

Medtech Sterilization and Patient Care:

The Critical Role of Ethylene Oxide

What is EtO?

Ethylene oxide (EtO) is one of the most common ways to sterilize medical technology, crucial for preventing infection in patients undergoing surgical procedures and other medical treatments. This proven method takes place in specialized facilities nationwide to supply hospitals and clinics with the timely, abundant, sterile supplies they need to treat millions of patients. The medtech industry welcomes updated regulations on EtO sterilization but is concerned that as written, the proposed regulations and their tight implementation timeframe could cause a number of sterilization facilities to close. Even a temporary shutdown of a handful of facilities could cause delays and disruptions in patient care. The industry is working with the EPA to suggest more workable regulations meeting the shared goals of protecting public health and serving patients.

What's at Stake?

Hospitals must have multiple surgical kits on hand for doctors and surgeons to have the necessary tools for their work. Every surgery and most non-surgical medical exams require a variety of medical tools and supplies. Surgical tray kits specialized for each procedure, assembled off site, provide sterility protecting patients and ensure the surgeon has the right items on hand.

EtO-sterilized supplies are used by all types of personnel, in all medical settings, including:

- Hospitals
- Walk-in medical clinics
- Dental offices
- Nursing homes
- Emergency personnel
- Home health care workers
- School nurses
- Mobile healthcare units

The sterilization of these medical devices and instruments is critical to patient health. Nearly 50% of all medical devices, 20 billion annually, are sterilized using EtO. Without EtO, patients would risk serious infection or lose access to lifesaving equipment. For many medical devices, no sterilization alternatives exist. **91% of surgeons say they cannot lose EtO as a medtech sterilization method.**



Hospitals

The United States has 6,129 hospitals with

- 919,649 total staffed beds
- 34,011,386 patient admissions annually¹
- 35,870 operating rooms
- Average of 6 operating rooms per hospital²



Surgical Procedures

- 40-50 million surgeries a year in the United States.³
- Types of procedures performed:⁴
 - Cardiac
 - General
 - Oncological
 - Orthopedic
 - Ophthalmological



Common Surgical Procedures Annually

- 1,000,000 breast biopsies⁵
- 300,000 hysterectomies⁶
- 850,000 knee replacements⁷
- 1.175 million c-sections⁸
- 500,000 open-heart surgeries⁹

Number of sterile instruments and devices in common surgical kits:¹⁰

- 37 instruments in a breast biopsy kit
- 59 instruments in an open-heart surgery kit
- 36 instruments in a hysterectomy kit
- 50 instruments in a total knee replacement kit



Common Instruments in a Surgical Kit Requiring EtO Sterilization, Assembly Off Site¹¹

- Sutures, gloves, gowns
- Surgical drape
- Long, heavy mayo scissors
- Short and long weighted speculums
- Right angle retractors
- Clamps
- Needle
- Single tooth tenaculum
- Suction apparatus
- Neurosurgery headlight
- Trocars
- Retractors
- Large open tray
- Laparoscopic instruments

¹ <https://www.aha.org/statistics/fast-facts-us-hospitals>

² <https://www.definitivehc.com/resources/healthcare-insights/number-of-us-operating-rooms>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7388795/#:~:text=Globally%2C%20a%20staggering%20310%20million,and%2020%20million%20in%20Europe>

⁴ <https://www.facs.org/for-medical-professionals/education/online-guide-to-choosing-a-surgical-residency/guide-to-choosing-a-surgical-residency-for-medical-students/fags/specialties/#:~:text=The%20American%20College%20of%20Surgeons,surgery%2C%20otorhinolaryngology%2C%20pediatric%20surgery%2C>

⁵ <https://my.clevelandclinic.org/health/diagnostics/24204-breast-biopsy-overview>

⁶ <https://my.clevelandclinic.org/health/treatments/4852-hysterectomy>

⁷ <https://my.clevelandclinic.org/health/treatments/8512-knee-replacement#:~:text=The%20surgery%20is%20very%20common,year%20in%20the%20United%20States>

⁸ <https://www.cdc.gov/nchs/fastats/delivery.htm>

⁹ <https://my.clevelandclinic.org/health/treatments/17525-heart-surgery>

¹⁰ AdvaMed member companies

¹¹ <https://www.ncbi.nlm.nih.gov/books/NBK430685/>