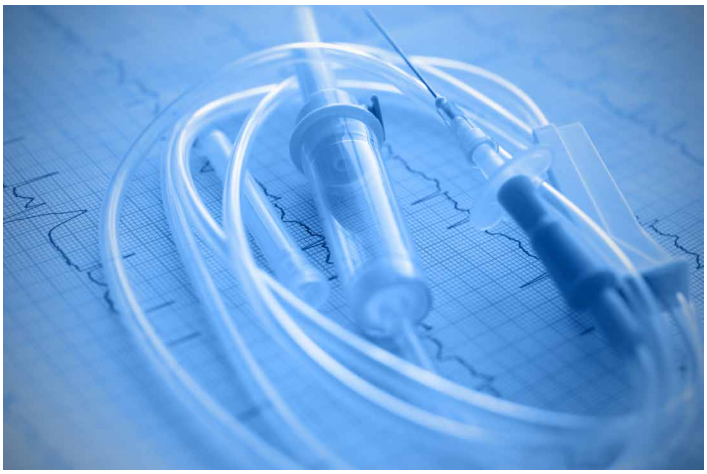
Options Abound in Sterilization of Medical Devices

Healthcare Market



The use of ethylene oxide for medical device sterilization has long been lauded for its ability to effectively reach tight spaces, its low cost and its global availability, making the method ideal for a long list of reusable and disposable medical devices that improve patient care and outcomes. But ethylene oxide is a toxic gas and a known carcinogen, and air quality issues in and around sterilization facilities have become problematic in recent months, bringing the potential health and environmental risks to the headlines. Consequently, device manufacturers and health providers face enormous business challenges as the industry tries to balance the needs of all stakeholders.

As the issue plays out through regulatory and legal channels, the U.S. Food & Drug Administration (FDA) released a statement from Commissioner Scott Gottlieb, M.D., warning of possible shortages that will undoubtedly affect medical device equipment manufacturers. With the industry scrambling, examining each link in your supply chain could offer new efficiencies while you find ways to meet the challenges of the current landscape. Here are a few factors to consider:

Consider supplier options

When better sterilization alternatives are not available, device manufacturers and health providers relying on ethylene oxide for sterilization may need to identify alternative suppliers to fill anticipated shortages. In light of the FDA's announcement, service providers are working to add capacity. Our vast network of material suppliers and partners includes sterilization service providers who can help you meet the needs for your application.

Explore alternatives in gas sterilants

When the health benefits of low-temperature chemical sterilization outweigh the potential risks of using a toxic gas, the next best choice might be a less toxic sterilant. In many cases, hydrogen peroxide can be an option, because it offers effective low-temperature decontamination with shorter cycle times and considerably fewer safety and environmental hazards. Hydrogen peroxide has been used to safely and effectively sterilize gowns and uniforms, dressings, and a variety of surgical instruments and supplies without impacting costs or time.

Examine different sterilization methods

When it comes to decontaminating reusable medical devices, there are numerous sterilization options to consider beyond ethylene oxide. A number of chemical and physical processes can be used (See sidebar, page 2), depending on factors such as material composition, device classification, intended use, and packaging and storage conditions.

Rethink your design or your process

Sometimes, adjusting a material, a component or the manufacturing process can afford new sterilization opportunities or eliminate these challenges altogether. No matter where your device is in its life cycle — new to market or well-positioned — applying fresh engineering and applications expertise to the task can help.

The key to opening up new options is to factor sterilization in the initial design and development rather than as an end-of-process step. With reusable medical devices, sterilization and design are inextricably linked; considering sterilization as an essential process rather than an end step allows device makers to plan ahead, avoiding problems rather than reacting to them when they occur.

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Know when to get help

The challenges facing healthcare manufacturers and providers are more complex than ever, and smart collaborations with partners that understand and can balance needs from all stakeholders will bring value to the table. With Nexeo Plastics as your partner for plastics and medical industry solutions, you can leverage our breadth and scale as a leading distributor of the source materials you use with the value-added resources you need to make transformational changes in your business.

No matter how your facility is affected by the regulatory issues around ethylene oxide — as a device maker, molder, sterilizer or provider — you can benefit from extra help. A trusted partner that combines deep healthcare industry experience, supply chain know-how and wide-ranging commercial expertise can help you bring your device to market and optimize your bottom line.

"Statement from FDA Commissioner Scott Gottlieb, M.D., on steps the Agency is taking to prevent potential medical device shortages and ensure safe and effective sterilization amid shutdown of a large contract sterilization supplier," U.S. FDA press release, March 26, 2019. Link: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-steps-agency-taking-prevent-potential-medical-device

Understanding Sterilization Options for Your Device

Chemical sterilization is a popular method for medical devices, because chemicals like ethylene oxide and hydrogen peroxide allow processing in lower temperatures and are therefore able to be used for a variety of materials. Plastics and electronics can be exposed in this sterilization process without adverse effects in form or function. Gases can penetrate the small spaces inherent in medical devices, as well as instruments or devices encased in plastic. But, they require lengthy processing times and are viewed as being less safe and less environmentally friendly.

Hydrogen peroxide has gained market favor as a safe, cost-effective and more expedient low-temperature option. Often hailed for its higher throughput with fewer regulatory constraints, it performs well in many healthcare applications.

Steam sterilization, by far the most widely used method for decontaminating reusable medical devices, typically uses an autoclave to sterilize at extremely high temperatures. While this process is generally highly effective and environmentally friendly, it tends to be unsuitable for heat- and moisture-sensitive devices.

Dry heat sterilization takes longer than wet steam due to inefficiencies in heating air with a low moisture content, but dry heat can be effective for devices with high heat resistance and low water tolerance.

Radiation sterilization using gamma rays or electron beams (e-beams) can penetrate packaging like chemical sterilants and is less time consuming. This process has proved effective for dense materials and is typically more appropriately suited for single-use devices, such as catheters and syringes.

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