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‘Immediately Discontinue’ Using Potentially Nonsterile Surgical Gowns, Packs From Cardinal Health, FDA Warns; Company Assessing Quality Issues

by Shawn M. Schmitt

The US agency is telling health-care providers to yank specific gowns – and procedural packs that contain the gowns – from shelves because their maker, Cardinal Health Inc., cannot assure their sterility. The agency is also warning that the problem could lead to a shortage of so-called Level 3 gowns, which are used in a wide-array of everyday surgical procedures.

The US Food and Drug Administration is telling health-care providers to “immediately” yank specific surgical gowns – and procedural packs that contain the gowns – from shelves because their maker, *Cardinal Health Inc.*, cannot assure their sterility.

The agency is also warning that the problem could lead to a shortage of the gowns.

Cardinal Health alerted customers on 11 and 15 January about the sterility problem with its so-called Level 3 surgical gowns and PreSource packs. Gowns are rated on a scale that measures barrier protection; Level 3 gowns offer moderate-risk protection and are used in everyday surgical procedures such as open heart surgery and knee replacements.

“Customers should immediately discontinue” using the gowns, said Jeff Shuren, director of the FDA’s Center for Devices and Radiological Health (CDRH).

“The FDA is working closely with Cardinal Health to understand and address the quality issues with these products, including the potential risks to users and patients, which specific product lots are impacted, and the potential impact on the supply chain,” *he said in a 16 January statement*.

> *"This issue may already be impacting patient care at health-care facilities, such as the cancellation of non-elective surgeries." – Jeff Shuren*

The company will issue a recall soon for the gowns and packs. To date, the agency hasn't received any reports of patient injuries.

Nevertheless, "we … understand this issue may already be impacting patient care at health-care facilities, such as the cancellation of non-elective surgeries," Shuren said. "There are very real consequences that medical device supply chain disruptions can have on patients, and we're committed to taking steps … to mitigate any adverse patient impact."

He said the FDA "is engaged in activities to mitigate supply chain disruption" and is "identifying alternative Level 3 gowns."

"There are numerous FDA-cleared surgical gown alternatives on the market that provide Level 3 barrier protection," Shuren said.

He urged health-care facilities to let the agency know if they're facing gown shortages by emailing *deviceshortages@fda.hhs.gov*.

Customers with questions about their inventory of gowns should contact Cardinal Health directly at *www.cardinalhealth.com/en/about-us/contact-us.html*.