microorganisms cell protein similar to poaching an egg in boiling water...

Example:

Egg white coagulates when you poach it in boiling water at 212°F. Frying an egg using dry heat requires at least 700°F and takes longer.

STERILIZATION

The more moisture present, the more heat can be carried, making steam one of the most effective carriers of heat.

Example:

When you cook beef at home, it becomes tough when roasted in a covered pan in the oven. But add a little water to the bottom of the pan, and the meat will be tender. The temperature is the same and the time of roasting the same, but the results are different.

STERILIZATION

Add pressure.

By putting the same roast in a pressure cooker you reduce the cooking time by 3/4, and you still get a tender product.

STERILIZATION

Processes conducted at high temps for a short period of time are preferred over lower temps for longer times.
STERILIZATION

“Gravity Cycle” or Gravity Displacement

Simplest steam sterilization cycle

How it works...
1. Steam is pumped into a chamber containing ambient air.
2. Steam is less dense than air, it rises to the top of the chamber and eventually displaces the air.
3. The steam fills the chamber, displaces the residual air which is then forced out through a drain in the bottom of the sterilizer.
4. By pushing the air out, the steam is able to directly contact the load and begin to sterilize.

STERILIZATION

Vacuum Cycle or Pre-vac

More efficient form of sterilization
Preferred method for porous loads

How it works...
1. Equipped with a vacuum system.
2. Starts with a series of alternating steam pressure injections and vacuum draws (pulses) to dynamically remove the air from the chamber. This allows steam to be sucked into areas where it would otherwise have difficulty penetrating.
3. The absence of air within the chamber allows the steam to immediately penetrate the load resulting in more reliable, efficient form of sterilization with shorter sterilization cycle times.

STERILIZATION

Exposure Time

When a set temp. is reached within the sterilizer chamber.

After the autoclave starts the exposure time is measured AFTER the autoclave reaches required operating conditions, NOT from the time you push the ON button.

STERILIZATION

Follow device and container instructions for proper use
IFU’s – Instructions For Use; Manufacturer’s Recommendations

CMS Clarifies Policy to Permit Use of Short Cycle Steam Sterilization in Ophthalmic ASCs

Following strong advocacy efforts by the American Academy of Ophthalmology (the Academy), the American Society of Cataract and Refractive Surgery (ASCRS), and the Outpatient Ophthalmic Surgery Society (OOSS), the Centers for Medicare & Medicaid Services has clarified that the practices of most ophthalmic ASC’s are in compliance with its rules governing instrument sterilization.

In order to comply with Medicare regulations and avoid citation in a facility survey, ASCs must adhere to the sterilizer manufacturer’s instructions for use (IFUs).

Sterilization

The confusion related to the nomenclature used to describe the sterilization processes. CMS believes that the term IUSS, which is now prohibited on a routine basis, refers to the practice formerly known as “flash” sterilization. According to CMS, the vast majority of ophthalmic ASC’s are practicing short-cycle steam sterilization, which is permissible as long as the sterilizer DFUs are followed. The agency will be educating Medicare surveyors regarding this clarification of its policy.
QUALITY CONTROL

Monitoring devises:
Tools to validate the autoclaving process...

Mechanical (Physical) Monitoring
Printouts, charts, gauges, digital displays

Measures:
- Time
- Temperature
- Pressure

Provides real-time evaluation of the sterilization conditions resulting in a permanent record.

QUALITY CONTROL

Policy and Procedure

At the end of each cycle, the operator should verify the correct parameters were met before the items are removed.

QUALITY CONTROL

Chemical Monitoring

Chemical Indicators (Indicator Strips) react to change in the physical conditions in the sterilizer.

Treated paper changes color when exposed to certain sterilization parameters.

QUALITY CONTROL

6 classes of Chemical Indicators

The classification structure is used only to denote the characteristics and intended use of each type of indicator when used as defined by the manufacturer.

This means that the class number does not mean that one class is necessarily better or measures more parameters of the sterilization process than another class.
QUALITY CONTROL

Class 1 Indicators
Process indicators. Are not enough to indicate sterility on its own. They only serve to differentiate processed packs from unprocessed ones. Designed to react to 1 critical process variable.

Class 2: Specific Test Indicator

Class 3 Single Variable Indicator
React only to one critical parameter of the sterilizer cycle. Not a typical indicator for steam. Hydrogen Peroxide gas plasma.

Class 4 Multi variable Indicator
React to two or more critical variables.

QUALITY CONTROL

Class 5 Integrating Indicator
React to all critical process variables (time, temp, and saturated steam).

Class 6 Emulating Indicator
React to all critical process variables. Demonstrates a passing condition after sterilization is achieved. It emulates the cycle. Measures all the critical variables (parameters) of steam sterilization and has a tighter tolerance. Measures more than Class 5.

QUALITY CONTROL

CLASS 2: Specific Test Indicator

Bowie Dick Test / DART Test (Daily Air Removal)

Named after its developers, J. H. Bowie and J. Dick

The Bowie-Dick Test originated as a method to verify air removal from the autoclave chamber. It is run as the first cycle every day, before any other instruments, sets, or devices are processed.

Used with sterilizers which use the pre-vacuum cycle.

Intended use it to evaluate the sterilizers performance.

Pre-vac sterilizers require a vacuum to be drawn during the first and last phases of the sterilization cycle, it is imperative to make sure that this is occurring.

STERILIZATION

Should be used inside all containers/packages.

AORN Standard

Internal CIs are used to verify the sterilant has reached the contents of the packages and that critical variables of the sterilization process has been met. Class 5 and Class 6 (cycle specific).

Determining factor in steam sterilization is ensuring heat/steam penetration. Color migrates along a path when exposed to all critical parameters of the sterilization process, ending at a "safe" or "passing" point.

Correlates to that of a biological indicator.

Is the chemical indicator visible?

A class CI should be placed externally to differentiate processed packs from unprocessed ones.

Example are indicator tape, labels, and strips.
QUALITY CONTROL

Biological Monitoring / Indicators (BI)

Bug Test

Self contained spores in a vial with sealed ampule of growth medium.

1. EXPOSE the BI to a sterilization process.

2. ACTIVATE it by crushing the ampule, allowing the growth medium to create a growth environment for the bug.

3. INCUBATE it to allow the growth of microorganisms.

Incubation produces acid byproducts causing the medium to change color.

Spores that were exposed to a sterilization process are killed, unable to produce acid.

No color change.

Control: Bug that was not sterilized

1. ACTIVATE

2. INCUBATE

3. WILL change color

4. Use a CONTROL each time

Indicator testing should be performed during critical assessments.

Daily / Weekly testing

Critical assessments include:
- Sterilization installation
- Relocation
- After a malfunction or failure
- After any major repairs

"Outside Testing" or 3rd party testing.

- Spore strip and control strip
- Exposed to a sterilization process
- Cycle parameters are documented
- Sent to an outside company for testing
- Results returned
- Provides results from an outside source
QUALITY CONTROL

Sterilizer should be taken out of service until corrected.

Policy and Procedure

STERILE STORAGE

Wrapped / packaged items:
- Rigid containers
- Wrappers
- Peel pouches

Select packaging validated for the sterilization process and cycle parameters of your instruments - IFUs.

STERILE STORAGE

Rigid containers

Can be used as a way of packaging surgical instruments for future use - IFU’s for storage.

Confirm which sterilization process and cycles the rigid container is validated for, match it up with the sterilization process and cycle parameters the instruments are validated for.

STERILE STORAGE

Wrappers

- Used for packaging instrument trays
- Double wrap to provide the best barrier
- Kept snug but not too tight and allow strike through
- Indicator tape to secure wrapping

*Precaution- adhesive in indicator tape is usually latex based.

AAMI Standard ST79 provides directions on how to properly wrap items for aseptic delivery.

STERILE STORAGE

Peel pouches

- Small, lightweight instruments
- Choose appropriate size to allow for circulation of steam
- Tip protectors should be used to prevent compromising the package, should be steam permeable, fit loosely

STERILE STORAGE

Labeling

Packages should be labeled for accurate identification and tracking
- Sterilizer # (if using more than one sterilizer)
- Cycle or load #
- Date of sterilization
- Description of contents
- Assembler identification (initials)
STERILE STORAGE

Do not use elastic bands to secure packages together.

STOP!

STERILE STORAGE

Do not crunch, bend, puncture or compress packaged instruments.

STERILE STORAGE

Do not stack wrapped items.

Stacking can result in damage of the wrap caused by undue pressure from weight!

STERILE STORAGE

Items should not be stored on floors or windowsills or other areas other than designated shelves or counters.

STERILE STORAGE

The shelf life of packaged items is event related.

Shelf life depends on the quality of the packaging material, storage conditions during transport and the amount of handling.

STERILE STORAGE

Prior to use, wrapped items should be visually inspected for integrity and labeling.
TRANSPORTATION

Transportation of sterile items should be controlled.

Sterile items should be transported in covered or enclosed cart/rigid containers.

Transporting instruments to and from surgery, instruments must be in closed containers to prevent contamination, spillage or damage.

Closed, rigid containers, covered carts, impermeable bags.