



Ethylene Oxide (EO) Myth Busting

Proven performance, effective results, definitive answers.

Ethylene Oxide (EO) has long been a key tool in the sterilization of medical devices that cannot be steam sterilized — because it has proven to be an effective and cost-effective sterilant.

But some in our industry have raised questions about its continued use.

- Isn't EO banned?
- Is it too dangerous?
- Is it outdated technology?
- Is it harmful to the environment?
- Isn't EO going away?

Chances are, you've heard the questions. Now, on these pages, you can learn the answers.

Is EO banned?

EO is not banned by any U.S. regulatory agencies.

Ethylene oxide continues to be broadly used for the processing of food products, cosmetics, museum artifacts, manufacturing and medical devices. According to EOSA, over 4 billion pounds of EO is produced each year in the United States. While most of the EO is used to make common household products such as detergents, polyester, cosmetics and antifreeze, only a small fraction is used for sterilization.

In the U.S., the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), among others, have all established regulations for the use of EO. They have not banned it. Confusion regarding this point may be the result of the EPA regulation banning of CFCs and HCFCs used in large EO bulk tanks.¹

However, this regulation does not apply to 3M™ Steri-Vac™ Sterilizers, since they use 100% EO and do not use HCFCs. The EPA reviewed the eligibility of ethylene oxide for registered uses, including EO sterilization in healthcare facilities, and determined that “the benefits of ethylene oxide use outweigh the occupational risks associated with its use,” provided that certain risk mitigation measures such as single chamber sterilization and aeration are adopted.

3M Steri-Vac EO sterilizers are installed in every continental state in the U.S. (including California and Washington). Some states such as California and Michigan require an EO abator be installed to reduce EO emissions, but EO is not banned (a common misconception). The 3M™ EO Abator reduces EO emissions virtually eliminating any emissions to the environment.

Is ethylene oxide sterilization safe for patients and staff?

EO sterilization is a safe and effective process for both staff and patients.

Being a microbiocidal chemical is what makes EO an effective sterilant, just like hydrogen peroxide and others. And like other hazardous processes, EO sterilization is safe when performed properly. In addition to state and local regulations relating to sterilization, at the federal level, the FDA, EPA and OSHA govern the sterilization equipment and sterilization process to ensure patient and operator safety. The 3M Steri-Vac sterilizers meet the safety requirements of all relevant safety standards from IEC, AAMI and ISO. To protect workers, OSHA has established exposure limits for EO. 3M Steri-Vac sterilizers, when properly installed and operated according to instructions, are designed to ensure operator exposure is below these levels.

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Safety is important. That's why we've engineered the 3M™ Steri-Vac™ GS Series to include many safety features:

- Software control system checks before and monitors during each cycle to ensure operator safety. The system will not allow chamber door to be opened until it is safe.
- Negative chamber pressure throughout the cycle eliminates potential operator exposure in the event of a leak.
- In-chamber aeration immediately following sterilization cycle removes the need to handle loads prior to full aeration.
- Single-dose EO cartridges eliminate the need for handling/switching out of large EO tanks.
- Engineered for operator safety, the cartridge is punctured only when the chamber door is sealed and the proper vacuum level has been reached inside the negative pressure sterilizer chamber.
- 10 air exchanges per hour ventilation.
- Smart software controls recognizes any system malfunction and locks chamber until it can return to a safe state.

Is EO sterilization an outdated technology?

There are times when “classic” technology performs better.

Ethylene oxide has been used for over fifty years in health care institutions as the primary method for sterilization of heat and moisture sensitive items. In 2011, more than 56% of all medical devices were sterilized by EO in the medical device manufacturing industry.² For best practice on today's most critical low temperature sterilization challenges, including flexible endoscopes, EO stands the test of time.

EO is easy on instruments.

EO is gentle on most device materials, which can help extend device life and reduce the need for repairs. EO sterilizers are the only low temperature sterilizers available without lumen length or lumen diameter restrictions.³

Is EO harmful to the environment?

With an optional EO abator system, you have almost no effect on the environment.

You can use proven EO technology with confidence and comply with current regulatory restrictions on EO emissions with the 3M™ EO Abator system. The 3M EO Abator is a highly effective device used to convert EO exhausted from a sterilizer airstream. The 3M EO abator uses an exothermic (heat producing) reaction to convert EO exhaust into CO₂ and water vapor. At normal operating temperatures and concentrations, conversion efficiency is 99.9%* virtually eliminating emissions of EO to the environment.

*When EO concentrations are greater than 100ppm. When EO concentrations are less than 100ppm, conversion efficiency is 99.0%.

Isn't EO going away?

3M remains a global supporter of EO technology. We have no plans to get out of the EO business.

Thousands of 100% EO 3M sterilizers are in use today, in over 70 countries and every state in the continental U.S. Just as important, 3M continues to install more units to address the growing needs of sterilizing complex medical devices, as well as the need for low-cost, low-temperature sterilization. We intend to support our customers today and long into the future.

To learn more about 3M EO sterilization options, visit go.3M.com/lowtemp



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¹ Phaseout of Class I Ozone-Depleting Substances, <https://www.epa.gov/ods-phaseout/phaseout-class-i-ozone-depleting-substances>

² The Ethylene Oxide Sterilization Association, Inc., Ethylene Oxide — Is It Being Banned? November 8, 2011, [https://www.eosa.org/sites/default/files/Rumors%20of%20EO%20Ban%202011-11\(2\).pdf](https://www.eosa.org/sites/default/files/Rumors%20of%20EO%20Ban%202011-11(2).pdf)

³ Rutala W., Weber DJ. Disinfection, sterilization, and antisepsis: An overview. *American Journal of Infection Control* 2016;44:e1-e6.