

# Sterilization

## A REVIEW OF THE BASICS

By Gayla Tilton and Myrna Kauffman



Although sterilization has been performed in healthcare facilities for many decades, the process is still misunderstood. Having a thorough basic understanding of the most common sterilization methods in use today can help healthcare professionals optimize the use of their current technologies and make future sterile processing innovations easier to grasp.

Today's fast-paced healthcare environment has created many challenges:

- ◆ Health insurance reimbursements are decreasing, which is forcing the healthcare industry to cut costs. This translates into fewer full-time employees. With fewer people to do the work, everyone is stretched a little further, and training time may be reduced. Insufficient training may directly affect patient safety if the sterilization process is compromised in any way.
- ◆ Over the past 15 years, fewer invasive procedures have been performed and more innovative minimally invasive surgeries have been developed. This trend has prompted an increase in the use of more sophisticated devices that are often complex and heat sensitive. Proper sterilization of these devices can be very challenging.
- ◆ To increase revenue, hospital administrators are requiring rapid turnaround of the OR to allow for the scheduling of more procedures. This demand, along with limited inventory of costly equipment, creates additional sterilization challenges.

These challenges underscore the need for a strong basic understanding of proper sterilization theory and technique in order to reduce risks, save time, and increase the productivity of sterilization operations. This article offers a tutorial and a beginning reference for healthcare professionals.

## Sterilization Basics

For all methods of sterilization there are two required conditions that must be met in order to assure that sterilization takes place:

1. Thorough decontamination of medical devices is required in order for the sterilization process to be successful. The manufacturers of sterilizers assume that the bioburden, or level of contamination, has been sufficiently reduced on the surfaces of instruments before they are placed in the sterilizer. Sterilizer manufacturers recommend an appropriate "kill time," or exposure time, that is based on this assumption. If the items are not visibly clean, the exposure time could be inadequate to sterilize the instruments.

2. The sterilant must come in contact with all surfaces to be sterilized. This means that items must be dismantled according to the manufacturers' instructions so that all surfaces are exposed to the sterilant.

Other variables that affect sterilization include:

- ◆ The dryness of devices to be processed
- ◆ The temperature and humidity of the processing area
- ◆ Whether or not the devices were properly prepared and loaded into the sterilizer
- ◆ Whether or not the sterilant is properly delivered into the system
- ◆ The sterilizer's condition and maintenance protocol
- ◆ Whether or not the correct sterilization method and cycle were used

## Methods of Sterilization

There are four common methods of sterilization used in healthcare today:

1. Steam sterilization
2. Peracetic acid liquid sterilization
3. Ethylene oxide sterilization
4. Hydrogen peroxide sterilization

There are high-level disinfectants with the ability to sterilize. They require lengthy immersion times (12 to 36 hours). These solutions are usually used only for high level disinfection. For this reason, they will not be reviewed here.

Whichever sterilization method is used, proper preparation and cleaning are two critical parts of the process. The goal is to remove all visible organic and inorganic "soils" by manually or automatically cleaning the devices before placing them in a sterilization system. Pre-cleaning makes devices safer for personnel to handle and pack, and allows sterilants to touch all surfaces during a sterilization process.

## Steam Sterilization

Steam sterilization was first introduced in 1880. The process used moist heat under pressure, much like a pressure cooker. The first commercial steam sterilizer, which used saturated steam under pressure, was sold in the United States in 1933. While no sterile processing method is perfect, steam sterilization certainly comes close. It is fast, non toxic, friendly to the environment, and economical.

Steam destroys organisms by coagulating the cell protein. Poaching an egg is an everyday example of protein being coagulated. In order to destroy all microbes, the steam must be able to come into contact with all surfaces. Steam can only sterilize the surfaces it can touch. For this

reason, air pockets are the greatest enemy of the steam process since they can prevent the steam from touching all surfaces. Air pockets can occur as a result of improper packing assembly and loading.

There are two types of steam cycles commonly used: gravity displacement and dynamic air removal, which includes the prevacuum and steam flush pressure pulse (SFPP) cycles. Gravity displacement steam sterilization was the first type of cycle introduced to hospitals. Operating rooms still use this type of cycle for “flash” sterilization. Gravity is used to displace the air as steam enters the chamber. A prevacuum cycle removes the air mechanically, which is more efficient. The SFPP cycle uses mechanical air removal above atmospheric pressure.

These cycles have three phases:

1. **Conditioning phase:** the air is removed, steam enters the chamber and the load is heated to a set temperature.
2. **Exposure phase:** the duration of this phase is scientifically determined. It consists of heating time, the actual kill time, plus a safety factor equal to 50% of the kill time.
3. **Exhaust phase:** after the exposure phase is completed, the steam is replaced with air, and the chamber returns to atmospheric pressure.

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#### **Peracetic Acid Liquid Sterilization**

The demand for faster turnaround time for heat-sensitive devices led to the development of peracetic acid

liquid sterilization. Ethylene oxide gas has been used for years to process heat-sensitive devices, but the aeration times needed at the end of the cycle to eliminate the gas made this method slow.

Peracetic acid was found to be sporicidal at low concentrations. It was also found to be water soluble, and left no residue after rinsing. It was also shown to have no harmful health or environmental effects. In fact, the food industry adopted peracetic acid as a sterilization method because of these beneficial properties and safety characteristics. Peracetic acid’s method of action suggests it disrupts bonds in proteins and enzymes. It may also interfere with cell membrane transportation through the rupture of cell walls and may oxidize essential enzymes and impair vital biochemical pathways.

To properly prepare for sterilization in a low-temperature liquid chemical sterile processing system, several steps must be followed:

- ◆ Meticulous pre-cleaning of the devices is necessary because many devices have small and intricately connected lumens. Improperly cleaned instruments prevent the sterilant from making surface contact.
- ◆ Any flexible endoscope with a lumen must also be leak tested to ensure there are no leaks that could allow fluid to enter the scope and cause damage. The Society of Gastroenterology Nurses and Associates (SGNA) provides specific guidelines for cleaning and leak testing. In addition, the medical device manufacturer provides specific recommendations.
- ◆ The appropriate tray/container must then be selected, and if the device has lumens, the appropriate connector attached. Specific instructions, diagrams and manuals for each connector are provided by the manufacturer.

The sterilant concentrate is provided in a sealed single-use cup and requires no pre-mixing or dilution. The empty container is discarded at the end of the cycle in regular trash receptacles.

Some of today’s processors monitor themselves for quality assurance, very much like a steam sterilizer. The printout provided at the end of the cycle shows the sterilization parameters that exist during the process. If any of the parameters are not met, the cycle cancels. The processor also has a diagnostic cycle that must be run once every 24 hours. This cycle checks the mechanics of the machine, the electrical and pneumatic systems, and the integrity of the sterile water filter membrane. Sterilant is not used in this cycle.

The disadvantages of this method of sterilization are that the devices must be immersible, must fit in the appropriate tray, and must be able to withstand the 55-degree Centigrade temperature the process uses. This

temperature setting is considered “low-temperature sterilization” and maintains the sporicidal activity of the peracetic acid at the diluted concentration.

### **Ethylene Oxide Sterilization**

Ethylene oxide (EO) has been used as a sterilant in healthcare since the 1950s. It is a colorless, odorless, and flammable gas. It is the 18th most commonly used industrial chemical, and more than eight billion tons are produced annually for the manufacturing of plastics, detergents, anti-freeze, and polyester. Only 1% of that amount is used in healthcare to sterilize heat- and moisture-sensitive devices.

Ethylene oxide was first discovered in 1859 and was initially used as an industrial and agricultural fumigant. In the 1920s, its disinfectant properties were identified, and by the 1940s the U.S. Army identified EO as a gaseous sterilant. In the 1950s, 100% EO sterilization was used to sterilize heat-sensitive devices and supported the accelerated development of heat-sensitive medical instrumentation. Because 100% EO is very flammable, safer, non-flammable EO blends were developed in the 1960s and, by the 1970s, EO had become the method of choice in the healthcare industry for sterilizing heat-sensitive items.

Personnel safety issues relating to the use of EO surfaced in the 1980s and resulted in the development of Occupational Safety and Health Administration (OSHA) permissible exposure limits and continuous monitoring requirements for work areas and personnel. Environmental concerns and the depletion of the ozone layer by the CFCs used in EO gas blends led to an international agreement, the Montreal Protocol, to phase out the use of EO/CFC blends. This was completed in 2000.

Ethylene oxide sterilizes through a chemical process known as alkylation. During this process the EO penetrates the microbial cells and reacts primarily with the nuclear material. This results in the cell's inability to metabolize and reproduce normally.

There are many advantages to using EO as a sterilant. It can be used to sterilize items that are incompatible with steam sterilization. It readily permeates and diffuses through commonly used materials, complex devices, and lumens because the EO molecule is small. Today, with the new 100% EO technologies, EO sterilization is safer and has relatively low sterilant and capital equipment costs.

However, the limitations of EO sterilization are significant. First, the sterilization cycle is much longer than other means of sterilization. Because EO can be harmful to staff and patients, each load requires a lengthy aeration step to ensure that EO is removed from the load. Sterilizers must follow certain requirements for ventilation, exhaust and monitoring because of the safety and environmental issues.

EO is also flammable; however, with the advent of the single-use 100% EO cartridge, the concern of flammability has been greatly reduced.

### **Hydrogen Peroxide Sterilization**

In the past decade a new method of sterilization using hydrogen peroxide has been introduced to the healthcare community. This method disperses a hydrogen peroxide solution in a vacuum chamber, creating a plasma cloud. This agent sterilizes by oxidizing key cellular components, which inactivates the microorganisms. The plasma cloud exists only while the energy source is turned on. When the energy source is turned off, water vapor and oxygen are formed, resulting in no toxic residues, harmful emissions, or the need for environmental monitoring.

The temperature of this sterilization method is maintained in the 40-50°C (104-122°F) range, which makes it particularly well-suited for use with heat-sensitive and moisture-sensitive medical devices. The sterilant chemistry is provided in a self-contained cassette. Depending on the sterilizer model, the sterilization cycle takes between 45-55 minutes. The instruments are wrapped prior to sterilization, and can either be stored or used immediately.

The types of wrap that can be used in a hydrogen peroxide sterilizer are non-woven or polypropylene wrap, Tyvek/Mylar peel pouches, polyethylene foam, and synthetic paper. If a facility wants a count sheet to go with an instrument set, it should be placed on the outside of the set after sterilization.

There are five phases of the hydrogen peroxide processing cycle:

1. A vacuum phase creates a vacuum in the chamber and the pressure drops to less than one pound per square inch. This phase lasts about 20 minutes.
2. In the injection phase, the aqueous hydrogen peroxide is introduced into the vacuum chamber and is vaporized into a gas, which creates a rise in pressure due to the increase of molecules.
3. During the diffusion phase the hydrogen peroxide vapor spreads throughout the chamber and the increased pressure drives the sterilant into the packs, exposing the instrument surfaces to the sterilant and killing the microorganisms.
4. During the plasma phase the radio frequency energy is applied, stripping the electrons from some of the molecules and producing a low-temperature plasma cloud. Following this reaction, the activated compounds lose their high energy and recombine to form oxygen and water. The vacuum, injection and diffusion phases are run a second time to assure optimal sterilization for even the most difficult-to-sterilize devices.

5. The purpose of the venting phase is to introduce filtered air into the chamber and return the chamber to atmospheric pressure so that the door can be opened. It lasts about one minute.

This method of low-temperature sterilization is monitored by a microprocessor for all the critical parameters and generates a printout at the end of the cycle for record keeping. If the critical parameters are not met, the cycle cancels and the printout shows the reason for the cancellation.

There are some limitations to using this process. Paper items (peel pouches, count sheets) and cloth (huck towels, linen, cotton, gauze) cannot be used to wrap instruments or enhance a set. Items must be completely dry before they are processed, or the cycle will abort. Hydrogen peroxide sterilization is not approved for flexible scopes, and rigid scopes with lumens have the following restrictions; the lumen size must be greater than 3mm in diameter and less than 400mm long.

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#### **Quality Assurance Monitoring for all Methods**

Quality assurance is an ongoing process, and everyone using any sterilization method should follow the recommended practices as defined by the Association for the Advancement of Medical Instrumentation (AAMI) and the policies and procedures of their facility. Though the AAMI Standards and Recommendations are not law, they are the recognized industry standards for sterilization and would be relevant in any legal proceeding. It is very important that all users of these methods of sterilization know how to read

and interpret the information presented by the quality assurance monitors in order to ensure compliance with AAMI recommendations and with each healthcare facility's own policies and procedures.

**NOTE:** There are no AAMI standards or recommended practices that refer to liquid peracetic acid sterilization or hydrogen peroxide sterilization.

#### **Physical Monitors**

The efficacy of every sterilization method must be monitored. The quality assurance of each process includes physical, chemical, and biological monitors. Physical monitors include gauges, printouts, Bowie Dick tests (for prevacuum cycles), and the diagnostic test for the SYSTEM 1 Sterile Processing System. These physical monitors permit the earliest possible detection of equipment malfunction because they evaluate the cycle while in progress. They verify parameters such as time, temperature, pressure, and concentration. These parameters are then recorded on a printout that becomes a part of the cycle documentation.

#### **Chemical Monitors**

Chemical monitoring is independent of the sterilizer; it is added by the operator to help evaluate cycle performance. Chemical indicators are used to detect failures of packaging, loading, or sterilizer function. The chosen chemical indicator must be specific for the sterilization method being used. Chemical indicators do not verify sterilization, they only confirm that one or more of the conditions were met during the sterilizing cycle.

There are two types of chemical indicators: external and internal. External chemical monitors are placed on the outside of each package in steam, EO, and hydrogen peroxide plasma sterilization and they allow healthcare personnel to differentiate between packages that have been exposed to the sterilant and those that have not.

Internal chemical indicators are used with every sterilization method. They are placed within each pack or container in the most difficult-to-reach area. These indicators are interpreted at the point of use after the pack is opened, and they indicate to the end user that the sterilant reached that point inside the pack.

Chemical integrators are multi-parameter indicators used inside each pack or container instead of a chemical indicator. The integrators assess all the critical process parameters. The integrator ink is correlated to a particular biological spore challenge and provides a confidence level of performance closest to the biological indicator; however, chemical integrators are not meant to replace the use of biological tests.



## Biological Monitors

Every sterilization method must be monitored with a biological indicator (BI). The BI responds to each parameter of the sterilization process and tests the ability of the cycle to kill microorganisms. According to the AAMI guidelines, a biological indicator should be used to verify cycle parameters of a new sterilizer installation, to re-verify a sterilizer's cycle parameters after major repairs, and routinely in a fully loaded chamber. For steam, peracetic acid, and gas plasma sterilization the biological monitoring should be performed at least weekly, but preferably daily. A biological indicator should be included in every load containing implantable devices and in every ethylene oxide load. AAMI guidelines also recommend that to verify the cycle parameters of a new system and to re-verify cycles after major repairs, three consecutive BIs should be run through cycles in an empty chamber and should result in three negative (no growth) outcomes after the required incubation period.

The bacterial spores used in the biological tests are the ones most resistant to kill by the various sterilization methods being monitored (these bacterial spores are not harmful to humans, however). *Geobacillus Stearothermophilus* is the spore used to test steam, peracetic acid, and gas plasma sterilization. *Bacillus atrophaeus* (formerly bacillus subtilis) is used for ethylene oxide sterilization. For each biological test, a "control" spore test strip is exposed to the growth medium and incubated without being processed in a sterilizing cycle. We would expect the control result to be positive since this indicates that the biological test strip contained viable spores.

## Environmental Monitoring

Ethylene oxide sterilization requires environmental monitoring. OSHA provides guidelines to protect workers where occupational exposure to EO is possible. Monitoring devices should be located both in the vicinity of the EO sterilizer and on each employee in the area in order to detect both the employee's passive exposure to EO and each employee's direct exposure.

## The Importance of Record Keeping

Record keeping is essential for epidemiological tracking and for ongoing assessment of the cycle effectiveness of all methods of sterilization. It can also be useful as a validation of best practices, for troubleshooting, and for sterilization process improvement.

It is very important to keep accurate and complete records that include evidence of cycle performance (printouts, BI, CI, and Bowie-Dick-type results), documentation of handling throughout the process (including decontamination

and prep and pack), and maintenance records. No national standard exists for how long these records should be kept. Therefore, state and local statute requirements and your facility's policies and procedures should be followed.

## Conclusion

The different sterilization methods that have been discussed here all share common requirements and characteristics. Whatever healthcare trends and innovations come along in the future, these basic sterilization principles and practices will most likely apply to the newest methods as well.

All healthcare personnel involved with reprocessing and sterilizing medical devices can benefit from a review of their current level of understanding of professional guidelines and best practices. We encourage you to seek out the organizations and materials listed here to learn more about best practices for your facility. †

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*Gayla Tilton, RN, and Myrna Kauffman RN, CNOR, are clinical education specialists at STERIS Corp.*

*In 1988, STERIS Corp.'s SYSTEM 1® Sterile Processing System came into the healthcare market with a buffered peracetic acid formulation (STERIS 20) that is nearly pH neutral and highly effective for sterilizing endoscopes and other heat-sensitive and delicate immersible devices. The SYSTEM 1 process is widely used today, often at or near the site of the device's use. During this process, endoscopes are sealed inside a countertop system and bathed in a specific use dilution of STERIS 20 for a precise exposure time, then rinsed with sterile water. At the end of the processing cycle, the devices are sterile and may be transferred aseptically and used immediately. This process takes about 30 minutes and provides the rapid turnaround time needed for minimally invasive procedures. For more information, visit [www.steris.com](http://www.steris.com).*