AdvaMed
Advanced Medical Technology Association

Ethylene Oxide

BACKGROUND: ETHYLENE OXIDE'S INVALUABLE ROLE IN PROTECTING PUBLIC HEALTH

ETHYLENE OXIDE (EtO or EO) is a colorless gas used commercially in a wide variety of ways, including the production of textiles, personal care items, and the sterilization of medical devices, cosmetics, and spices.

EtO is one of the most common ways to sterilize medical devices, which is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments.

More than 50 percent of all medical devices are sterilized with EtO, and for many of those it is the only option known to modern science.

Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. For the majority of these products, EtO sterilization is the most effective and efficient—and often the only viable—sterilization technology. The gentle yet thorough nature of EtO allows for the sterilization of many critical medical technologies and devices that would otherwise be destroyed and rendered unusable by other sterilization methods.

Many medical devices cannot be sterilized by methods other than EtO for the following reasons:

- *Gamma* and *e-beam radiation* can make plastics brittle, or cause certain non-woven materials to literally disintegrate
- *Steam* is high temperature and will melt plastics and/or damage products sensitive to heat and/or moisture
- *Hydrogen peroxide* and *gas plasma* are intended for small scale, surface sterilization only and cannot penetrate devices that have interior chambers or two surfaces that are in contact with each other (e.g., piston and barrel of a syringe)

EtO also has the unique ability to penetrate packaging and plastic without damaging them and effectively sterilize otherwise hard-to-sterilize product configurations (e.g., inside tubing, products that have two touching surfaces, connectors, etc.).

Medical Devices that Require EtO Sterilization:

Fiberoptic endoscopes	Renal Hemodialysis sets
Specula	Tubing sets/bloodlines
Surgical kits	Gowns and drapes
Syringes	Heart valves
Sutures	Pacemakers
Catheters	Surgical Drills
IV sets	Pumps
Plastic tubing	Respirators
Inhalation therapy supplies	Electrical equipment
Surgical telescopes	Uterine monitors
Anesthesia masks and circuits	Surgical staplers
Renal Peritoneal Dialysis sets	Diagnostic electrode catheter

In addition to the high level of efficacy that EtO provides, it is highly compatible with a wide variety of medical device materials of construction, enabling medical device companies to manufacture many devices that would not be possible without EtO. The high level of performance and effectiveness of medical devices when sterilized by EtO is well understood. If EtO could not be used for sterilization of healthcare products, there would certainly be significant, and likely disastrous, adverse public health consequences. Elimination of this sterilization technology would introduce the real risks of increased morbidity and mortality.

Strict government regulation controls EtO use in the U.S. FDA and other global regulators play an important role in ensuring that manufacturers' sterilization methods are properly validated. FDA regulations, guidance and harmonized international standards include provisions that address the use of EtO and other sterilants for medical devices. Manufacturers must conduct exhaustive studies to demonstrate that the required sterility assurance levels are achieved by the process and to confirm that exposure to the sterilization process does not adversely affect the device's performance, safety or effectiveness.

Manufacturers must comply with FDA's Quality Systems Regulation (QSR) relative to the methods used in, and facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. This includes the use of contract sterilization firms, as the contract sterilizers are considered vendors and part of the regulated manufacturing process.

Manufacturers using established sterilization methods, such as EtO, comply with voluntary consensus standards recognized by FDA and other global regulatory authorities. An international standard (ISO 11135:2014) specifies requirements for the development, validation and routine control of an EtO sterilization process for medical devices in both the industrial and health care facility settings.

Under the Clean Air Act, the U.S. Environmental Protection Agency (EPA) sets limits on certain air pollutants. The EPA has set emission standards for EtO under the National Emission Standards for Hazardous Air Pollutants (NESHAP) rule, which applies to commercial sterilization operations. In addition, the U.S. Occupational Safety and Health Administration (OSHA) sets permissible EtO exposure limits for workers under the Toxic and Hazardous Substances rule.

Manufacturers' finished products must meet global standards for device biocompatibility testing and assessment of EtO residuals remaining on the finished product post-sterilization. These requirements ensure patients and health care providers are not exposed to unacceptable levels of chemical residues from the sterilization process. Changing sterilization methods or making process changes requires manufacturers to reestablish product biocompatibility through repeat studies.