

January 22, 2020

Cardinal Health Recalls Certain Surgical Gowns

At Issue: Cardinal Health Jan. 21 [notified](#) customers of an urgent medical device recall related to specific production lots of single-sterile and bulk non-sterile Cardinal Non-Reinforced Surgical Gowns, Cardinal Fabric-Reinforced Surgical Gowns and RoyalSilk Non-Reinforced Surgical Gowns. Some of the affected gowns were manufactured at locations that did not maintain proper environmental conditions as required by law, and as a result, Cardinal cannot provide assurances that identified item codes and lot numbers were properly sterilized.

The distribution of affected gowns occurred between Sept. 1, 2018 and Jan. 10, 2020. Affected hospitals should identify and segregate impacted lots. Cardinal Health Presource Kits are **not** part of this recall, but will be subject to separate field action at a later date, the company said. Kits containing affected gowns should remain segregated from other supplies and not used.

Our Take: Providing high-quality patient care is the top priority for America's hospitals and health systems. In order to provide that care, hospitals rely on device manufacturers and distributors to provide properly sterilized equipment, including surgical gowns, for vital procedures every day. In this instance, Cardinal Health's failure to meet and ensure legally required environmental conditions at its contract manufacturing facility has left hospitals across the country scrambling to acquire necessary surgical gowns to care for patients. We remain concerned about the lack of transparency about the potential contamination and continue to press Cardinal Health and the Food and Drug Administration (FDA) on that issue, as it is critical to any required look-back endeavor that hospitals must undertake. In addition, we find it unsettling that this potential contamination could have gone on for nearly 18 months without detection. We urge Cardinal Health and the FDA to reassess their oversight of contract manufacturers, with a particular emphasis on why they failed to identify this potential danger more rapidly. The AHA remains in communication with Cardinal Health and government agencies to address the issue and mitigate supply chain disruption. We will continue to provide more information as it becomes available.

What You Can Do:

- ✓ Share this advisory and the Cardinal Health recall letter with your materials management staff, risk managers, infection control staff and clinical leadership.
- ✓ Ensure any gowns or surgical kits containing the gowns have been removed from the available supply in your hospital(s). Return the gowns per the instructions in the Cardinal Health [recall notice](#) and retain the surgical kits in a secure place until further notice from Cardinal Health.
- ✓ Report to the FDA any shortage issues you are encountering by emailing deviceshortages@fda.hhs.gov.
- ✓ Communicate all concerns or difficulties to your local Cardinal Health representative.

Visit AHA's [webpage](#) for the latest information and resources on this issue. If you have further questions or need assistance, contact Mark Howell at mhowell@aha.org or Roslyne Schulman at rschulman@aha.org.

Key Takeaways

- Recall announced for certain Cardinal Health Association of the Advancement of Medical Instrumentation (AAMI) Level 3 and RoyalSilk surgical gowns.
- Affected gowns were distributed between Sept. 1, 2018 and Jan. 10, 2020.
- Affected gowns should be identified by item code and lot number and then segregated.
- Specific information about the type of environmental hazard and potential contamination has not yet been disclosed.
- Cardinal Health Presource Kits are **not** part of this recall, but those containing the affected gowns should be segregated and not used.