TERUMO BLOOD AND CELL TECHNOLOGIES

FAQs –

An overview of our medical device sterilization process

What is Terumo Blood and Cell Technologies?

Terumo Blood and Cell Technologies (Terumo BCT) makes healthcare products that help save lives. It has been in Lakewood, Colorado, for about 60 years.

- Terumo BCT products collect, separate, and process blood and cells.
- If you have ever donated blood or have had a loved one receive a blood transfusion or bone marrow transplant, you have likely interacted with our products.
- Lakewood is Terumo BCT's global headquarters. The company is one of the largest manufacturers in the greater Denver area with 2,000 employees in Colorado and about 8,000 employees globally.
- Blood and cells are indispensable in sustaining our lives and hold the potential to treat many serious diseases.
- Our products are used in lifesaving medical procedures in 150 countries by blood centers, hospitals, therapeutic apheresis clinics, cell collection and processing organizations, researchers, plasma centers, and private medical practices.

What is ethylene oxide (EtO), and how is it used?

EtO is a naturally occurring substance and is also commercially produced. It is also found in emissions from SUVs, school buses, generators, and charcoal grills.

- EtO is the only effective, viable way to sterilize more than 20 billion lifesaving medical devices in the U.S. It is the only effective, viable sterilization method for about 50% of the medical devices in the nation.[1]
- Medical products sterilized with EtO are essential for patients who need access to lifesaving medical devices, including surgical instrument kits, heart valves, pacemakers, ventilators, blood bags, syringes, blood and cell collection kits, and bandages.
- EtO is proven and has been used for the last 80 years to sterilize medical devices.
- Companies using EtO are highly regulated.
- Less than 0.05% of all commercial EtO is used for medical device sterilization in the world.[2] EtO penetrates packaging and medical-grade materials without damaging them to remove contaminants such as spores, germs, and viruses.
- In total, over 99% of commercially produced EtO is used outside of the healthcare industry to produce textiles, cosmetics, and personal care items.

Why does Terumo BCT use EtO?

Terumo BCT uses EtO to sterilize medical devices that are sensitive to heat or moisture and cannot be sterilized by other methods. Terumo BCT's operations are highly regulated; the company's sterilization operations are the most highly regulated parts of the company.

- Terumo BCT adheres to strict standards set by regulators, including the U.S. Food and Drug Administration (FDA), U.S. Environmental Protection Agency (EPA), Colorado Department of Public Health & Environment (CDPHE), U.S. Department of Transportation, and Occupational Safety and Health Administration (OSHA).
- Not only is EtO used to sterilize items we make, such as blood bags, but it is also used to sterilize things like surgical masks, gloves and gowns, bandages, ventilators, and syringes.[3]
- EtO sterilization protects patients and blood donors from outside infections. Severely restricting the use of EtO could put patients at risk, and infection risk would likely increase.[3]

How does Terumo BCT use EtO?

Terumo BCT's sterilization operations adhere to strict regulations from the FDA, EPA, CDPHE, OSHA, and other regulators.

- Terumo BCT's current emissions control system is highly effective. It captures and destroys more than 99% of the EtO we use in the sterilization process. We invested $22 million to install a new, state-of-the-art emissions control system to further reduce our emissions. That system is operating as intended.
- The amount of EtO we emit is well below our permissible limits[4]
- Terumo BCT is going even further.
- Terumo BCT has developed even more efficient sterilization cycles to reduce how much EtO is needed for sterilization at our Lakewood campus.

What agencies regulate the use of EtO?

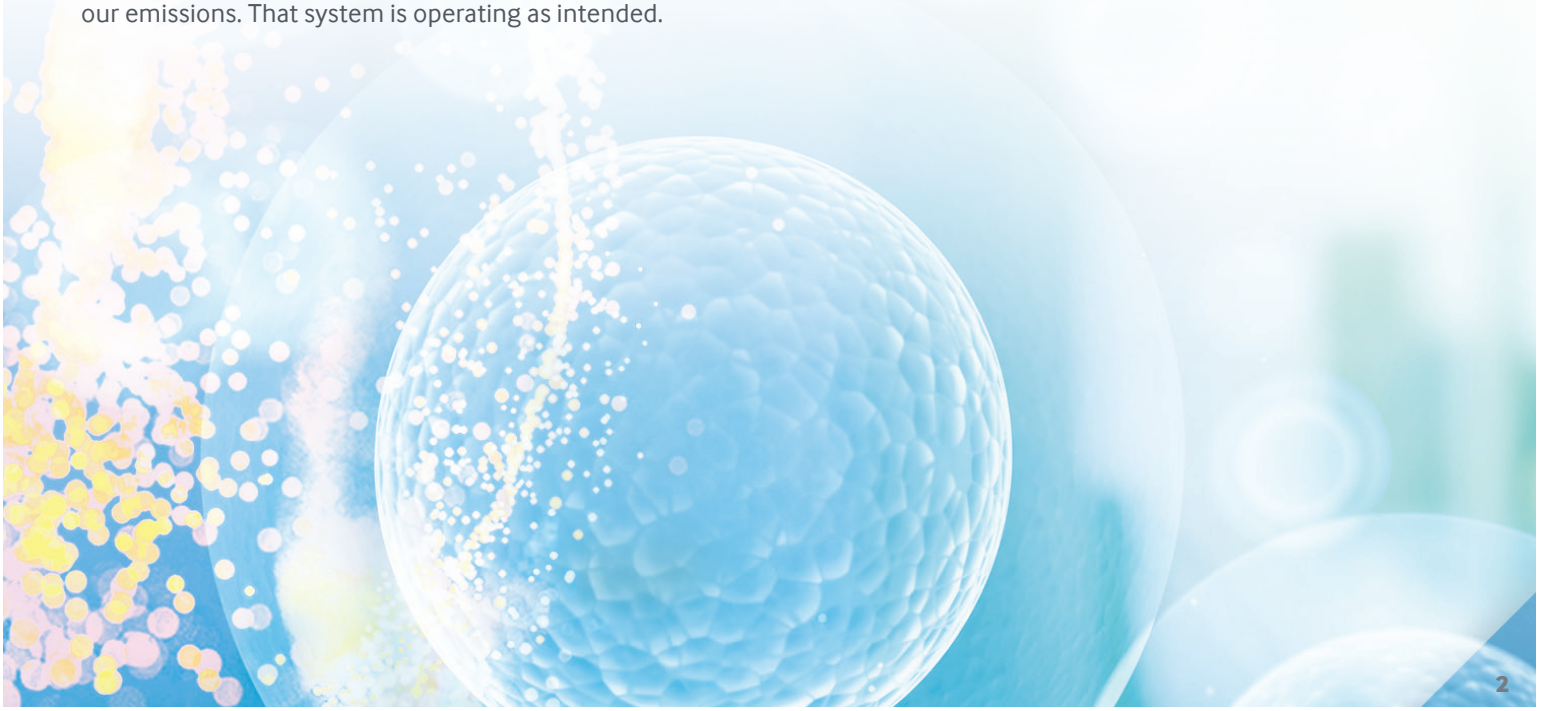
Terumo BCT's use of EtO has been highly regulated by FDA, EPA, CDPHE, OSHA, and other authorities for decades.

- Terumo BCT's critical sterilization effort is the most regulated part of the company, which operates in the already highly regulated healthcare industry.
- The EtO emissions standards set by local and federal regulators have been designed to protect people living near sterilization facilities, employees working in sterilization facilities, patients using EtO-sterilized products, and the environment.
- Records relating to emissions, maintenance of our equipment, and handling of EtO are reviewed and audited by federal and state regulators.
- Terumo BCT has a track record of actively working with the FDA, EPA, CDPHE, OSHA, and local and state authorities to manage EtO safely.
- Our emissions are carefully monitored and recorded. The emissions, maintenance of our equipment, and handling of EtO are all regularly reviewed and audited by federal and state regulators.

Does Terumo BCT comply with emissions standards?

Yes, Terumo BCT's EtO emissions are far below permitted levels, and the company is doing more to reduce our emissions.

- Terumo BCT invested $22 million and installed a state-of-the-art emissions control system that is expected to further reduce our emissions. That system is operating as intended.



Why are the EPA and EtO emissions in the news now?

EPA reviewed the past emissions standards in the Clean Air Act for industries that use EtO to determine whether these standards should be changed.

- As part of this review, EPA has reevaluated its previous understanding of risk related to EtO and conducted community engagement to share updated information about EtO.
- As part of its review, the EPA estimated risk from EtO through computer modeling using a hypothetical scenario in which a person would need to breathe in EtO continuously for 24 hours every day, every year, for 70 years.[5]
- The EPA acknowledges that its hypothetical model is improbable. The model is intended only to be health protective and to be used by the EPA in evaluating any changes to existing regulations, according to the agency.
- The EPA finalized its rules in 2024. The deadline to comply is October 2026. Terumo BCT is committed to meeting or exceeding all relevant health and safety standards.

Has the CDPHE conducted health studies around Terumo BCT's Lakewood campus?

Yes. Using information from the Colorado Cancer Registry, CDPHE has evaluated cancer rates in areas near the Lakewood campus on two occasions.

- In 2018, CDPHE performed a "Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado." In that study, CDPHE compared actual cancer rates in Terumo's census tract to estimated cancer rates statewide and found no increased incidence of cancer, concluding: "The incidence of all cancers combined and five individual types of cancer in the community surrounding Terumo BCT were no different than expected based on cancer rates in the remainder of Colorado for the years 2000 through 2017."[6]
- In 2023, the Colorado Central Cancer Registry at CDPHE repeated and expanded on the previous 2018 study to include two additional years of data (2018 and 2019), as well as two additional census tracts surrounding the Terumo BCT facility. It again looked at all cancers combined and five individual types of cancers, concluding: "Overall cancer rates in this area [near TerumoBCT in Lakewood] were similar to statewide rates."[7]

How do you ensure the safety of your employees?

Our sterilization facility is designed to keep employee exposure to EtO below OSHA action levels and far below permissible limits.

- We conduct regular EtO monitoring of our sterilization facility employees to confirm that exposure levels are within OSHA limits.
- On a regular basis, employees wear badges that collect EtO exposure data. Terumo BCT also continuously monitors inside the sterilization facility. Most EtO readings from employees do not detect EtO or are extremely far below OSHA standards.
- The sterilization facility has a 24/7 monitoring system that emits an alert if elevated levels are detected. Levels inside the building are far below permissible limits.

References

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[3]AdvaMed. Ethylene Oxide & Sterilization. Accessed February 2024. https://www.advamed.org/our-work/key-issues/sterilization-ethylene-oxide/

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[5]EPA, Ethylene Oxide (EtO) Risks and Your Health. Accessed February 5, 2024. https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-eto-risks-and-your-health

[6]Colorado Department of Public Health and Environment (CDPHE). Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado. Published December 3, 2018. Accessed May 2023. https://drive.google.com/file/d/1WEe0kCfkXW2RQC4jRFsIC803u_6P1Mub/view

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