

## FDA Statement

# Statement from FDA Commissioner Scott Gottlieb, M.D., on steps the Agency is taking to prevent potential medical device shortages and ensure safe and effective sterilization amid shutdown of a large contract sterilization facility

## For Immediate Release

March 26, 2019

## Statement

A critical focus for the FDA is preventing and mitigating potential medical product shortages. As part of these efforts, we're taking steps to address potential medical device shortages due to the recent closure of a large sterilization facility in Illinois. We're working to ensure that safe and effective sterilization of medical devices continues and hospitals, health care providers and patients have access to critical devices.

Earlier this year, the FDA became aware that the Illinois Environmental Protection Agency (EPA) issued a state EPA Order (<https://www2.illinois.gov/Pages/news-item.aspx?ReleaseID=19717>) to stop a contract sterilizer, Sterigenics, from sterilizing medical products and other products with gas called ethylene oxide at their Willowbrook, Illinois facility. The state EPA order was due to the presence of levels of ethylene oxide higher than the EPA found to be acceptable in air around the facility.

As the agency responsible for ensuring the safety and efficacy of all medical devices, the FDA has been closely monitoring the situation and working with device manufacturers affected by the closure to minimize any impact to patients who need access to these medical devices.

Certain medical devices need to be sterilized to reduce the risk of those devices causing infections in patients from living microorganisms. Sterilization of medical devices is a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and transmitting infections. It's critical to our health care system. And ethylene oxide is a commonly used method of medical device sterilization. It's considered a safe and effective method that helps ensure the safety of medical devices and helps deliver quality patient care. Devices sterilized with ethylene oxide range from wound dressings to more specialized devices, like stents, as well as kits

used in routine hospital procedures or surgeries that include multiple components made of different materials. However, the FDA recognizes the environmental considerations that are currently impacting manufacturers' ability to use this process.

To that end, and in light of the recent state EPA order, the FDA has been working to quickly and proactively secure alternative locations and methods for the sterilization of devices that were previously processed at the Willowbrook facility in order to mitigate potential product supply issues. We're taking steps to prevent patient harm from potential device shortages that could delay or disrupt critical care. At the same time, we're undertaking new efforts to encourage innovative and improved sterilization options.

### Steps to Prevent Potential Shortages

First, the FDA is actively working to prevent potential medical device shortages that may arise from the closing of the Willowbrook facility. Upon learning that the facility was ordered to stop sterilizing hundreds of various types of medical devices, we immediately reached out to the medical device manufacturers that relied on Sterigenics' services to better understand which devices were affected by the facility ceasing operations and to assess the potential impact to patients. We are working directly with manufacturers, as needed, to help them transition to another sterilization site or sterilization method.

According to the FDA's Establishment Registration & Device Listing database, Sterigenics listed a total of 594 types of devices that undergo an ethylene oxide sterilization process at the Willowbrook facility and therefore could be affected ([https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start\\_search=1&showList=1&establishmentName=&regNum=&StateName=&CountryName=&RegistrationNumber=1450293&OwnerOperatorNumber=&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=&regNum=&StateName=&CountryName=&RegistrationNumber=1450293&OwnerOperatorNumber=&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC)) by the closure. These include products such as sutures, clamps, knives, stents and needles. At this time, the FDA isn't aware of any device shortages attributable to the Willowbrook facility closure. We're closely monitoring the situation and will continue to provide updates. There's a risk that for some sterile packaged products that are already in distribution, existing supply may be diminished—or even depleted—as health care facilities use their inventory before alternative arrangements can be made accommodate the sterilization of new products coming off manufacturing lines. This could lead to temporary or “spot” shortages of some products until sterilization can be restored.

In addition, the FDA is aware that Viant, another contract sterilizer, recently made public (<https://tribwxmi.files.wordpress.com/2019/03/viant-letter-1.pdf>) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) that their Grand Rapids ethylene oxide sterilization facility is scheduled to close later this year after receiving attention ([https://www.michigan.gov/documents/deq/deq-tou-AQD-Viant-Factsheet\\_648588\\_7.pdf](https://www.michigan.gov/documents/deq/deq-tou-AQD-Viant-Factsheet_648588_7.pdf)) from the Michigan Department of Environmental Quality for air quality issues. According to the FDA's Establishment Registration & Device Listing database, Viant listed a total of 46 types of devices that undergo an ethylene oxide process at the Grand Rapids facility which, in the future, could be affected ([https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start\\_search=1&showList=1&establishmentName=viant&regNum=&StateName=MI&CountryName=&OwnerOperatorNumber=&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=2&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=3009493875](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=viant&regNum=&StateName=MI&CountryName=&OwnerOperatorNumber=&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=2&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=3009493875)) by the closure of the facility. These include devices such as catheters and surgical mesh.

Because of the shutdown of the Sterigenics Willowbrook facility and the planned closing of the Viant Grand Rapids facility, the FDA is urging medical device manufacturers that use these facilities to begin assessing any potential downstream impacts of the closures on device distribution through their supply chain to end users (such as health care facilities), and ultimately on patient care. We're also encouraging medical device manufacturers to consider

alternative contract sterilizers that can process their devices. We've already communicated the steps manufacturers need to take to make changes to their contract sterilizers and maintain availability of their devices. We're committed to working closely with manufacturers to expedite our review of any site change submissions to ensure they can efficiently switch to other contract sterilizer facilities while still ensuring safe and effective sterilization of their devices.

Second, while every effort is being taken to prevent a potential shortage, we're monitoring the situation closely and stand ready to act quickly with strategies intended to limit the impact of device supply interruptions on patients. These include looking at making devices available from other sources if needed.

Early awareness of a potential shortage enables us to be proactive and develop a plan to mitigate its effects on patient care. We're taking steps to proactively identify potential shortages. Among other steps, we've established a **device shortages mailbox (mailto:deviceshortages@fda.hhs.gov?subject=)** so that any user, patient or organization within the supply chain that's aware of a delay in distribution of new product, and/or anticipates a shortage, can notify us.

Third, as we continue to monitor any shortages associated with facility closings, we're also working with stakeholders—including sterilization experts, medical device manufacturers and other government agencies—to identify innovative ways to sterilize medical devices that don't raise the same concerns as those identified at the Willowbrook facility. About half of all sterilized medical devices undergo sterilization using ethylene oxide. In view of the concerns about the environmental impact of this method, we recognize the importance of identifying new and improved ways of sterilizing medical devices.

We've already started exploring ways we can continue to ensure sterilization processes are safe and effective, and evolving with the current science. This includes considering validation of methods that would support using lower levels of currently-used agents like ethylene oxide gas, thereby reducing environmental exposure risks, while still ensuring effective device sterilization. There may also be ways to employ—and eventually validate—new sterilization agents or processes that don't come with the same environmental risks but still enable the safe and effective sterilization of devices.

To advance these efforts, we plan to discuss this issue with the infection control community at the May 2019 **Healthcare Infection Control Practices Advisory Committee (HICPAC) (https://www.cdc.gov/hicpac/)**. We will also host a public advisory committee meeting that will be announced later this year dedicated to discussing how best to encourage innovation in medical device sterilization. In addition, later in 2019, we will announce a public innovation challenge to encourage development of novel sterilization methods, which could include new devices or new modalities that are safe and effective for sterilizing medical devices.

Finally, we recognize that new challenges may arise from the current situation. To help ensure transparency and communication about the use of ethylene oxide in medical device sterilization, today we **launched a new FDA web page (/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm634204.htm)** to act as a resource on this sterilization method as well as any future actions we take regarding shortages or other activities associated with this issue. We'll update this site as new information becomes available. We'll continue to act to help ensure patient access to safe and effective medical devices. And we'll work directly with manufacturers, contract sterilizers, government agencies and other public health stakeholders to evaluate potential impacts and take additional steps as needed to avert device shortages. We're seeking to not only limit the immediate impact of these facility closures, but also to identify new and improved methods for medical device sterilization.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our

nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

#### Inquiries

#### Media

✉ **Alison Hunt** (<mailto:Alison.Hunt@fda.hhs.gov>)

☎ 240-402-0764

#### Consumers

☎ 888-INFO-FDA

#### Follow FDA

🐦 **Follow @US\_FDA** ([https://twitter.com/US\\_FDA](https://twitter.com/US_FDA))   
(</AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

📘 **Follow FDA** (<https://www.facebook.com/FDA>)   
(</AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

🐦 **Follow @FDAMedia** (<https://twitter.com/FDAMedia>)   
(</AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

**More in Press Announcements**  
(</NewsEvents/Newsroom/PressAnnouncements/default.htm>)

**2017** (</NewsEvents/Newsroom/PressAnnouncements/2017/default.htm>)

**2016** (</NewsEvents/Newsroom/PressAnnouncements/2016/default.htm>)