Cardinal Health announces voluntary field actions for select procedure packs containing affected surgical gowns

DUBLIN, Ohio, Jan. 30, 2020 /PRNewswire/ -- Today, in continued coordination with the U.S. Food and Drug Administration (FDA), Cardinal Health announced it is initiating two voluntary field actions for select Cardinal Health Presource® Procedure Packs containing gowns that were part of last week's recall of AAMI Level 3 surgical gowns. These procedure packs, also known as kits, had been placed on voluntary hold at the time of the gown recall.

"I apologize to patients and our customers. We understand the gravity of this situation and the disruptions to the healthcare system that will impact patient care," said Mike Kaufmann, CEO of Cardinal Health. "We are fully committed to making this right, and we are doing everything we can to ensure it never happens again."

Cardinal Health is initiating actions involving 2.9 million procedure packs manufactured between September 2018 and January 2020 that contain affected gowns:

- A voluntary correction of 374,794 procedure packs with components separated from the affected gown by inner, sealed packaging or other packs within the sterilization pouch. These packs can be "over-labeled," allowing the components within inner, sealed packages to be used after the gown is discarded. All other components including the gowns are to be removed and discarded. Approximately 62,976 of these packs remain in Cardinal Health inventory.
- A voluntary recall of 2,518,653 procedure packs containing gowns with components that are not separated from the affected gown by inner, sealed packaging. Those procedure packs should not be used and must be returned. Approximately 357,127 of these packs remain in Cardinal Health inventory.

The affected procedure packs were placed on hold earlier this month. The gowns in the procedure packs are a subset of the 9.1 million gowns recalled last week. Procedure packs may be standard or customized to a customer's specifications and can contain a variety of components which may include one or more gowns. Cardinal Health customers will receive detailed instructions for handling the affected procedure packs on or about Monday, February 3.

The decision to recall the packs is necessary based on information Cardinal Health received in December 2019 that Siyang Holymed, one of our FDA-authorized suppliers in China, had shifted production of some gowns to unapproved sites, in uncontrolled environments. On this basis, Cardinal Health cannot assure sterility of the gowns, presenting a potential risk to patient safety. Cardinal Health has terminated its relationship with Siyang Holymed.

Cardinal Health is taking the following actions to address supply shortages as quickly as possible:

- Increasing its manufacturing production of similar and replacement products;
- Offering more protective AAMI Level 4 gowns to help bridge the supply gap;
- Working to identify alternatives – including in many cases working with industry partners who offer comparable products; and
- Mobilizing employees from all parts of the company to work directly with health care providers to replace gowns and procedure packs.

Cardinal Health had previously experienced supply chain issues with Siyang HolyMed. In spring 2018, Cardinal Health learned this supplier outsourced some of its production to a non-registered, non-qualified facility. At the time, Cardinal Health conducted a quality review supported by laboratory testing and concluded there was no impact to its products. Based on the results of the quality review, the company determined a field action was not necessary, and therefore did not coordinate any such action with the FDA.

Moving forward, Cardinal Health is engaging third-party experts to conduct a comprehensive review of quality assurance processes and business practices and committing to the execution of corrective and preventive actions. With management support, the Cardinal Health Board of Directors formed a special committee of the Board to oversee management's actions in connection with the recall and related activities. The Committee is chaired by Director John Weiland, former vice chairman, president and chief operating officer of medical device company C.R. Bard, Inc.

In connection with these surgical gown-related recalls, in the second quarter of our fiscal year 2020, we expect to record a $96 million charge. This charge represents our best estimate of costs for the recall, including inventory write-offs and other remediation costs, such as costs to replace recalled products. It is possible that the amount of ultimate loss may differ materially from this accrual. This charge, and any future increases or adjustments, will be excluded from our non-GAAP financial results.

For more information and the latest updates, please visit www.cardinalhealth.com/SurgicalGownProductRecall.

About Cardinal Health
Cardinal Health, Inc. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. The company enhances supply chain efficiency for clinically proven medical products, pharmaceuticals and cost-effective solutions. To combat prescription drug misuse, the Cardinal Health Foundation and its education partners created Generation Rx, a national drug prevention education and awareness program. The Foundation actively supports an array of other solutions, including efforts to reduce opioid prescribing, promote drug take back and safe disposal and expand collaborative community work.

Cardinal Health is backed by nearly 100 years of experience with operations in nearly 46 countries. For more information, visit cardinalhealth.com. Follow us on Twitter, Facebook and LinkedIn.

Cautions Concerning Forward-Looking Statements
This release contains forward-looking statements addressing expectations, prospects, estimates and other matters that are dependent upon future events or developments. These statements may be identified by words such as "expect," "anticipate," "intend," "plan," "believe," "will," "should," "could," "would," "project," "continue," "likely," and similar expressions, and include statements reflecting future results or guidance, statements of outlook and various accruals and estimates. These matters are subject to risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied. These risks and uncertainties include the risk that current and future costs associated with the recalls of our surgical gowns and related kits, including inventory write-off costs and other remediation costs, could have a material negative impact on our financial results; the risk that we could lose sales and customers due to the recalls or otherwise; the risks that these recalls could lead to actions by regulators or other governmental entities, and we may receive claims and lawsuits by customers and patients, including class action product liability lawsuits; and the risk that the recalls and related operational impacts could have unintended consequences, such as business disruption and distraction of management and other key employees. Cardinal Health is subject to additional risks and uncertainties described in Cardinal Health's Form 10-K, Form 10-Q and Form 8-K reports and exhibits to those reports. This release reflects management's views as of January 30, 2020. Except to the extent required by applicable law, Cardinal Health undertakes no obligation to update or revise any forward-looking statement.

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