From Novel to Established, a Journey of VHP Sterilization

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For over 30 years, healthcare facilities have relied on vaporized hydrogen peroxide (VHP) to sterilize temperature sensitive medical devices. From its origins as a novel technology, VHP has gained the trust of healthcare, regulatory bodies, and standards organizations. With the release and Food and Drug Administration (FDA) recognition of a low temperature vaporized hydrogen peroxide standard (ISO 22441), the FDA classified vaporized hydrogen peroxide sterilization as an "Established Category A method of sterilization for products labeled sterile."[4] This is good news for manufacturers of sterile products looking to move away from Ethylene oxide (EO) as this puts VHP sterilization on equal terms with EO and steam sterilization processes.

FDA's classification of VHP sterilization is part of a broader initiative to reduce the use of EO sterilization applications. This change is expected to increase adoption of VHP sterilization over the more environmentally hazardous EO sterilization applications used to sterilize products today. This leaves many healthcare facilities asking, "What does this mean to healthcare's medical device processing?" The answer, increased adoption of VHP sterilization as a choice for reusable device sterilization.

Evolving to address sterile processing challenges

1993 to 2009 VHP Sterilization focus to replace EO

EO sterilization began as means to sterilize temperature sensitive materials incompatible with steam sterilization. It has sterilized single use sterile items, reusable medical devices, and non-medical items like spices for many years. However, some of these materials easily absorb EO requiring extensive aeration times to remove the chemical from those materials. Sterilization cycle times ranged between 8 to 12 hours to complete mostly due to aeration needs. The long cycle times created bottle necks and required excess inventory to accommodate sterile processing needs. Additionally, EO's carcinogenic and mutagenic nature created concerns and stricter regulation of its use. In 1993 the first VHP sterilizer was made available to healthcare facilities with the goal to provide a low temperature alternative to EO sterilization.

At that time, vaporized hydrogen peroxide sterilization was a novel

Learning Objectives

1. **Define what is meant by "established sterilization process"**
2. **List key breakthroughs in VHP sterilization development**
3. **Pair medical devices with the VHP sterilization cycle type**

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Figure 1:
Sterile Processing Technician preparing to sterilize a 3D printed surgical guide

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sterilization method. It had proven safety and effectiveness but was a new form of sterilization with no established standard to define its use. Its popularity grew as manufacturers of rigid and small flexible endoscopes, batteries, and specialty surgical instrumentation began to include VHP sterilization in their instructions for use. By 2008, VHP sterilization was no longer 'novel' but 'non-traditional' as FDA had evaluated sterilizer data as part of a quality systems regulation evaluation and determined the methods to be adequate.

2011 to 2015 VHP Sterilization used to preserve device integrity

Medical devices continued to evolve as did their cost, increasing repair and replacement budgets. Facilities sought methods to preserve their medical device investment, one of which was VHP sterilization. Its low temperature process offered a broad range of material compatibility. Combined with a lesser vacuum, as compared with steam sterilization, it preserved the integrity of instrument adhesives and delicate optics. The demand to use VHP sterilization for a wide variety of rigid endoscopes brought a need to sterilize longer stainless-steel channels with smaller diameters.

Batteries previously sterilized through an immediate use steam sterilization cycle to limit exposure to high temperatures were sterilized through a low temperature, terminal VHP sterilization cycle preserving the battery's life.

VHP sterilization is limited by the total number of channels within a load; the length and diameter of a channel; and the number of channels within a single device. Several new claims came during this time including multiple channel devices and narrow lumens typical of urology and pediatric devices.

2016 to 2018 Fast terminal cycle to help reduce immediate-use steam sterilization

The year 2013 defined the term Immediate-use Steam Sterilization (IUSS) and brought new policies intended to reduce its use. Quick turn processes and loaned equipment vendor policies met some success. However, late loaned trays and back-to-back cases continued. Added delays came from waiting for quick turn steam sterilized items to cool.

VHP sterilization responded to the need for speed by increasing load weights up to fifty pounds. With no need to cool sets after sterilization, sets return to use immediately after cycle completion. VHP sterilization also addressed the need for quick turns of terminally sterilized single items. For the time needed to run an IUSS cycle, VHP sterilization could complete and release a terminally sterilized instrument. By the end of 2018, VHP sterilization was a common sterilization method processing many of the same types of instrumentation as steam sterilization.

2023 First FDA cleared sterilization application for 3D printed medical models

Continued addition of instrumentation claims led to a major advancement outside the category of medical instrumentation. In 2023, a VHP sterilization platform became the first sterilizer with FDA cleared claims to sterilize 3D printed anatomical models and patient specific guides. Anatomical models allow visualization of surgical site anatomy. Patient specific surgical guides help surgeons precisely position cutting instruments for accurate osteotomies or pin and screw placement. Up until this point, facilities would have to develop and validate sterilization cycles for these items. Most healthcare facilities were not equipped to perform sterilization validation, toxic residual analysis,

Lesson:

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Quiz Answers:
1. B, 2. E, 3. A, 4. B, 5. A, 6. D, 7. A, 8. D, 9. C, 10. B

cytotoxicity, and material analyses. Using an FDA cleared cycle saves facilities both time and money while supplying assurance of the sterilization process.

Given the long history of safety and effectiveness coupled with its growth and evolution, it is easy to see why this once novel sterilization process is now seen as established.

Established yet different when sterilizing medical devices

VHP sterilization joined steam and EO as established sterilization platforms, but it is different from them in many ways. The obvious differences include the sterilant, exposure time, and aeration requirements. The not so obvious difference is the determination of which devices to process within the sterilization platform.

Steam and EO sterilizers have defined sterilization cycle parameters that have been validated using a specified load configuration. The load configuration is defined within standards and guidelines and does not include specific instrumentation characteristics. Steam, for example, defines the worst-case load based on the weight of the metal mass included within the sterilizer using wrapped trays and a total load capacity. It does not include testing of lumen lengths, diameters, or instrumentation itself. This requires each device manufacturer to select the steam sterilization cycle best suited for their instruments and validate that the sterilization cycle parameters previously cleared by the FDA for the sterilizer are right for their instrument. The instrument vendor must provide this information to the user as part of the instrument's instructions for use (IFU). If a steam or EO sterilization cycle is not listed in the IFU, it cannot be used for that device.

VHP sterilizers are different. These sterilizers define the instrument characteristics and packaging for each sterilization cycle as well as the largest load configurations for each cycle. Instruments that have the specified characteristics are tested and validated by the sterilizer manufacturer. Any instrument that falls within the defined instrument characteristics for the sterilization cycle validated by the VHP sterilizer manufacturer can be sterilized within it. The device manufacturer does not have to test and validate the instrument in the VHP sterilizer for a user to be able to use the VHP sterilizer cycle. The user must confirm that the instrument meets the cycle's requirements and is compatible. The critical instrument characteristics to review include:

- Length and diameter of lumens and channels
- Number of lumens and channels in the instrument
- Compatibility of the instrument's materials
- The type of sterile packaging

Obtaining this information from the device manufacturer can be challenging. To help, VHP sterilizer manufacturers have worked with device manufacturers to create searchable lists of instrumentation that can be sterilized within their respective sterilizers.

What can be sterilized?

VHP sterilizers provide sterile processing departments flexibility when managing workloads and workflow. Requiring only electricity and sterilant, VHP sterilizers can serve as a backup sterilization process when steam sterilizers go down such as during a boil alert, flood, or other emergency event. Understanding what can be sterilized within a VHP application is critical when planning for general workflow and emergency situations.

VHP sterilizers have various sterilization cycles based upon the types of devices. The cycles and cycle claims will vary between sterilizer manufacturers. Refer to your sterilizer operator's manual for the types of devices that can be sterilized in any given cycle.

The general instrumentation cycle is the first type of cycle. This cycle sterilizes instrumentation with diffusion restricted spaces, such as hinges and box locks but not with lumens. "Non Lumen" and "Express" cycle are common names. Instrumentation can be composed of a variety of materials compatible with VHP. Forceps, light cords, cameras, and da Vinci endoscopes are some of the devices that are sterilized in general cycles.

The second cycle type sterilizes instruments with stainless steel lumens. This cycle type has a wide variety of names including "Lumen" and "Standard" cycle. The length and diameter of the lumen is important and not every cycle can sterilize the same lumens. These cycles typically allow mix loads of lumened and non-lumened instrumentation. Some sterilizer cycles are FDA cleared to sterilize stainless steel instruments that have two or three channels. Typical instrumentation includes rigid cystoscopes, orthopedic drills, trocar sheaths and some eye instrumentation.

Flexible endoscope cycles are the third type of sterilization cycle. As the name suggests, these cycles sterilize a variety flexible endoscopes. Typically cycle names include "Flexible" and "Flex" cycle. The lumen lengths within endoscopes play an important part in deciding if an endoscope can be sterilized within a cycle. Typical flexible endoscopes include bronchoscopes and surgical flexible endoscopes. Large flexible endoscopes, such as choledochoscopes and colonoscopes, contain a dry lubricant within the interstitial space of the endoscope that is incompatible with VHP sterilization.

The fifth and last cycle type is a specialty cycle designed to sterilize anatomical models and patient

specific guides that were 3D printed within the hospital. It is important that the material used to construct the model is compatible with the system and that any lumens within the model meet the diameter and length requirements specified for the special cycle.

VHP sterilizer and device manufacturers often give sterilization information based on a single device but rarely is a device sterilized alone. Building sets for VHP sterilization will require knowledge of the requirements of all the instrumentation within the set, the tray or container used to hold the instrumentation and all accessories including wraps, instrument organizers, and items used to protect wraps from punctures and tears. The set, in its entirety, should be compatible and packaging materials validated for VHP sterilization. Packs that hold items that can be sterilized in different sterilization cycles should be reconciled to the cycle that is common between all items within the set.

VHP sterilization into the future

Vaporized hydrogen peroxide has rapidly advanced over its short thirty plus years of use as a healthcare sterilization choice. Its continued application and new advancements in 3D printed models and guides is just the first of many new sterilization applications to come in this established sterilization process's future. **HPN**

References online at hpnonline.com/55001566.

From Novel to Established, a Journey of VHP Sterilization - Practice Quiz

1. **What is an "established sterilization process"?**
   - A. A 510(k) cleared sterilization cycle
   - B. A sterilization process listed in an Instructions for Use
   - C. A category of sterilization cycles listed by the FDA
   - D. A sterilizer sold in the United States

2. **What were the challenges of EO sterilization addressed by VHP sterilization?**
   - A. Compatibility issues with EO sterilization
   - B. Long cycle times
   - C. Chemical hazards of EO
   - D. All of the above
   - E. B and C

3. **Why is the low temperature, lesser vacuum of VHP sterilization cycle preferable for rigid endoscopes?**
   - A. Preserves the integrity of instrument adhesives and optics
   - B. Creates shorter sterilization cycles
   - C. Allows sterilization of more than one channel
   - D. Reduces dependence on aeration

4. **How many stainless-steel lumens in single device can some cycles sterilize?**
   - A. 1
   - B. 2-3
   - C. 4-5
   - D. 6

5. **Which sterilization process does not require time to cool instruments prior to use?**
   - A. VHP Sterilization
   - B. Steam Sterilization
   - C. Dry Heat Sterilization
   - D. Steam Formaldehyde Sterilization

6. **How do healthcare facilities benefit from using VHP sterilization to sterilize 3D printed medical models?**
   - A. There is no benefit
   - B. Cycle times are faster
   - C. The 3D printer runs faster
   - D. Save money on costly validations

7. **Healthcare facilities can choose to sterilize a device in VHP sterilization cycle based on the device's characteristics and sterilization packaging.**
   - A. True
   - B. False

8. **What is considered when deciding a medical device's ability to be sterilized in a VHP sterilization cycle?**
   - A. Lumen length and diameter
   - B. Compatibility the instrument
   - C. Sterilizer manufacturer's device matrix
   - D. All of the above

9. **Which VHP sterilization cycle type can be used to sterilize a bronchoscope?**
   - A. General cycle type
   - B. Stainless-steel Lumen cycle type
   - C. Flexible cycle type
   - D. Specility cycle type

10. **When building a set, which sterilization cycle should be used?**
    - A. The cycle most recommended
    - B. The cycle common to all instruments
    - C. The shortest cycle time
    - D. The longest cycle time

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