



**ASP**™ Advanced  
Sterilization  
Products

# Ethylene Oxide

Hazards, Environmental Impact and Alternatives



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# Commercial Sterilization:

## Safeguarding Patients and Addressing Environmental Concerns

There are two primary medical applications of ethylene oxide (EO) sterilization: commercial sterilization of newly manufactured, single-use devices, and in-hospital sterilization of reusable medical devices. About half of all single-use medical devices undergo sterilization in large commercial ethylene oxide (EO) facilities prior to patient use.<sup>[12]</sup> This is typically referred to as terminal sterilization and the sterilization chambers used are big enough to accommodate whole pallets of devices per load.

Despite a long history of commercial use, toxic emissions from EO sterilization facilities have become a source of growing concern. Lawsuits and stricter regulations are emerging in response to the health risks associated with EO exposure in areas where these commercial facilities are located.<sup>[13, 15, 22]</sup> The risks to those exposed include an increased chance of cancer and reproductive problems for people living near the plants and workers handling the gas.<sup>[9, 21]</sup>

The U.S. Environmental Protection Agency (EPA) is tackling ethylene oxide (EO) occupational and environmental exposure with a regulatory two-pronged approach.<sup>[23]</sup> One regulation focuses on stricter emissions limits for sterilization facilities (Amendment for Ethylene Oxide Commercial Sterilizers), while the other aims to enhance protections for workers and nearby residents around EO manufacturing plants.<sup>[11, 15, 23]</sup>





# In-Hospital Ethylene Oxide Sterilization:

## Long Cycles, Safety Concerns, and Environmental Impact

Not only is EO used in commercial sterilization operations, but hospitals and other healthcare settings also use small-scale ethylene oxide (EO) sterilizers as a low-temperature sterilization (LTS) method to reprocess reusable medical devices and instruments that can't withstand the heat of steam sterilization. While EO sterilization is effective, it has several negative aspects and some unanswered questions that must be considered.

First, there is a problem with reprocessing efficiency. EO requires a lengthy cycle compared to other low-temperature alternative sterilization methods.<sup>[7,8]</sup> There are three different stages to an EO sterilization cycle which are preconditioning, sterilization, and degassing or aeration.<sup>[25]</sup> Total reprocessing time including aeration can take longer than an average hospital shift, requiring additional instruments/devices/endoscopes to be purchased to prevent delays or procedure cancellations.<sup>[6,8]</sup> In a study at West China Hospital, Chengdu, Sichuan, China, Chen et al. noted that hydrogen peroxide gas plasma sterilization had the highest efficiency for low-temperature sterilization technologies with 8 sterilization cycles being able to be carried out at their facility in one day vs only one for EO sterilization.<sup>[8]</sup>

A study showed H<sub>2</sub>O<sub>2</sub> had **8X** throughput compared to EO

Study conducted at West China Hospital, Chengdu, Sichuan, China, Chen et al. <sup>[8]</sup>



Second, in hospital EO sterilization requires significant engineering and administration controls to prevent occupational exposure and fires, as well as to catalyze the waste gases.<sup>[4, 8, 14, 20]</sup> Environmental monitoring is required by government agencies such as OSHA to prove the equipment is functioning in a safe way to prevent occupational and patient exposure.<sup>[20, 21]</sup> According to a National Institute of Occupational Health and Safety (NIOSH) bulletin, there are a variety of failure modes in EO sterilization which can lead to occupational exposure to carcinogenic and toxic EO gasses for which controls must be put in place to minimize exposure risk:<sup>[20]</sup>

- Leaks from gasket, valve or other equipment failure
- If using a compressed gas supply, supply cylinders and supply lines may leak EO gas
- Potential for EO cartridge exposure from punctured cartridge or leaks in the discharge line
- If using a separate aeration chamber, operators may be exposed while transferring a load from sterilizer to aerator
- Inadequate ventilation around EO sterilizers or ventilation system failure
- A leak in the dedicated ventilation ductwork where the EO sterilizer is located
- Exhaust from first opening of sterilizer door after sterilization cycle completes
- Accidental release from aborted cycle or interrupted cycle without complete exhaustion of EO gasses
- Downwind discharge from hospital exterior ducting

Because the odor of EO cannot be detected below about 700 parts per million of air (ppm), operators can be exposed to high concentrations without being aware.<sup>[20]</sup> It only takes a small amount of EO release into a room to create exposures that exceed the safety limits many times (1g of EO released into a room 10 x 10 x 8 ft can create a concentration > 20 ppm).<sup>[20]</sup> In the U.S. the current employee permissible exposure limits (PEL) for those working with EO is 1 ppm measured as an 8-hour time-weighted average (TWA), and employee exposure may not exceed the short-term excursion limit of 5 ppm EO exposure over any 15-minute sampling period.<sup>[21]</sup>

Third, the carcinogenic and toxic effects of EO are becoming better known.<sup>[9]</sup> Hospital-based EO sterilization use has decreased in favor of HPGP.<sup>[4]</sup> This downturn stems from growing awareness regarding the carcinogenic and harmful reproductive effects associated with EO and better efficiency for HPGP.<sup>[4, 15]</sup> Notably, several nations have taken decisive action to limit or eliminate other industrial EO uses by completely discontinuing the utilization of EO sterilization of food processing and imposing stringent regulations, such as limiting imported food products' EO residue to 0.1 mg/kg.<sup>[27]</sup> This rigorous standard applies across all member states of the European Union.<sup>[27]</sup>





# The Balancing Act:

## Reusing Medical Devices and Mitigating EO Risks

While ethylene oxide (EO) sterilization is used for low-temperature sterilization (LTS) in some healthcare settings globally, especially in regions lacking access to alternative methods, its limitations are crucial to consider. In addition to environmental emissions and occupational exposure, a potential key concern is increased patient exposure to EO as reusable medical devices undergo repeated sterilization cycles.<sup>[17,25]</sup> Repeated use can degrade the materials in these devices, potentially leading to increased absorption and the release of residual EO during patient use.<sup>[17,25]</sup>

# Exploring the Chemistries of Leading LTS Platforms:

## Chemical Breakdown and Safety Considerations

Fortunately, alternatives to EO sterilization exist for heat-sensitive reusable medical devices requiring low-temperature sterilization. These include hydrogen peroxide gas plasma (HPGP), vaporized hydrogen peroxide (VHP), and peracetic acid (PA) sterilization. All these methods offer lower-temperature sterilization processes, making them suitable for a wide range of medical devices while minimizing environmental impact.<sup>[24]</sup> It is important to note that like EO, HPGP, VHP and PA have limitations as well, but none of these alternatives have the same carcinogenic and reproductive risk potential posed by EO.<sup>[24]</sup> (See table 1 below)





# Environmental and Health Concerns with Ethylene Oxide Sterilization

Ethylene oxide (EO) sterilization, a long-established method, faces increasing scrutiny due to its environmental impact and potential health risks. While the core process involves EO gas ( $C_2H_4O$ ) killing microorganisms, its breakdown can create concerning byproducts:<sup>[25, 26]</sup>

## Ethylene glycol ( $HOCH_2CH_2OH$ ):

This forms when EO reacts with water. While not as highly toxic as EO, large exposures can harm the heart, lungs, and kidneys.<sup>[26]</sup>

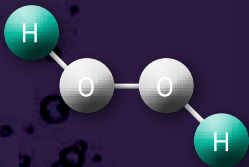
## Ethylene chlorohydrin (ECH) ( $HOCH_2CH_2Cl$ ):

ECH arises when EO reacts with chloride ions found in water. ECH may cause effects on the central nervous system, cardiovascular system, kidneys and liver. This may result in cardiac disorders, low blood pressure, kidney impairment, liver impairment and respiratory failure. Exposure could cause death. This raises concerns about worker exposure and environmental contamination.<sup>[19, 28]</sup>

## Carbon Dioxide ( $CO_2$ ):

While not as toxic as ethylene glycol and ethylene chlorohydrin, excess  $CO_2$  production is considered harmful to the environment as a greenhouse gas contributing to global warming.<sup>[10]</sup>

In contrast, alternative sterilization methods like hydrogen peroxide ( $H_2O_2$ ) offer a significant safety advantage:<sup>[24]</sup>



## Hydrogen peroxide:

This breaks down naturally into water ( $H_2O$ ) and oxygen ( $O_2$ ), both harmless byproducts.





# Shifting Focus:

## Hospital-Based Sterilization Units and Safety

The growing awareness of EO's drawbacks has fueled interest in smaller, hospital-based sterilization units employing safer methods.<sup>[4]</sup> Hydrogen peroxide gas plasma (HPGP) stands out for its long safety record in hospital settings.<sup>[7]</sup> Each low-temperature sterilization method has its benefits and drawbacks (See Table 1.)

**Table 1 Sterilization Methods - Advantages and Disadvantages<sup>[24]</sup>**

STERILIZATION METHOD	ADVANTAGES	DISADVANTAGES
Steam	<ul style="list-style-type: none"> <li>✓ Nontoxic to users, patients and environment</li> <li>✓ Easy cycle control and monitoring</li> <li>✓ Quick microbiocidal action</li> <li>✓ Organic/inorganic soils least impact effectiveness</li> <li>✓ Rapid cycle time</li> <li>✓ Penetrates medical packaging and device lumens</li> </ul>	<ul style="list-style-type: none"> <li>× Degrades heat-sensitive materials/devices</li> <li>× Can damage microsurgical instruments over time</li> <li>× Potential for rusting on metal surfaces</li> <li>× Heat/burn risk for users</li> </ul>
Hydrogen Peroxide Gas Plasma	<ul style="list-style-type: none"> <li>✓ Safe for the environment</li> <li>✓ Leaves no toxic residuals<sup>[25]</sup></li> <li>✓ Cycle time about 1 hour or less on average</li> <li>✓ No aeration necessary</li> <li>✓ Low processing temperatures &lt;50C safe for heat and moisture sensitive items</li> <li>✓ Simple to operate, install and monitor</li> <li>✓ Compatible with most medical devices</li> <li>✓ Only requires electrical outlet</li> <li>✓ Breaks down into water and oxygen</li> </ul>	<ul style="list-style-type: none"> <li>× Cannot process cellulose, linens and liquids</li> <li>× Endoscopes or other devices with long lumens may require booster (outside US)</li> <li>× Requires synthetic packaging</li> <li>× Mild toxicity of hydrogen peroxide sterilant (&gt; 1ppm TWA)</li> </ul>
EO (100%)	<ul style="list-style-type: none"> <li>✓ Penetrates packaging materials and device lumens</li> <li>✓ Single dose cartridge available</li> <li>✓ Negative pressure chamber to minimize exposure risk</li> <li>✓ Simple operation</li> <li>✓ Compatible with most medical materials</li> </ul>	<ul style="list-style-type: none"> <li>× Requires complete removal of organic/inorganic soils and water to be effective</li> <li>× Toxic / flammable / carcinogenic</li> <li>× Requires long aeration time to remove EO residues</li> <li>× Different medical devices materials adsorb and absorb EO at different rates</li> <li>× EO emissions regulated by state and federal mandates (in US)</li> <li>× Units with catalytic cells can convert EO gas to CO2 and H2O but release CO2 into the environment</li> <li>× EO cartridges must be stored in flammable liquid cabinet</li> <li>× Engineering controls such as an isolated room with high air exchange rates and specialized flow are required</li> </ul>
EO Mixtures	<ul style="list-style-type: none"> <li>✓ Same advantages as above</li> </ul>	<ul style="list-style-type: none"> <li>× EO mixtures typically delivered via gas cylinder creating potential for EO exposure and greenhouse gas emission</li> <li>× Chlorofluorocarbons (CFC) are banned in many countries</li> <li>× Potential hazards to users and patients</li> <li>× Same toxicity / flammability / carcinogenicity as pure EO but with the added environmental harm of greenhouse gas emissions</li> </ul>
Peracetic Acid	<ul style="list-style-type: none"> <li>✓ Rapid cycle times (30 to 45 minutes)</li> <li>✓ Low temperature liquid immersion process (50-55C)</li> <li>✓ Environmental-friendly breakdown products</li> <li>✓ Flow dynamics through lumens facilitate organic and inorganic soil removal</li> </ul>	<ul style="list-style-type: none"> <li>× Some materials incompatible (aluminum, anodized coatings)</li> <li>× Use for immersible instruments only</li> <li>× One at a time processing for endoscopes and small batches of instruments decrease efficiency</li> <li>× Exposure to skin, eye and mucous membranes is corrosive</li> </ul>



# EO and Reusable Devices:

## Material Dependence of EO Uptake Impacts Safety

Research demonstrates that various medical device materials exhibit different affinities for EO.

The phenomenon can be categorized into two main processes:

- **ADSORPTION:**

EO molecules physically adhere to the high surface area of a material. Factors like porosity and surface roughness influence the amount of adsorbed EO.

- **ABSORPTION:**

EO dissolves within the material's bulk structure. The chemical composition and polymer structure of the material play a key role in absorption.

Studies have shown that there are differences in the levels of EO absorbed by different materials used in the construction of medical devices.<sup>[17,18]</sup> This translates to potentially higher residual EO levels on certain materials after sterilization.

# Permissible EO Residual Limits and Monitoring:

## Setting the Safe Levels

Regulatory bodies establish permissible limits for residual EO and its toxic byproduct, ethylene chlorohydrin (ECH), on sterilized medical devices. These limits aim to minimize patient exposure while ensuring device sterility.

The primary standard is described in ISO 10993. It doesn't provide a single limit, but rather a tiered approach based on the anticipated duration of patient exposure to the device.<sup>[18]</sup>

- **Limited Exposure Devices (First 24 Hours):** This category applies to devices with minimal contact or short-term use. The allowable limits are about 2x the prolonged exposure limits.
- **Prolonged Exposure (1 Day to 30 Days):** Devices with extended patient contact fall into this category. The permissible limits for EO and ECH are stricter.
- **Prolonged Exposure (More Than 30 Days):** Implants and other devices with long-term contact have the most stringent allowable limits.





# Unexplored Patient Exposure Potential:

## Residual EO on Long-service Devices

Residual EO poses a potential health risk to patients if not adequately removed during the aeration process after sterilization. Concerns include:

- **Cytotoxicity:** Residual EO can damage human cells upon contact.<sup>[5]</sup> For example, an endoscope with residue comes in contact with the patient's mucous membranes.<sup>[25]</sup>
- **Mutagenicity and Carcinogenicity:** Long-term exposure to EO has been linked to an increased risk of cancer and genetic issues. An example would be patients who are being followed for bladder cancer and have repeat cystoscopies may have repeat exposure if EO is not properly removed from cystoscope surfaces.

# Device Aging and EO Off-gassing

There is no available research on the long-term effects of device aging on residual EO levels. Typically, EO cycle validation is done by device manufacturers before the materials have undergone repeated clinical use and sterilization cycles.<sup>[1,2]</sup> Further investigation is warranted to verify the adequacy of recommended cycle parameters (including aeration times) for longer in-service devices. It is also important to know if there may be limitations on the number of times a device may be used and undergo EO sterilization safely and stay below EO residue limits.<sup>[18]</sup>

Here are some potential scenarios:

- **Material degradation:** As a device ages, its material properties may change. This could alter the ability of the material to retain absorbed EO, potentially leading to delayed release and patient exposure. Surface characteristics may change under repeated conditions which include cracks, fissures or micro fissures which may increase the surface area available for EO adsorption (EO coating the surfaces).<sup>[18]</sup> Additionally, certain plastics may degrade with repeat EO exposure.<sup>[18]</sup>
- **Cracks and crevices:** Over time, devices may develop cracks or crevices. These areas may trap residual EO and pose a challenge for complete off-gassing during aeration.





# Further EO Bioavailability Research Needed

To ensure patient safety, a deeper understanding of EO interactions with medical device materials is crucial.

## Key areas for further research include:

- **Standardized residue monitoring methods:** Developing standardized methods to assess EO adsorption and absorption for devices in-service to monitor increases in bioavailable EO.<sup>[25]</sup> Devices may need to be monitored over their in-service life cycle if found to have changes in EO adsorption/absorption to determine proper cycle times to allow for adequate aeration.
- **Long-term aging studies:** Investigating the impact of device aging on residual EO levels and off-gassing efficiency is necessary for establishing appropriate in-service life recommendations.
- **Material innovation:** Exploring alternative materials with lower EO affinity or developing surface modifications to minimize EO uptake could be beneficial.<sup>[18]</sup>





# Hydrogen Peroxide Gas Plasma Sterilization:

## A Strong Contender

In the realm of medical device sterilization, hydrogen peroxide gas plasma (HPGP) is rapidly gaining traction as a superior alternative to the established method of EO sterilization. HPGP utilizes gas plasma technology to directly remove hydrogen peroxide residual from the chamber and instruments. Once hydrogen peroxide diffuses through the chamber and surrounds the instrument in the load, the low-temperature gas plasma is excited by applying an electric field. Plasma causes the hydrogen peroxide vapor to break apart into free radicals. When plasma energy is terminated, the free radicals lose their high energy state and recombine as oxygen and water vapor.<sup>[7]</sup> HPGP offers a compelling value proposition for healthcare facilities seeking a safer, more efficient, and environmentally friendly sterilization solution.



### Safety First:

Unlike EO, a known carcinogen, HPGP utilizes hydrogen peroxide vapor, a non-carcinogenic compound.<sup>[24]</sup> This significantly reduces the risk of occupational exposure for healthcare workers handling sterilized equipment when compared to EO. Additionally, HPGP eliminates the need for complex aeration procedures required with EO, further minimizing potential hazards.



### Efficiency Boost:

HPGP boasts faster cycle times compared to EO.<sup>[4, 7]</sup> The hydrogen peroxide vapor effectively penetrates complex instruments and reaches areas inaccessible to traditional methods. Strides are being made to improve penetration of long lumen devices for which EO has an advantage. This translates to quicker turnaround times for sterilized equipment, ensuring a readily available supply of critical medical devices without the need to carry a large inventory of surgical and medical devices.



### Environmental Champion:

HPGP is an environmentally friendly alternative. The hydrogen peroxide vapor breaks down into water vapor and oxygen after sterilization, leaving no harmful residues. In contrast, EO emissions are tightly regulated due to their environmental and occupational impact.<sup>[3, 15, 16]</sup> Pure EO still results in carbon dioxide production, and where still used, EO mixed gasses may harm the environment.



### Material Compatibility:

Hydrogen peroxide gas plasma offers a reliable sterilization solution for materials and devices sensitive to high temperatures and humidity, such as certain plastics, electrical devices, and corrosion-prone metal alloys. Demonstrating remarkable compatibility, this method has proven effective for sterilizing over 95% of the medical devices and materials subjected to testing.<sup>[7]</sup> It's always advisable to consult the manufacturer's recommendations to ensure compatibility with specific materials.

Overall, **gas plasma hydrogen peroxide sterilization** presents a compelling case for healthcare facilities seeking a **safer, faster, and more environmentally conscious** approach to medical device sterilization.



# Conclusion:

## A Clear Shift Towards Safer Sterilization

Ethylene oxide (EO) sterilization has long been a mainstay in healthcare settings, but growing concerns about its safety for patients, healthcare workers, and the environment necessitate a paradigm shift.

### EO's Drawbacks:

- **Carcinogenic:** EO exposure poses a significant cancer risk for both healthcare personnel and potentially, patients.
- **Environmental Impact:** EO emissions contribute to air pollution and are tightly regulated.
- **Residual Concerns:** Residual EO on sterilized devices, especially after repeated cycles, raises patient safety concerns.
- **Material Dependence:** Different medical device materials absorb and release EO at varying rates, complicating monitoring and potentially increasing patient exposure risks.
- **Limited Efficiency:** Lengthy aeration times after EO sterilization hinder operational efficiency.

## Hydrogen Peroxide Gas Plasma:

### A Safer Alternative

Gas plasma hydrogen peroxide (HPGP) sterilization offers a compelling alternative to EO, addressing its limitations and prioritizing safety:

- **Safe for People and Environment:** HPGP utilizes hydrogen peroxide, which with the help of plasma, breaks down into harmless water vapor and oxygen, eliminating health and environmental risks.
- **Faster Processing:** HPGP boasts shorter cycle times compared to EO, improving efficiency in fast-paced healthcare environments.
- **Effective Sterilization:** HPGP effectively sterilizes a broad range of medical devices, making it a versatile solution.

### The Path Forward:

While EO remains in use in some settings, a clear shift towards safer alternatives like HPGP is essential. Further research on standardized EO residual monitoring methods, long-term aging effects, and material innovation to minimize EO uptake can further enhance patient safety.

By adopting HPGP and exploring other safe sterilization methods, healthcare facilities can prioritize patient and staff well-being while ensuring effective sterilization practices and environmental responsibility.





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