

URGENT: FIELD SAFETY NOTICE (Removal)

Event-2020-03230

Specific product codes and lots of:

- **Cardinal Health™ Isolation Gown, Lab Coat and Kendall™ Gown**

January 7, 2021

Dear Valued Customer:

The purpose of this letter is to inform you that Cardinal Health has issued a Medical Device Recall for specific production lots of **Cardinal Health™ Isolation Gowns, Lab Coats and Kendall™ Gowns** due to potential rips, holes, tears, incomplete and/or open seams, staining, foreign material or debris on the gowns and lab coats. In addition, product distributed in the EU was found to not be CE-marked. Please see Attachment 1 for affected product codes and lots.

Product Advisory Overview	<p>Cardinal Health has initiated a medical device recall for the following Cardinal Health™ branded isolation gowns and lab coats and Kendall™ branded gowns due to a failure by the contract manufacturer to maintain a proper Quality Management System. Please see the table in Attachment 1 for a listing of the impacted products.</p> <p>Usage Cardinal Health™ branded isolation gowns and lab coats and Kendall™ branded gowns are intended to provide minimal barrier protection to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material where minimal fluid settings are expected. They are not intended for use in the operating room.</p>
Why you are being contacted:	<p>You are receiving this letter because our records indicate that you have purchased Cardinal Health™ Isolation Gowns, Lab Coats or Kendall™ Gowns.</p>
Actions requested on your part:	<ol style="list-style-type: none"> 1) REVIEW your inventory for affected product. 2) SEGREGATE and QUARANTINE all on-hand product that is confirmed to be labeled per Attachment 1. 3) NOTIFY any customers to whom you may have distributed or forwarded affected product about this product action. 4) REVIEW, complete, sign and return the enclosed Acknowledgement Form by following the directions on the Form. 5) CONTACT your local sales representative to facilitate return of the affected product. Your local sales representative will inform you of either product replacement or credit options. 6) CUSTOMERS that did not receive product directly from Cardinal Health should return product through the location where they purchased it.
Description of the problem:	<p>The contract manufacturer failed to maintain an effective Quality Management System required for the production of gowns and lab coats. As a result, gowns and lab coats produced by this contract manufacturer could have rips, holes, tears, incomplete and/or open seams,</p>

	<p>staining, foreign material or debris (see attachment 2). The affected gowns and lab coats could provide insufficient barrier protection for the end user and patient. These hazardous situations could result in potential harms including unspecified infection or exposure to body fluids.</p> <p>Cardinal Health has not received any reports of patient or user harm or injury related to this issue.</p> <p><u>What other actions is Cardinal Health taking?</u></p> <p>Cardinal Health has ceased contract manufacturing with this supplier.</p>
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We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cardinal Health is committed to maintaining your confidence in the safety and quality of the products that we supply.

Respectfully yours,

Michael Lee
Director, QRA Management

Attachment 1 – Affected Product List

Product	SKU	Lot
Gown Isolation W/Ties Univ Ylw	1100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	V1100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties XI Ylw	1101PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Blu	1200PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	2100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	V2100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	2150PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Blue	2200PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties XI Blue	2201PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS Large Blue	2202LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS X-Large Blue	2203LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS 2X-Large Blue	2204LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS Medium White	2301LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS Large White	2302LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Lab Coats SMS 2X-Large White	2304LC	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	V2100PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Blue	552200PG	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Isolation W/Ties Univ Ylw	NON24258N	All lot numbers from 18KXBXXXXX to 20KXBXXXXX
Gown Kendall Blue RG	CT5000	All lot numbers from 1901XXK to 2010XXK
Gown Kendall Blue L	CT5100	All lot numbers from 1901XXK to 2010XXK
Gown Kendall Blue L	CT5101	All lot numbers from 1901XXK to 2010XXK
Gown Kendall Blue XXL	CT5102	All lot numbers from 1901XXK to 2010XXK

Attachment 2 – Defect Examples

Contamination including staining, foreign material and debris



Rips, holes and tears



Incomplete and/or open seams

