Issue Paper
Medical Device Sterilization in Santa Teresa, NM

Summary:
The El Paso-Juarez region (comprised of Southwest Texas, Northern Chihuahua, Mexico, and Southern New Mexico) is home to a robust medical device manufacturing ecosystem that has been operating, growing, and innovating for over 30 years. Cd. Juarez, Chihuahua, Mexico, is the largest exporter of medical devices in all of Mexico, with over 90% of medical devices production being exported to the United States.[1] Over 40 medical device manufacturers and a large network of industrial suppliers operate along this region of the U.S.-Mexico border to produce hundreds of millions of FDA-compliant medical devices and equipment that are used in medical offices and facilities across the U.S. daily. These medical devices and equipment include those used to combat COVID-19: masks, gloves, gowns, face shields, oxygen concentrators, and much more. The Sterigenics facility is Santa Teresa, New Mexico, is one of the largest ethylene oxide sterilizers in the country and serves this robust market of medical device manufacturers in the region and beyond.

All medical devices must go through thorough regulatory oversight which includes a validated sterilization process to be authorized for use. Ethylene oxide is one of the limited methods currently available to effectively sterilize medical products and devices. In recent years, ethylene oxide sterilization facilities have come under scrutiny by various states including Illinois, Georgia, and now New Mexico. Primarily, these issues have stemmed around gas emissions of Ethylene Oxide.

The use of Ethylene Oxide for sterilization is complex and highly regulated. Companies providing these services, such as Sterigenics and STERIS, must abide by a multitude of regulations and are subject to oversight by federal, state, and local agencies. The high regulatory standards for sterilization facilities have created a narrow market in which very few companies offer these services.

Ethylene oxide sterilization is the only method that satisfies FDA-approved sterility validations for many critical medical devices. In most cases, switching sterilization methods in not a viable option. Since most medical devices are required to be sterilized and there are so few ethylene oxide sterilizers available in the U.S., capacity for current medical device production is at a premium, and market growth is nearly impossible. While ethylene oxide as a sterilization method has become a recent target for regulators and certain states, medical device manufacturers are left with little options in how or where they sterilize their products. As has been noted in Illinois and Georgia, any closures or delays at sterilization facilities have wide-spread impacts to the global medical device industry.

As a global hub for medical devices production and distribution, any disruptions to the Sterigenics facility in Santa Teresa, NM will impact the national and global supply of life saving medical devices.

[1] Instruments and Appliances Used in Medical Sciences: Commercial exchange, international purchases and sales, market and specialization | Data México (datamexico.org)

Ethylene Oxide:
Ethylene Oxide (EO) is a natural gas that kills off bacteria, viruses, and spores. EO and its derivatives also help to make many of the products we use every day, such as certain plastics, household and industrial cleaners, adhesives, textiles, detergents. Importantly, EO is used for the sterilization of medical devices and pharmaceutical products. Like many chemicals and gasses, EO is considered hazardous and is dangerous in large quantities. EPA and other state and federal regulators monitor EO and its emissions.

While more than fifty percent of medical devices are sterilized using EO, sterilization composes less than 1% of the EO used in the U.S.

Medical Device Sterilization:
Most medical devices on the market must meet certain sterilization guidelines in accordance with the FDA and other regulatory agencies. Medical devices are sterilized in a variety of ways including using moist heat (steam/autoclave), dry heat, radiation (gamma or electron beam), ethylene oxide gas, vaporized hydrogen peroxide, and other sterilants.

The choice of sterilization method depends largely on the material composition of the medical device, how it is classified (Class I, II, or III), and its intended use. Packaging, transportation, and storage conditions are also important factors in determining a method of medical device sterilization.

FDA and other global regulators play an important role in ensuring that manufacturers' sterilization methods are properly validated, and manufacturers must conduct exhaustive studies to demonstrate that sterility is achieved. Validation is also a requirement of Good Manufacturing Practice regulations for medical devices. If a new type or class of device is being sterilized for the first time, developers must also ensure that the sterilization procedure itself has not had a negative effect on the quality or integrity of the device itself or any its components.

For many medical devices, sterilization with ethylene oxide may be the only viable method that effectively sterilizes and does not damage the device during the sterilization process. Medical devices made from certain polymers (plastic or resin), metals, or glass, or that have multiple layers of packaging or hard-to-reach places (for example, catheters) are likely to be sterilized with ethylene oxide as it is the only viable option that is compatible with the device.

The choice of an appropriate sterilization technique can mean the difference between a medical device that never gets regulatory clearance and one that can save the life of a patient. In the worst-case scenario, an improperly sterilized method / device can lead to increased safety risk and recalls. Therefore, choosing the most appropriate sterilization method is a critical part of the production life cycle of medical devices.

EO Sterilization:
EO sterilization facilities are charged with implementing safety and technology practices at every step of their production process – from receiving to pre-conditioning to sterilizing, processing, and shipping. Each step is controlled and monitored for environmental health and safety and regulated by state and federal agencies.

The FDA inspects industrial facilities that sterilize medical devices to make sure that they have validated sterilization processes that meet FDA-recognized standards. State health departments also inspect

health care facilities that use ethylene oxide to sterilize medical devices. Further, the US Environmental Protection Agency (EPA) reviews and enforces the Clean Air Act regulations for sterilization facilities that emit ethylene oxide to ensure that they protect the public from significant risk.[2]

In response to concerns related to EO sterilization, the FDA has worked with manufacturers to advance innovative ways to sterilize medical devices with lower levels of EO, employ new methods of sterilization, or establish viable alternatives that will maintain safety and effectiveness of devices. Until then, EO sterilization remains the most common method for sterilization of devices in the U.S.

Sterigenics Facility in Santa Teresa, NM:
Sterigenics, one of three divisions of Sotera Health, provides a variety of sterilization services at 48 facilities in 13 countries. One of Sterigenics' largest EO facilities is in Santa Teresa, NM along the U.S.-Mexico border, which is a global hub for medical device production. Each day, 2.5 million essential medical products and devices are sterilized at Santa Teresa. This facility has 52 employees and plays a critical role in the medical device industry supply chain, not only in the region but across the U.S.

The Santa Teresa facility is subject to stringent regulatory oversight by federal and state agencies, including U.S. Environmental Protection Agency, U.S. Food & Drug Administration, U.S. Department of Transportation, and the U.S. Department of Homeland Security. Additionally, the facility operates under an Air Quality Permit issued by the New Mexico Environment Department (NMED).

In December 2020, the New Mexico Attorney General filed a lawsuit which makes certain allegations regarding the emissions of EO from the Santa Teresa facility. However, Sterigenics has a long history of meeting and exceeding all safety regulations and protocols and objects to the lawsuit and its allegations.

Impacts to Healthcare
Hospitals, patients, and health care providers around the world depend on sterilization for safe and effective lifesaving products. Roughly 50% of all medical products that require sterilization in the U.S. are sterilized using EO – comprising more than 20 billion devices sold in the U.S. every year.[3]

Additionally, out of the 81 essential medical devices deemed medically necessary to combating pandemics and other public health emergencies such as COVID-19, at least 49 or 60% of them, are sterilized using EO. This includes surgical masks, gloves, and gowns, catheters, syringes, oxygenators, ventilators, oximeters, tracheostomy tubes, bandages, tubes for ventilators, IVs, prefilled syringes, and more. Especially during a pandemic, EO sterilization is critical to health care systems and to the continued availability of safe and effective medical devices.

Regional Impact
The region surrounding Sterigenics' Santa Teresa facility is home to more than 40 medical device manufacturers, the majority of which rely on EO sterilization to maintain the safety and effectiveness of their products. Without more options for sterilization or more capacity at existing EO sterilization facilities across the U.S., manufacturers are not able to significantly scale or grow their production capabilities. Per FDA requirements, those manufacturers using EO sterilization cannot switch sterilization methods for devices that have already been validated and allowed to enter the market.

[2] Ethylene Oxide Sterilization for Medical Devices | FDA
[3] Ethylene Oxide Sterilization and Medical Devices | AdvaMed

Transitioning to alternative sterilization methods would require sizeable investments in R&D, engineering, and FDA approval processes, and would take 2-4 years for most manufacturers.

Any impacts to the Santa Teresa facility will jeopardize the region's supply chain and create large bottlenecks of medical products and supplies that cannot get to the patient, provider, or end-user. Any delays or disruptions to these processes will ultimately impact health care systems as well as the health and quality of life of the public. Additionally, any disruptions to Sterigenics' operations will endanger the region's already under-served market for sterilization services and impact the ability of local manufacturers to continue current production levels. Secondary impacts can include lost revenues, reductions in workforce, plant closures, and overall weakening of the growing medtech industry across the El Paso-Juarez region. Until viable alternative methods for EO sterilization are discovered and made accessible to manufacturers, we should work with facilities such as Sterigenics Santa Teresa to address concerns and find short, medium, and long-term solutions that will avoid impacts to their operations and essential services.