3M™ Steri-Vac™ Frequently Asked Questions

Question: Is ethylene oxide (EO) being banned for use as a medical device sterilant?

Answer: No. In fact, the use of EO for sterilization of single-use medical devices has steadily increased over the past 10 years and EO is now used to sterilize over half of all single-use medical devices in the United States.

Question: How does the safety of EO compare with hydrogen peroxide (H_2O_2)?

Answer: All chemicals used in low temperature sterilization processes are toxic – after all, their function is to kill/inactivate microorganisms. Like other chemicals, these sterilants pose a threat to workers if they are exposed to greater than recommended levels.

- The National Fire Protection Association (NFPA) rates substances on a number of hazards using a scale of 0-4 with 4 being the highest risk. As a Health Hazard, NFPA rates both H_2O_2 and EO as "3" (extremely hazardous).
- The Occupational Safety and Health Administration (OSHA) has established a 1 part per million (ppm) 8-hour time weighted average Permissible Exposure Limit (PEL) for H_2O_2, the same as for EO. Area monitors are available to protect workers from accidental exposure to both EO and H_2O_2. EO users must follow the requirements of OSHA's occupational exposure standard for EO (29 CFR 1910. 1047).
- NIOSH's Immediately Dangerous to Life or Health (IDLH) toxicity level is set at 75 ppm for H_2O_2 and 800 ppm for EO. In the hospital sterilization application, concentrated H_2O_2 solution poses a risk to health care workers as it is a severe irritant/corrosive to the skin and eyes, and inhalation of mist or vapors may be severely irritating to the nose, throat and lungs. EO can cause severe skin and eye irritation and is a cancer and reproductive hazard.
- Vaporized H_2O_2 is a newer sterilization technology using a toxic chemical. Hence, there are not yet any regulations to mandate safety standards for health care workers using the system.

Question: Is EO more dangerous to use than other low temperature sterilization systems?

Answer: No. Modern EO sterilization systems are designed to operate safely and efficiently. Verification of operator safety can easily be demonstrated by the routine use of personnel monitoring badges. These devices, such as the 3M™ 3550 EO Monitoring Badge, are extremely sensitive and specific to EO. They are used widely to demonstrate worker safety as well as compliance to OSHA regulations for EO.

Question: What is aeration?

Answer: Most items sterilized in EO systems will absorb small quantities of EO. Aeration is the process to remove these residuals to a safe level for both personnel and patients. The aeration process simply consists of holding the sterilized items at a specific temperature for a specified time. Medical device manufacturers provide the recommended aeration time for items for which they recommend EO sterilization.

Question: Why do I need to aerate product items sterilized with EO but not with other low temperature sterilization systems?

Answer: The key to successful sterilization using chemicals is to attain prolonged contact with the chemical sterilant and the microorganisms in/on the medical item. These microorganisms reside on the surfaces of the medical items (both external and internal surfaces such as lumens). EO penetrates extremely well into lumens and channels and also into the device materials themselves. Therefore, time is needed to remove the residual EO from the devices before they can be used for patient care (i.e., the process of aeration). Other low temperature sterilants do not penetrate well and therefore do not require time for aeration.

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Question: Why doesn't 3M shorten the aeration times for the EO process?

Answer: The removal of EO residuals in the medical items is time related. Increased temperature and pulsed vacuums have been shown to shorten the aeration time, but not significantly. Unfortunately, long aeration times are inherent with the use of the EO process.

Question: What is an abator?

Answer: An abator is an emission control device that catalytically converts EO to water and carbon dioxide with 99.9% efficiency (when EO concentrations are > 100 ppm). Some states and localities (or other jurisdictions) in the U.S. require the use of emission control devices for EO sterilizers.

Question: What utility connections does the Steri-Vac™ sterilizer require?

Answer: Your service technician will provide detailed installation information. But briefly, requirements include room ventilation (at least 10 changes per hour), connections to electrical power, vent lines, compressed air lines, and connection to a dedicated exhaust system for the local exhaust hood.

Question: Does 3M provide installation of Steri-Vac™ systems?

Answer: 3M provides site planning and installation guidance to the customer, which is typically passed on to the contractor. Completed installations are certified prior to use of the equipment.

Question: Is the Steri-Vac™ EO system cost-effective?

Answer: Yes. Both initial costs and cost per load compare very favorably with other low temperature sterilization systems.

Question: What is the load capacity vs. chamber size?

Answer: Sterilizers used in health care facilities are generally characterized by the terms "chamber size" and "usable" chamber size (load capacity). Chamber size is the volume of the chamber as calculated by multiplying width × height × depth (or π radius^2 × depth for a circular chamber). This value is indicated in cubic feet or cubic meters. Usable chamber size (or load capacity) reflects the actual quantity of goods that can be placed in the chamber at one time. The usable chamber size in some sterilizers is smaller than the chamber size due to:

- Chamber geometry (a cylindrical chamber will lose usable space as a result of the shelf located near the bottom of the chamber),
- Components inside the chamber such as a metal screen, or
- Restrictions that load items do not touch the interior surfaces of the chamber

Question: What are the 3M recommendations for storage of Steri-Gas™ cartridges?

Answer: The 3M recommendations for storage of Steri-Gas™ cartridges are more stringent than those in the NFPA (National Fire Protection Agency) codes. It is recommended that a maximum of 12 cartridges (i.e., 1 box of 4-100 or 8-170 cartridges) be kept in the immediate sterilizer area and that additional cartridges be stored in a flammable liquid storage cabinet vented to the outside atmosphere.

Question: What items can and cannot be EO sterilized?

Answer: Unlike other low temperature sterilization systems, virtually all medical device materials and packaging are compatible with the EO sterilization process. Liquids, wood and leather items are not recommended for EO or other chemical processes. Additionally, due to the strong penetrating power of EO, there are no defined lumen restrictions as with the alternative systems.

Question: Is a separate room required for an EO sterilizer?

Answer: It is recommended that wherever possible an EO sterilizer should be located in a separate containment area with appropriate ventilation. This recommendation is intended to provide the maximum operational safety including control of personnel traffic patterns. If a separate area is not available, an EO sterilizer can be installed in an open area as long as the ventilation system is rated for at least 10 air changes per hour and traffic patterns are controlled.

Question: Is an EO area monitor required when using an EO sterilizer?

Answer: While OSHA doesn't specify the use of an area monitor, it does require employers to have a method to alert employees to emergency situations. An EO monitoring system is an effective method of satisfying this requirement.

Question: Isn't ozone sterilization the process of the future?

Answer: The alluring aspect of ozone sterilization is that the sterilant (ozone or O_3) is produced in the sterilizer from oxygen (O_2) supplied from a cylinder. Upon completion of the cycle, the O_3 is converted back to O_2. The limitations of O_3 as a sterilant, however, are virtually the same as with vapor phase hydrogen peroxide. There are limitations of the O_3 process relative to medical item materials compatibility as well as penetrability, such as lumen restrictions. While ozone sterilization may have niche applications, it is not currently considered a general purpose low temperature sterilization process.

Question: Is the U.S. Environmental Protection Agency (EPA) restricting the use of ethylene oxide?

Answer: No, the EPA issued a regulation in 2007 controlling air emissions from hospital sterilizers using ethylene oxide. The regulation basically requires hospitals to adopt a management practice of sterilizing full loads of items having a common aeration time. An exemption to full loads is allowed under medically necessary circumstances. The use of an air pollution control device, such as the 3M™ EO Abator, is an alternative compliance method. After February 28, 2010, the EPA requires hospitals and health care facilities to use a single chamber process for sterilization and aeration.

Question: How long are Steri-Vac cycles?

Answer: The Steri-Vac™ 5XL and 8XL are both able to run warm (55° C/131° F) and cool (37° C/99° F) cycles. Approximate sterilization cycle times, not including aeration, are:

- 8XL: warm cycle – 3.75 hours; cool cycle – 5.5 hours
- 5XL (with local exhaust hood): warm cycle – 2.75 hours; cool cycle – 4.75 hours

Consult medical device manufacturers for recommended aeration times.

Question: What are the recommended practices for monitoring?

Answer: EO: ANSI/AAMI ST41:2008 recommends routine sterilizer efficacy monitoring of every load with a Process Challenge Device (PCD) containing a biological indicator. AORN 2010 "Recommended Practices for Sterilization in the Perioperative Practice Setting" recommend *Bacillus atropheus* spore testing be performed with every load. H_2O_2: ANSI/AAMI ST58:2005 recommends a process challenge device with an appropriate biological indicator be used at least daily but preferably in every sterilization cycle and in each load containing implantable devices. AORN 2010 "Recommended Practices for Sterilization in the Perioperative Practice Setting" recommend routine sterilizer efficacy monitoring be done daily, preferably with each load; and that each load containing an implantable device be monitored with a BI and quarantined until the results of the BI testing are available.