

ETHYLENE OXIDE



A Critical Building Block for the Sterilization of Medical Equipment

Ethylene oxide is a versatile building block of chemistry. It helps make many of the products we use every day, such as plastics, safety glass, adhesives, and textiles.

One area where ethylene oxide is used is in the sterilization of medical equipment.



How is it used?

It is estimated that ethylene oxide sterilizes 20 billion medical devices each year, helping to prevent disease and infection.

- ✓ During ethylene oxide sterilization, products are exposed to ethylene oxide gas under vacuum in a sealed chamber with defined humidity and temperature conditions. Keeping medical devices sterile is essential to the safety of our healthcare system and the health of our patients.
- ✓ Ethylene oxide is important for medical equipment and articles that cannot be exposed to high heat or steam. Medical devices that use ethylene oxide sterilization¹ include heart valves, pacemakers, surgical kits, gowns, drapes, ventilators, syringes, catheters, ophthalmologic instruments, ampoules for spinal anesthesia, and equipment for intravenous infusions.²
- ✓ It is a common sterilant for medical devices and is used to sterilize over 50% of medical devices sterilized by a manufacturer or contract sterilizer.³ Ethylene oxide can penetrate multiple layers of packing and is compatible with a broad range of device materials including certain polymers (plastic or resin), metals, or glass.⁴
- ✓ The effectiveness of the technology for broad-spectrum antimicrobial sterilization is well established. The high throughput/low cost of this technology allows for large sterilization capacity which guarantees the supply chain of medical devices sterilized using the technology is preserved.⁵
- ✓ According to the [Federal Drug Administration](#),⁴ the unavailability of ethylene oxide as an industrial sterilant for medical devices is a concern.
- ✓ While FDA-approved hydrogen peroxide sterilization for certain medical uses, ethylene oxide is the only acceptable sterilization method for many delicate, complex, and sophisticated medical devices manufactured with sensitive materials. The removal of ethylene oxide as an option could lead to device shortages.
- ✓ In the [American Hospital Association's Letter on EPA's Proposed Standards for the Use of Ethylene Oxide](#), the AHA and its members wrote that the proposed 18-month compliance timeline is too aggressive and could result in significant disruption to the supply chain leading to decreased sterilization capacity and supply availability across the country.

The demands of our nation's healthcare system continue to grow. Overly conservative restrictions on the production of ethylene oxide could put the needs of the healthcare sector at risk. Our member companies are dedicated to the responsible manufacture and use of ethylene oxide, and we support strong, science-based regulation of this important chemistry.

¹ Federal Drug Administration

² AdvaMed

³ The New England Journal of Medicine

⁴ Federal Drug Administration

⁵ American Hospital Association

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