

News Short Template

Categories (**highlight category**):

Biologics	<i>(biology of bone, inflammatory signals, science of arthritis)</i>
Company News	<i>(corporate mergers, fund raises, executive hires or fires, plant openings or closings, sales news)</i>
Extremities	<i>(products or procedures for elbows, shoulders, hands and wrists, foot and ankles, product awards)</i>
Large Joints	<i>(products or procedures for hips or knees, product awards)</i>
Legal & Regulatory	<i>(FDA news, lawsuits)</i>
People in the News	<i>(surgeon or doctor news, retiring, hiring, awards, deaths, milestones for ortho community)</i>
Reimbursement	<i>(Medicare or other payer news)</i>
Spine	<i>(products or procedures for back pain, spine surgery, product awards)</i>
Sports Medicine	<i>(products or procedures to treat sports related injuries, product awards)</i>
Trauma	<i>(products or procedures for fracture and soft tissue repair resulting from a traumatic injury)</i>

Key Words: FDA, Gottlieb, medical devices, medical instruments, shortages, Sterigenics, Viant, ethylene oxide, EtO, O



Caption: Sterigenics prevents disease ... and pollutes the air in Illinois, EPA says; Source: <https://www.sterigenicswillowbrook.com/>

FDA: Shortages of Sterile Ortho Instruments, Devices Possible

Food and Drug Administration (FDA) Commissioner Scott Gottlieb said in a March 26 announcement that there could be unpredictable "spot" shortages of hundreds of sterile medical devices and instruments due to the recent closing of a Sterigenics sterilization operation in Illinois and the coming closing of another plant owned by Viant in Michigan.

Of the two plants, the sudden but not wholly unexpected closing of the Sterigenics plant in Willowbrook, Illinois on February 15 by the Illinois Environmental Protection Agency (IEPA) is by far the greater concern for orthopedic surgery.

Gottlieb said the FDA currently "isn't aware of any device shortages attributable to the Willowbrook facility closure." However, no one has a handle on hospitals' and surgical centers' inventories of these vital items. Also, it's quite possible that his announcement could trigger extra ordering, creating artificial shortages.

Both plants use ethylene oxide (EtO), a carcinogenic and highly toxic gas, to sterilize medical instruments and devices, many of which are used in orthopedic operating rooms. About half of all sterilized medical devices are treated with EtO, the FDA says.

"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 by the closure. These include products such as sutures, clamps, knives, stents and needles," Gottlieb's statement says.

The list of devices and equipment sterilized at the Willowbrook facility is listed at [this web page](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=®Num=&StateName=&). (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=®Num=&StateName=&)

A spot check reveals that the first 10 of the 594 are specifically for orthopedics, and there are more small orthopedic devices farther down in the list. In addition, many items on the list are general surgery devices and kits, some of which might be used in orthopedic surgery. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=1450293&OwnerOperatorNumber=&O)

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[wnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&EstablishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC\)](#)

Most of the devices sterilized by Viant are for cardiopulmonary surgery, but a couple are listed as being for general surgery. That list of 46 devices and tools which could be in temporary short supply is available at [this web page](#).

(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=viant®Num=&StateName=MI&CountryName=&OwnerOperatorNumber=&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&EstablishmentType=2&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=3009493875)

It's likely that hospitals and surgery centers don't know whether the devices they use have been sterilized by either of these plants. Most of their sterilization work is done for manufacturers, some of which use distributors. The lists above don't name these manufacturers or distributors. Items are listed by their proprietary names in FDA databases. For example, here's item #3 on the Sterigenics list:

"Fastener, fixation, nondegradable, soft tissue Magnum X Plus, M-Connector, MagnumWire; Fastener, fixation, nondegradable, soft tissue Magnum X Plus, PerfectPasser Connector, MagnumWire; Fastener, fixation, nondegradable, soft tissue Magnum X With Independent Tensioning; Magnum X Implant."

To check with your manufacturer or distributor, you'd need to know or look up the fact that this proprietary name is an Arthrocare/Smith & Nephew product.

"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 to accommodate the sterilization of new products coming off manufacturing lines," Gottlieb's statement says. "This could lead to temporary or 'spot' shortages of some products until sterilization can be restored."

How This Dilemma Happened

The U.S. Environmental Protection Agency (EPA) had first found excessive levels of EtO in the air around the Willowbrook plant in the spring of 2018 and has been monitoring the air at several locations since. New emissions tests in January 2019 found the highest levels yet recorded.

New Illinois Gov. J.B. Pritzker then had the Illinois state EPA order Sterigenics to stop working with EtO and seal that part of the plant on [February 15](#). The state said the plant posed an "imminent and substantial endangerment to residents and off-site workers in the Willowbrook community." The off-site workers include the Village of Willowbrook's local government and police station, which are right across the street.

According to the Agency for Toxic Substances and Disease Registry, which is part of the Centers for Disease Control, regular exposure to 2.1 micrograms of ethylene oxide per cubic meter of air theoretically triggers more than 6 cases of cancer for every 1,000 people exposed. The highest level EPA recorded outside the plant in December was 11.7 micrograms. Then, in January, it hit 14.3. However, the village had its own air monitoring, which found as much as 320 micrograms per cubic meter right outside the police station, according to the [Chicago Tribune](#).

Also, "we've established a device shortages mailbox (deviceshortages@fda.hhs.gov) 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," Gottlieb's statement said. FDA has also created a new educational [web page on EtO](#). (<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm634204.htm>) — *BD*

Commented [SK1]: Did he order them on February 15, or they have to seal plant on February 15?