Frequently Asked Questions (FAQ)
Medical Device Sterilization

Sterilization is a key part of the medical device manufacturing process. Poor or incomplete sterilization can lead to transmission of infectious diseases and compromised patient health.

Why are medical products sterilized?

Medical devices are sterilized prior to their use to remove potentially harmful germs and other microorganisms.

How are medical products sterilized?

Medical products are sterilized by steam, dry heat, liquid chemicals, radiation, and certain gases such as ethylene oxide (EtO), vaporized hydrogen peroxide, nitrogen dioxide, and chlorine dioxide.

Can all medical devices be sterilized using the same method?

No. Medical devices are composed of many different types of materials that can be damaged if exposed to the wrong type of sterilization. For example, radiation can make plastics brittle. Steam can damage electronics. Heat can melt acrylics.

What is the most common method of medical device sterilization?

EtO is used to sterilize 50% of all medical devices sold in the United States, a total of more than 20 billion devices annually.

What is ethylene oxide (EtO)?

EtO is a gas that is toxic to microorganisms and non-corrosive to materials such as plastic, metal, glass, and rubber.

How long has EtO been used as a sterilization agent?

A patent for sterilization by EtO was issued in the United States in 1938.

Why is EtO a preferred method of medical device sterilization?

For many medical devices, EtO is the only sterilization method that does not damage a device during the sterilization process. It is often the most effective sterilizing agent for devices that have many packaging layers or hard-to-reach areas. An open heart surgery kit has 200 components of different types.

Which medical products are sterilized with EtO?

Life-saving items commonly used to treat patients across all care settings made with materials as diverse as polyurethane and gels for hydrocolloid wound care dressings, stents for heart surgery, catheters for delivering or draining fluids, and custom procedure packs such as for emergency Caesarean sections.

How does EtO sterilize medical devices?

The process involves exposing products to EtO gas under vacuum in a sealed chamber.

What type of facilities sterilize medical devices using EtO?

Industrial facilities or healthcare settings such as a hospital may sterilize devices using EtO. Learn more about EPA's EtO emission standards for sterilization facilities and Centers for Disease Control guidelines for EtO sterilization in healthcare facilities.

Does the government regulate EtO use?

Yes. Certain medical devices must be sterilized to get approval from the U.S. Food and Drug

Administration (FDA) for their marketing and use. The Clean Air Act requires the U.S. Environmental Protection Agency (EPA) to regulate emissions of hazardous air pollutants from industrial facilities. Learn more about Clean Air Act regulations for EtO.

What is the FDA's role?

The FDA reviews a manufacturer's sterilization method to make sure it meets international consensus standards that deem it is within safe limits. The agency inspects industrial facilities that sterilize medical devices and medical device manufacturing facilities. Learn more about the FDA's Recognized Standards Program.

What is the FDA's position on medical device sterilization with EtO?

The FDA considers EtO a safe and effective sterilization method that helps ensure the safety of medical devices and deliver quality patient care. The FDA is focused on preventing and mitigating potential medical product shortages, which could occur with the closure of medical device sterilization facilities. Read the FDA's EtO Sterilization Facility Updates.

Is the FDA exploring alternative sterilization methods?

Yes. The FDA is exploring ways it can continue to ensure sterilization processes are safe, effective, and evolving with current science. This includes validation of methods that would support using lower levels of agents such as EtO. The agency is looking into the possibility of using new sterilization agents or processes.

What is the EPA's role in medical device sterilization with EtO?

The EPA classified EtO as a human carcinogen in December 2016. It is one of 188 hazardous air an pollutants regulated by EPA. Learn more about the EPA's regulations for gases such as EtO, agency efforts to reduce EtO emissions and health information from the EPA about EtO.

What is the EPA's position regarding EtO emissions?

EPA published a final rule in August 2020 that requires additional controls on certain equipment and processes that emit EtO. Learn more about EPA actions on EtO.

What do providers say about EtO?

Providers urge caution in considering limiting the use of EtO until there is an action plan to ensure patient access to critical medical devices. Caregiver associations told the FDA that many complex medical devices such as angioplasty balloons and pacemakers rely on EtO for sterilization to ensure patient safety. New sterilization techniques would require new processes to be developed, tested, and validated. Necessary protocols must be developed and replicated throughout supply chains. These steps likely will increase cost to patients. Read a letter from provider associations outlining their position on EtO.