Importance of EtO

EtO's unique chemical structure means that it can sterilize medical devices of all different shapes, sizes, and material compositions. In many cases, the design of a medical device means that EtO alternatives like steam or radiation cannot achieve the needed levels of sterility assurance. In addition, using alternative sterilization methods can often result in material degradation, compromising device integrity and rendering devices unsafe for patient use.

More than 50 percent of all medical devices are sterilized using EtO, **TOTALING MORE THAN 25 BILLION DEVICES ANNUALLY.**[1]

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.**[2]

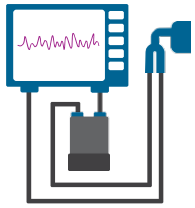
To achieve device sterility, many medical devices rely on EtO. **Eliminating or severely restricting the use of EtO could PUT PATIENTS AT RISK BY THREATENING THE HEALTH CARE SUPPLY CHAIN.**

EXAMPLES OF MEDICAL DEVICES WHOSE DESIGN AND MATERIALS REQUIRE EtO STERILIZATION

Heart Valves/Pacemakers

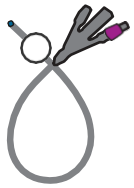
Surgical Kits

Gowns & Drapes



Ventilators

Syringes



Catheters

Surgical Telescopes

[1] https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices; AdvaMed medical device industry survey (2019)
[2] See FDA QSR practices https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices