Low Temperature H_2O_2 Plasma Sterilizers

By Can Ahiska

Sterilization and Disinfection

Terminology

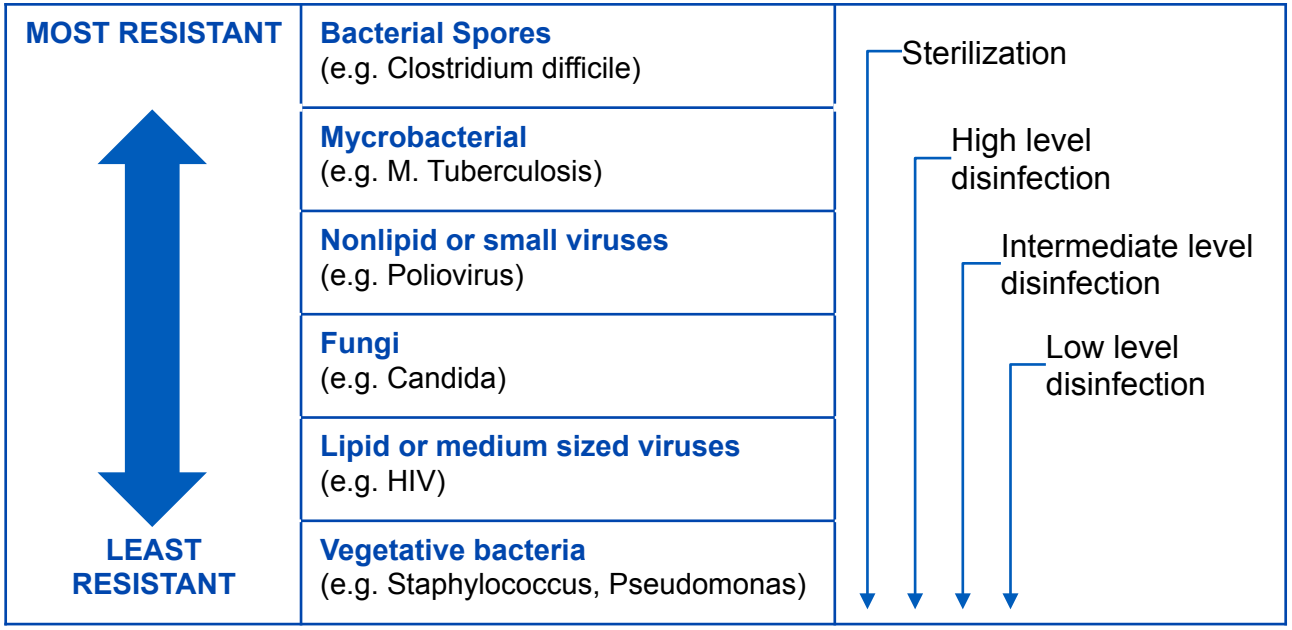
- **Sterilization:** A physical or chemical process that completely destroys or removes all microbial life, including spores.
- **Disinfection:** It is killing or removing of harmful microorganisms so they no longer cause diseases.

- **Disinfectant:** Products used to kill microorganisms on inanimate objects or surfaces. Disinfectants are not necessarily sporicidal, but may be sporostatic, inhibiting germination or outgrowth
- **Antiseptic:** A product that destroys or inhibits the growth of microorganisms in or on living tissue.
- **Aseptic:** Characterized by the absence of pathogenic microbes.

Sterilization and Disinfection

Order of Resistance to Biocides

Varying resistance to chemical biocides of different types of organisms



1968 – E. Spaulding Classification System

Earle H. Spaulding Classification System

Rational approach to disinfection and sterilization of patient-care items and equipment according to degree of risk of infection:

Three Categories:

1. Critical
2. Semi-Critical
3. Non-Critical

Sterilization and Disinfection

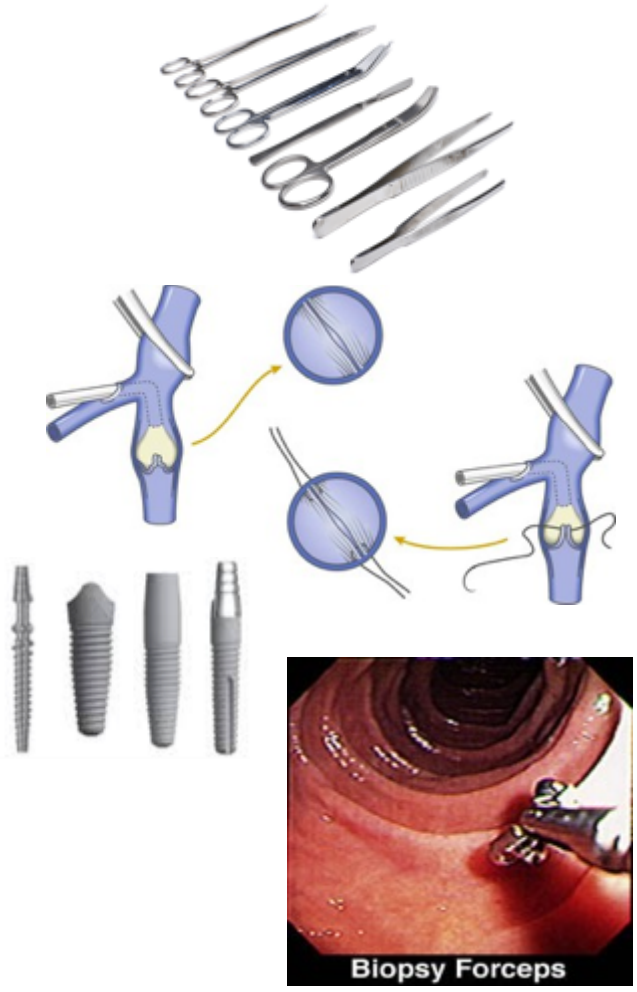
Critical Items

Critical Items:

- Objects that enter sterile tissue (breaks mucus membrane) or the vascular system
- High risk for infection if contaminated with microorganism.
- Critical items must be sterile because microbial contamination could transmit disease.

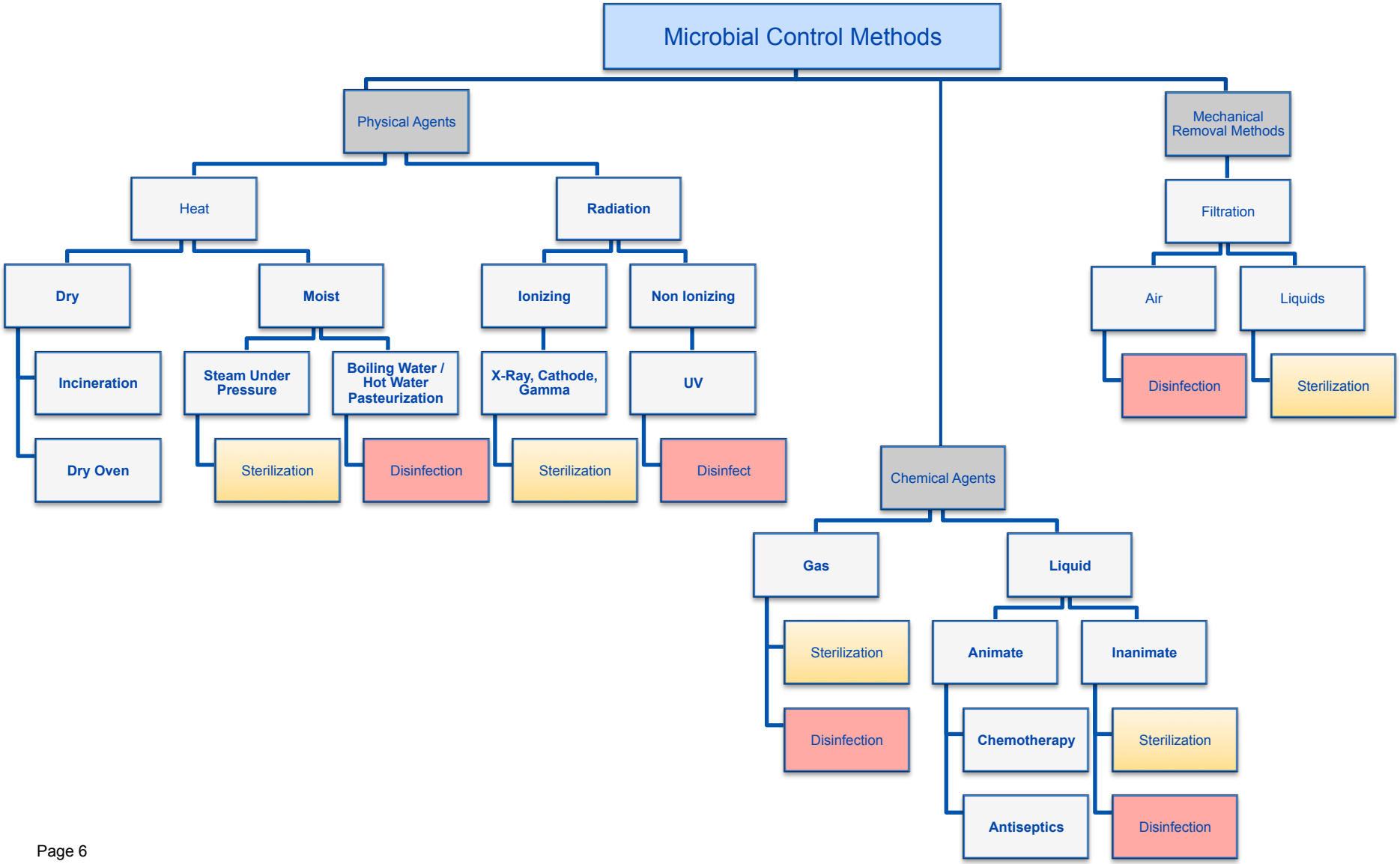
Critical Items Include:

- Surgical instruments
- Cardiac and Urinary Catheters
- Implants
- Biopsy Forceps
- Ultrasound probes used in sterile body cavities
- etc…



Sterilization

Methods of Sterilization



Sterilization Technologies

Steam Sterilizers

- The oldest and most cost-effective method for sterilization of items that are not heat/moisture-sensitive
- Destruction of microorganisms is dependent on temperature, pressure and time of exposure
- Steam must contact all surfaces of the item to be sterilized
- The outer jacket surrounding the sterilizer chamber to avoid excessive condensation in chamber.

Steam Sterilizers

Advantages vs Disadvantages

Advantages	Disadvantages
Readily available	Unsuitable for an increasing number of heat and moisture sensitive devices (between 110°C-135°C)
Short cycle time	Efficacy dependent upon attention to detail
Nontoxic	Air retention and /or condensate pooling
Environmentally safe	Some instruments tend to loose sharpness after repeated exposure to steam
Economical	Water quality may promote stains or corrosion on instruments
Use with heat and moisture stable devices	Without good drying the packages are damp when removed from the sterilizer.
	Without good drying the packages are damp when removed from the sterilizer.

- Very powerful advantages making steam a cost / efficacy-effective sterilizer of choice
- However, some very real limitations due to its high-temperature and moisture dependency

Sterilization Technologies

Ethylene Oxide

- Introduced on 1940-50’s
- Low temperature sterilization
- Ethylene oxide sterilization is a chemical process consisting of four primary variables: gas concentration, humidity, temperature and time
- Ethylene oxide is an alkylating agent that disrupts the DNA of microorganisms, which prevents them from reproducing.
- Highly Penetrative
- Flammable and very Hazardous

Ethylene Oxide Sterilizers

Advantages vs Disadvantages

Advantages	Disadvantages
Effective sterilization for heat and moisture sensitive Items	Specific process of Microbiological destruction not studied
Highly Penetrating Gas	Lengthy cycle time and aeration
	Instruments must be completely dry
	Flammable if not mixed with flame
	Toxic fumes
	Category 1 carcinogen
	Mutagenic
	High Installation and Hidden-Costs

- EtO gas characteristics make it a very effective sterilization agent, but also difficult to handle in hospital environment.
- EtO remains an effective sterilization method for industrial scale applications due to low-temp, and scalability.

Sterilization Technologies

Formaldehyde Sterilizers

- Introduced on 1940-50’s
- Higher temperature than EtO
- Formaldehyde gas is produced by liquid formaldehyde that is passed through a heated evaporator.
- Highly Penetrative
- Toxic and Hazardous

Formaldehyde Sterilizers

Advantages vs Disadvantages

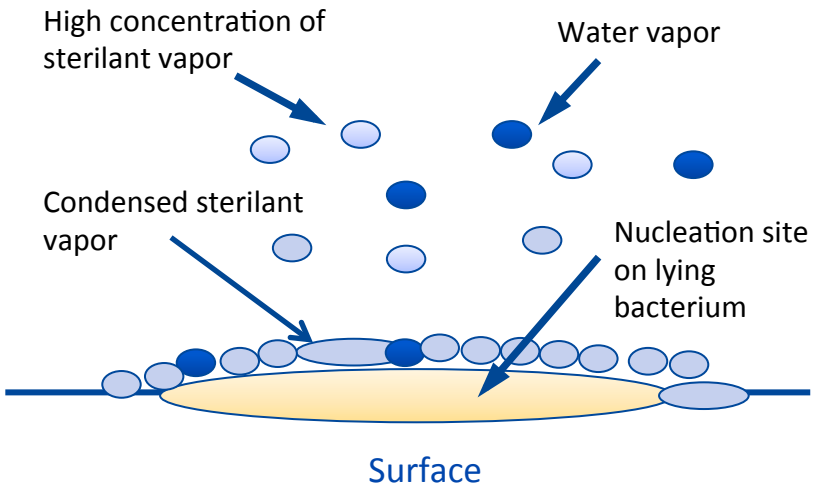
Advantages	Disadvantages
Can sterilize heat and moisture sensitive items in approximately 3 hours	Formaldehyde exposure as regulated by OSHA is 0.75 ppm over 8 hour period
In newer system, FO is supplied in bags or bottles	Irritating to mucous membranes, carcinogenic
	Higher temperature than EtO
	Formaldehyde residue can remain on the sterilized goods if the rinsing phase is not 100% efficient. This can be harmful for the patients.
	Adequate ventilation and alarm system needed for older models
	A relative humidity of ~ 75% is required in order to be effective as the gas has to dissolve in a film of moisture surrounding the bacteria
	Formaldehyde has not been FDA cleared for use in healthcare facilities and only recognized in some countries
	High Installation and Hidden-Costs

- FO gas characteristics make it a very effective sterilization agent, but also presents significant residuals hazards.

H2O2 Plasma Sterilization

Basic Principles of Plasma Based Sterilizers

- Living microorganism are hygroscopic (attracted to water)
- Sterilant and water are polar organic
- Preferentially they both condense on nucleation site formed by the lying bacteria.
- They compete therefore high water vapor presence reduces sterilization efficacy
- Viruses sizes are also efficient nucleation sites
- A great quantity of highly concentrated vapours arrives and condense on the surface of bacteria colonies living in the materials
- During the sterilization process the atmosphere constituted almost entirely by the vapour sterilizing in the chamber



Why do we need a plasma ?

Main Market Drivers for H2O2 Sterilization Devices

SHIFT FROM ETO

- Heavy regulations on EtO has been a good driver for the H_2O_2 sterilizer market for a time. In the U.S and EU countries there has been a huge reduction on EtO installations after heavy regulations (reached almost 0). In some other regions (ME, Asia and Africa), although there are still considerably amount of EtO installations, new sales rates are declining very fast and replaced with H_2O_2 sterilizers.

MORE OPERATIONS

- The number of over 60s will increase from 605 million in 2000 to over 2 billion by 2050
- This translates into high surgical procedures growth of over 10% p.a. in DMs

MINIMAL INVASIVES

- Endoscope market growing at ~8% per year in DMs
- MIS growing at 10% p.a.; $55bn market, Asian MIS market is growing at 15% plus p.a.
- Development of more advanced instruments, requiring delicate low temperature processing
- MIS means high turnout/turnover surgeries
- Approx. 9 million procedures applied at 2013 in US.

EMERGING MARKETS

- Surgical procedures growth in EMs two to fives times higher than in DMs, eg. over 25% for trauma procedures
- MIS increasing rapidly, worldwide

H2O2 Plasma Sterilization

Paradigm Shift in Low Temperature Sterilization

ETHYLENE OXIDE (EtO)

- ✔ Effective
- ✘ **Costly** installation & operation
- ✘ **Hazardous** on humans/environment (carcinogenic) ➔ **Heavily Regulated**
- ✘ **Very Long** Process duration

FORMALDEHYDE

- ✔ Effective
- ✔ Relatively economic in comparison to EtO
- ✘ **Hazardous** on humans/environment (carcinogenic) ➔ **Heavily Regulated**
- ✘ **Long** Process duration

HYDROGEN PEROXIDE PLASMA

- ✔ **Effective**
- ✔ **Economical**
- ✔ **No toxic residue**
- ✔ **Short** Process duration

Why do we need a plasma ?

Basic Features of H2O2 Sterilization Devices

CONCENTRATED STERILANT PROVIDEST THE HIGHEST STERLISATION EFFICACY – Water vapor molecules in a sterilization chamber compete with the Sterilant molecules; therefore concentration of Sterilant increases the sterilization efficacy.

BROAD MATERIAL COMPATIBILITY VIA DUAL MODE CONCENTRATOR INJECTOR – With dual mode technology offers both variable concentration and none concentration cycles. Programs employs concentrated Hydrogen peroxide for optimized process duration.

NO TOXIC RESIDUAL - In-chamber plasma ensures Sterilant residue removal from medical instrument surfaces. The in–chamber plasma and in-line efficient catalytic converter ensure that there is no residual H2O2 leakage from the sterilizer.

ISO 14937 COMPLIANT TEST VALIDATION FROM ACCREDITED LAB - Sterilization processes must be validated to 10^{-6} SAL (Sterility Assurance Level) by an ISO/EN 17025 accredited European laboratory. ,

QUALITY - Products should be manufactured under continuous quality control to appropriate medical and product quality standards with EN ISO 13485, EN ISO 9001, and full CE (EMC EN 60601-1-2, EMC EN 60601-1-2, and LVD IEC 61010-1) certification.

RAPID THROUGHPUT – With shortest cycle times for the low temperature sterilization, plasma sterilizers is one of the best and fastest methods to process delicate medical instruments in your hospital.

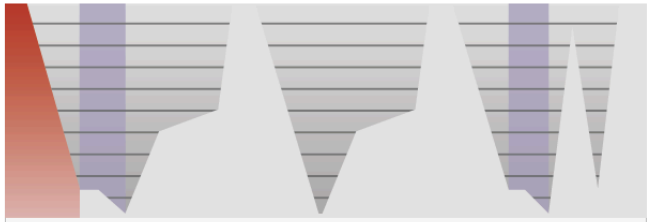
The Ideal Sterilizer!?

- Safe for people and the environment
- Low temperature
- Short cycle
- Material compatibility
- Easy to install
- Cost effective
- Easy Monitoring

Low Temperature H_2O_2 Sterilizers

How does a plasma sterilizer works ?

Vacuum Conditioning



The Sterilization process requires deep vacuum for the hydrogen peroxide to remain in vapor phase at low temperatures.

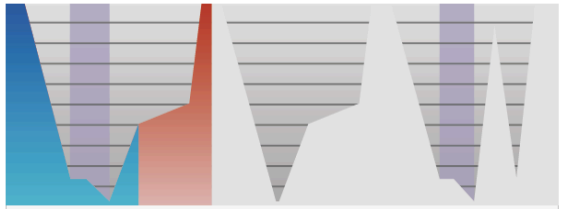
Plasma Conditioning

The Chamber is pre-conditioned with plasma in order to:
(i) remove moisture
(ii) enable homogenous heat distribution.

1st Hydrogen Peroxide Injection

The previously conditioned H2O2 Sterilant is injected into the sterilization chamber as a vapor.

1st Diffusion

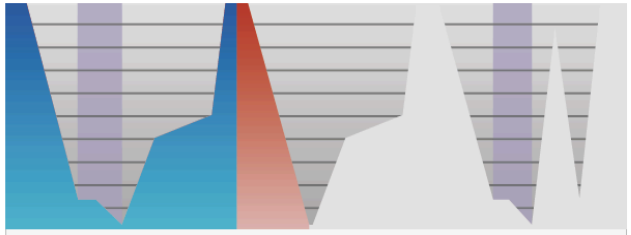


After injection into the chamber, the H2O2 is maintained as a vapor in order to enable homogenous and effective diffusion inside the lumens and cavities of the surgical instruments.

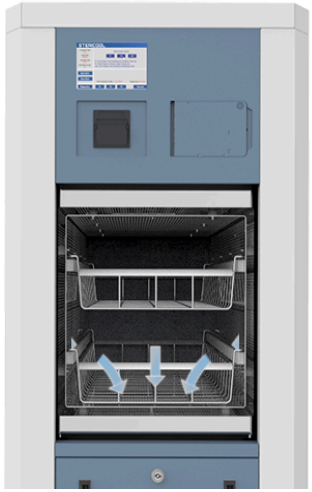
Low Temperature H_2O_2 Sterilizers

How does a plasma sterilizer works?

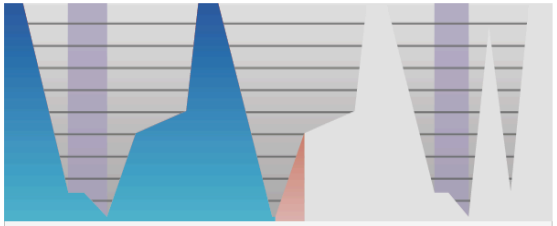
Vacuum Operation



The Chamber is evacuated to vacuum in preparation for the 2nd Injection Phase.

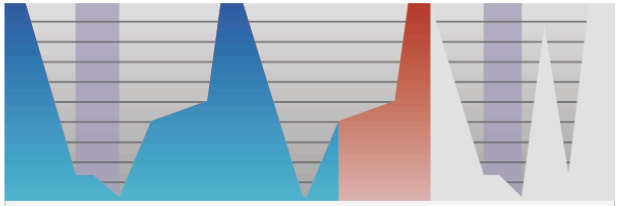


2nd Hydrogen Peroxide Injection



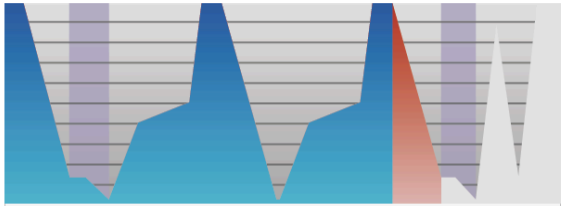
Once again: The previously conditioned H2O2 Sterilant is injected into the sterilization chamber as a vapor.

2nd Diffusion



Once again: After injection into the chamber, the H2O2 is maintained as a vapor in order to enable homogenous and effective diffusion inside the lumens and cavities of the surgical instruments.

Vacuum Operation

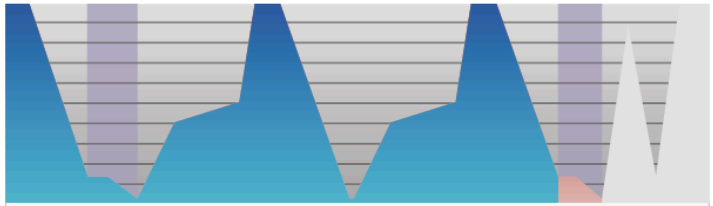


The Chamber is evacuated to vacuum in preparation for the Plasma Abatement stage.

Low Temperature H_2O_2 Sterilizers

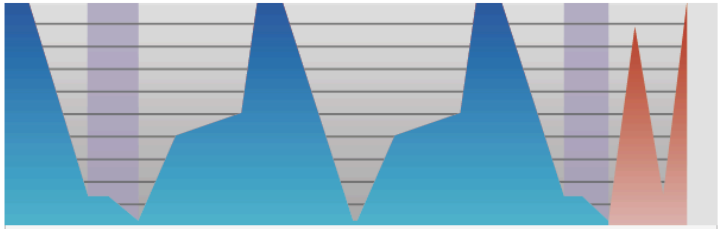
How does a plasma sterilizer works?

Plasma Abatement



The plasma at the end of the cycle, ensures that all H2O2 is decomposed (to water vapor and oxygen) and contributes to the sterilization via the UV and free radicals generated.

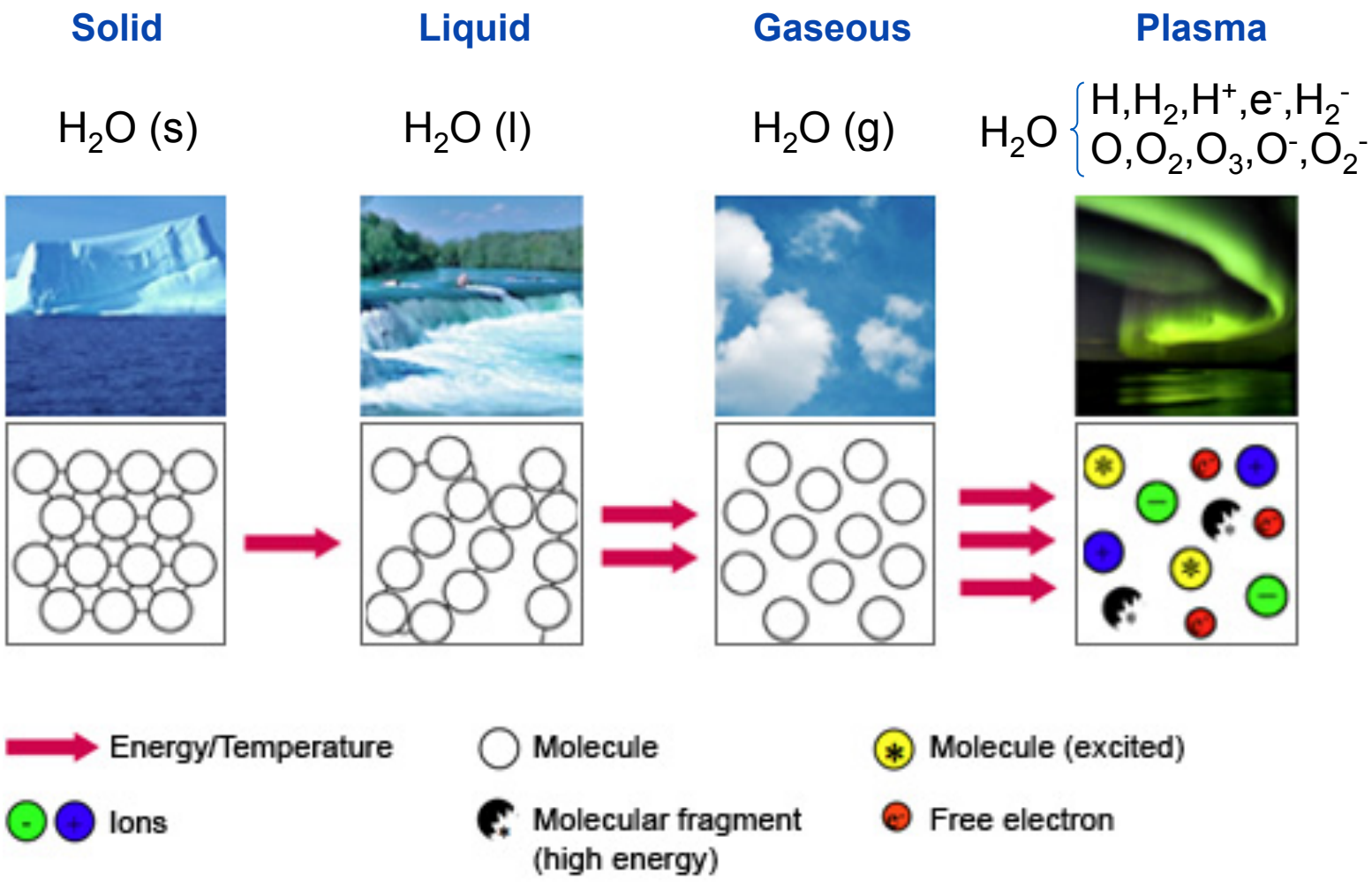
Optional Areation



The Chamber is vented with purified dry air to provide further cleansing.

Plasma

Fourth State of Matter

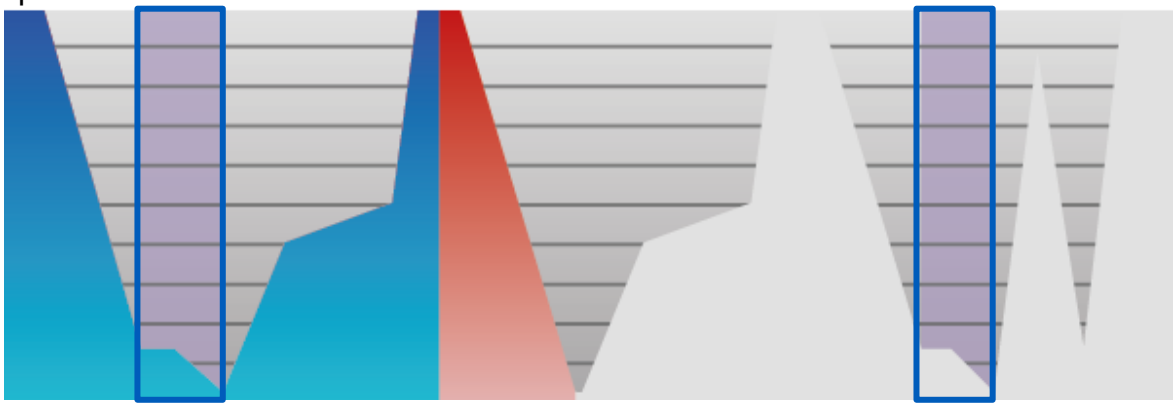


Low Temperature H_2O_2 Sterilizers

Why In-Chamber Plasma ?

3 key uses of plasma in H_2O_2 sterilizers:

- Min. residual sterilant left on medical instrument surfaces.
- Homogeneous Heating and Humidity reduction.
- Increases sterilization efficacy.
- Min. H2O2 exposure to environment



Conditioning Decomposition

- **Pre-cycle conditioning**: prior to injection of H_2O_2 Sterilant, plasma application generates controllable homogenous heating up to 55°C at low pressure vacuum for the preconditioning of the instruments and moisture removal.
- **Post-cycle decomposition:** during the cleansing phase of the sterilization cycle, plasma application is used to decompose the H_2O_2 Sterilant (to water vapor and oxygen).

Low Temperature H_2O_2 Sterilizers

Concentration Technology

In-situ H_2O_2 Concentration substantially improves sterilization efficacy:

- The presence of water vapor adversely effects the sterilization efficacy of the H_2O_2 sterilization process. With reduction of water vapor in the sterilization chamber this technology ensures repeatable lumen cycle performance.
- In-situ device concentration technology to:
  - Increase the sterilization efficacy
  - Reduce cycle time

Controllable Dual Mode Concentrator:

- A H2O2 sterilizer must offer dual mode injector technology provides users more flexibility of programs to better protect your medical instruments and provide increased sterilization efficiency at the same time.

Material Compatibility

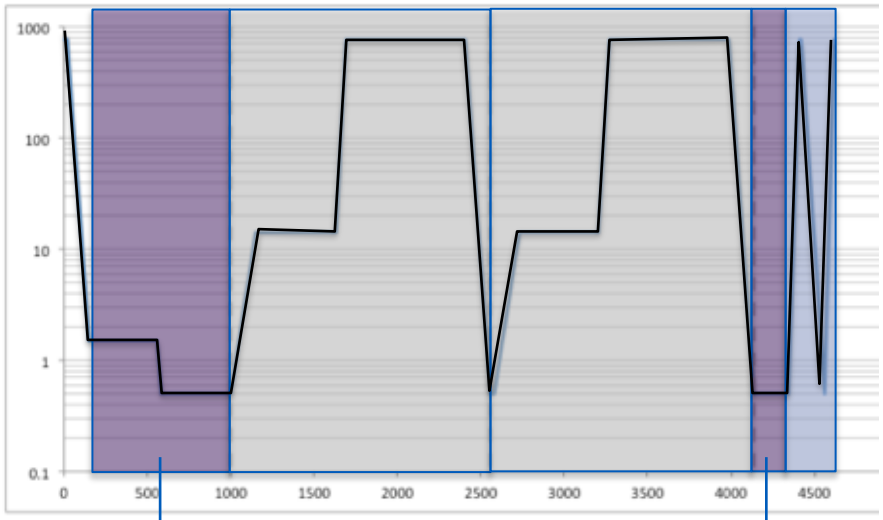
Physical factors that affect Material Compatibility

1. H_2O_2 Exposure

Duration: With identical diffusion (contact) durations
For <u>all cycles</u>, must have *identical H_2O_2 exposure!*

2. Temperature

Sterilization process within same in-chamber temperature range



5. Diffusion Pressure

Same pressure band as most brands.

3. Residuals

- Aeration (air-wash)
- Plasma

4. Plasma *(Power* & Duration)

Plasma Technology power must be optimized otherwise lead to etching.

Sterilization Technologies

“Ideal” Characteristics Summary

	Steam	EtO	FO	H2O2 Plasma
High efficacy	✓ Water quality dependent	✓	✓	✓
Rapid activity	✓	✗ Long aeration required	✓	✓
Strong penetrability	✓	✓	✓	✓
Material compatibility	✓ / ✗ Not for sensitive instruments	✓	✓	✓ Not for Cellulosics
Nontoxic	✓	✗ Hazardous!	✓ / ✗ Hazardous!	✓
Adaptability	✓ / ✗ Bench top mobile	✗ Heavy installation requirements	✓	✓ ✓
Monitoring capability	✓	✓	✓	✓
Cost-effectiveness	✓	✗ Hidden operating costs	✓	✓

Low Temperature Sterilization

Sterility Assurance

Validation & Routine Process Monitoring

Biological Growth Test:

- H_2O_2 Geobacillus stearothermophilus spores (106 population)
- Incubation time/conditions:24 hours at 55°C

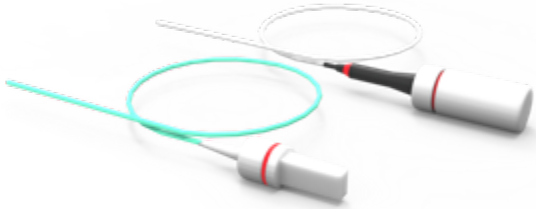
Chemical Indicators :

- Routine monitoring hydrogen peroxide chemical indicator
- Per-Tyvek Hydrogen peroxide chemical indicator

Routine Monitoring Kit

For routine process monitoring to ensure that the sterilizers are continuously operating at peak performance.

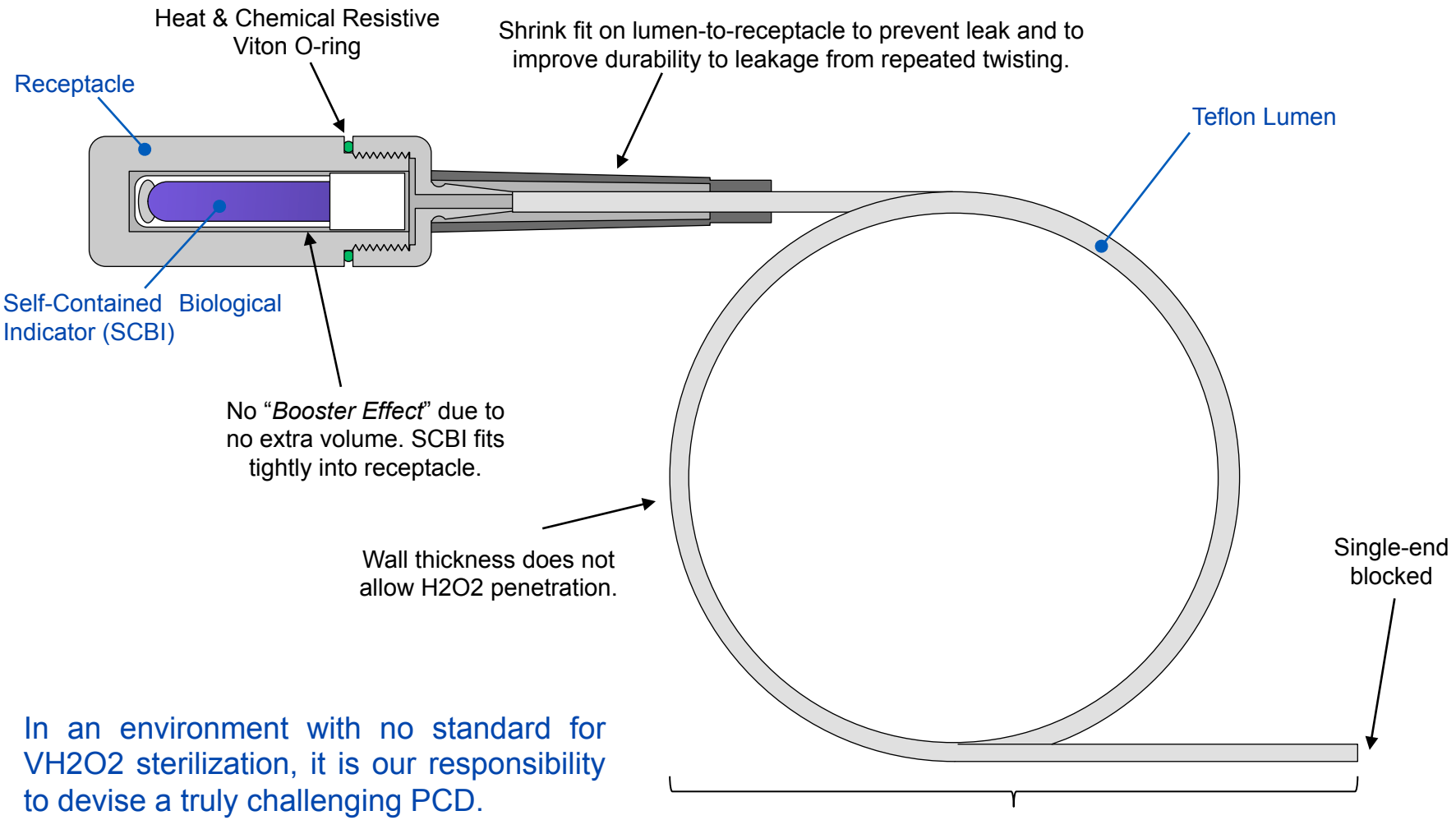
- Compliant with ISO 14937 routine monitoring guidelines
- 2x1200mm PCD-BI Test Challenge Device with 1x Box ST800
- (Supplementary) 2x1200mm CI Helix Challenge Test with 1x Box ST810



Sterility Assurance

Validation & Routine Process Monitoring

Full conformance with EN ISO14937 Article 8.3 (a) and (b) is only possible with an appropriate PCD-BI.



In an environment with no standard for VH2O2 sterilization, it is our responsibility to devise a truly challenging PCD.

Preparing

Preparing of Load

Preparing
General Guidelines

- **Always** follow the **instrument manufacturer's instructions**/recommendations during Preparation, Packaging and Placing.
- Full **PPE must be worn** for handling and cleaning contaminated equipment/devices
- Reusable medical instruments must be **thoroughly cleaned** before disinfection or sterilization, and thoroughly **dried before sterilization**.
- **Tools** used to assist in cleaning, such as brushes, must be cleaned and **disinfected after use**.
- **Equipment** used during cleaning process should be regularly **maintained, cleaned and calibrated** as per manufacture's instructions.
- All **consumables** (e.g. ultrasonic solutions) should be **replaced** as per manufacturer's instructions.

Preparing

Preparing Instruments for Sterilization

The process for cleaning should include written protocols for disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping.

- **Disassembly -** Instruments should be disassembled prior to cleaning as per the manufacturer's recommendations/instructions.

- **Sorting -** Sort equipment/devices into groups of like products requiring the same processes.

- **Soaking -** Soak equipment/device in an approved soaking solution to prevent drying of soil, making cleaning easier.

- **Physical removal of organic material -** Gross soil may be removed using tools such as brushes and cloths.
  - **Manual -** If manual cleaning is performed, physical removal of soil must occur under the water level to minimize splashing.
  - **Washer-disinfectors** are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to reduce potential risk to personnel.
  - **Ultrasonic washers** are strongly recommended for any semi-critical or critical medical equipment/ device that has joints, crevices, lumens or other areas that are difficult to clean.

Preparing
Preparing Instruments for Sterilization

The process for cleaning should include written protocols for disassembly, sorting and soaking, physical removal of organic material, rinsing, drying, physical inspection and wrapping.

- **Rinsing –** Thorough rinsing following cleaning is necessary as residual detergent. Perform the final rinse for instruments containing lumens.

- **Drying –**Prevents dilution of chemical disinfectants which may render them ineffective and prevents microbial growth. Equipment/devices may be air-dried (recommended for instruments with lumens) or dried by hand with a clean, lint-free towel.
  - Low Temperature H2O2 Plasma Sterilizers rely on moisture-free and deep-vacuum pressure conditions for an effective sterilization process, therefore effective drying is essential to prevent any unnecessary cycle aborts.

- **Inspection -** Visually inspect all instruments to ensure cleanliness and integrity (e.g. cracks, defects, adhesive failures).
  - Repeat the cleaning if necessary!

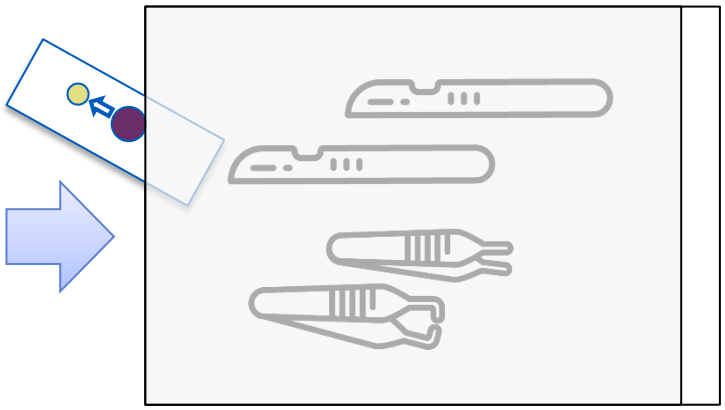
Do not reassemble equipment/device prior to disinfection/sterilization.

Packaging

Preparing of Load

Chemical Indicators

- **One H_2O_2 Chemical Indicator *recommended to* be placed in *every* sterilization package**

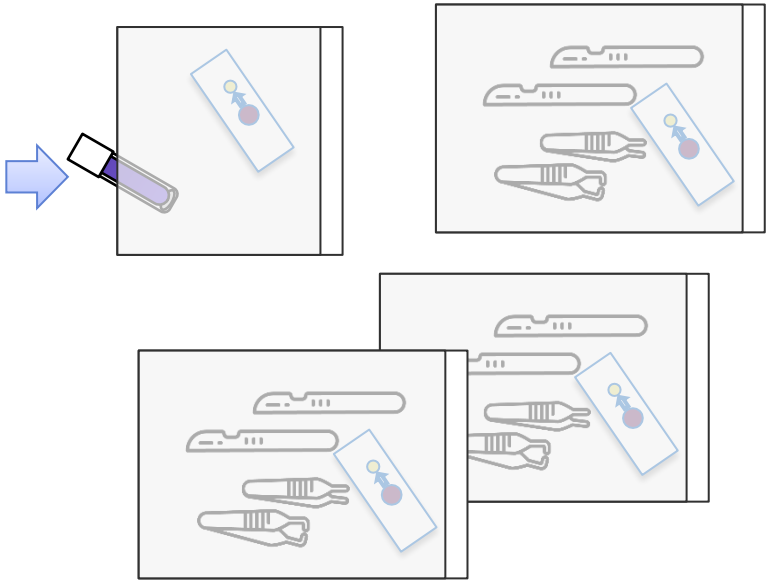


Chemical indicators: use sensitive chemicals to assess physical conditions such as temperature during the sterilization process. Chemical indicators such as heat sensitive tape change color rapidly when a given parameter is reached. A chemical indicator should be placed in every sterilization package to ensure the sterilization agent has penetrated the packaging material and actually reached the instruments inside.

Packaging

Biological Indicators

- **One Tyvek sealed Biological Indicator *recommended* be placed with the load in *at least one* sterilization cycle *every day*.**
- Recommended use, one Tyvek sealed Biological Indicator per cycle.



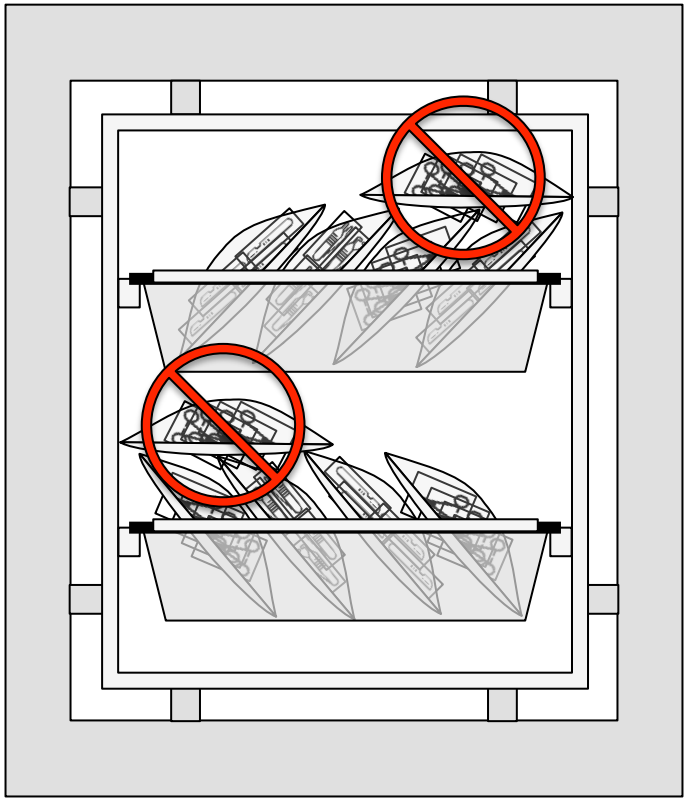
Biological indicators (BIs): are the most accepted means of monitoring the sterilization process because they directly determine whether the resistant microorganisms (e.g., Geobacillus or Bacillus species) are present post-cycle, rather than determining whether the physical and chemical conditions necessary for sterilization are met. Because spores used in BIs are more resistant and present in greater numbers than are the common microbial contaminants found on patient care equipment, an inactivated BI indicates that other potential pathogens in the load have also been killed.

Placing

No Top Loading

Top Loading:

It is recommended not to place packaged instruments above each other (i.e. a second layer above the first layer of instruments in the tray). Top loading may limit the free diffusion of H2O2 gas throughout the load.



Thank you!