

Cleaning plant troubles could lead to hospital tool shortage (Update)

October 25 2019, by Matthew Perrone



In this Tuesday, June 28, 2016 file photo, a doctor prepares for a surgical procedure at a hospital in Washington. On Friday, Oct. 25, 2019, the U.S. Food and Drug Administration warned hospitals that they could soon face shortages of critical surgical tools and equipment due to a dwindling supply of the chemical used to sterilize many U.S. medical devices. (AP Photo/Molly Riley)

Hospitals could soon face shortages of critical surgical tools because several plants that sterilize the equipment have been shut down, government health officials said Friday.

The Food and Drug Administration flagged the issue in an online statement to medical professionals, saying the result could be years of shortages of supplies used in heart surgery, knee replacements, C-sections and many other procedures.

The warning follows the recent closure of several sterilization facilities that use ethylene oxide. The gas is critical for cleaning medical equipment, but it can be hazardous at elevated levels and is increasingly being scrutinized by state health and environmental officials.

"The impact resulting from closure of these and perhaps more facilities will be difficult to reverse," said FDA acting commissioner Ned Sharpless, in a statement, adding that the shortages "could compromise patient care."

The FDA urged hospitals to inventory their supplies and alert government officials if they face major shortages. The agency said regulators could help identify alternative devices for those impacted by the issue.

Sterilization is a daily process at hospitals and many other health care facilities, used to remove bacteria from medical scopes, catheters, surgical kits and other reusable instruments. Hospitals use various cleaning methods, including heat, steam and radiation. But the oxide gas is the only method for cleaning many devices made from plastic, metal or glass, according to the FDA. About half of all sterilized medical devices in the U.S. are cleaned with the gas, according to studies cited by the agency.

Exposure to dangerous levels of ethylene oxide can cause cancer including leukemia and lymphoma , according to the National Institutes of Health. Factories that emit the gas are subject to safety standards by both state and federal environmental laws.

Earlier this year, Illinois authorities closed a large plant owned by sterilization company Sterigenics after detecting high outdoor levels of the gas. This month, the company announced the plant would not reopen.

Another Sterigenics plant in Georgia has been closed for maintenance since August after state officials detected potentially dangerous emissions at the Atlanta facility. The company has been working to reduce emission levels from the plant.

The FDA will hold a two-day meeting next month to discuss new sterilization techniques for devices.

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