HEALTHCARE PURCHASING NEWS

October 2020

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LEARNING OBJECTIVES

1. *Examine the goals of sterilization and options for the sterile processing department*
2. *Compare and contrast steam and vaporized hydrogen peroxide sterilization processes*
3. *Review quality control tools and procedures for sterilization processes in healthcare facilities*

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SELF-STUDY SERIES

Breaking the chain of infection

Sterilization options for the SPD

by Craig Wallace, President, Wallace Sterilization Consulting, LLC

Sterilization of medical instruments began in the 1870s with rudimentary heat and moisture-based systems and has evolved into the highly complex and effective processes used by healthcare facilities today. Sterilization of instruments is critical to infection prevention and patient safety. The sterilization process breaks the chain of infection by preventing transmission of pathogens between patients. New processes and equipment technology have been developed to accommodate the evolution of medical device designs and materials, as well as increasing demands for lower costs and increased throughput from the Sterile Processing Department (SPD).

Sterilization basics

The term "sterile" means "*free from viable organisms*".[1] While this certainly seems straightforward, the science behind "sterile" is actually quite complex. For medical devices, sterile is expressed as a probability that any given device is non-sterile (has at least one viable organism on it). The accepted probability for medical devices is no more than one chance in one million that a device is non-sterile after the sterilization process. This is called the Sterility Assurance Level or SAL and is typically written as 1×10^{-6}. The term "sterilization" means "*validated process used to render product free from viable microorganisms*".[1] In the United States, sterilizer manufacturers are required to demonstrate that each programmed sterilizer cycle is validated under laboratory conditions and demonstrate to the FDA that the process achieves the required SAL of one in one million probability of a non-sterile device.[2]

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 one-in-one-million probability of a non-sterile device.

Packaging, sometimes called the sterile barrier system, is also an important factor in the sterilization process. The sterile barrier system is intended to protect the sterile medical device from any environmental contamination until it is presented for use on the patient. Per AAMI ST 79, the sterile barrier system selected should address the following:[4]

a) allow air removal to permit sterilant penetration of the package contents;
b) provide a barrier to microorganisms during sterilization processing, handling, distribution, transport, and storage;
c) resist tearing or puncture;
d) allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity;
e) maintain protection for the sterile contents during storage and transportation to the point of use;
f) allow for aseptic presentation;
g) be free of toxic components and non-fast dyes;
h) be non-linting;
i) be compatible with the intended methods of sterilization, sterilization parameters, and the devices to be sterilize

The healthcare facilities' packaging procedures should be based on instructions for use (IFU) from the sterilizer manufacturer, medical device manufacturer, and packaging system manufacturer.

Sterilization quality control

So, how do you know if the sterilization process has been successful? You can't see if the device is sterile, and there is

no practical way to do lab sterility testing on enough devices to ensure that the required SAL of no more than one contaminated device out of every one million devices has been met. 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 confirm an SAL, they can provide information on the sterilizer cycle performance that can be used to make a decision on whether or not 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 gross 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 sterilizer 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. A "pass" result for all these indicators provides a sound rationale that the process was correct and effective, and the load contents are safe for patient use.

Sterilization options for the SPD

There are two general types of sterilization processes available to the SPD. The first is high temperature sterilization, which in healthcare means moist heat or steam. The second is often called low temperature sterilization. The most common processes for low temperature sterilization in healthcare are vaporized hydrogen peroxide (VH202), and ethylene oxide. VH2O2 is much more common now and will be the focus of this discussion.

Steam was the first technology used for sterilization of medical devices and is still the most heavily used process in hospitals today. It is fast, highly effective, and cost efficient. The development and use of the low temperature processes were driven by the development of medical devices with materials or design that were not compatible with the high temperature, high pressure, and/or high humidity of the steam process.

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. 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 them directly. Residual air in the sterilization chamber or device container can reduce the level of saturation and therefore the amount of energy transferred, thus reducing the effectiveness of the sterilization process.

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). 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 chemical sterilization process that uses hydrogen peroxide vapor as the sterilizing agent. These cycles typically operate at approximately 50°C to 55°C and are commonly called low temperature sterilization (as compared to the temperatures in steam cycles). The critical parameters for VH2O2 sterilization processes are temperature, exposure time, and concentration of hydrogen peroxide. The concentration of hydrogen peroxide is more critical and 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 vapor. Hydrogen peroxide is in a vapor state, which means it tends to condense easily 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).

There are many different VH2O2 cycles available in the varied 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 sterilizer manufacturer and medical device manufacturer IFU is critical.

Comparison – steam vs. VH2O2

Steam and VH2O2 sterilization processes are both completely effective at achieving the required SAL when they are run under the same conditions as their original validations. However, the challenges and variability presented by rigorous daily use in a busy SPD can expose the inherent differences between these two processes.

The physical action of the steam compared to the chemical action of VH2O2 leads to some practical considerations in the real-life use of these processes. While exposure time and chamber process temperature are critical variables in both

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

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processes, these variables are relatively easy to measure and control. Achieving the correct "quality" or concentration of the sterilant itself (steam or VH2O2) in the medical device load is the greatest challenge and presents the most significant risk of process failure and unsafe instruments.

Steam processes rely on the basic physical action of steam condensation and heat transfer to kill microorganisms. Steam processes are designed with an excess of saturated steam available and therefore can compensate for normal variations in load size, load temperature, and device mix. The chemical action of VH2O2 and reliance on adequate concentration for all microorganisms present on the device, coupled with the complex and unstable nature of hydrogen peroxide, present some unique practical challenges with these processes. VH2O2 processes do not typically operate with the same excess of sterilant as steam, so they can be more sensitive to variations in load size and composition. Too much material in the load, or a load that is too cool, can cause an excess of H2O2 condensation, resulting in poor distribution or inadequate sterilant in the chamber. VH2O2 can also interact with certain packaging or medical device materials that can absorb or degrade the hydrogen peroxide, again resulting in poor distribution or inadequate concentration in the chamber.

While following the IFU is imperative for any sterilization process, it is particularly important for VH2O2 processes. The unique nature of the hydrogen peroxide chemical process makes this technology approach much more technique sensitive than steam, that is, packaging, loading, and load composition must be carefully managed by the SPD staff to ensure effectiveness of the process.

Quality control 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 load in VH2O2. This fits well with the possibility of more variability in VH2O2 processes. 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.

A few words about biological indicators

Performance and labeling requirements for biological indicators for steam are well defined in ISO standards, but at this time 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. This determination is not made by the sterilizer manufacturer.

Biological indicators are placed inside of PCDs to monitor sterilization cycles. The BI 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.

Summary

By breaking the chain of infection and preventing cross contamination between patients, sterilization processes used in healthcare facilities are critical to patient safety. Steam and vaporized hydrogen peroxide processes are both effective when used properly. Vaporized hydrogen peroxide processes are more technique sensitive, however, and require strict adherence to packaging and loading recommendations. Quality control testing using physical monitors, chemical indicators, and biological indicators inside of PCDs provides information on the quality of the process, which can guide the decision on whether devices can be released for patient use. HPN

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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.

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3M Healthcare sponsored this article.

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Craig is the Convenor of the ISO Biological Indicator Working Group (TC 198, Working Group 4), the ISO committee responsible for international biological indicator performance standards, as well as a U.S Technical Expert for Chemical Indicators (ISO WG 6) and Moist Heat Sterilization (WG 3). He is also the Co-Chair of the United States (AAMI) Biological Indicator Working Group, and an active member of several other AAMI working groups including chemical indicators, vaporized hydrogen peroxide sterilization, and ethylene oxide sterilization.

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

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Breaking the chain of infection

Sterilization options for the SPD

Circle the one correct answer:

1. **"Technique sensitive" is a term to describe potential variability introduced by packaging or loading procedures that can have a significant impact on the outcome of the VH2O2 sterilization process.**
   A. True
   B. False
2. **Sterilizer manufacturers determine which biological indicators can be used to monitor their sterilizers.**
   A. True
   B. False
3. **AAMI ST58 states: "A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle"?**
   A. True
   B. False
4. **Inappropriate loading may not be detected by the physical monitors of the sterilizer (cycle printout).**
   A. True
   B. False
5. **Sterilization is a process that can break the chain of infection by preventing cross-contamination between patients.**
   A. True
   B. False
6. **Steam is a chemical sterilization process.**
   A. True
   B. False
7. **"Sterile" actually describes a probability that any given device is contaminated with a viable organism.**
   A. True
   B. False
8. **The original technology for sterilization of medical instruments was a chemical process.**
   A. True
   B. False
9. **AAMI ST79 requires a BI in a PCD to be used with every load containing an implant.**
   A. True
   B. False
10. **Vaporized hydrogen peroxide processes are dependent on the concentration of hydrogen peroxide, as well as the temperature and exposure time.**
    A. True
    B. False

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