

July 2008

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Learning Objectives

1. Compare the uses of various low-temperature sterilization processes for packaged devices
2. Discuss the newest healthcare technology - vaporized hydrogen peroxide (VHP) - and its history and various applications
3. Understand the benefits and drawbacks of available low-temperature sterilization systems in order to make educated decisions for the readers' facilities

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The lowdown on low temperature sterilization for packaged devices

by Pamela Carter, RN, BSN, CNOR, and Michael Wright

With so many surgeries, so many delicate instruments, so many sterilization options and so little time, even the most seasoned sterile processing manager's head can be left spinning. The intent of this self study guide is to improve your understanding of the available low-temperature sterilization technologies for packaged devices (including a very new low-temperature alternative) by comparing their capabilities and challenges. Once armed with this information, you can potentially simplify your processing and equipment decisions.

With so many low-temperature sterilizers to choose from, how can you narrow down your choices?

All the systems and methods we will discuss here are FDA cleared technologies, so they are all effective at sterilizing packaged devices. Each modality, however, has its own costs and benefits, and should be weighed based on the goals of your sterile processing department. Unfortunately, there is no "silver bullet" that provides the perfect combination of a fast cycle time and a broad range of material compatibility. According to the International Association of Healthcare Central Service Materiel Management, sterile processing professionals must consider eight basic requirements when evaluating low-temperature sterilization systems; effectiveness, safety, monitoring, quality assurance, sterilant penetration, material compatibility, adaptability and approval. In this self-study article, we will briefly discuss the sterilization parameters and special requirements for sterilization, and compare the "pros" and "cons" of each technology.

A day in the life of a packaged device

Sterile processing departments (SPDs) must process heat- and moisture-sensitive instruments for same-day, next-day and emergency uses. They typically sterilize

packaged delicate medical devices during the day for re-use later in the daily schedule, and at the end of each day, to store in preparation for the first surgical cases scheduled the following morning. They also proactively sterilize packaged sets and devices that can wait in sterile storage for unplanned emergencies. Until 2008, there were three options for these purposes; ethylene oxide (EO), gas plasma, and ozone systems.

EO gas sterilization

Ethylene oxide was first used in the 1950s to sterilize heat and moisture-sensitive medical devices. Today, EO systems are manufactured by 3M and STERIS Corporation, among others. EO is a colorless gas that readily and rapidly permeates medical devices, and is sporicidal and non-corrosive. However, it is also flammable and combustible at high concentrations and high volumes. Today, 100% EO is used as an alternative to the blended mixtures as it does not contain environmentally hazardous compounds (hydrochloroflourocarbons or HCFCs). 100% EO does not contribute to ozone depletion.

EO is a reactive chemical that is an alkylating agent. It contacts molecules in the presence of moisture, altering their size and shape. As a result, the molecules become unable to perform necessary functions, and this leads to the organism's death.¹

Sterilization parameters: The important variables that ensure efficient sterilization with EO are time, temperature, EO concentration, and a relative humidity of at least 35 to 85%. These variables are controlled during the sterilization process in the conditioning, sterilization and aeration phases of an automated system.

Special requirements: Effective December 29, 2008,² the new record-keeping by Environmental Protection Agency standards requires that hospitals without an air pollution control device (catalytic con-



verter or acid-water scrubber) record that a full load was run and if not, provide a statement indicating that it was “medically necessary” (air pollution control equipment reduces the quantity of EO from sterilization and aeration processes). In addition, aeration of toxic EO is required to remove it from instruments and devices for use or storage; environmental and personnel monitoring (equipment and badges) is required to determine the level of EO exposure; and record-keeping of each cycle is required.

Pros of EO: Ethylene oxide sterilization offers superior penetration and compatibility for devices including flexible endoscopes, has no lumen restrictions and no packaging restrictions, and offers broad compatibility with device components and other materials.

Cons of EO: The process requires prolonged, lengthy aeration cycles, environmental and personnel monitoring, and a new record-keeping protocol per EPA; the cost of EO blend mixtures is high, there are specific installation requirements, and EO is toxic and flammable.

Gas plasma sterilization

The gas plasma process has been in existence since the early 1990s and has become popular due to its short cycle times, which facilitate faster instrument turnaround. Low-temperature *hydrogen peroxide gas plasma* sterilization uses a combination of hydrogen peroxide vapor and plasma. Hydrogen peroxide vapor is generated from 59% liquid peroxide. Some systems generate a metered dosage at a predetermined volume onto a heated vaporizer and introduce it into the sterilization chamber, while others use a single-unit dose cartridge that is punctured and pulled into the evacuated chamber during the sterilization process (this process is used in STERRAD® sterilizers). Some of these systems condense water from the sterilant, which results in a hydrogen peroxide concentration of approximately 95% (please see sidebar). At the completion of the cycle, the by-products are vaporized water and oxygen.

Sterilization parameters: The important variables that ensure sterilization are time, temperature, H₂O₂ concentration, and vacuum level. The process phases include a leak test, conditioning, sterilization and aeration, with a cycle time variance of 28

to 75 minutes. Cycle times are dependent upon model type, device design, materials types and load size.

Special requirements: None.

Pros of gas plasma: Gas plasma systems have rapid cycle times, and require no aeration and no personnel monitors. They have non-toxic by-products (water and oxygen) and are compatible with a wide variety of materials and devices including limited single-channel flexible surgical scopes, instruments processed with gas plasma have a long shelf life, and the H₂O₂ sterilant cassette is self-contained.

Cons of gas plasma: The process is extremely moisture-sensitive (the cycle may abort if excess moisture is present), certain models have limited capacity, and specific flexible scope materials may not be compatible with the process. High H₂O₂ concentrations (up to 95% on certain models) are necessary, and there are special loading considerations (avoid contact with chamber walls, not too many metal instruments) due to the plasma coil. The process also has some penetration limitations (follow lumen diameter and length guidelines). In addition, mechanical problems have been documented that can lead to H₂O₂ residuals within the load or the release of H₂O₂ from the chamber.¹

Ozone sterilization

Ozone is an effective low temperature sterilization method. It requires no sterilant purchase because the system itself generates O₃ using only water and oxygen (this type of sterilizer is available from TSO₃, Inc.). Ozone is diffused through the load by a vacuum/humidification process and organisms are killed by oxidation, which attacks an organism’s structure and makes it non-viable. At the end of each cycle, ozone is exhausted through a catalytic converter. The total cycle time is 4 to 5 hours.

Sterilization parameters: The key variables for sterilization are time, temperature, O₃ concentration, relative humidity of at least 85 to 100% to precondition the load, and a sterilization temperature maintained at 30 to 36 degrees Celsius. Approximately 700 to 800 liters of oxygen and few milliliters of water are used during the processing.

Special requirements: Systems require medical grade oxygen and deionized water.

Pros of ozone: Cycles are inexpensive and there is no sterilant to handle. No venting or personnel monitors are required, and the systems produce non-toxic by-products and have a large processing capacity.

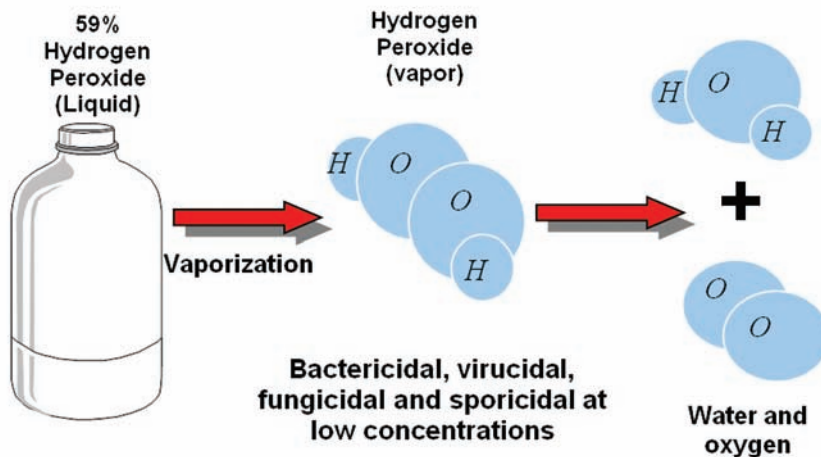
Cons of ozone: The cycles are long and there are some penetration limitations (you must follow lumen diameter and length guidelines). There are safety and ergonomic concerns because of the large oxygen tanks supplying the system. In addition, ozone processes have no flexible scope sterilization claim, and not all device and packaging materials are compatible with the process.

New kid on the sterile processing block – VHP sterilization

Vaporized hydrogen peroxide (VHP) technology was originally developed by STERIS Corporation and introduced in the early 1990s. It soon became a “gold standard” for pharmaceutical sterilization, in critical environments where drugs are produced and packaged. The applications of VHP have extended beyond pharmaceutical production to include the sterilization of medical devices and room surfaces (research labs, etc.). More recently, the technology has been used to decontaminate entire buildings. During the anthrax attacks in the United States in 2002, VHP played an integral part in the clean-up effort. The systems were used to fumigate areas contaminated with the toxin. It was also used after the flood waters of Hurricane Katrina receded in New Orleans and in hospitals abroad, to limit MRSA outbreaks. Two new VHP systems have been introduced within the last 1 ½ years for use in healthcare facilities; one for room sterilization and one for processing packaged, heat and moisture-sensitive instruments for terminal sterilization and storage.

VHP is created by dropping liquid hydrogen peroxide onto a hot surface, instantaneously transforming it into a dry vapor form. VHP is extremely effective as an antimicrobial (bactericidal, fungicidal, virucidal and sporicidal) agent. In contrast, *liquid* H₂O₂ requires a much higher concentration (370mg/L) than gaseous H₂O₂ (1-2mg/L) to achieve the same 1-log reduction of living organisms

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(D-value). Since VHP is injected under vacuum conditions to sterilize devices, the vapor easily permeates the packaging and the load, contacting all surfaces and penetrating hard-to-reach lumens. The newest VHP-based low-temperature sterilization system (V-PRO™ 1 Low Temperature Sterilization System) offers a more productive, less process-sensitive alternative to EO, gas plasma, and ozone systems.

This system's VHP automated cycle is 20 minutes faster than some gas plasma cycles, three to four hours faster than the ozone process, and so much faster than the EO process that up to 16 additional loads can be processed each day.

Aborted cycles have become a challenge for the SPD because they result in repackaging, reloading and reprocessing of the devices, and they cost the department in additional sterilant and staff time. Aborted cycles can also impact surgical suite productivity in the form of delayed or cancelled procedures and a disrupted OR schedule. Aborted cycles can often be an issue with gas plasma systems, which are highly sensitive to the way in which contents are loaded into the chamber, to residual moisture on the instruments, and to the amount of metal contained in the instrument packs. Any of these factors may cause unnecessary cycle aborts. In contrast, the VHP sterilization process is not hypersensitive to load contents and positioning, and the cycle includes a pre-conditioning phase that automatically detects and removes excess moisture, which helps to alleviate aborted cycles and their frustrating consequences.

Sterilization parameters: Important variables to ensure sterilization are time, temperature, H_2O_2 concentration and vacuum level. The process phases include conditioning, sterilization and aeration for a short cycle time (55 minutes).

Special requirements: None

Pros of VHP: The system offers a rapid cycle time and a larger processing capacity than other systems. No plasma is necessary for this process. A pre-conditioning phase detects and removes excess moisture, and no aeration or personnel monitors are required. The by-products of the process are non-toxic (water and oxygen), and the process is compatible with many devices. Instrumentation processed with VHP has a long shelf life, and the sterilant is generated from a closed H_2O_2 (Vaprox®) cartridge.

Cons of VHP: There are penetration limitations that require adherence to the system's lumen diameter and length guidelines, and the VHP process has no flexible scope sterilization claim. In addition, VHP should not be used to sterilize cellulose materials (disposable towels, paper, etc.).

Select the best processes and systems for your needs

In a busy SPD, even modest improvements to processing volume and time can make a huge difference in the department's productivity each day. Specifically, variables such as cycle time and aborted cycles can affect the total number of loads that can be successfully sterilized each day, so both should be reduced as much as possible.

Patient and staff safety is another critical factor to consider when selecting sterilizers. If exposure to potentially harmful

agents can be minimized or avoided, the risks to the facility and its occupants can be reduced as well. At the same time, the facility must have technologies in place that provide them with the capability to process every material and device they reuse, since contaminated instruments also pose a risk to patients.

Achieving effective, safe and productive sterilization of packaged heat-sensitive reusable devices requires a balancing act. Sterile processing decision-makers should consider the sterilization options available in the marketplace and combine them in a way that best meets their hospital's current and future needs. **HPN**

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Benefits of hydrogen peroxide

Chances are you have a brown bottle of 3% hydrogen peroxide (H_2O_2) in your medicine cabinet at home to clean scrapes or wounds. Besides its traditional use as an antiseptic, H_2O_2 has also been used in various applications around the world as a preservative, disinfectant, fumigant and sterilant. While it is a strong oxidizing agent, it has very effective antimicrobial activity without being overly aggressive on surfaces. In its normal form at room temperature, it's a colorless, odorless and stable liquid usually provided at concentrations less than 60%. It is available in concentrations from 3% to 90%, but at concentrations above 60% it's considered to be more reactive and unstable, and may pose a health hazard. H_2O_2 is environmentally friendly, since it breaks down into water and oxygen very easily.

The lowdown on low temperature sterilization for packaged devices

Circle the one correct answer:

1. VHP technology has been in existence for nearly 20 years and used in a variety of applications, including the sterilization of packaged medical devices and room surfaces.
 - a. True
 - b. False
2. Which of the following parameters must be met to achieve sterilization using VHP technology?
 - a. Time
 - b. Temperature
 - c. Vacuum
 - d. Hydrogen peroxide concentration
 - e. All of the above
3. Which of the following factor(s) increase(s) the chance for an aborted cycle in gas plasma processes?
 - a. Loading the chamber – contact with sterilizer walls
 - b. Residual moisture on instruments
 - c. The amount of metal contained in instrument packs
 - d. All of the above
4. VHP uses alkylation to deactivate harmful microorganisms.
 - a. True
 - b. False
5. The EPA has mandated that all EO sterilizers must use an air pollution control device or document all loads.
 - a. True
 - b. False
6. The benefits of EO sterilization include:
 - a. No lumen restrictions
 - b. Superior Sterilant penetration
 - c. Flexible endoscope compatibility
 - d. No monitoring required
 - e. a, b and c
 - f. All of the above
7. Which of the following is required for ozone sterilization?
 - a. Oxygen
 - b. Water
 - c. Hydrogen Peroxide
 - d. Nitrogen
 - e. a and b
 - f. c and d
 - g. a and c
8. A large volume of hydrogen peroxide is necessary to create VHP.
 - a. True
 - b. False
9. Which of the following is the greatest benefit of EO sterilization?
 - a. Cycle Time
 - b. Penetration
 - c. Material Compatibility
 - d. No personnel monitoring
 - e. a and b
 - f. c and d
 - g. b and c
10. Which of the following technologies is cleared for use in the SPD to sterilize packaged devices?
 - a. EO
 - b. Gas Plasma
 - c. Ozone
 - d. VHP
 - e. All of the above

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