

EtO Sterilization and Medical Devices

Ethylene Oxide (EtO) gas is one of the most common ways to sterilize medical devices, a process which is critical for preventing infections and ensuring patients have safe surgeries and medical treatments. EtO sterilization is a highly regulated process, and device manufacturers, hospitals and third-party sterilizers must follow rigorous controls established by FDA, EPA, OSHA and other government agencies to protect patients, workers and the environment.



PRE-CONDITIONING:

Medical devices are pre-conditioned using heat and humidity for optimal processing. This step may take place in a dedicated ancillary space or a processing chamber where the product is stored at elevated temperature and humidity for a prescribed amount of time.



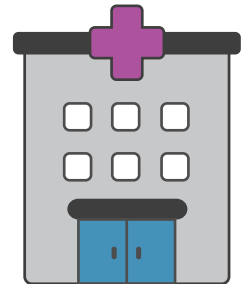
STERILIZATION:

Following pre-conditioning, the medical devices are loaded in the processing chamber, and EtO enters the chamber from an ancillary source. The EtO gas saturates the product, resulting in sterilization.



AERATION:

After sterilization, product continues to give off small amounts of EtO. The medical devices are further degassed within the chamber or in a dedicated ancillary space. The remaining EtO is evacuated from the chamber and destroyed (abated) either by converting it to ethylene glycol or oxidation. The removed gas is destroyed in an environmentally responsible manner.



Importance of EtO

For many medical devices, due to their size, shape, complexity or material composition, ethylene oxide is the only option for sterilization. For these products, alternatives such as steam, radiation or other sterilants do not achieve the needed levels of sterility assurance. In addition, for some medical devices, using non-EtO sterilization methods will result in material degradation, rendering the products potentially unsafe for patients.



56 percent of all medical device types are sterilized using EtO, **TOTALING MORE THAN 25 BILLION DEVICES ANNUALLY.**¹



Most surgeries involve at least **ONE DEVICE THAT HAS BEEN STERILIZED BY ETO.**



As part of the **U.S. FDA's Quality System Regulation** and other global requirements, manufacturers must validate that their sterilization processes are **IN COMPLIANCE WITH INTERNATIONAL STANDARDS.**



To achieve device sterility, many medical devices rely on EtO. **Eliminating or severely restricting the use of EtO could PUT PATIENTS AT RISK BY THREATENING THE HEALTH CARE SUPPLY CHAIN.**

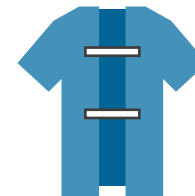
EXAMPLES OF MEDICAL DEVICES WHOSE DESIGN AND MATERIALS REQUIRE EtO STERILIZATION



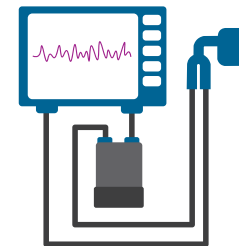
Heart Valves/Pacemakers



Surgical Kits



Gowns & Drapes



Ventilators



Syringes



Catheters



Surgical Telescopes