
Section Six: Sterilization

🕒 Estimated
Contact
Time:
1 ¾ - 2 hours

This module is designed to:

.... provide an overview of the sterilization process. It details the reasons for sterilization and the different methods of achieving it. You will become familiar with the types of sterilizers, their components, and how to effectively monitor sterilization cycles.

Following instruction, you should be able to:

- ☑ Identify types of sterilizers and their components.
- ☑ Identify and sequence the steps in sterilizer cycles.
- ☑ Identify EtO monitoring and personal protection requirements.

What is Sterilization?

The surfaces that we come into contact with during our everyday lives are teeming with microbial life. Even this page, though it looks clean, could harbor thousands of tiny, living organisms. While most of them are harmless, some could make you sick or even, given the right environment and time to grow, cause death. Sterilization completely destroys all forms of microbial life on a surface. It is an absolute. An object cannot be “almost,” “practically sterile,” or “sterile to a degree.”

Because of the relationship of microorganisms to infection and disease (see Module 2, Microbiology) many of the supplies and medical devices that SPD manages must be sterilized. In SPD, sterilization is normally accomplished by one of two methods: saturated steam under pressure or gas. Two other methods, dry

heat and chemical sterilization, exist, but are rarely used for terminal sterilization in VA.

Achievement of true sterilization is a function of probability, and the process is influenced by the laws of chance. There are many factors that can influence whether an item can be sterilized.

Factors Affecting Sterilization

- The number of organisms and their resistance to the sterilizing agent
- Debris, such as protein soil, oils, grease, or blood on the item that provides protection for the organisms.
- Proper loading techniques
- Functional efficiency of the sterilizing equipment
- Achieving required sterilization parameters
- Human performance—how well the people cleaning, packaging, and monitoring the sterilizers do their job
- Post sterilization handling techniques

There are several different types of equipment used to terminally sterilize medical supplies and equipment. Steam and ethylene oxide sterilizers are the two most commonly used in hospitals and clinics.

Steam Sterilization

For items that can withstand high temperatures and moisture, steam is one of the most reliable methods for sterilization. Steam is very effective in killing microorganisms. It is relatively easy to produce, inexpensive, and the process can be effectively monitored. Steam sterilizers use moist heat, in the form of saturated steam under pressure, to destroy microbial life forms, including viruses and spores. The steam coagulates the microorganism's *cytoplasm* and damages the cytoplasmic membrane, killing the cell. Microorganisms can be killed using heat alone, but the addition of water vapor, in the form of steam, allows the process to work at lower temperatures with less exposure time. This helps to extend

the life of medical devices, which must be subjected to repeated sterilization cycles.

Did you know?

The coagulation of the microorganism's protoplasm can be compared to the chemical change that occurs in the white of an egg when it is poached.

Three factors affect the steam sterilization process.

- Surface contact
- Time and Temperature
- Temperature and Pressure

Surface Contact

For the steam to effectively kill all microorganisms on a surface, it must contact the entire surface. Sometimes there are barriers such as; bubbles of air, debris left from improper cleaning, obstructions due to overloading or improper packing.

Time - Temperature Relationship

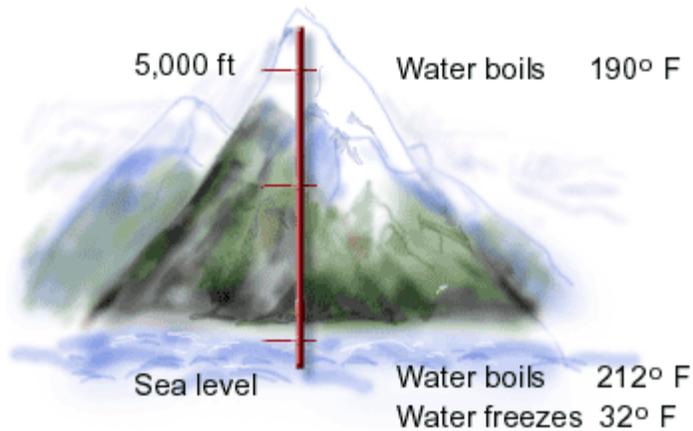
In order to kill some of the most resistant forms of microbial life, the sterilization process must continue for a minimum time at a steady temperature.

As the temperature increases, the kill time decreases. The total exposure time equals the heat up time, plus the kill time, plus the safety factor. The heat up minutes

are the time required for the load contents to come to the desired temperature, AFTER the chamber has reached the selected sterilizing temperature and all the air has been removed from the chamber. Kill time is the recommended time that the sterilizer must remain at the designated temperature in order for the microorganisms to be eliminated. Safety factor minutes are factored in to provide a margin of error.

**30 - 45 minutes
@ 250 degrees F
or
3 - 5 minutes
@ 270 degrees F**

Temperature—Pressure Relationship



For proper steam quality there is a constant relationship between temperature and pressure.

Pressure is used to help increase the temperature in the sterilizer chamber. At sea level, water freezes at 32 degrees F and boils at 212 degrees F. At an elevation of 5,000 feet above sea level, water will boil at approximately 190 degrees F because of the

lower pressure. Depending on pressure, water will boil anywhere from 35 degrees F to 704 degrees F. By raising the pressure of the saturated steam, the sterilizer is able to reach the kill-temperatures necessary to destroy the most resistant forms of microbial life.

Did you know?

Geographic location can also affect the pressure required. Pressure must be increased by .5 pounds for each 1,000 feet above sea level. The increased pressure compensates for the decreased atmospheric pressure.

Steam Quality

The quality and purity of the steam can affect the sterilization process. Steam quality refers to the amount of moisture in the steam. The steam used in sterilization is saturated steam. It is 97 percent dry with 3 percent moisture content. Saturated steam has a constant relationship between temperature and pressure. The temperature of saturated steam cannot be reduced or increased without a corresponding reduction or increase in pressure. When you increase the temperature of saturated steam without increasing the pressure, it becomes superheated steam. Superheated steam is "dried out" and does not have the moisture content that is required for effective steam sterilization.

Wet steam occurs when the temperature of saturated steam is decreased without the corresponding drop in pressure. Wet steam may occur at peak operation periods when excessive demand on

the boiler may lower temperatures, when improper trapping of the steam line to the sterilizer permits a moisture buildup in the lines immediately adjacent to the unit, or an uninsulated line allows the steam to cool. Steam with a high moisture content can cause wet packs in the sterilization process.

Sterilization can also be affected by impure steam, which contains solid, liquid, or vapor contaminants.

- Rust, pipe scale deposits, sludge, or particles can cause solid impurities from gaskets.
- Liquid additives that are used to control the pH level and retard scale and corrosion in the boiler feed water can show up in the steam.
- Volatile amine additives, which are used to prevent corrosion in steam and condensate return lines, can vaporize and become mixed with the steam.

Steam can also pick up additives from linen wrapping materials that have been improperly rinsed or treated with chemicals.

Since it does not contain microorganisms, the steam may be considered sterile, but it is far from "pure." Impure steam can cause linen spotting and instrument staining. If problems arise that appear to be caused by steam impurity, it is important to discuss the problem with Engineering Service, boiler maintenance workers, the sterilizer manufacturer, or the laundry plant manager, in order to determine the source of the problem.

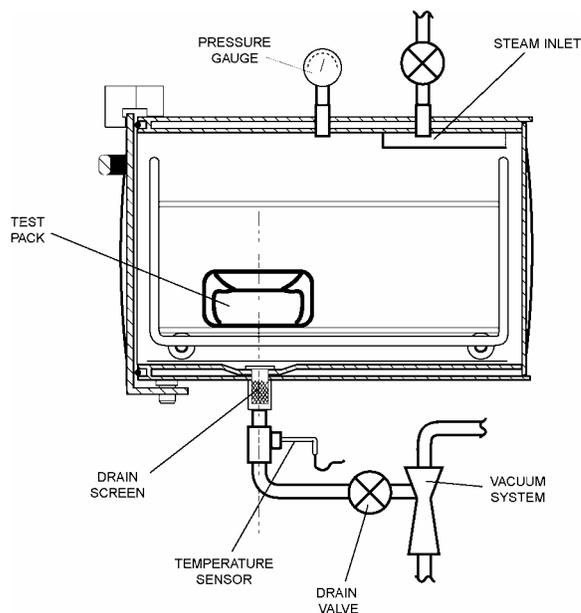
Steam Sterilizer Equipment

Steam sterilizers can come in different sizes, from large floor models to units capable of handling only a few supplies. The sterilizer unit is connected to a steam feeder system and a steam condensing system that converts the steam into water following the sterilizing operation.

The body of the sterilizer can be encased in a stainless steel cabinet; however, the plumbing and the body of the sterilizer are usually housed in a dedicated room with only the door, control panel, and

gauges visible to the staff. Though manufacturer and model may vary, most steam sterilizers have basically the same components;

- a. Door
- b. Jacket
- c. Chamber
- d. Steam inlet
- e. Chamber drain
- f. Pressure gauge
- g. Temperature gauge
- h. Operator controls
- i. Mechanical Monitoring controls
- j. Vacuum pump (with prevacuum units)



Processing temperature for steam sterilizers ranges from 250 degrees F to 275 degrees F. There are two basic cycle types; gravity displacement and pre-vacuum.

Pre-vacuum

In the pre-vacuum cycle, steam is injected only into the jacket until the proper pressure is reached. This prevents condensation from forming on the cool chamber walls. The conditioning phase involves an initial purge during which steam is forced in, pushing air out through the chamber drain. A series of steam pulses and

vacuum pulls follows. During the steam pulse, the chamber valve closes and steam is injected through the steam inlet valve. During the vacuum pull, the steam inlet valve closes and air or steam is pulled from the chamber by a powerful vacuum system, which creates a negative pressure within the sterilizer chamber. The pulse/pull sequence consists of three steam pulses and four vacuum pulls. After the last pull, there is negative pressure within the chamber. When steam is introduced it penetrates the chamber and contents very quickly, in a turbulent manner since it is not impeded by air.

Once the thermometer reaches the pre-selected temperature, the steam inlet valve and the chamber drain close and the exposure time begins. If the temperature drops during the exposure cycle, the steam valve opens and steam again enters the chamber until the temperature returns to the selected level.

After the preselected exposure is complete, the steam is removed from the chamber by the vacuum system. Sterile filtered air is mechanically injected into the chamber to relieve the vacuum. When the cycle is complete, the door is opened and the cart of items is moved to the cool down area.

Gravity Displacement

In a gravity displacement sterilizer, steam is injected into the jacket until the proper pressure has been reached. This heats the chamber and prevents condensation from forming on the interior walls and wetting the load. With the drain open, the cycle is initiated and steam is injected through the inlet valve. Because air is nearly twice as heavy as steam, it is pushed or displaced to the bottom of the sterilizer and flows out through the chamber drain line. It is important to remember this top to bottom flow when loading the sterilizer. If items are loaded incorrectly, air may become trapped, preventing the sterilant from contacting all surfaces.

When the thermometer in the chamber drain line reaches the preselected temperature, the steam inlet valve and the chamber drain valve close and a timing mechanism tracks the preselected exposure time. If the temperature drops during the exposure cycle, the steam valve will reopen and add steam until the proper

temperature is achieved. During the exhaust phase, steam is quickly exhausted and sterile, filtered air is injected to cool and dry out the load. After the exhaust phase, the chamber door is opened slightly to continue the drying process. At the end of the drying cycle the contents are removed and placed in the cool down area.

Testing Sterilizer Function

The Bowie-Dick test is performed on pre-vacuum sterilizers to test the effectiveness of the vacuum system. The test consists of a package of chemical indicator that changes color in an effective vacuum.

The Bowie-Dick test is performed daily according to the manufacturer's instructions. Test packs must be placed in an empty sterilizer, on the bottom rack of the sterilizer, near the drain. This is the most difficult area in the chamber for creating an effective vacuum.



Table Top Sterilizers

Tabletop steam sterilizers are gravity-displacement sterilizers that are small enough to be placed on a counter. They are usually found in dental offices or clinics. The unit contains an electric generator that turns water into steam, which is injected into the chamber for a predetermined time.



Did you know?

Fabric wraps should not be ironed because ironing causes the weave to tighten, inhibiting steam penetration. Ironing also dries out the fabric, causing it to absorb excess amounts of moisture, which results in superheating. Superheating can cause fabrics to scorch or burn. Fabrics should be laundered and rehydrated between each sterilization process or if the item becomes outdated on the shelf.

Ethylene Oxide (EtO) Sterilization

Ethylene oxide sterilization has been used effectively to sterilize heat and moisture sensitive medical devices for more than a half century, but because of the toxic nature of the gas, its use must be carefully controlled and monitored. EtO sterilization functions through alkalization, which causes a chemical interference in the cell, disrupting the reproductive process. EtO is expensive and time consuming and should be used ONLY for heat sensitive items that cannot be sterilized using steam.

If water and EtO mix during the sterilization cycle, a by-product, polyglycol is produced. This byproduct can be hemolytic—it destroys blood cells. Always assure that items have been properly dried prior to sterilization.

There are two commonly used types of ethylene oxide sterilizers. Full size units are often housed in a separate room or enclosure. They use a mixture of EtO and carrier gas such as Hydrochloric Fluorocarbon (HCFC) or Carbon Dioxide. Tabletop units are small chamber stand-alones that use 100% EtO cartridges. Both require a well-designed ventilation system.



Because of Federal mandates involving the release of chlorofluorocarbons (CFC's) into the atmosphere, EtO mixtures containing Freon will no longer be used.

The basic EtO sterilization process has four phases:

1. The vacuum phase removes most of the residual air from the chamber and the packaged items.
2. Once sufficient vacuum has been accomplished, humidity is injected into the chamber for a 20- to 30-minute conditioning period. It diffuses throughout the load, bringing the contents of the load to the desired temperature and a relative humidity of 50 to 75 percent.

3. The ethylene oxide gas is pumped in under pressure, and the chamber pressure rises, helping to achieve sterilization. The sterilizer remains in this “exposure” phase for the preset amount of time, with the chamber maintained at constant pressure, humidity, and temperature.
4. Once this phase is completed, a second vacuum cycle removes the gas from the chamber and exhausts it to the outside atmosphere. Air is drawn in through a bacteria retentive filter and then re-evacuated from the chamber, removing most of the ethylene oxide. This is known as the “purge” cycle. This air wash usually lasts for 10 to 30 minutes, but some sterilizers continue the filtered air purge until the door is opened.

The parameters that can impact the success of this sterilization process are time, temperature, moisture, and the concentration of the sterilizing agent. A typical cycle is 2 hours at 130° F. A cold cycle can be run at 100° for 4 hours to process items that cannot withstand the higher temperature.

Loading and Unloading the EtO Sterilizer

Place items to be sterilized on metal sterilizer carts or in wire baskets to minimize handling and allow safe transfer of items from the sterilizer to the aerator. Arrange items loosely on the cart to ensure that the sterilant has access to all surfaces. Do not allow them to touch the sterilizer chamber walls during the sterilization process.

Aeration

All items sterilized by EtO must be aerated. Items that are not properly aerated can cause burns to the patient, physician, or staff handling the item. Many EtO sterilizers are equipped with an aeration cycle at the end of the sterilization cycle. This allows the load to completely aerate, removing all traces of EtO gas prior to opening the door or touching the items. This is the safest way method. If there is no aeration cycle, the sterilizer door must be cracked open for 15 minutes prior to beginning the unloading process. All staff should remain away from the area during this time.

If the sterilizer does not have an aeration cycle, you may have to remove the sterilizer load and place it in a separate aerator. Pull the cart to the aerator, slide the load in, close the door and begin the cycle immediately. A minimum aeration cycle is 12 hours at 122 degrees F, but always consult the manufacturer's instructions for specifics.



Room or ambient aeration (where the sterilized items are placed in an isolated, well-ventilated room until the gas dissipates) is not recommended.

Personnel Monitoring

EtO is a colorless gas with an ether-like odor. Coming into contact with EtO has caused cancer in laboratory animals and been associated with higher incidents of cancer in humans. Additional side effects of exposure to EtO include adverse reproductive effects, chromosome damage, and neurotoxicity. In its liquid form, EtO exposure can cause eye irritation, lung injury, headaches, nausea, vomiting, diarrhea, shortness of breath, and cyanosis. Monitoring activities are recommended in areas where EtO is used.

The Occupational Safety and Health Administration (OSHA) requires periodic monitoring of employees who work around EtO. Permissible exposure limits have been set by OSHA and are found in 29 CFR Section 1910.1047. These limits include:

- **Permissible Exposure Level (PEL)**

The individual Permissible Exposure Level has been set by OSHA to ensure that no employee has been exposed to airborne concentrations in excess of 1 part per million (ppm) parts of air during an 8-hour Time Weighted Average (TWA) period. If the EtO concentration level in an area exceeds the PEL, a respirator must be worn until the problem is corrected.

Level	Limit
PEL	< 1ppm in 8 hour TWA
ACTION	.5 ppm in 8 hour TWA
STEL	5 ppm in 15 minute period

- **Action Level**

The action level is the point at which you must take action to avoid reaching the permissible exposure level and is usually set at half the PEL. For EtO it is .5 ppm in an 8 hour TWA. If an employee is exposed at or above the action level they must be monitored again in 6 months.

- **Short Term Excursion Limit (STEL)**

The STEL requires that no employee be exposed to an airborne concentration of EtO in excess of five parts of EtO per million parts of air (5 ppm), averaged over a 15-minute period. STEL monitoring is done during those times when the possibility of exposure is high, such as during tank changes, purge, or exhaust cycles. If the 15-minute STEL is above 5 ppm, the exposure problem must be remedied and monitoring must be repeated until two consecutive measurements, at least 7 days apart, are below the STEL action level of .5.

Additional monitoring is required whenever there has been a change in the production, process, control equipment, personnel, or work practices that may result in new or additional exposures. After receiving the results of monitoring, the SPD Chief must notify the employee, in writing within 15 working days, of the results. This can be done either individually or by posting the results in an appropriate location accessible to the employees.



Individuals who work in the EtO area must wear monitoring badges to keep track of their exposure. Monitoring must be done at least twice, seven days apart. If the readings are below the action level, monitoring can be discontinued until there is a change, such as equipment repair or replacement, or change of procedure. If the reading is above the action level, but below the PEL, monitoring must

be repeated every six months.

A medical surveillance program, that includes a medical examination and consultation, must be in place and available to all employees who are or may be exposed to EtO for at least 30 days a year. Medical exams are available to employees

- prior to assignment in SPD
- at the termination of employment in SPD
- at least annually
- as soon as possible after potential exposure to EtO
- at the employee's request, as medically appropriate, for any exposure.

Area Monitoring

Two alarm systems are required by OSHA;

- An EtO emergency alarm that is designed to avoid exposure above the STEL level.
- A ventilation alarm alerts personnel if there is a malfunction in the ventilation system.

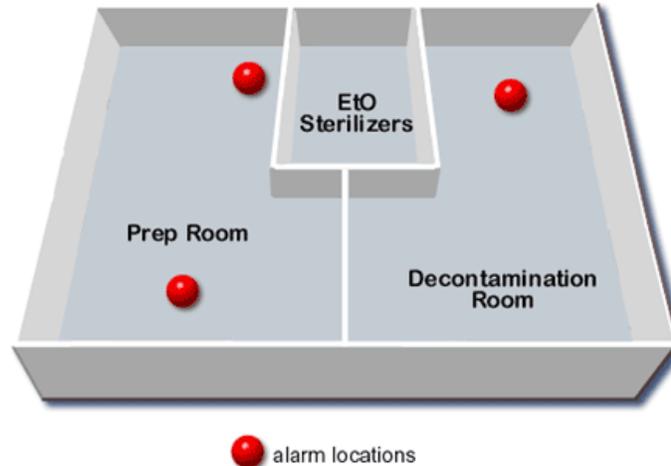
In addition, some medical centers have another alarm system to detect high EtO levels in the work area before employees are exposed to them. Most systems have both a low and a high alarm which are set at or below OSHA exposure levels. The low alarm in the work areas should be set at the action level of .5

ppm so the SPD Chief knows that action should be taken to determine the cause. The high alarm in these areas should be set at the PEL of 1 ppm. In the tank room and equipment maintenance access areas, the STEL is 5 ppm, so the alarm should be set at this level to notify anyone working there to evacuate immediately.

Alarm Levels	
Low Alarm Level	.5 ppm
High Alarm Level	1 ppm
Tank and Equipment Area	5 ppm

Placement of the sensing ports for the monitoring system is important. There should be a monitoring point:

- directly in front of the EtO sterilizer,
- at the work stations in the preparation room,
- directly in front of the sterilizer in the Decontamination room.



Changing the EtO tanks and moving items from the sterilizer to the aerator represent a high risk EtO exposure and require increased precautions. Personal protective clothing must be worn when changing EtO tanks, whether they are 100% EtO cartridges or mixture EtO tanks.

PPE for changing tanks includes:

- impermeable coveralls
- butyl gloves
- head coverings
- full face piece respirator (SCBA)

EtO Precautions

In addition to protective clothing, working with EtO requires a number of additional precautions. Liquid EtO is easily ignited.

- Care should be taken to prevent any sparks or exposure to heat, flames, or other items that might cause the EtO to ignite.
- Non-sparking tools should be used when opening or closing metal containers of EtO.
- If impermeable clothing or skin becomes wet with liquid EtO, immediately enter a shower and remove the clothing.



EtO is a hazardous substance that is highly flammable. Use caution when handling. Fire extinguishers and showers should be readily available, and SPD technicians must know where they are and how to operate them.

EtO must be properly stored and handled to reduce the risk associated with its use. Storage guidelines must be strictly followed.

100 percent EtO Cartridges	No more than a three-day supply—up to 12 fifty-gram cartridges—may be stored in the sterilizer area. If more than 48 cartridges are required in inventory, the storage area must conform to National Fire Protection Association (NFPA) recommendations. Containers containing EtO must be returned to the manufacturer or disposed of in accordance with the manufacturer’s instructions and in compliance with EtO health and safety requirements, and applicable local regulations.
EtO Gas Mixture Cylinders	Cylinders of EtO gas mixtures, such as 10/90, are stored in a temperature-regulated, designated area that meets building codes and OSHA regulations. Tanks are stored and used in an upright position and are securely fastened in place by suitable straps or chains. Cylinders of EtO gas mixture are transported to and from SPD on cylinder carts with chains securing them during transit. All EtO cylinders are stored in an area away from the flow of traffic. Cylinders that have been used and removed from service are handled in the same manner as full cylinders.

Mandatory Annual EtO training

Each SPD employee is required to attend annual training on EtO, which includes:

- EtO sterilizer and aerator operation and maintenance
- work practice/precautions for safe use of EtO
- safe handling and storage of EtO tanks
- physical and health hazards
- accidental spill/leak plan
- emergency first aid procedures
- personal protective equipment
- professional EtO monitoring methods



The SPD Chief will develop a local policy, with concurrence by the Industrial Hygienist, indicating what steps should be taken in the event of an EtO emergency.

Plasma

Plasma sterilizers operate by vaporizing a chemical compound and passing it through an electromagnetic field, which strips electrons from some of the atoms and accelerates the particles. This creates particles that kill microorganisms (including bacterial spores) by disrupting their cell membranes. The chamber size varies from 2.5 to 5.0 cubic feet and the sterilization cycle takes about one hour. There is no residual from the chemical, so aeration is not required. Plasma sterilizers are useful for sterilizing rigid and flexible scopes, surgical and microsurgical instruments, surgical power equipment, and glassware.



Plasma sterilizers are not designed to sterilize cellulose-based items such as linen and paper.

Dry Heat

Dry heat sterilizers are not used in VA medical centers because there is no way to validate and maintain the sterility of the items. On rare occasions, you may be asked to sterilize powder substances, like talc, which require dry heat. Do not comply with this request. Recommend that the user order the powder pre-sterilized from the vendor.

Did you know?

Liquids will not be sterilized in VA facilities because there is no way to confirm that liquids are sterile or that the sterilization process has affected them.

Chemical

While chemicals are most often used for high level disinfection, chemical sterilizers do exist. They use peracetic acid and sterile water to clean and sterilize heat sensitive, immersible items such as flexible and rigid scopes and microsurgery instruments. They operate at 50 - 55.5 degrees C and achieve sterilization in 20 - 30 minutes. The equipment consists of a processor unit, a control panel, a recording/printing device and various sized inserts and

instrument trays. These sterilizers are relatively small and are limited by the fact that there is only room for one scope or small instrument tray at a time. The containers used cannot be sealed, so the sterile item must be used immediately.

Flash

Flash sterilization should only be used in emergency situations. This includes items that are dropped and single instruments that may be called for during a case.

If a specific instrument set is needed for another case on the same day, there must be enough time to send the instruments to SPD for decontamination and sterilization. Instruments should not be cleaned in the operating room by scrub nurses, and then flashed. This practice will lead to cross-contamination, and can cause grave patient outcomes. It is the responsibility of the Chief of SPD, and the Operating Room Manager to determine if additional sets of instruments must be purchased to avoid this situation. Under no conditions should implants, instruments with lumens, power equipment, or large trays of instruments be flash sterilized.

Flash sterilizers are basically gravity displacement sterilizers set on the “en” or non-wrapped cycle. When using one, you must place items in the tray so that they are not crowded. Do not use towels for cushioning.

Verifying Sterility

Sterilization is a complex process and since the only way to measure sterility is to test a surface to determine if there are living microbes present, there is no practical way of proving that an item is sterile without contaminating it. We rely on biological, chemical, and mechanical tests to verify that an item has been exposed to a processing cycle in a sterilizer.

Sterilization records must be kept for a minimum of 3 years. All records for an individual sterilizer should be stored together.

Biological

A biological indicator contains live spores. They are present in greater concentration than might be found on an item that has been through the decontamination process. If the sterilization process is

sufficient to kill the high concentration of spores in the indicator, then it will be more than enough to eliminate any bioburden on items in the sterilizer load.

Biologic indicators must be incubated for 48 hours and examined for color change to determine if the bacteria are viable. The presence of live bacteria in the test sample indicates that the sterilization process was not effective. If there is no color change, then there is no bacterial growth and sterility was achieved. For steam sterilizers, biologic testing must be conducted:

- once a day in a full load
- in every load that contains an implant
- after any sterilizer repairs

Incubation is conducted at 55 degrees C. For EtO tests, incubation is at 37 degrees C and testing must be conducted in every load. A control indicator (unsterilized test vial) must be incubated daily for each type of sterilizer to ensure that the test bacteria are viable. The control indicators must be from the same lot number as the tests used in the sterilizers for that day.

Did you know?

Genobacillus Stearothermophilus (*Bacillus stearothermophilus*) are the spores used in steam sterilization. *Bacillus Atrophaues* (*Bacillus subtilis*) are used in EtO sterilization.

A positive biologic indicator doesn't necessarily mean that the sterilization cycle failed. Positive tests can also be caused by user error or contamination following processing. Regardless of the cause, if a positive test indicator is found, all items processed in the sterilizer since the last known good biologic indicator must be recalled and all items unwrapped, reprocessed and resterilized.

Chemical

Chemical indicators are made of paper that has been chemically treated to change color when it is subjected to the sterilization process. They are used both inside and on the outside of wrapped packages of supplies. External chemical indicators are placed on the outside of every package and are often used to hold the package

closed. When used inside the package, their presence does not guarantee that package contents are sterile, but indicates to the user that the contents of the package were subjected to sterilizing conditions. If the indicator has not completely changed color, the contents may not have been subjected to a full scale sterilizing process and, therefore, should not be considered sterile. External indicators must be examined for complete color change after sterilization before placing the lot number on the package and again before the item is distributed.

Mechanical

Mechanical monitoring tracks sterilization parameters. Gauges, graphs, and recorders are used to ensure that optimum sterilization conditions were met. Sterilizers automatically generate a printout or graph of the cycle length, temperature, and pressure that the operator must verify. Sterilizers without this feature should not be used. Sterilization records must contain:

- Contents of the load
- Operator
- Date and time
- Cycle length
- Temperature

Sterilizing Implants

Implantable devices, or “implants,” are items that will be surgically implanted and totally contained in the body (covered with tissue).

Examples include;

- orthopedic hardware items such as pins, screws, nails, rods
- total joint system replacement hardware
- heart valves
- cranial shunts and reservoirs
- breast and penile prostheses
- micromesh
- vascular grafts

Every sterilizer load containing an implantable device must be monitored using the appropriate biological indicator. Implants

must be quarantined for 48 hours in order to allow time for the biologic test to be cultured and the sterilization confirmed. If an emergency situation occurs, SPD will process the implant as usual and, if an early release is necessary, the Chief of SPD must obtain a written approval from the Chief of Staff in order to release the implant from quarantine.

Reprocessing implants may occasionally be necessary. It is important to follow the manufacturer's guidelines in order not to compromise the implant. Some manufacturers require special gloves and aseptic cleaning procedures when handling implants. It is the responsibility of SPD to ensure that reprocessing does not alter the composition of the implant or alter the implant's intended use. The manufacturer will also provide information on how many times the implant can safely be reprocessed. Written documentation from the manufacturer about reprocessing guidelines should be available and followed by all SPD employees. SPD must have a Standard Operating Procedure in order to track the number of times an implant has been used and reprocessed.



Implantable devices **will not** be processed by flash sterilization.

The Food and Drug Administration (FDA) mandates that certain medical devices be tracked so that they could be located, if it was necessary to provide their users with notification regarding health risks. This includes implants, both in use and in stock. SPD employees must be familiar with the Safe Medical Device Act tracking program that is in use in the medical center where they work.

Processing Loaner Instruments

The Chief of SPD must establish a protocol for handling instruments that are on loan. Loaner instruments must be obtained far enough in advance to allow them to be processed. You must have a count sheet for all loaner instruments.

If the same instruments are needed for multiple cases in a single day, the cases must be scheduled to allow enough time for the

instruments to be reprocessed. The Chief of SPD must work with the Operating Room Manager to determine when additional sets of instruments must be purchased in order to avoid having to reprocess instruments for same day use. Instruments must not be cleaned and flashed in the operating room by scrub nurses. This can lead to cross contamination, and cause grave outcomes with the patient.

Summary

Sterilization is a critical component of the SPD mission. It is an absolute state—either something is sterile or it is not sterile.

Sterilization can be affected by a number of factors;

- the number and type of microorganism,
- presence of debris,
- loading techniques,
- efficiency of the equipment, and
- post sterilization handling.

There are a number of different types and models of sterilizer. You must become familiar with the operation of the equipment that is specific to your work location.

You must also be familiar with the local policies governing the processing of implants and loaner equipment.

✓ Check What You Know

1. How can you prove that something is sterile?
 - a. Examine the label
 - b. Check the chemical indicator
 - c. You can't
 - d. Look it up on the sterilizer log

2. What is the purpose of the Bowie Dick test?
 - a. Ensure sterilization occurs
 - b. Check the efficiency of the sterilizer
 - c. Ensure that effective vacuum is achieved
 - d. Check for air displacement

3. What factors can affect the steam sterilization process?
 - a. time
 - b. temperature
 - c. surface contact
 - d. pressure

4. Order the steps in the steam sterilization process.
 - a. conditioning
 - b. exposure
 - c. come down
 - d. drying

5. Following EtO sterilization, why is aeration important?
 - a. Residual EtO can cause burns to the patient, physician, or staff
 - b. It speeds up the sterilization process
 - c. It removes excess moisture, reducing the risk of polyglycol forming
 - d. It removes all excess EtO from the items

6. Order the steps in the EtO sterilization process.
 - a. Remove residual air
 - b. Inject steam and bring to required temperature and humidity
 - c. Inject EtO gas under pressure
 - d. Exhaust gas and purge chamber

7. Match the term to its limit.

PEL	5 parts EtO per million parts of air in a 15 minute period
Action Level	One part EtO per million parts of air over an eight hour period
STEL	Usually half the permissible exposure limit

8. What types of monitoring are used in the medical center sterilization process?
 - a. Chemical
 - b. Biological
 - c. Remote
 - d. Mechanical

9. The cycle phases for a prevacuum sterilizer include conditioning, three _____ and four _____, followed by exposure and then the _____ of filtered air.

10. Standard aeration times, as outlined in MP-2 Subchapter E, subpart 108-76.303(c), are: 50o Centigrade (122 degrees F) for _____ hours.
11. Liquids must
- be tightly sealed before sterilization
 - not be mixed in sterilizer loads with other items
 - not be sterilized in VA facilities
 - carefully monitored to prevent flashback.
12. Steam sterilization is the best method for:
- anything that is needed in a hurry
 - all reusable items
 - items that can withstand heat and moisture
 - plastic and rubber items
13. Which form of sterilization is known to be harmful to the ozone layer?
- Steam
 - EtO
 - Plasma
 - Flash
14. Standard steam sterilization time is:
- 250 degrees F for 30 minutes
 - 270 degrees F for 4 minutes
 - 130 degrees F for 1 hour and 45 minutes
 - 100 degrees for 4 hours
15. When loading sterilizers;
- Always put the larger items on top

- b. Place items so that they overlap
- c. Avoid allowing items to touch the sterilizer walls
- d. Leave at least one shelf empty to prevent condensation

16. Chemical indicators are used for:

- a. ensuring that items are sterile
- b. indicating that an item has been exposed to the sterilization process
- c. preventing bleed through or wicking
- d. overriding biological indicators.

17. Biologic controls must be run

- a. In every load
- b. Once a week or more, as needed
- c. At least once per day when the sterilizer is in use
- d. Whenever a problem is detected or suspected

18. When can items be removed from the aerator

- a. Only when the aeration cycle is complete
- b. Before the aeration cycle finishes with a signed release from the Chief of SPD
- c. When something is needed in the O.R.
- d. 6 - 8 hours after processing

19. What is the Action Level for EtO exposure?

20. What is STEL and what are the limits?

Terminology

The following terms were used in this module.

aeration	The process of circulating air through a processed sterilizer load
aerator	A device designed to circulate air through a loaded sterilizer cart
ambient aeration	The process of pulling an EtO processed load out into a room and allowing the EtO to dissipate into the air over time
biological indicators	A small glass or plastic vial containing a sample of bacteria, whose temperature and pressure tolerances are known, used to determine the effectiveness of a sterilization cycle The sample is processed along with the sterilizer load and is then cultured in the laboratory for 48 hours to determine if any of the bacteria survived
control indicator	A biological indicator that is cultured without being subjected to the sterilization process in order to determine that the bacteria in that lot number is alive
exposure time	The heat up time, plus the kill time, plus the safety factor
spores	A primitive, unicellular body produced by plants and some microorganisms that is capable or developing into another individual being
sterile	a condition absent of microscopic life
SCBA	SCBA—Self contained breathing apparatus
TWA	Time weighted average. The average amount of an allowable substance in a specified period of time.