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Ethylene Oxide Sterilization of Medical Devices

At A Glance

At Issue

In light of closures and potential closures of certain facilities that use gas ethylene oxide (EtO) to sterilize medical devices prior to their distribution and use, the Food and Drug Administration (FDA) is concerned about the future availability of medical devices and possible medical device shortages. In addition to background on the issue, this advisory highlights potential alternatives to EtO, including the advantages and disadvantages of each, as well as a resource to identify companies that sterilize instruments and equipment in the U.S.

AHA Take

Providing high-quality patient care is the top priority for America's hospitals and health systems. Our members also are committed to protecting and advancing public health. Medical devices are necessary to provide many types of services to patients, and effective sterilization is critical to significantly mitigating the risk of infection. However, the process used to sterilize those devices must fully consider and substantially eliminate any detrimental effects on public health. The AHA continues to monitor the situation and is urging government agencies and device sterilizers to develop both near- and long-range solutions that will address shortage concerns and appropriately consider and alleviate any public health implications due to the use of EtO sterilization processes.

What You Can Do

- ✓ Share this advisory with your leaders, including your chief medical officer, chief nursing officer, materials manager and others who are responsible for medical device acquisition and inventory.
- ✓ Discuss the availability of alternative sterilization processes with materials management personnel and suppliers.
- ✓ Share information related to this issue with the AHA.
- ✓ Watch for further updates.

Key Takeaways

- Ethylene oxide is used to sterilize about 50% of medical devices in the U.S.
- While some alternative methods currently exist, there are potential device incompatibility issues.
- The FDA recently held a public meeting to address potential shortages due to concerns about EtO.
- Any additional commercial sterilization facility closures could result in shortages for specific medical devices.
- Hospitals and health systems should develop a feasible contingency plan should EtO no longer be available for the sterilization of certain devices.
- The AHA will continue to update members on this issue.

Further Questions

Contact Mark Howell, senior associate director of policy, at 202-626-2317 or mhowell@aha.org.

Background

Ethylene oxide (EtO) sterilization is a chemical process consisting of four primary variables: gas concentration, humidity, temperature and time. During this process, EtO acts as an alkylating agent, effectively disrupting the DNA of microorganisms to prevent them from reproducing, ultimately resulting in sterile products suitable for medical use. Although most hospitals have gravitated away from using EtO for on-site sterilization, commercial sterilization facilities still use EtO. About 50% of all medical devices, including catheters and surgical mesh, in the U.S. are sterilized using EtO.

In December 2016, the U.S. Environmental Protection Agency (EPA) classified EtO as a carcinogen after linking it to cases of breast cancer, lymphoma and leukemia.[1] Over the course of the last year, public concerns about the emissions from sterilization facilities using EtO resulted in the permanent closure of a facility in Willowbrook, Ill., as well as temporary closures for at least two facilities in Georgia. In addition, at least one state legislature (Illinois) is considering a bill that would phase out hospital in-house use of EtO and require EtO commercial sterilization facilities operating within the state to relocate to "scarcely populated areas." Currently, shortages due to current closures are not expected, ***but*** any additional commercial sterilization facility closures could result in shortages for certain devices.

The FDA Nov. 6-7 convened an expert panel to discuss the EtO sterilization situation and to examine potential alternatives to EtO. The FDA expects the panel to make a series of recommendations on implementable next steps. Further, the FDA has initiated an innovation challenge to identify alternatives and reduce EtO emissions. In addition, the EPA is expected to release the second of two proposed rules focused on curbing the level of allowable EtO emissions produced by commercial sterilizers.

Currently, the AHA is aware of several alternative technologies that have emerged to improve sterilization time and reduce toxicity; however, it is unclear whether these alternatives can effectively sterilize the devices that currently undergo EtO sterilization. Regardless of compatibility, it is clear that substantial research and investment likely will be needed to effectively scale-up alternative options of large-scale, high-volume device sterilization.

Alternatives to EtO

As potential closures to additional sterilization facilities using EtO are possible, hospitals and health systems should identify and assess whether devices can be acquired from commercial sterilizers who do not utilize EtO.

Current alternatives to EtO include[2]*:*

[1] https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf#nameddest=woe
[2] Content provided by Dr. Lena Shahbandar, M.D. in her article, "Alternatives to Ethylene Oxide"

- Hydrogen Peroxide and Ozone
- Vapor-Phase Hydrogen Peroxide
- Plasma (Hydrogen Peroxide)
- Peracetic Acid
- Radiation (Gamma and Electron Beam)
- Nitrogen Dioxide

The following chart describes some advantages and disadvantages of each sterilization alternative[3]:

Sterilization Method	**Advantages**	**Disadvantages**
Hydrogen peroxide vapor or plasma	• Safe for the environment, worker • Shorter processing time • No toxic residues • Used for heat and moisture sensitive items	• Potential material incompatibility with brass, zinc, copper, nickel/silver plating • Eye damage with contact • Cannot be used for cellulose like linen and paper
Peracetic acid	• Environmentally friendly byproducts • Safe to workers	• Potential material incompatibility • Used for immersible instruments only
Gamma radiation	• 60-year history • No harmful emissions • Entire volume of product is sterilized • Gas-permeable packaging is not needed	• Possible harmful changes in some plastics and tissue allografts • Question of safety of consumption of irradiated food • Requires requalification of irradiator operation annually (approximately)
E-beam	• 60-year history • No harmful emissions • Uses less product within the irradiator than gamma • Fast processing time	• Not suitable for products with challenging product geometries and localized high-density materials

[3] https://www.isms.org/Membership/Annual_Meeting/resources-lateA/

Nitrogen dioxide	• Readily penetrates packaging and complex geometry • Nontoxic/noncarcinogenic residuals • Fast processing time	• Limited compatibility questions with certain plastics • Not fully available

For hospitals and health systems looking for alternatives, this medical device directory provides a list of companies that sterilize medical supplies and equipment in the U.S. and the types of sterilization methods they employ.

Next Steps

AHA will continue to monitor the situation and provide updates as necessary. If you have further questions, please contact Mark Howell, senior associate director of policy, at mhowell@aha.org.