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Livewire
INFECTION CONTROL
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NEWS LETTER

FROM THE DESK OF EDITORIAL BOARD

EDITORIAL BOARD

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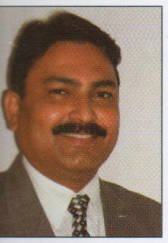

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Dear Friends,

We have received some very positive feedback from the readers. However, we would like to encourage the readers to ask questions also if there are any. We will try to clarify them to the extent possible for us.

After the OT layout and perioperative preparation, we are now talking about sterilization. The most important aspect here is prevention of cluster infections. We must understand sterilization and its monitoring thoroughly because even though the task is done in our absence, we still have to monitor it and ensure that it has been done properly. With the advancement of science, we have better machines available and better monitoring methods are also available.

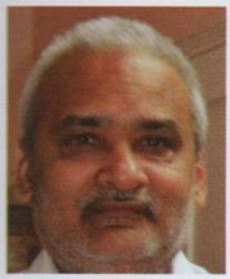
It is our endeavour to give you enough details so as to enable you to take care of the sterilization activities. The articles presented are written by experts in this field of activity. However, readers are encouraged to source further details from the relevant textbooks.

At the same time, we urge all of you to follow all precautions with the sterilization activity without leaving any loophole for a mishap to occur. To ensure that, whatever step is necessary must be done. This is the only way to prevent cluster infections.

At this juncture, we would like to remind our elite readers to ensure sterility of the pre-sterile items purchased from the market because, as end users, it is our responsibility to ensure the sterility. We need to teach our circulating staff also to look for the expiry date, cracks or holes in the opening and the sterility indicator before they open the sterile pack. For example, our circulating staff found holes in a double-packed pre-sterile visco-elastic material, but the company did not take any action even after we informed them. And all of you will agree that none of us is in a position to check the integrity and sterility of the pack at the time of usage, and for that very reason, we have to train our circulating staff to do it.

We keep hearing about cluster infections every now and then. What happens after a cluster infection is well known. Please be careful, monitor the sterilization activity well so that you can sleep comfortably.

STERILIZATION



Dr. Mehul Shah,
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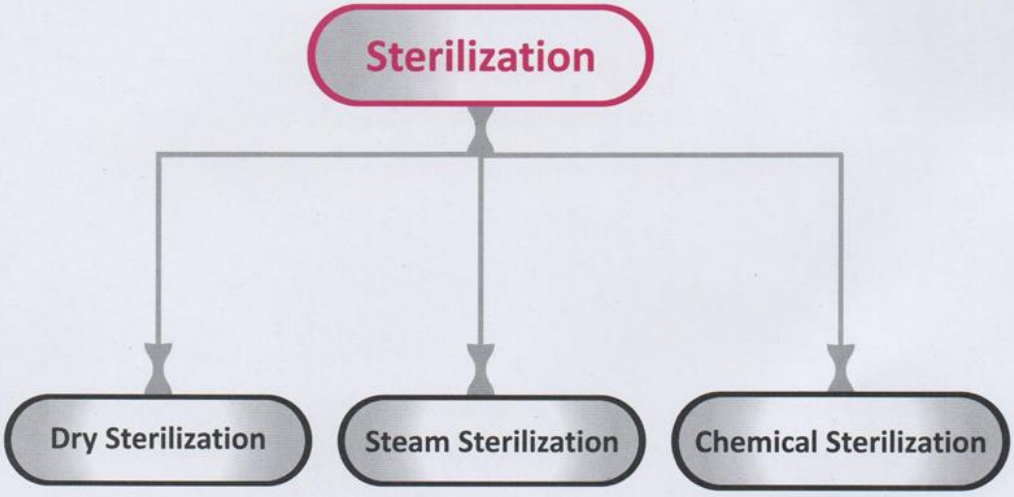
Dr. Mehul has done his graduation and post-graduation from Ahmedabad, did retina fellowship from Retina foundation and Sankara Nethralaya. He is working at Drashti Netralaya, developed special interest in Ocular trauma, Published 185 articles in peer reviewed journals, 4 chapters in books and reviewed 47 articles in international peer reviewed journals. He has experience of construction of state-of-the-art operation theatre approved by NABH and provided guidelines to number of hospitals to construct operation theatres.

Supplies, instruments and equipment used in the operating room are rendered sterile when they are completely free of living organisms, including bacterial spores.

Methods of Sterilization



Steam under pressure

- The most dependable and efficient method of sterilization.
- Mode of action: Causes the destruction of microorganisms by coagulation of the protein within the cells.
- How it works: Transfers heat by condensing steam back into water (hot steam touches the cold surface of the item – steam condenses back into water. This transfers the heat of the steam to the surface of the item.)

○ Effectiveness depends on four variables:

- Temperature (higher the temperature, faster the kill).
- Exposure time (longer the exposure time, more likely that all organisms will be killed).
- Direct contact of steam with every surface of every item.
- Type of steam sterilizer

a) Gravity displacement sterilizer

- Steam under pressure is injected into chamber, forcing air to leave the chamber through a drain at the bottom front of the chamber.
- Complete replacement of air with steam depends on how good the steam is, how clear the drain and drain lines are, and how supplies are placed in the chamber.
- Temperatures: 123°C (254°F); 133°C (272°F).

b) High-vacuum or pre-vacuum sterilizer

- Vacuum pump on drain line sucks air out of the chamber as steam is being 'injected in'.
- Functions at 133°C (272°F).

○ Guidelines for steam sterilization

1. Items should be clean and free of oils.
2. Fabric/linens must be freshly laundered or re-hydrated and textiles (gauze, cotton) new or re-hydrated before use – prevents the creation of super-heated steam
3. Items with multiple parts must be dismantled and lumens should be flushed with distilled water.
4. Wrappers must be of heavy paper, tightly woven cloth or properly sealed peel-pouches.
5. Chemical sterilization indicators should be placed on the inside and outside of each package to verify that steam contacted the outside and penetrated into the centre.
6. The sterilizer must be loaded loosely with alternating layers to enhance circulation and contact of steam.
7. Exposure time begins only when the correct temperature has been achieved.
8. Items must be cool and dry before removing them from the sterilizer. Hot items may cause moisture from the cooler room air to condense on them, making them wet.

Chemical sterilization

Works by making microorganisms unable to reproduce or unable to metabolize nutrients; in other words, it starves them to death.

Used to sterilize temperature-sensitive items, e.g. lensed instruments (scopes and mirrors), plastic items, sutures such as nylon and vicryl.

Types of chemicals:

a) Ethylene oxide (EO) gas

EO gas sterilizers are machines similar to steam sterilizers. These machines have tanks or cartridges of EO gas and an inert gas, which are pumped into the sterilizer chamber in a specific concentration, at a specific temperature and relative humidity.

b) 2% alkaline glutaraldehyde solution

This liquid is poured into a sterile basin with a lid, and items to be sterilized are submerged in the solution for 8–10 hours. The exposure time varies from one brand to another. If diluted by placing wet items in the solution or if concentrated by allowing evaporation to occur, the solution will be ineffective for killing bacterial spores.

- Both EO and glutaraldehyde are highly toxic to the skin, mucous membranes, and other tissues of both the patients and healthcare workers. Therefore, items sterilized by EO must be thoroughly aerated before use and items sterilized by glutaraldehyde must be rinsed with copious amounts of sterile distilled water before use.
- Both chemicals are highly carcinogenic and allergenic and, therefore, must be used in very well-ventilated rooms.
- Glutaraldehyde may damage lensed instruments by dissolving the glue that holds the lenses in place. It may also damage flexible fiberoptic 'scopes' if there are any holes or tears in the scope.

○ Guidelines for EO gas sterilization

1. Personnel who load and operate the sterilizer must be well trained.
2. Fabrics and textiles should be new or freshly laundered – not re-hydrated by sprinkling and spraying.
3. Items must be completely clean and dry.

   - Organic matter interferes with gas contact and penetration.

   - Water + ethylene oxide = ethylene glycol, a highly toxic liquid.

4. Items 4, 5 and 6 in the 'Guidelines for steam sterilization' apply.
5. Aerate sterilized items for an appropriate amount of time, based on the type of material the item is made of and the aeration method used (aeration chamber or ambient air) so as to remove all residual EO which makes the item safe to handle and use.

○ Guidelines for the use of activated glutaraldehyde

1. Use only in a well-ventilated room.
2. Gloves should be worn when in contact with the solution – gloves must be sterile when removing items at the completion of the soaking time.
3. Soak and rinse pans must be sterile, with a sterile lid.

   - Three rinses with sterile distilled water.

   - Lids prevent evaporation, thereby maintaining proper concentration and also help to control fumes.
4. Items to be sterilized must be clean and dry with multiple parts dismantled and lumens filled so that solution can contact all surfaces. Wet items would add water to the solution, thereby diluting it.
5. Solution container should be labelled with expiry date – 14–28 days depending on the brand of glutaraldehyde.

Dry heat

This is the most infrequently used method of sterilization. It is a form of hot air used to sterilize petroleum products, bulk powders, and anhydrous oils that steam and EO cannot penetrate. It is also used for sharp instruments that are chrome-plated. Dry heat works by transferring heat through the process of conduction. A long exposure period is required because hot air penetrates slowly and unevenly. Overexposure or repeated exposure may ruin some items. There are gravity convection sterilizers and mechanical (motor driven) convection sterilizers.

Exposure time requirements:

Temperature		
180°C (356°F)	mechanical	45 mins.
	Gravity	60 mins.
160°C (320°F)	mechanical	90 mins.
	Gravity	120 mins.

- Dry heat cannot be used to make sterile irrigation solutions. The temperature only boils them and, therefore, will not kill bacterial spores that may be in the solutions.
- Guidelines are the same as for steam sterilization except that items with multiple parts do not have to be disassembled. Also, smaller packages must be used to ensure conduction of heat to the centre of the pack.

Packaging Instruments and Supplies for Sterilization

○ Purposes of packaging

- Keep the item sterile from the time it is sterilized until the time it is used.
- Protect items from moisture.
- Protect items from damage.
- Protect items from invasion by insects.

- **Each instrument or item should be inspected prior to packaging to be sure it is in good functioning condition.**

- **Packaging material**

  - Chosen according to type of sterilization, the conditions under which the item will be stored, and the best way to protect the item.
  - Paper wrappers should be brown kraft or non-woven paper.
  - Cloth wrappers should have at least 140 thread count (that is 140 threads in both directions in every square inch – 2.5 cm × 2.5 cm).
  - The wrappers should consist of two layers of fabric sewn together. Items must be wrapped with two wrappers, which are free of holes, folded sequentially in an envelope style so that they can be opened aseptically.
  - Peel pouches are 'sacks' of various sizes in which individual instruments or items can be sterilized. They are usually paper on one side and plastic on the other, but some are paper-and-paper or plastic-and-plastic.
  - If peel-pouches are used for multiple items or one item with multiple parts, the items should be placed in one peel- pouch, which is then placed in a second peel-pouch. This is necessary to ensure aseptic opening of the peel-pouch.
  - The best method to seal it is to heat-seal it, making at least two seals across the top of the pouch.
  - If a heat sealer is not available, the peel-pouch can be tape-sealed using the following steps:

    - Place the peel-pouch on a flat surface.
    - Fold down the corners of the open end.
    - Fold the top edge down so it is even with the bottoms of the folded corners.
    - Fold the top down again.
    - Using chemical indicator tape, seal the edge and sides of the folded flap around to the back.
    - Put on a second piece of tape a little lower than the first to ensure a good seal.

  - Metal canisters can be used for sterilizing linen packs
  - Glass test tubes may be used for sharp, delicate, or otherwise special individual instruments.
  - Test tubes with screw caps must have the cap placed on very loosely when the test tube is put into the sterilizer; the cap is then tightened down when the test tube is taken out of the sterilizer.
  - Test tubes can also be sealed with kraft paper; all the edges of the paper must be tape-sealed to the test tube.

Storage and Shelf-Life of Sterile Supplies

The storage of sterile supplies should protect items from moisture, dust, dirt and insects.

Shelf-life is event-related; that is, the sterility of an item depends on the type of packaging material used, to what extent the integrity of the packaging material is maintained, and the storage conditions. If events occur that compromise the integrity of the packaging, the item is no longer considered sterile.

Under ideal conditions, sterile supplies can be considered sterile indefinitely. Ideal conditions include

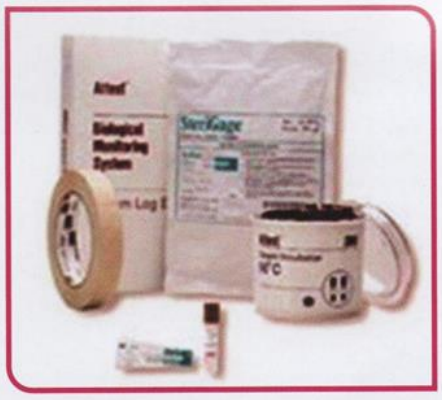
- well-ventilated storage rooms with controlled temperature and humidity;
- use of closed storage cabinets;
- use of heat-sealed peel-pouches; and
- placing cloth or paper-wrapped items in dust covers after they have cooled (heat-sealed, heavy-duty plastic bags).

- When less than ideal conditions are present, shelf-life duration time frames should be adhered to. Items should be labelled with their expiration dates based on the following time frames:

Packaging material	Shelf-life
Cloth or paper; item in only one wrapper	3 days
Peel-pouch sealed with tape	28 days
Peel-pouch sealed with heat	12 months
Cans or canisters	28 days
Vials, bottles, test tubes with screw-on cap	As long as cap is not unscrewed
Vials, bottles, test tubes covered with paper taped onto them	28 days
Irrigation solutions	Until the vacuum is lost (test for the click: hold the bottle around the middle and smack the cap of the bottle; if you hear a "click", the vacuum is still present)

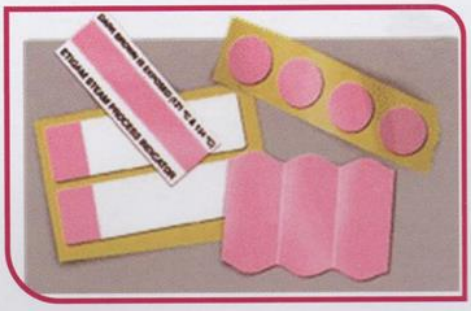
If storage conditions are crowded, humid, dusty, or likely to have a lot of insects, decrease the shelf-life by one-fourth to half the times listed above.

MONITORING AUTOCLAVE AND ETO



AUTOCLAVE

- CHEMICAL
- BIOLOGICAL
- SOFTWARE RECORDING PARAMETERS



AUTOCLAVE LABELS

Autoclave user log

- Maintain user logs for two years
- Complete user log with every use

Log Number	Date	Time	Initials	Lab Biosafety Level (BSL 1, 2 or 3)	Lab Room #	Biohazard Waste	Media	Other	Time (min.)	Temp. (°C)	Pressure (PSI)	Results (Pass/Fail)	Tape strip here. If autoclave generated documentation, please initial to indicate that waste load met parameters.
EX	1/1/2005	10:30 AM	JD	2	EHS 123	X			60	121°C	15	pass	CITP strip tapped here showing pass
1													
2													
3													
4													
5													
6													

Autoclave Maintenance Log

- Maintain Maintenance logs for five years
- Complete Maintenance log for Every repair
- Maintain records of yearly calibration

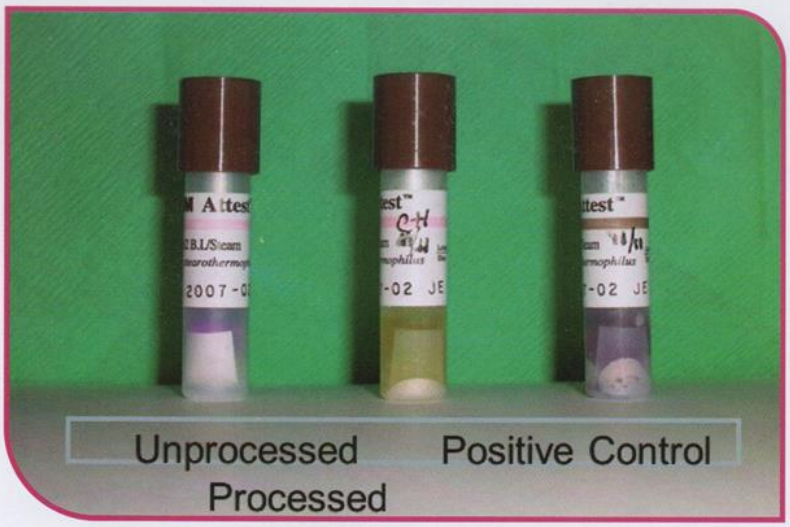
AUTOCLAVE MAINTENANCE LOG (to be kept with copy of instruction manual at each autoclave)

Building/Room:_____ Serial Number:_____ Model:_____ Make:_____

contact person:_____

Date	Problem	Remedial action/ Operator initials	Service Description	Comments

Biological indicator test results



- Maintain result logs for five years
- Complete Result log with every monthly test

Biological indicator test result log (Monthly)

Building/Room#:_____ Room E-Bar Number:_____ Serial #:_____

Model:_____ Biological Indicator Type and Brand:_____

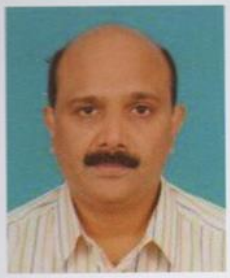
Contact Person/Department:_____

Operator name	Date of Autoclaving and Incubation	Cycle Selected and Temperature	Cycle Time	Incubation Time (Hours)	Biological Indicator Lot Number and Expiration Date	Result Pass Fail

- Important source of problem

Source of error	Rectification
Human error	Training and monitoring
Equipment	Training and maintenance
Material	Training and monitoring

STERILIZATION



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Medical Director from 2013
AHALIA foundation eye hospital, Palakkad From 2010 to Present
Worked at Gomabai Netralaya, Neemuch: 1998- 2010
(Medical director from 2002)

Sterilization is the process of killing all the microorganisms in a material or from the surface of any article, including spores.

Disinfection is to reduce the number viable microorganisms from the surface of the object or in any sample.

Sterilization in the hospital

Sterilization starts from the OPD area as soon as the patient reports to the doctor for an eye examination.

- Tonometry: Goldmann Applanation Tonometer, Perkins Tonometer and Schiotz Tonometer – make sure all these instruments are well-sterilized either with isopropyl alcohol or medicated spirit.
- Antibiotic eye drops should be put after each procedure.
- Same protocol can be applied to all OPD procedures to minimize the risk of transfer. A boiler should be used for sterilizing the instruments such as syringing cannulas, probes and common forceps for OPD procedures.
- Chin rest of the slit lamp or other machines should be wiped with spirit or an alcohol wet swab.
- When the patient is admitted to the ward for treatment or preparation for the surgical procedure, the ward staff should take care of all the disinfection and sterility protocols.

Pre-sterile items

These are the items used for surgical procedures:

Linen

Surgeon's gown, staffs' kurta pyjamas, cap, masks, patient's gown, leggies, eye drapes, trolley covers and OT sheets, etc. These items should be sterilized with steam sterilization, i.e. autoclave. In this procedure, pressure of the autoclave should be 15–25 pounds (depends upon the model), temperature 121°–134°C and duration of 20–30 minutes. But in routine practice, it is 45 minutes at 121°C with 15–20 pounds of pressure in most of the hospitals.

Irrigating fluids and viscoelastic

As per the literature, these items should not be passed in excessive heat because the pH value may change, but most of the practitioners have experienced that it is very much helpful to minimize the risk of post-operative infections. For sterilizing these products, autoclaving is the best method but take care to keep these items on the shelf for at least 48 hours before use as viscoelastic becomes opaque just after heating and takes about 48 hours to come to a normal state.

Rubber and plastic items

Items such as gloves, eye shields, vitreous probes, endo lights and plastic tubings should be sterilized in the ETO sterilizer because these items are heat-sensitive and may melt in steam sterilization.

Lumened instruments

For endoscope or tubular instruments, ETO should be done although most of the practitioners prefer chemical disinfection for such instruments.

Surgical instruments

Stainless steel or titanium instruments, including sharp items such as scissors and blades, can be sterilized in the hot air oven or in steam sterilization.

In the hot air oven, the temperature should be 160°–180°C for 1 ½–2 hours. The instruments can also be autoclaved for 45 minutes.

Between surgeries, the instruments can be sterilized in a cassette sterilizer for 3–5 minutes.

Causes of failure

Any day in the sterile processing environment can be challenging, but a suspected sterilization failure can become even more frustrating. Sterilization failure can be detected at any time during processing or just prior to the use of an item. Such failure may be identified at any of the following stages of the process:

- When a pack is opened and the internal chemical indicator shows inconclusive results.
- If a biological indicator test shows growth of microorganisms.
- If there is moisture on or in the pack
- During the review of the cycle parameters.
- When chemical indicators fail in the sterilization load.

There are five basic factors to investigate whenever there is a suspected sterilization failure:

- Equipments failure – sterilization machine is malfunctioning.
- When organic residue or debris are there on the instruments due to poor washing.
- Improper functioning of valves or filters during sterilization.
- Human errors are the most frequent cause.
- Procedural errors – e.g. phaco handpiece – the company says that it should be kept in sterilization for not more than 20 minutes and protocol says 45 minutes.

Investigation

To get to the cause of suspected sterilization failure, all the following five factors must be investigated and ruled out to confirm that all problems have been identified:

○ Determine the extent of failure

- Stop using the sterilizer causing the failure. Identify the extent of failure – as to whether this is a single event within a single pack or a complete sterilization load. E.g. A pack opened in the OT reveals an inconclusive result on the internal chemical indicator and when compared with other pack on the indicator.
- Check for servicing of the equipment; it might be possible that the machine is not giving the optimum results.
- Check for growth of organisms with biological indicators.

Who will monitor and when

Remember one thing: to work in an OT is not something to be taken lightly. It needs lots of dedication, affection, caring and honesty towards the patients and the organization. That means all the persons working in the OT should monitor all the aspects of sterilization but when the OT is going to start, the OT incharge should see the internal indicators and then show it to the operating surgeon. If everything is okay, the surgery can be started. This practice should be followed for each pack opened every time.

The OT incharge and surgeon incharge are both responsible in the end.

Shelf-life and expiry date

All packaging should be stored in a dry, well-ventilated, easily accessible place, sheltered from sunlight, bad weather and away from any ignition source. Remember – the older stock should be used first so keep the new sterilized items behind the old stock. Shelf-life of ETO packs is 3–6 months as mentioned by INVENTEC (France).

In Gomabai Netralaya, we keep stock for a maximum for 6 months

Shelf-life for steam-sterilized items (paper pack) is 4–6 weeks if double-wrapped and 2–3 weeks if wrapped in a single sheet. However, this is done for storage in a closed shelf. If it is an open shelf, the shelf-life will be less. Sterilized items kept in autoclaving drums should not be used after 24 hours.

Expiry date

The date of sterilization should be mentioned clearly along with the expected expiry date. If items have to be kept on the shelf, all the indicators should also have the date of processing along with the name and signature of the staff members who are performing the cycle.

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