Understanding Key Factors In Steam Sterilization

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Many factors influence whether a sterilization process will, in fact, result in a sterile medical device, starting with how the device is used and the level of contamination. It is important to understand that the cleaning of a device—removing as much bioburden as possible—is crucial to effective sterilization. But even if a device has been adequately cleaned, it may not be sterile at the end of the sterilization process. Why? There could be several reasons. The design and configuration of a device could impede penetration by the sterilant, the device could be loaded into the sterilizer in a way that hinders contact between all surfaces and the sterilant, the concentration or exposure time of the sterilant could be inadequate, or a wet pack at the end of the cycle could result in recontamination. This article examines crucial factors in effective steam sterilization: conditioning, steam penetration, “wet packs,” and understanding the difference between verification and validation.

Conditioning

The conditioning phase of the sterilization cycle refers to the process of eliminating all air from the chamber, which houses the device or equipment to be sterilized. The chamber must be cleared of all air to ensure that the steam contacts all of the device surfaces to be sterilized. The process for conditioning depends on the type of steam sterilizer being used.

As the name suggests, a gravity displacement sterilizer relies on gravity to remove air from the chamber. Steam is injected into the chamber. As it builds, the colder air, which is heavier, is pushed down and out through a drain. Device and load configuration can have a major impact on the ability of the sterilizer to remove air from the chamber. Dynamic processes are faster at removing air and allowing the steam to quickly come into contact with the device surfaces. Dynamic air removal involves either a steam flush pressure pulse (SFPP) or a pre-vacuum method. With SFPP, steam is injected into the chamber through a series of steam flushes, which also push air out.

In the pre-vacuum method, air is removed via a vacuum pump, followed by injecting steam into the chamber, which helps to push out any remaining small amounts of air. This is usually done three to four times. Once the final vacuum is pulled, steam is injected to fill the chamber. Since all of the air has been removed from the chamber, the dispersion dispersion...
contact of the steam is usually very rapid. However, some device configurations can require additional exposure time to allow the steam to reach all surfaces. This has resulted in extended cycles being approved for the sterilization of some devices. The U.S. Food and Drug Administration (FDA) approves standard steam sterilization cycles for healthcare applications and does not allow the conditioning phase of the cycle to be changed.

Steam Contact
If the steam cannot reach all of the surfaces, sterilization of the device will fail. A variety of steam penetration tests are available to help with this challenge. Different tests are designed for specific product families.

Steam penetration tests check the amount of noncondensable gas (NCG) present in the sterilizer chamber. Too much NCG will prevent steam from contacting the surfaces to be sterilized.

Quality assurance testing is performed on products that are routinely sterilized to ensure that there is adequate steam contact. Process challenge devices are designed to simulate a product to be sterilized, offering a challenge to the sterilization process that is equal to or greater than the actual device.

Leak Test
Many dynamic air removal steam sterilizers have a leak test built into the machine. This test measures the leakage of air into the chamber. It is complementary to the air-removal test, known as Bowie-Dick or DART (daily air removal test). The maximum rate of air leakage should be 1.0 mm Hg/minute. The presence of NCG in larger quantities could affect the ability of steam to contact all surfaces to be sterilized. According to ANSI/AAMI/ISO TIR 17665-2:2009, the leak test should be performed quarterly. Some experts recommend running this test weekly, and others prefer to run it daily. Individual facility preferences and manufacturer recommendations influence test frequency.

Bowie-Dick Test
Intended to be run at the same time each day, the Bowie-Dick test is used to evaluate the efficacy of air removal and steam penetration. The test involves a chemical indicator test sheet inside a pack that meets the criteria specified in the ANSI/AAMI/ISO 11140 series of standards. A specified cycle is run, and the test sheet must show a uniform color change. Results that are not uniform are considered a failure.

Extended Cycles
One solution to steam penetration issues might be an extended cycle. The time needed at the point of exposure does not change. But if it takes longer for the steam to reach a given point, then an extended sterilization exposure time might be needed. If that is not possible (e.g., in healthcare facilities in the United States), then the device needs to be redesigned or the exposure time needs to be increased to compensate for the extra time needed for the steam to reach all contact points.

Wet Packs
A wet pack refers to moisture remaining after completion of the sterilization and cooling cycles. Such packs may lose their barrier properties, which could allow bacteria to migrate to the inside of the package and contaminate the contents or shorten the shelf life of the package. When steam encounters an object with a lower temperature, the steam gives up energy to the object that it condenses upon. For the condensation to be re-evaporated, the same amount of energy must be applied to the condensed water. At the end of the sterilization cycle, a vacuum is used to remove the steam from the sterilization chamber. The condensed water produced during the exposure phase must either be drained away or re-evaporated. Under ideal conditions this is not a problem since the energy needed for re-evaporation is exactly the same amount of energy that was produced during condensation! In a properly working system, wet packs should never be a problem. Unfortunately, wet packs do occur.

For the condensate to be re-vaporized the condensate must be kept in contact with its energy. This energy was given up to the product upon which the steam condensed. If the condensate gets separated from the product then there is no energy to be used for re-vaporization. This condensate must instead be drained away. If the condensate is not re-vaporized or drained away a wet pack occurs.
A number of things can cause the condensate to become separated from its energy. Poor steam quality may cause wet pack problems. Steam might condense in the pipes leading to the sterilizer. Sometimes this condensate can find its way into the sterilizer chamber. Since the energy that produced the condensate is in the pipes and not the chamber or product there is no energy available for re-vaporizing the condensate. This condensate must be drained away. Steam quality also can be affected if the demand for steam is higher than the steam generator or boiler's capacity. In this situation the steam pressure will drop causing a boil, and some water will be carried along with the steam into the sterilizer chamber. This water never evaporated to become steam and therefore did not condense, and thus it does not have any energy to use for re-evaporation at the end of the sterilizer cycle. Anything that causes a large amount of condensation to occur might result in a wet pack. If a sterilizer door is allowed to stay open between cycles it might cool off, which can cause a large amount of condensation to occur at the beginning of the sterilization cycle. This condensate can be blown onto the load during the turbulence which occurs in the cycle. Again, the source of the energy and the condensate has been separated. Large amounts of metal in the load also can cause large amounts of condensation to occur. This condensation will drip off the product and can cause re-vaporization problems for products that the condensate drips upon. Products that absorb the condensate will not dry at the end of the cycle because there is no energy available to re-vaporize the condensate. The following conditions may also separate the condensate from its energy source: support devices, multiple tray layers, stacking of trays, dented or deformed trays. Most steam sterilizers dry the load under vacuum conditions. If no energy is available for re-vaporization the vacuum will insulate the load. For this reason, increasing the dry time will have little effect on eliminating wet packs. The best way to eliminate wet packs is to eliminate the conditions which will cause the wet pack.

Most of these problems can be prevented by configuring the device and the load to minimize the accumulation of condensate and the separation of the condensate and its energy. Textile and peel packs should be placed above trays. Place wrapped trays above sterilization containers. Provide adequate space between packs and trays. Do not stack containers or packages. A water separator will help to prevent carryover of water from the steam pipes. Ensuring that the steam generator or boiler has enough capacity to accommodate peak load periods will help prevent carryover of water.

**Verification vs. Validation**

Verification is “the confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.”

Whereas, validation is “a documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification.”

Processes that can be confirmed with objective evidence only need to be verified each time that they are run. However, processes that do not provide objective evidence that the process has been accomplished need to be validated. This is the case with sterilization processes. For many reasons, it is impossible to prove that an item that has been sterilized is sterile. Once the process used to sterilize a particular device has been validated by the manufacturer, then verification is conducted by the user each time that the process is run. Verification ensures that the parameters of the validated process were achieved and provides a strong probability that the process achieved its goal, i.e., a sterile device.

Product quality assurance testing as described in ANSI/AAMI ST79 is used to confirm that the manufacturer’s validated processes being used at a particular facility works in the particular sterilizers and for the particular devices that the facility sterilizes.
This testing, like process validation, is specific to a particular machine. Product quality assurance testing is performed by developing product families and designating a master product for each product family. The master product which represents all members of the product family is then used for all testing. Results of testing apply to all members of the product family which the master product represents. Facilities might need to develop more than one product family.

Conclusion
Steam sterilization has a long history of use; the mechanism of kill is well understood and the process seems straightforward. However, the process is more complicated than it seems at first. Many factors have an impact on whether a sterile product will actually be produced.

References