

Alternatives to Steam Sterilization

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The sophistication of surgery has resulted in the need for more than the traditional steam sterilization. While most devices can be safely steam sterilized, there are many devices, which are heat and/or moisture sensitive. So what are the alternatives and how realistic are they?

Today, there are many alternatives to steam. Ethylene oxide gas (EO), low temperature gas plasma (LTGP), peracetic acid, ozone and liquid chemicals (e.g. glutaraldehyde). They all have advantages and disadvantages.

Ethylene Oxide Gas

Ethylene oxide (EO) gas is a chemical agent used for the sterilization of heat, pressure and/or moisture sensitive items. It is a member of the ether family also known as peroxide. EO is a liquid that, at room temperature, becomes a gas. It is used as a fumigant, pesticide and for sterilization.

There are several types of EO used for sterilization. The most common is the 100% in undiluted unit dose cartridges. This formulation has become more predominant since the ban of CFC's in 1995 because of their ozone depleting action.

Mixtures of ethylene oxide include the addition of inert gasses such as hydrochlorofluorocarbons (HCFC's) and carbon dioxide. However the HCFC's have been banned after 2023 in U.S. Another formulation is EO with carbon dioxide. EO is flammable in both the liquid and gaseous state.

Regulations – The Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) regulate EO. There are regulations for storage of EO. EO is used frequently for sterilization because it has the ability to be absorbed by many materials. OSHA regulations require that operators of the sterilizers must demonstrate competence in all of the parameters of EO sterilization and a comprehensive knowledge of the system in use. In addition, employee exposure to EO must be monitored and special ventilation; alarm systems, spill plans and medical surveillance are required. EPA regulates EO released into the atmosphere (many states prohibit EO release into the environment; EO abatements are required). In 2008 the EPA initiated new regulations requiring only full loads of ethylene oxide be run unless the facility has an abatement system. However, there is a clause in the regulation that if a less than full load must be run for a medical necessity, the Sterile Processing Director or facility

administrator need to document the medical necessity.

As of Feb 28, 2010 aeration should be done in the same chamber as sterilization. The aerator must have a dedicated exhaust and provide continuous, filtered air washes. This means loads can no longer be transferred to a back-up aerator.

Achieving Sterility with EO

Items must be clean before sterilization. Materials to be sterilized, and packaging, should be maintained in an environment with a relative humidity of at least 50%. Items to be sterilized must be completely dry. All traces of lubricants (exception is instrument lubricants which must be compatible with EO) must be removed. Most packaging materials that are acceptable for steam are also acceptable for EO.

The usual cycle times range from 1-12 hours depending on the temperature. (Usually 105 minutes at 130°F.)

Due to the toxic nature of the EO gas, all items processed must have the EO removed (aerated) before the device is considered safe for handling or use on a patient. A mechanical aeration cabinet is used (most common today the aeration cycle is built into the sterilizer). It must have a dedicated exhaust. The temperature determines the length of time needed for aeration. The usual aeration times are:

- 122°F for 12 hours
- 130°F for 10 hours
- 140°F for 8 hours.

Aeration time is affected by heat; the higher the temperature, the shorter the aeration time. Typical aeration times and temperatures are 122°F (50°C) for 12 hours, 130°F (54°C) for 10 hours, or 140°F (60°C) for 8 hours.(ANSI/AAMI ST41, Section 8.8) As noted earlier, however, it is critical to follow the device manufacturer's aeration instructions. Assumptions should never be made about the time required for aeration of a particular item. For patient and staff safety, it is very important for the CS/SPD technician to verify that the load has received the correct amount of aeration time at the specified temperature before items are released by carefully reviewing the printout time and temperature for the entire aeration cycle. If all cycle parameters were met, the printout should be signed and the load release. If the aeration cycle parameters are not met, the load should not be released.

Problems Associated With EO

The benefits of EO outweigh the risks. However, one must be aware of the health hazards associated with EO residuals caused by improper or inadequate aeration, which can cause death or irreversible tissue damage.

EO is classified by OSHA as a carcinogen and a reproductive hazard. OSHA regulations include employee exposure measures, sterilization installation and engineering controls, medical surveillance, leak detection, emergency situations, as well as other aspects.

Costs – ethylene oxide gas is more expensive per cycle than steam and most of the alternative sterilization methodologies due to the necessary compliance with OSHA regulations. In addition, the extended time to properly and safely aerate devices (a complete cycle can take 12-16 hours) makes turnover of devices unrealistic.

Low Temperature Gas Plasma (LTGP)

This system was cleared in 1993 as an alternative to ethylene oxide. It uses a small amount of liquid hydrogen peroxide, which is energized with radio frequency waves into gas plasma. Cycle time is 45-50 minutes depending on the load configuration. The temperature is below 122 degrees F. (50 degrees C.). The hydrogen peroxide is provided in multi-dose cassettes containing 10 single doses of liquid (nominal) 59% hydrogen peroxide.

The sterilizers chamber size is approximately 3 cubic feet however there is also a double capacity chamber size available. It is important to remember that due to the short cycle time, a large chamber is not necessary for all facilities.

All devices processed in LTGP **must be thoroughly cleaned and dried.** Any moisture remaining in devices can result in an abort of the cycle. Compressed air can be used to blow out moisture out of lumens and other hidden places.

As with all devices, only those devices which meet the clearances for the LTGP system and/or are cleared by the device manufacturer, should be processed in this system.

The system only requires an electrical hook-up so installation is inexpensive. There are restrictions on lumen diameter and length. (NOTE: There is now a smaller unit that is compatible with most lumens).

The phases of the basic LTGP include:

● **Vacuum** – all air removed from the chamber and packages until the pressure is reduced to below atmospheric pressure.

● **Injection** – once the correct pressure has been reached, a pre-measured amount of concentrated (59%) hydrogen peroxide (H₂O₂) is pumped from the cassette into the Valve Vaporizer Bowl and vaporized into the chamber.

● **Diffusion** – The diffusion stages drives hydrogen peroxide vapor into the small crevices and lumens of the devices in the chamber. The chamber will return to atmospheric pressure in order to accomplish this.

● **Plasma** – A vacuum decreases the pressure and radio frequency (RF) energy is radiated within the chamber from the electrode screen. The RF energy ionizes the hydrogen peroxide, creating hydrogen peroxide gas plasma and leads to the generation of free radicals and other chemical species, which destroy organisms.

- The injection/plasma phases are repeated a second time.
- Vent** – At the end of the second sequence, the Radio Frequency (RF) is turned off. Air is then vented into the chamber through bacterial HEPA filters, returning it to atmospheric pressure.

At the end of the sterilization cycle, a 10 second continuous audible alarm sounds, alerting the operator that the cycle is complete and items can be removed from the sterilizer. The printer prints a summary of the cycle parameters. The operator can then open the door, remove all of the sterilized items and close the door. There are no toxic residues so the items can immediately be used.

Packaging materials - Instrument trays used in LTGP should be designed to optimize diffusion of the hydrogen peroxide and not interfere with the Radio Frequency (RF) energy or absorb hydrogen peroxide. Do not use linen, paper wraps, peel packaging materials, or any cellulose-based material. Check with tray manufacturers before purchase/use of containers. **The following packaging materials are compatible with LTGP;** trays from the sterilizer manufacturer; Tyvek (all plastic) pouches (no paper plastic pouches) and polypropylene based wraps.

Safety Considerations - LTGP system uses a 59% liquid hydrogen peroxide (nominal solution). Avoid contact with skin and eyes. Skin contact can cause tingling, irritation or burning and a white discoloration. Contact with the eyes can cause tissue damage. Refer to the Material Safety Data Sheets for Hydrogen Peroxide.

NOTE: There are now several types of LTGP sterilizers; follow the sterilizer manufacturer's instructions for use carefully.

Ozone Sterilization

Ozone sterilization was cleared for use in the US in 2004. It uses oxygen that is subjected to an intense electrical field that separates oxygen molecules into atomic oxygen. It then combines with other oxygen molecules to form ozone. At the end of the cycle oxygen and water vapor safely vent into room, leaving no toxic residues.

Ozone Sterilization is easy to use. The sterilizer is 4.3 cubic ft in size.

Ozone Sterilization cycle parameters (repeated twice):

- Vacuum
- Humidification
- Ozone injection/exposure
- Ventilation

Ozone Sterilization - requires a well ventilated room with 10 air exchanges/hour.

Installation only requires an electrical outlet, oxygen source and demineralized water for humidification. The total cycle time is 4 hours.

LIQUID CHEMICALS

Activated Glutaraldehyde – is a liquid high-level disinfectant (however with prolonged soak times sterilization can be achieved). Thorough pre-cleaning of devices is required! It is mainly used for immersible items. It is critical that the solution makes contact with all surfaces of the device to achieve high-level disinfection (HLD). Follow the manufacturer's instructions for use regarding temperature of the solution, etc. If a specific temperature is recommended, a thermometer is needed to verify the proper temperature has been achieved and maintained throughout the disinfection process.

Today, the main use is for flexible and rigid scopes. It is non-corrosive to plastic, metal and lensed instruments. Glutaraldehyde has a shelf life (printed on the jug – determined by the manufacturer) and a use life. One formulation adds a buffer to make the solution last longer.

Because the minimum effective concentration (MEC) of the solution can fall below the required level (even before the stated expiration date) it is now recommended that the efficacy of the solution be tested **before each use**. The test strips are placed into the solution and interpreted per the manufacturer's instructions. Test strips should be purchased from the solution manufacturer (more accurate). The minimum soak time is determined by the disinfectant manufacturer and is often affected by temperature.

The use life of the disinfectant can be adversely affected by soils, temperature and in-use dilution (from not removing all rinse water after cleaning).

Glutaraldehyde - The 2% alkaline solution is effective against all vegetative bacteria, viruses, TB and fungi. The solution can be toxic; therefore thorough rinsing is required to remove all residues. Three separate rinses should be performed and the water should not be reused. For cameras and rigid scopes, sterile water should be used. It is important to understand that the quality of the rinse water can re-contaminate the device. Most often, sterile water is used for the rinse.

When using glutaraldehyde, proper ventilation is needed. The vapors can be a respiratory irritant. The liquid can be a skin irritant. The solution should only be used in a limited traffic area. A local exhaust hood may be needed to capture vapors during processing. The hood should be connected to a non-re-circulating exhaust system to the outside. There are also self contained systems. The hood should be monitored for efficacy.

Special personal protective equipment is needed when using glutaraldehyde. It is recommended to wear eye shields, fluid resistant mask (for liquid not fumes), butyl or nitrile rubber gloves (no vinyl or neoprene) and a polyethylene gown with long sleeves. Store the solution covered (in a basin).

OSHA has established a ceiling limit for employee exposure at 0.2ppm. However there is no OSHA standard for glutaraldehyde. Therefore, OSHA defers to the American

Conference of Governmental and Industrial Hygienists, which recommend that at no time should the ceiling limit of 0.05 ppm be exceeded. Employee monitoring for exposure to glutaraldehyde fumes must be performed. This is usually conducted by an outside service that analyzes air/ gases.

A Spill Plan is needed in the event the solution is spilled. For disposal, check the local or state regulations. Usually, it is recommended that the glutaraldehyde be diluted with copious amounts of running water before emptying into the (drain) sanitary sewer line. Dispose of containers per label instructions.

Ortho-phthaldehyde (0.55%) Cidex OPA

Another high-level disinfectant is Cidex OPA. It is a non-glutaraldehyde product that is non-toxic and has a label claim for a 12-minute soak time for high-level disinfection at a minimum temperature of **20°C (68°F)** for manual high level disinfection.

When used in **an automated endoscope reprocessor**, set the machine for the appropriate time and temperature (for Cidex OPA 5 minute soak time at a minimum temperature of 77°F. 25°C). If the temperature cannot be adjusted a 12-minute soak time is needed. The 5-minute claim DOES NOT apply to OPA when used without an AER.

No employee monitoring is needed. It has a 14 day use life. Any unused portion can remain in the original bottle for 70 days. Cidex OPA should be used in a well-ventilated area. Routine PPE is needed. You may have to double glove because the product stains protein. This is seen as an advantage because if the device is not properly the protein soils will stain grey/black. This product is non-forgiving, you must use as directed.

LIQUID PERACETIC ACID PROCESSING SYSTEM

Peracetic acid is FDA-cleared as a liquid chemical sterilant. Because processing with peracetic acid is a wet system, it can only be used for immersible items. Devices to be processed are not packaged, so care must be taken to avoid recontamination after processing. Like immediate use or flash sterilization, the peracetic acid processing system is a point-of-use, just-in-time system. Therefore, the processor should be located as close to the point of use as possible. It is essential to follow the sterilizer manufacturer's written instructions for use. The STERIS® 1E™ Liquid Chemical Sterilant Processing System is cleared for processing of immersible, semi-critical and critical heat-sensitive medical devices, including multi-channel, flexible surgical endoscopes.

It is important to verify with the device manufacturer that the device is compatible with the peracetic acid processor and to verify with the device manufacturer that the device was validated for the specific processor in use.

Only those devices that have been validated by the device manufacturer for compatibility with the Steris system 1E should be processed in this method.

The peracetic acid is provided in powder (dry) form in a single-dose container. The container of powdered concentrate is punctured during the cycle, and the concentrate is diluted with water inside the processor chamber, creating the sterilant. A new container of peracetic acid is needed for each cycle. The use dilution enters the chamber and is heated at a temperature of approximately 46°C- 55.5°C (115°F-131°F) for 6 minutes. The use dilution drains from the chamber.

Two post-rinses occur after the processing cycle. All water is filtered using pre-filters, UV irradiation and a MaxPure™ filter) to ensure that processed items are not recontaminated. It is important to monitor the filters and change them periodically as recommended by the manufacturer. Filter changes should be documented. It should be noted that the facility's water quality can affect how frequently filters must be changed. The total cycle time is 23-25 minutes. The manufacturer recommends that at the completion of the cycle, the user verify that the peracetic acid container is empty because the physical monitors do not measure the presence or concentration of peracetic acid.

All items being processed must be thoroughly cleaned first. The processor is a table-top unit that has processing trays and containers to position devices such as multi-channel, flexible endoscopes, rigid endoscopes, and associated instrumentation for processing. It is of paramount importance that when processing flexible endoscopes in the peracetic acid processor, the user must be thoroughly familiar with the processor and know the correct QUICK CONNECT to attach to the flexible endoscope. If an incorrect QUICK CONNECT is used, the peracetic acid will not reach all areas of the endoscope for effective processing.

The CS/SPD technician must carefully review loading to ensure effective processing.

Monitoring the Cycles:

EO sterilization is monitored using internal and external chimerical indicators specifically designed to react to the parameters for EO sterilization. The spore used to monitor EO cycles is *bacillus atrophaeus*. Because of the critical parameters needed for sterilization, AAMI recommends biological monitoring of each cycle/load of EO.

LTGP is monitored using special internal and chemical indicators specifically designed to react to hydrogen peroxide. The chemicals used in the indicators are sensitive to fluorescent light; therefore they should be stored away from direct light (follow the manufacturer's instructions for storage conditions). The spore used to biologically monitor LTGP is *geobacillus stearothermophilus*. AAMI recommends BI testing daily preferably with each load.

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Ozone sterilization has special internal and chemical indicators to monitor this process. Appropriate FDA-cleared CIs should be used in each package. In addition, BI monitoring should be performed daily, preferably with each cycle/load. The BI is a self-contained BI containing *Geobacillus stearothermophilus* spores and intended specifically for ozone sterilization.

The Peracetic acid system requires a diagnostic test be performed daily before the system is placed into use. It is recommended to use a chemical indicator specific for peracetic acid in each

cycle. Follow the manufacturer's instructions for use and appropriate color change. The CI manufacturer's instructions for use (including interpretation of the color change) and storage (including the expiration date) should be followed. At the end of the process if a CI suggests inadequate processing, the contents of the load should not be used.

At this time there is no biological test for this system since it is a liquid chemical system.

SUMMARY

There are a number of alternatives to steam sterilization available today. All have advantages and disadvantages. It is important for an organization to extensively review the alternatives and what would best meet the need of your organization. Consider what types of surgical instrumentation you need to process. Two very important considerations are space and cost. The space requirements can be significant and you want to know what the process will cost in both capital and operational expense. It is also important to involve other members of the team in the purchase of this type of equipment. Often, engineering or construction services will work closely with the vendor to meet the requirements for the installation of a sterilization system. This is important work to do prior to finalizing a purchase to reduce implementation problems later on.

REFERENCES:

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TSO3 website for Ozone Sterilization.

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POST TEST QUESTIONS: Alternatives to Steam Sterilization

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POST TEST QUESTIONS:

- 1) The sterilization system that is the most expensive per cycle is:
 - A) low temperature gas plasma
 - B) dry heat
 - C) steam
 - D) ethylene oxide gas

- 2) To render ethylene oxide less explosive and flammable ETO has been mixed with a number of inert gasses including all of the following **EXCEPT**:
 - A) CFCs
 - B) HCFCs
 - C) Oxygen
 - D) Carbon dioxide

- 3) ETO sterility can best be achieved when the relative humidity of the environment is maintained at
 - A) 40%
 - B) 50%
 - C) 60%
 - D) 70%

- 4) The recommended **minimum** aeration time when the aerator is set at 140°F. Is
 - A) 8 hours
 - B) 10 hours
 - C) 12 hours
 - D) 15 hours

- 5) Low temperature gas plasma sterilization uses liquid hydrogen peroxide in what concentration?
 - A) 39%
 - B) 49%
 - C) 59%
 - D) 69%

- 6) For low temperature gas plasma and ETO sterilization, prior to sterilization, it is essential that items
- A) be completely dried
 - B) be visibly moist
 - C) with lumens be flushed with distilled water
 - D) be lubricated with water soluble lubricant
- 7) The phase of low temperature gas plasma sterilization that drives the hydrogen peroxide vapor into the small crevices and lumens is called
- A) Vacuum
 - B) Injection
 - C) Diffusion
 - D) Plasma
- 8) Liquid chemical disinfectants and sterilants should have the minimum effective concentration (MEC) of the solution tested with what frequency:
- A) Twice a week
 - B) Weekly
 - C) Daily
 - D) Before each use
- 9) The best type of gloves to wear when working with glutaraldehyde solutions is
- A) Latex
 - B) Butyl or nitrile rubber
 - C) Neoprene
 - D) Vinyl
- 10) The recommended soak time for high level disinfection with manual soaking of items in Ortho-phthaldehyde is:
- A) 5 minutes
 - B) 10 minutes
 - C) 12 minutes
 - D) 15 minutes

See next page

Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

No refunds (all sales are FINAL), prices subject to change.

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.
Sorry, no personal checks.

Please see the form on the following page.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

Sterile Processing University, 59 Allerton Road, Lebanon, NJ 08833.

Name: _____

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For Credit Card Orders Only: ___ Visa ___ MasterCard ___ Discover

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If you have any questions, please email heidi@spdceus.com

Thank you!