HEALTHCARE PURCHASING NEWS

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Sterilization Choices for the SPD

by Craig Wallace

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LEARNING OBJECTIVES

1. *Review the fundamental principles of medical device sterilization.*
2. *Discuss the most common sterilization methods used in hospitals.*
3. *Examine the quality control tools used for hospital sterilization processes.*

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Proper sterilization of surgical instruments is critical to infection prevention and patient safety. The sterilization process breaks the chain of infection by preventing transmission of pathogens between patients. Hospitals today can choose between different sterilization processes to accommodate the broad array of medical device designs and materials. Rigorous sterilization quality control programs help ensure that the devices are safe and ready for patient use.

Sterilization Fundamentals

The term "sterile" means"free from viable organisms."[1] It is impossible to conduct microbiological laboratory tests on the medical devices themselves to determine if they are sterile, as these tests would render the devices unfit for use on patients. So, the determination of sterility will be based on the original validation of the sterilization process supported by rigorous testing of each individual sterilization cycle (more on this testing later in this article). In the United States, sterilizer manufacturers are required to demonstrate that each programmed sterilizer cycle is validated under laboratory conditions and demonstrate to the U.S. Food and Drug Administration that the sterilizer achieves the required level of effectiveness and safety.[2]

In addition to the sterilizer itself, the effectiveness of the cleaning process is critical to the overall success of the sterilization process. The CDC Guidance for Disinfection and Sterilization states: "Cleaning reduces the bioburden and removes foreign material (i.e., organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent."[3] Careful adherence to cleaning instructions provided by the sterilizer manufacturer or the medical device manufacturer will help ensure that the sterilization process will perform as intended and the processed devices will meet the required level of safety.

Packaging is also an important factor in the sterilization process. The packaging system is intended to protect the sterile medical device from any environmental contamination until the instrument is presented for use on the patient. The healthcare facilities' packaging procedures should be based on instructions for use from the sterilizer manufacturer, medical device manufacturer, and packaging system manufacturer.

Today's Sterilization Processes

There are two general types of sterilization processes available to the hospital. The first is high temperature sterilization, which is accomplished by steam sterilization. The second is called low temperature sterilization. Low temperature sterilization processes rely on chemical action rather than physical effects. The most common low temperature sterilization process used in healthcare is vaporized hydrogen peroxide (VH2O2).

Steam sterilization

Steam sterilization is considered a physical sterilization process. It relies on saturated steam, that is, water vapor that is in a state of equilibrium between the gas and liquid phases. The steam condenses on surfaces and releases energy that will kill the microorganisms present on the surface. Steam will transfer heat energy to a medical device and can kill the microorganisms on the device even if it does not contact the microorganisms directly.

The critical variables of a sterilization process are the physical aspects of the process that have the greatest impact on the effectiveness of that process. The critical variables for a steam sterilization process are temperature, exposure time, and steam quality (level of saturation). Steam quality is critical to the process and can be very difficult to measure. Poor quality steam can be caused by residual air in the sterilization chamber, air leaks in the steam supply system, or poor boiler water quality. Sterilizer or loading issues can cause wet steam or superheated steam in the chamber. These steam quality issues can reduce the level of saturation and therefore the amount of energy transferred on condensation, thus reducing the effectiveness of the sterilization process.

Typical steam sterilization processes in healthcare today operate at 132°C or 134°C and remove air from the chamber with a series of vacuum or steam pulses at the start of the cycle. Cycles that operate at 121°C and use gravity to remove the air are also used but are less common.

Vaporized hydrogen peroxide sterilization

Hydrogen peroxide sterilization is a low temperature chemical sterilization process that uses hydrogen peroxide vapor as the sterilizing agent. Hydrogen peroxide will oxidize critical molecules and kill the microorganism. Vaporized hydrogen peroxide cycles typically operate at temperatures of approximately 50°C to 55°C which are well below the temperatures used in steam sterilization processes. The critical variables for VH2O2 sterilization processes are temperature, exposure time, and concentration of hydrogen peroxide. The concentration of hydrogen peroxide is more complicated than it sounds. VH2O2 sterilization is a chemical process which means that hydrogen peroxide molecules must directly contact a microorganism to kill it. So, to sterilize a device, every microorganism on the device must be contacted directly by the hydrogen peroxide. Hydrogen peroxide is in a vapor state, which means it tends to easily condense into liquid on surfaces, like water vapor on the mirror in the bathroom after a hot shower. The condensed liquid hydrogen peroxide will not further penetrate into the devices and may reduce the amount of vaporized hydrogen peroxide available in the rest of the chamber. In addition, hydrogen peroxide itself is a somewhat unstable molecule, and will tend to break down into other chemicals. (For example, the hydrogen peroxide solution in your home medicine cabinet is in a light-proof, brown bottle and must be stored in a cool place, to protect the unstable hydrogen peroxide molecule). These properties of vaporized hydrogen peroxide make it very important to properly maintain the sterilizer and also to follow the instructions for use (IFUs) provided by both the device manufacturer and the sterilizer manufacturer.

There are many different VH2O2 cycles available in the VH2O2 sterilizers used in healthcare today. Some cycles use a gas plasma exposure to reduce the amount of residual hydrogen peroxide after the cycle is complete. Each cycle is intended for a specific set of medical devices, and careful adherence to the sterilizer manufacturer's and medical device manufacturer's cycle recommendations is critical.

Sterilization Quality Control

The sterile processing team must decide if each instrument load has been correctly processed and is safe and ready for use on patients. The challenge is that you cannot see if the devices are sterile, and there is no practical way to do microbiological testing on each device to determine if it is sterile. However, you can perform other types of tests on each sterilizer cycle to provide information on whether the expected and required conditions were achieved in that cycle. While these quality control (QC) tests cannot absolutely confirm sterility, they can provide information on the sterilizer cycle performance that can be used to decide on whether the devices in that cycle can be considered safe and ready for patient use.

The quality control programs for healthcare sterilization processes are typically based on testing the sterilizer and process with a combination of physical monitors, chemical indicators (CIs), and biological indicators (BIs). Each of these monitoring tools provides different information about the sterilization process that, when combined and evaluated by a knowledgeable individual, can provide the information needed to decide whether to release the load contents for patient use.

The physical monitors are sensors that are located in the sterilizer chamber and measure physical parameters such as temperature and pressure and provide a cycle printout. This information is useful for ensuring that the correct cycle was selected and confirming that no cycle errors occurred. The physical monitors provide basic information from distinct points in the chamber wall and are not able to provide information related to loading or information from inside the sterilizer load. Chemical indicators use reactive inks that will respond to specific process conditions with a chemical or physical change that can be interpreted by the user (e.g., a change in ink color or a moving front). Chemical indicators are placed on both the outside and inside of packages and provide information on the physical quality of the process from those locations in the load. Biological indicators are placed inside process challenge devices (PCDs) in the most challenging location in the chamber and provide the only direct measurement of the lethality (killing power) of the cycle. In the BI/PCD system the BI's spores are intended to represent the microorganisms on the medical devices. The PCD is separate and represents the challenge to the process provided by the device packaging and the load. The BI/PCD combination then provides a representative challenge to the process like the organisms on devices inside of the load, yet the BI/PCD is easy to retrieve and test without opening any packaged devices. A "pass" result for all these indicators (physical, chemical, biological) provides a sound rationale that the process was correct and effective, and the load contents are safe for patient use.

Performance and labeling requirements for biological indicators for steam are well defined in ISO standards, but currently there are no standards defining the performance requirements for biological indicators for VH2O2 processes. This means that the end user should rely on regulatory clearances by the FDA to provide confidence that the biological indicators they are using will perform appropriately in the labeled cycles. The FDA makes the determination regarding suitability of BIs for specific VH2O2 cycles through the regulatory clearance.

Recommended Practices

AAMI standards provide recommended quality control monitoring practices for load release for steam and VH2O2 cycles.[4,5] The recommendations are summarized in Table 1.

The monitoring recommendations for load release for steam and VH2O2 are quite similar. It should be noted that BI/PCDs are optional for testing of non-implant loads in steam while BI/PCD testing is preferred for every cycle in VH2O2. Many healthcare facilities monitor every cycle in both processes with a BI in a PCD to provide the highest level of quality control and a uniform standard of care for all patients.

Table 1 – AAMI Monitoring Recommendations for Routine Release of Loads

	STEAM	VH2O2
Physical monitoring	Every cycle	Every cycle
Chemical indicators - external	Every package	Every package
Chemical indicators - internal	Every package	Every package
Biological indicators inside a PCD	Optional[a] Every cycle[b]	Daily, preferably every cycle[a] Every cycle[b]

a. Non-implant loads b. Loads containing an implant

Summary

By preventing cross contamination between patients, sterilization processes used in healthcare facilities are an essential part of an infection prevention program. Steam and vaporized hydrogen peroxide processes are both effective when used properly. Quality control testing using physical monitors, chemical indicators, and biological indicators inside of PCDs provides information

Self-Study Test Answers: 1. C, 2. B, 3. B, 4. D, 5. A, 6. C, 7. A, 8. C, 9. D, 10. D

on the quality of each process and will facilitate the decision on whether instruments can be released for patient use. HPN

References:

1. ISO 11139:2018. Sterilization of health care products m Vocabulary of terms used in sterilization and related equipment and process standards.

2. Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities. 1993. United States Food and Drug Administration.

3. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. (Update May 2019). Centers for Disease Control.

4. ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation. 2017.

5. ANSI/AAMI ST58, Chemical sterilization and high-level disinfection in health care facilities. Association for the Advancement of Medical Instrumentation. 2013 (R2018).

Craig Wallace, President of Wallace Sterilization Consulting, LLC, has over 26 years of experience in the field of medical device disinfection and sterilization.

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Sterilization Choices for the SPD

Circle the one correct answer:

1. **Steam sterilization is what type of sterilization process?**
   - A. Chemical
   - B. Low temperature
   - C. Physical
   - D. Organic

2. **Vaporized hydrogen peroxide is what type of sterilization process?**
   - A. High temperature
   - B. Low temperature
   - C. Physical
   - D. None of the above

3. **The term sterile means __**
   - A. clean.
   - B. free from viable microorganisms.
   - C. safe.
   - D. inexpensive.

4. **Sterilization quality control program will use information provided by __**
   - A. biological indicators.
   - B. chemical indicators.
   - C. physical monitors.
   - D. All of the above

5. **Physical monitors __**
   - A. provide information on temperature and pressure inside the chamber during the cycle.
   - B. can determine if the load is sterile or not.
   - C. contain viable microorganisms.
   - D. can be placed on the outside of packages.

6. **Chemical indicators __**
   - A. contain viable microorganisms.
   - B. are built into the chamber wall.
   - C. respond to the process with a chemical or physical change that can be interpreted by the user.
   - D. None of the above

7. **Biological indicators __**
   - A. contain viable microorganisms.
   - B. can be placed on the outside of packages.
   - C. do not require incubation.
   - D. None of the above

8. **A process challenge device is intended to __**
   - A. create confusion in the sterile processing department.
   - B. be used with the physical monitors.
   - C. represent the challenge to the process provided by the device packaging and the load.
   - D. be used in an empty chamber

9. **For steam loads containing implants, AAMI ST79 recommends __**
   - A. monitoring every load with physical monitors.
   - B. placing a chemical indicator inside of each package.
   - C. monitoring every load with a PCD containing a BI and a Type 5 chemical indicator.
   - D. All of the above

10. **Vaporized hydrogen peroxide loads that do not contain implants, AAMI ST58 recommends __**
    - A. monitoring every load with physical monitors.
    - B. placing a chemical indicator inside of each package.
    - C. monitoring one cycle per day, but preferably every cycle, with a PCD containing a BI.
    - D. All of the above

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