

Steam Sterilization

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Today there are many choices for sterilization in the healthcare facility:

- Saturated steam under pressure
- Ethylene oxide gas
- Low Temperature gas plasma
- Peracetic Acid
- Dry Heat
- Ozone

Regardless of the sterilization method the sterile processing technician must follow the device manufacturer's instructions. These should be obtained and saved where they can be referenced each time the device is processed.

This Inservice will focus on steam sterilization. Steam should always be the preferred method of sterilization unless otherwise directed by the manufacturer of the device. In addition, the technician should always follow the sterilizer manufacturer's directions for operating the sterilizer. Sterilization equipment should not be used unless the technician is competent in its use. For sterilization, items must first be scrupulously cleaned! Sterilization begins in the decontamination area.

For steam sterilization, the phases of the sterilization cycle are:

- Come-up time (time to heat-up the load and the chamber)
- Exposure time (time the load must be held at the specified temperature in order to achieve sterilization)
- Come-down time (when the steam is exhausted).

At this point, the sterilizer will enter the dry cycle.

There are three parameters for steam cycles:

- Time
- Temperature
- Pressure

The sterilization time varies with the temperature. The lower the temperature the longer the exposure time; the higher the temperature the shorter the exposure time. There are special cycles for liquids; liquids require a gravity displacement cycle with slow exhaust to prevent explosion of the bottles.

There are two basic types of sterilizers; pre-vacuum (also known as high vacuum) and gravity displacement. The pre-vacuum sterilizers can also operate as gravity displacement. The usual cycle for pre-vacuum sterilizers for wrapped items is:

- Time - Usually 3-4 minutes exposure time
- Temperature - 270 to 274°F (132-134°C)
- Pressure - 28-30 psi

You should notice that the higher temperatures require higher pressures.

The drying time is dependent on your facility, the age of the sterilizer and the load contents.

In gravity displacement sterilizers the usual cycle is:

- Time - 20-30 minutes exposure
- Temperature - 250°F (121°C)
- Pressure - 15-17 psi

The major differences between pre-vacuum and gravity displacement sterilizers are:

- Pre-vacuum depends on mechanical removal of air from chamber and packs
- Gravity - the air is displaced by steam with gravity as the force pushing the air out.

It is important to remember that the greatest resistance to steam sterilization is removal of air! Therefore, the pre-vacuum sterilizer is more effective since it is more efficient at air removal.

How Steam Enters the Chamber -The steam is generated in a boiler located in Engineering (unless the facility is using a self generating steam sterilizer). The steam travels through high pressure steam lines to Sterile Processing. The steam enters the sterilizer from the top of the jacket which surrounds the chamber. The jacket provides strength to the chamber and insulates the chamber preventing the formation of condensate. As long as the steam supply is "on", there should be steam in the jacket and heat inside the chamber. (Most sterilizer manufacturers require that there be 60-80 pounds of steam pressure in the steam supply line. There is a gauge behind the sterilizer to record the steam line pressure.) The steam remains in the jacket, ready to be used when a cycle is started. When a cycle is started, the steam enters the chamber from the back through a baffle plate. This plate disperses the steam throughout the chamber. The air inside the chamber and packs is pulled in through a vacuum (in pre-vacuum sterilizers) or pushed out by the steam through gravity pull until all the air is removed. The steam continues to flow into the chamber and out through the chamber drain line (located on the bottom of the chamber, usually in the front). The steam continues down the drain line to the steam trap (also known as thermostatic valve). This valve remains open as long as the air is passing by it. However, once the valve senses steam passing by, the valve closes; this permits the steam to now build up inside the chamber. The steam then enters the packs. Once the packs are heated

up and saturated with steam, the sterilizer starts timing the cycle. The timing is the "exposure or sterilization" time selected. This is the time when the microorganisms are being killed and is the most critical part of the cycle. When the exposure time is completed, the steam trap valve opens and the sterilizer exhausts the steam through the steam trap. Then the drying phase starts.

There are three main phases to steam sterilization:

- *Conditioning phase:* During this phase, air is removed from the sterilizer chamber and steam is injected. In gravity-displacement cycles, the steam passively displaces the air through a port or drain in the bottom of the sterilizer. In pre-vacuum steam cycles, air is actively removed by one or more vacuum excursions. During this phase, the packs within the sterilizer are gradually heated by the steam. The length of the conditioning phase varies with the materials in the load and is controlled by the sterilizer.
- *Sterilization/exposure/"holding" phase:* In this phase, the prescribed exposure temperature is maintained for the prescribed amount of time. For example, if the sterilizer is set for a 4-minute exposure, the load will be held for 4 minutes at the set temperature.
- *Exhaust phase:* After the exposure phase, steam is exhausted from the sterilizer through the chamber drain line.

After the steam has been exhausted, the sterilizer goes into the drying phase of the cycle, which typically lasts about 30 minutes. To achieve drying in a pre-vacuum steam sterilizer, filtered air is drawn into the chamber. In a gravity-displacement sterilizer, the heat in the chamber walls causes moisture to evaporate. For drying of wrapped items, gravity displacement dries poorly as compared to pre-vacuum sterilizers.

The minimum exposure times, temperatures, and pressures for steam sterilization of wrapped items are as follows:

- Pre-vacuum steam, 4 minutes at 270°F (132°C) and 28 to 30 pounds per square inch (psi)
- Pre-vacuum steam, 3 minutes at 275°F (135°C) and 28 to 30 psi
- Gravity-displacement steam, 30 minutes at 250°F (121°C) and 15 psi
- Gravity-displacement steam, 15 to 25 minutes at 270°F (132°C) and 27 psi
- Gravity-displacement steam, 10 minutes at 275°F (135°C) and 30 psi

Again, these are minimum exposure times. The device manufacturer's written instructions for exposure time and other parameters should always be followed. Any exposure time less than the minimums should be questioned.

Steam quality - The quality of the steam supplied to the sterilizer is important to successful sterilization and effective drying. Steam quality is a measure of the relative dryness of the steam. Ideally, the incoming steam should be at least 97% dry saturated steam and at most 3% entrained water (AAMI ST79:2006). However, the moisture content of steam is important to the transfer of heat to items being sterilized. When items are placed inside the sterilizer, they are at room temperature (cool). When the hot steam makes contact with the cool items, condensation forms and energy (in the form of heat) is released, heating up the packs. Therefore, steam sterilization occurs by condensation.

"Superheating" of steam occurs when "saturated steam at any given temperature is subjected to a higher temperature . . . This occurs when heat is added to dry steam in the absence of water" (Perkins, 1982). In other words, the steam is "dried out." Without the moisture, the effect is that of dry heat sterilization, which not only can overheat the materials but also could result in ineffective sterilization.

For sterilization to occur, the steam must make direct contact with all surfaces of the device. Air is an enemy to the steam sterilization process because air and steam do not mix. Therefore, it is essential that all the air be removed from the chamber and packages. If air is entrapped in a package, the steam will not be able to get inside (think of the concept that "no two objects can occupy the same place at the same time"). Complete air removal is important because air will interfere with steam contact with the device. In a pre-vacuum cycle, the sterilizer draws one or more vacuums; i.e., a pump "sucks out" the air from the chamber and the packs. After air removal, the steam heats up the load to the temperature set on the sterilizer. The steam transfers its latent heat energy to the items inside the sterilizer. When this energy transfer occurs, the steam condenses and becomes water.

DRYING

Drying is critical to sterility maintenance. If packages are still moist when the sterilizer door is opened, bacteria can land on the packages and "wick" or travel inside the package. Drying time depends on several factors:

- The device manufacturer's instructions
- The sterilizer manufacturer's instructions
- The age of the sterilizer
- The packaging system used (e.g., drying time is typically longer for containerized items than for wrapped items)
- The weight and configuration of the sets
- The loading configuration of the sterilizer

Regardless of the method of air removal, the air and steam exit through the chamber drain, a small opening usually located in the front of the sterilizer chamber on the chamber floor. A basket inside the drain collects lint and other debris. This basket must be cleaned out

daily (by flushing it with running water or using a brush to remove the debris) to prevent clogging of the drain line. A clogged drain line can contribute to wet packs.

Wet Packs - Wet packs represent one of the greatest problems in sterility maintenance. Both AORN and AAMI do not the use of an item that is wet at the end of the steam sterilization cycle, even if it is inside a rigid container (AAMI ST79:2006; AORN, 2006). Wet packs can be caused by a number of problems, including:

- Clogged drain lines
- Improperly drained steam supply lines
- Incorrect loading of the sterilizer (e.g., items are packed too tightly on the cart or placed incorrectly on the cart)
- Incorrect packaging materials or methods
- Insufficient drying time
- Sets or trays that are too heavy
- Incorrect configuration of instrument sets

Whenever wet packs occur, a complete investigation of the causes must be conducted and corrective actions implemented.

Most CS/SPDs are faced with heavy and/or multi-level sets, which make drying difficult. The use of rigid container systems and heavy wrapping materials can also impede drying. It is the responsibility of the facility to ensure that sets and other packaged items can be dried after sterilization in the sterilizers being used. The heaviest sets should be selected and then sterilized, dried, and cooled. The sets should then be opened and inspected for moisture on the instruments, a wet or moist towel (if used inside the set), or visible water. None of these scenarios is acceptable. If a problem is noted, the first step is to check the configuration of the set (i.e., how the instruments are arranged in the set). If the instruments are well distributed within the set, then the next thing to try is preconditioning of the load. Preconditioning is done by placing the load in the sterilizer, closing the door, and waiting 10 to 15 minutes before initiating the cycle. (An egg timer can be used as a reminder to start the cycle.) The preconditioning process heats up the instruments (from the jacket heat in the sterilizer) and reduces the amount of condensate formed. Another thing to try is to extend the drying time of the cycle in 10-minute increments (unless the drying time is already set at 30 to 40 minutes). If these procedures do not solve the wetness problem, then it will be necessary to divide the set into smaller sets. The testing should be documented (type of set tested, date of testing, test results, and name or other identifier of the person who performed the testing). Repeat testing is not required unless changes are made to the set.

Loading the Sterilizer - When loading steam sterilizers, instrument sets in mesh-bottom pans or in perforated metal trays should be placed flat on the sterilizer rack. The mesh

bottom of the pan or the perforations in the tray permit air removal and steam penetration in this position (provided that the perforations are large enough). Instrument sets in solid-bottom Mayo trays should be tilted on their edge (side) to permit condensate to run off. All items should be loosely loaded. Multiple similar items (e.g. towel packs) should be loaded so you could put your fist between the packs. In mixed loads containing basins and line packs, place the line items on the top shelf and metal items on bottom to prevent condensate from over wetting packs which will interfere with drying. Any item that can retain moisture (e.g. basin) should be tilted on its side to permit the condensate to run off.

Textile packs should be placed on their side to facilitate air removal (through the folds) and steam penetration; they should not be placed flat. In the proper position, the folds of the textile items should be vertical in relation to the cart. In a mixed load (textile items and metal goods), the textile packs should be placed on the top shelves and the metal instruments on the lower shelves. If the textile packs are placed on the shelf below the metal instruments, they could become wet. Basin sets or other devices that can collect and retain water should be tilted on their sides.

Paper-plastic peel pouches should be placed on their edge (side) with the clear side of one pouch facing the paper side of the next pouch. Peel pouches should be placed in a wire basket or peel pack separator. Peel pouches should not be placed face up or face down on the cart (moisture could accumulate in or on the package).

Rigid sterilization containers should be placed flat with a small space between each container. They should not be stacked unless the container manufacturer has provided technical data demonstrating that the containers can be stacked and still allow sterilization. The container manufacturer may also specify a specific height to which the containers can be stacked inside the steam sterilizer (e.g., 10 inches in total height).

There should be at least one inch of space between packages and the chamber wall to prevent scorching of packaging material. The sterilizer cart should be checked for correct positioning of packages and containers before it is placed inside the sterilizer.

Unloading the Sterilizer - At the completion of the sterilization cycle, the door to the sterilizer is cracked (or opened) and items remain inside for 15-20 minutes to come down in temperature. Then the cart is removed and placed in a low-traffic area away from air conditioning ducts or vents. *The items should remain, untouched, on the sterilizer cart for 30 minutes to 2 hours after sterilization.* This is to prevent contamination of the packs due to the pores on packaging or filters (on rigid containers) remaining open until the package is completely cooled. A peel pouch probably would only need 30 minutes of cooling however an Orthopedic set (due to its weight) could take as long as two hours to completely cool. It has been stated that most contamination of packs occurs within the first hour of sterilization so this is important to remember.

SUMMARY: Steam sterilization is a major responsibility of the sterile processing technician. The sterilizer operator must be knowledgeable in all phases of the steam sterilization cycle and how to monitor the process.

QUIZ ON STEAM STERILIZATION

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1. What percentage of steam is required for effective steam sterilization?
 - A) 79%
 - B) 87%
 - C) 97%
 - D) 99%
2. The parameters for steam sterilization include:
 - A) temperature, concentration, time
 - B) concentration, humidity, time
 - C) time, temperature and humidity
 - D) time, temperature and pressure
3. How much space should be left between packs and the sterilizer chamber walls?
 - A) 1"
 - B) 2"
 - C) 3"
 - D) 4"
4. After steam sterilization, the minimum amount of time packs should remain untouched on the autoclave cart is how long?
 - A) 10 minutes
 - B) 15 minutes
 - C) 20 minutes
 - D) 30 minutes
5. According to literature, when do the majority of packs get contaminated?
 - A) when the package is opened
 - B) when the package is transported
 - C) during the first hour after sterilization
 - D) during the first day after sterilization
6. How should peel packages be positioned for sterilization?
 - A) facing up
 - B) facing down
 - C) in between packs
 - D) on their edge (side)

7. Steam sterilization occurs through a process known as
 - A) Compensation
 - B) Condensation
 - C) Conduction
 - D) Convection

 8. The phase of the steam sterilization cycle where air is removed and steam enters and heats up the packs is called:
 - A) condition phase
 - B) exposure phase
 - C) exhaust phase
 - D) drying phase

 9. A wrapped basin set should be loaded:
 - A) in between other basins
 - B) tilted on its edge
 - C) right side up
 - D) over line packs

 10. What is the recommended steam pressure for steam entering the steam sterilizer from the main steam line?
 - A) 20-40 pounds
 - B) 40-60 pounds
 - C) 60-80 pounds
 - D) 80-100 pounds
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Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

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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.

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Thank you!