Sterile Processing of Ophthalmic Surgical Instruments

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Objectives

1. Environment
2. Cleaning and Decontamination Process
3. Sterilization – Various Methods
4. Quality Control
5. Storage / Return to Sterile Field
Dirty Decontamination

Clean Sterilization
Dirty Decontamination

Clean Sterilization
Temperature

As high as 24°C  75°F

Relative humidity in all work areas 30-60%

Sterile storage not to exceed 70%
Decontamination

Purpose
Remove all organic material (blood, nucleus fragments) and inorganic material, soil and debris (viscoelastic, saline salt crystals) that collects on the surface of instruments, in grooves, in lumens, on hinges before sterilization.

• Lens matter, visco-elastic agents can permanently block lumens.
• Saline salt crystals, blood and body fluids can cause pitting and deterioration of the surface of instruments. Difficult to remove.
• Organic material, soil, and debris blocks the sterilizing agent (steam, gas) from making complete contact with the surface of the instrument.
• Effective sterilization cannot occur if debris is left on or inside instruments. Non penetrable.
When?

**Immediately.** Start on your back table. Decontamination should begin immediately, during the surgical procedure, to prevent drying of blood, soil and debris on the surface and inside lumens.

How?

**Instructions For Use (IFU)**

Follow the manufacturer’s guidelines or instructions for use (IFU) or each device / instrument.
PPE and COVID-19

Universal precautions

Personal Protected Equipment (PPE)

- Utility gloves
- Liquid resistant gown
- Liquid resistant shoe covers
- Face mask
  - fluid resistant
- Eye protection
  - goggles, face shield

Keep aerosols down

- Wash under the water line
- Keep the lid on the ultrasound
Manual Cleaning

- Instruments should be wiped clean using a moistened sponge (instrument wipe).

- A **soft** toothbrush can be used to clean each instrument.

- Instruments with lumens should be flushed with “critical” water (treated, distilled, sterile) water followed by compressed air.
Mechanical Cleaning

Characteristics of a cleaning agent:

- Low sudsing/foaming
- Biodegradable
- Easily rinsed off
- Non-abrasive
- Disperse organic soil
- Non-toxic
Instructions For Use – IFU’s.

The cleaning solution should be mixed with measured amounts of water and detergent. **Do not guess.**

*Rinse...Rinse...Rinse* Instruments must be thoroughly rinsed with copious amounts of water for adequate removal of detergent.

Use of tap water for rinsing should be compatible with the IFU for the detergent and equipment.

The final rinse should be with critical water.
Water temperature

IFU detergent

Too hot = coagulation of proteins

Too cold = may not activate the detergent
Detergents and TASS

Toxic anterior segment syndrome (TASS): Acute, severe, intraocular inflammation of the anterior segment after intraocular surgery

Potential causes:

- Contaminated balanced salt solutions
- Intraocular irrigating solutions with abnormal pH, osmolarity or ionic composition
- Viscoelastic agents
- Intraocular medications (antibiotics in the irrigation solutions or intracameral antibiotics)
- Topical ointments
- Preservatives
- Metallic precipitates
- Inadequate sterilization of surgical instruments and tubing
- Inadequate flushing of instruments between cases resulting in build-up of viscoelastic
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.

*Disassemble - If it wasn’t manufactured that way, it doesn’t get sterilized that way.*
No lumens in detergent
Lubricants

- Lubricant is needed for hinged instruments only; scissors, needle holders and forceps.
- Lubricant prevents the development of stiff joints and inhibits the development of corrosion.
- The instruments are dipped, one by one, into the lubricant; DO NOT soak them.
- DO NOT put cannulas in lubricant.
Dry

Instruments must be dried thoroughly before being stored.

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

Difference between stains, rust and pitting:

Stain - a discoloration on an instrument’s surface.

Rust - a red or orange coloration on the surface of surgical instruments resulting from oxidation.

Pitting - erosion / corrosion) of an instrument’s outer surface, renders it beyond repair. Tiny visible small dots, large deep holes.
Identifying Stains

Brown-orange
   Possibly rust- when instruments lose their finish (chrome, nickel) they become susceptible to rust
   Phosphate residue from high alkaline detergent. Neutral pH (6-8)
   Water quality – last rinse with critical water
   Saline

Dark brown / black
   Dried blood
   High acidic detergent. Neutral pH

Blue-Gray
   Cold sterilization solutions - Manufacturer’s recommendations

Light and dark spots
   Water spots from inadequate drying – can lead to rust
Removing Stains

- Nonabrasive cleaner
- Commercial stain remover
- An eraser may be sufficient to remove the stain

If more than 5% of the instruments are stained – QA study.

A thorough investigation or quality assurance study to determine the cause.
Sterilization

Chemical (liquid, gas)
- Glutaraldehyde
- Ethylene Oxide

Heating
- Moist Heat
Although heating provides the most reliable, best understood method to rid objects of transmittable agents, it is not always appropriate...

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

Oxidizing agents: aldehydes...Glutaraldehyde

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

Used as a sterilizing agent by completely immersing items in the solution for an extended period of time.
Advantages

If infrequent sterilization is required, it is an inexpensive option.

It is safe for lensed instruments.
Disadvantages

- The same properties that make glutaraldehyde a good sterilizing agent...makes it harmful to humans.

- Releases toxic fumes, especially when heated.

- The fumes have a pungent odor and are irritating to the eyes, nose, throat and respiratory tract.

- There is no reliable method of monitoring the sterilization process.

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

- Residual solution can be extremely toxic to intraocular and extraocular tissue.
An organic chemical and member of the ether group.

Ethylene Oxide (EO) depends on 4 factors:
- Gas Concentration
- Temperature
- Humidity
- Time
A typical EO process consists of:

- Pre-conditioning Phase
- Sterilization Run
- Post Sterilization
- Aeration
Advantages

- Compatible with packaging material that prolong storage life.
- Completely permeates porous materials.
- Noncorrosive, 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, complex process
- EO in its pure form is extremely flammable requiring special precautions when determining storage
Moist Heat
(saturated steam under pressure)

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

Pressure Cooker

1. Moist heat kills microorganisms by causing coagulation of proteins.

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

3. Death is caused by irreversible damage to all metabolic functions of the organism.
Moist vs. Dry Heat

Steam coagulates a microorganism's cell protein similar to poaching an egg in boiling water...

Example:

Egg white coagulates when you poach it in boiling water at 100°C 212°F

Frying an egg using dry heat requires at least 371°C 700°F and takes longer.

The more moisture present, the more heat can be carried, making steam one of the most effective carriers of heat.
When you cook beef at home, it becomes tough when roasted in a covered pan in the oven.

Add a little water to the bottom of the pan—meat becomes tender. The temperature is the same and the time of roasting is the same, but the results are different.

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.
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.
Vacuum Cycle (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.
Immediate Use Sterilization (IUSS)

The shortest possible time from the item being removed from the sterilizer to the aseptic transfer onto the sterile field.

Only used only in critical situations which there is not sufficient time to process instruments through terminal sterilization.

- When a specific instrument is needed in an emergency
- When a non-replaceable instrument has been contaminated and needs to be replaced immediately
- When an item has dropped on the floor and is needed to continue a surgical procedure
Rules

• Must be processed in the same manner – cleaned/decontaminated

• Placed in a container intended for the cycle parameters to be used

• Used immediately, not stored for later use

• Should not be used for purposes of convenience e.g. lack of adequate supply of instruments to meet surgical volume

• Must be compatible with the instruments IFU

• Documented - the reason for IUSS - dropped instrument
Quality Control

Microorganisms cannot be seen with the naked eye.
You can’t look at an instrument and know it is sterile.

Quality Control to effectively monitor the parameters needed for effective sterilization.

Sterility assurance is verified using 3 types of monitors:
• Mechanical / physical monitoring
• Chemical monitoring
• Biological monitoring
Mechanical Monitoring

Tools to validate the autoclaving process.

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

Printouts, charts, gauges, digital displays

Measures:

• Time
• Temperature
• Pressure
Accountability...

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

- Initial the printout
- Logbook with cycle info and person who removed the items
- Tracking
Chemical Monitoring

Chemical Indicators (CI)

Treated paper changes color when exposed to certain sterilization parameters.

Should be used inside **ALL** containers / packages.

Internal CI’s are used to verify the sterilant has reached the contents of the packages and that critical variables of the sterilization process has been met. Type 5 and Type 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.
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 better than the other.
Type 1

Process Indicators

Designed to react to 1 critical process variable.

Are not enough to indicate sterility on its own. They only serve to differentiate processed packs from unprocessed ones.
Type 2

Specific Test Indicator

Bowie Dick Test / DART Test (Daily Air Removal)

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

A method to verify air removal from the autoclave chamber. It is run as the first cycle each day the sterilizer is used, 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.
Type 3

Single Variable Indicator

Reacts only to one critical parameter of the sterilizer cycle. Not a typical indicator for steam. Hydrogen peroxide gas plasma.

Type 4

Multi variable Indicator

Reacts to two or more critical variables.
Type 5
Integrating Indicator
Reacts to all critical process variables (time, temp, and saturated steam).

Type 6
Emulating Indicator
Reacts to all critical process variables. Has a tighter tolerance.
Biological Monitoring / Indicators (BI)

“Bug Test”

Self contained spores in a vial with sealed growth medium.
Biological Testing

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

*Use a Control each time*
Critical assessments

Sterilization installation

Relocation

After a malfunction or failure

After any major repairs

1. Three consecutive empty steam cycles are run with a biological and chemical indicator in an appropriate test package or tray.

2. Three consecutive empty cycles are run with a Bowie-Dick test (prevacuum steam sterilizer).

Each type of steam cycle used for sterilization (e.g. prevacuum and gravity displacement) is tested separately.

The sterilizer is not put back into use until all biological indicators are negative and chemical indicators show a correct end-point response.
Outside Testing or 3rd Party Testing

Provides results from an outside source
Record Keeping

Sterilization records are maintained according to the facilities policies and procedures.

Every sterilization cycle and modality should be documented and include:

1. Contents of each load
2. Load identification (sterilizer A, Load #)
3. Exposure parameters (4 minutes at 132°C  270°F with dry time)
4. The operator’s name or initials: accountability!
5. Results of physical, chemical, and biological monitors – record confirmation

Patient Pacheco: 4 January, 2022, sterilizer B, load # 22 – the records of that load should be retrievable. Should have the ability to go back to that printout or manufacturers record and see that sterilization parameters were met with operator confirmation.
Ultrasonic Cavitation Testing

How do you know your ultrasonic cleaner is working properly?
Ultrasonic Cavitation Testing

Cavitation: The rapid creation, and destruction of vacuum bubbles or "cavities" in a liquid.

The microscopic bubbles, when forced into contact with a solid surface, collapse.

The surrounding liquid fills the area the bubble once occupied, creating an intense "scrubbing" action as the cleaning solution rushes against the object being cleaned.
**Storage**

**Wrapped / packaged items**

- Peel pouches
- Rigid containers
- Wrappers

Sterilizer **AND** Instruments **AND** Container must **ALL** be **compatible**.

Select packaging validated for the sterilization process and cycle parameters of your instruments – IFU’s.
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.
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.
Wrappers

Used for packaging instrument trays.

Double wrap to provide the best barrier.

Kept snug but not too tight allowing strike through.

Indicator tape to secure wrapping

* Precaution- adhesive in indicator tape can be latex based.
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)
Labeling

- Be visible
- Non-toxic ink: No chemical or toxic substances are released during use.
- Immediately dry
- Waterproof
- Heat-resistant
- Acid-resistant.

Sharpie item # 13601 Black Ink
Storage

• The shelf life of packaged items is **event related**.

• Shelf life depends on the quality and integrity of the package, storage conditions, and amount of handling.

• Prior to use wrapped items should be visually inspected for integrity.
Do not use elastic bands to secure packages together.

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

Do not stack wrapped items. Stacking can result in damage of the wrap caused by undue pressure from weight!

Do not store items on the floor or windowsill or other areas other than designated shelves or counters.
Tip Covers

Must contain holes or an opening for steam to penetrate.
Loading an Instrument Tray

Must leave room for steam penetration
Transportation

Should be transported should have adequate protection transported in a way to prevent contamination. e.g. covered containers.

To the Sterile Field
All instruments that were on the sterile field, **whether used or not used, are considered contaminated**.

Containment of contaminated instruments should be achieved using some type of container that has been identified to prevent staff from coming into contact with the instruments and prevention of airborne microorganisms during transport.
Contaminated

Transported in a way to prevent contamination, spillage or damage.

Container must be:

- Leakproof
- Puncture-resistant
- Marked with a biohazard label

Examples:

- Closed carts
- Bins with lids
- Impermeable bags
- Rigid sterilization container systems *

* The use a rigid container for transporting contaminated instruments should be confirmed by the IFU.
Education

Personnel who perform sterilization activities must:

1. Receive adequate training and have their skills verified
2. Competency verification activities related to sterilization processes
3. Continuing education to review and update knowledge
4. In-service training on new instruments, devices and equipment and IFU’s
Thank you!