

URGENT MEDICAL DEVICE RECALL

EVENT #: 2020-02735

January 21, 2020

Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health is voluntarily recalling specific production lots of single-sterile and bulk non-sterile Cardinal Health™ Non-Reinforced Surgical Gowns, Cardinal Health™ Fabric-Reinforced Surgical Gowns and RoyalSilk® Non-Reinforced Surgical Gowns. The affected gowns were distributed between September 1, 2018 and January 10, 2020. Note that gowns manufactured prior to 2018 are not affected by this recall.

The affected surgical gowns also are used as components in Cardinal Health™ Presource® Kits, which are not part of this recall, but will be subject to a separate field action at a later date. At this time, continue to segregate and discontinue use of surgical packs that include affected gowns from your current inventory. Packs with lot numbers not listed on the spreadsheet provided by your Cardinal Health sales representative are not affected by this recall.

We are working closely with the U.S. Food and Drug Administration (“FDA”) to address this issue. Report surgical gown and procedure pack shortage issues you are encountering to the FDA at deviceshortages@fda.hhs.gov and to Cardinal Health.

Issue Description

Cardinal Health is conducting this recall because some of the affected gowns were manufactured at locations that did not maintain proper environmental conditions as required by law, were not registered with the FDA, were not qualified by Cardinal Health and commingled with properly manufactured gowns. As a result, Cardinal Health cannot provide assurances that the identified item codes and lot numbers were properly sterilized. An improperly sterilized surgical gown could compromise a sterile field and increase the risk of a surgical site infection.

Cardinal Health is initiating this voluntary recall on the item codes and lot numbers in the following four (4) tables. **Refer to Exhibit A for more information on identifying affected lots.**

Item Code	Item Description	Single-Sterile or Bulk Non-Sterile	Lot #
90970NA	AAMI 3 FABREINF SCRUB SURG GWN L NS	Bulk Non-Sterile	XXXXXJ or XXXXXJX
9511NB	AAMI 3 FABREINF SURG GOWN L NS		
9541NA	AAMI 3 FABRIC REINF SURG GOWN XL NS		
9571NA	AAMI 3 FABRIC REINFORCED 2XL NS		
91070NB	AAMI 3 FABNF SCRUB SURG GWN XL NS		

Item Code	Item Description	Single-Sterile or Bulk Non-Sterile	Lot #
9511	AAMI 3 FABREINF SURG GOWN LARGE	Single-Sterile	XXXXJXXX
9571	AAMI 3 FABRIC REINF SURG GOWN 2XL		
9541	AAMI 3 FABRIC REINF SURG GOWN XL		
ASG9511	AAMI 3 FABRNF SURG GOWN L 2 TOWELS		
ASG9541	AAMI 3 FABRNF SURG GWN XL 2 TOWELS		
ASG9541EL	AAMI 3 FABRNF SURGGWN XL LONG 2 TWL		

Item Code	Item Description	Single-Sterile or Bulk Non-Sterile	Lot #
90270NB	AAMI 3 NONREIN SCRBNURGOWN BNS L	Bulk Non-Sterile	XXXXXJ or XXXXXJX
90370NB	AAMI 3 NONREIN SCRBNURGOWN BNS XL		
9515NB	AAMI 3 NONREIN SURG GOWN L BNS		
9545NC	AAMI 3 NONREIN SURGGOWN BNS XL		
9575NB	AAMI 3 NON-REINF SURG GOWN 2XL BNS	Single-Sterile	XXXXJXXX
9575EL	AAMI 3 NONREINF SURG GOWN 2XL XLONG	Bulk Non-Sterile	XXXXXJ or XXXXXJX
9585N	AAMI 3 NONREINF SURG GOWN 3XL BNS	Single-Sterile	XXXXJXXX
ASG9515	AAMI 3 NON-REINF SURG GOWN LG 2 TWL		
95995	AAMI 3 NON-REINF SURG GWN 3XL XLONG		
ASG9545	AAMI 3 NON-REINF SURG GWN XL 2 TWL		
9585	AAMI 3 NONREINF SURGICAL GOWN 3XL		
9599	AAMI 3 NONREINF SURGICAL GOWN 4XL		
9545	AAMI 3 NON-REINF SURGICAL GOWN XL		
9575	AAMI 3 NON-REINF SURGICAL GOWN XXL	Bulk Non-Sterile	XXXXXJ or XXXXXJX
95995N	AAMI 3 NON-RNF SURG GOWN 3XL LONG		
9575ELNA	AAMI 3 NONRNF SURG GWN 2XL XLNG BNS	Single-Sterile	XXXXJXXX
9515	GOWN SURG LG W/TOWEL ST BACK	Single-Sterile	XXXXJXXX

Item Code	Item Description	Single-Sterile or Bulk Non-Sterile	Lot #
90280NC	AAMI 3 ROYALSILK SCRBNURGOWN BNS L	Bulk Non-Sterile	XXXXXJ or XXXXXJX
90380NC	AAMI 3 ROYALSILK SCRBNURGOWN BNS XL		
9578NB	AAMI 3 ROYALSILK SURGGOWN BNS 2XL		
9518NC	AAMI 3 ROYALSILK SURGGOWN BNS L		
9548NC	AAMI 3 ROYALSILK SURGGOWN BNS XL		
9578	ROYALSILK 2XLARGE	Single-Sterile	XXXXJXXX
95998	ROYALSILK 3XLARGE/XLONG		
95998N	ROYALSILK 3XLARGE/XLONG NS	Bulk Non-Sterile	XXXXXJ or XXXXXJX
9518	ROYALSILK LARGE	Single-Sterile	XXXXJXXX
9548	ROYALSILK XLARGE		

Cardinal Health's records indicate you may have received product associated with this recall.

Actions Required:

1. **CHECK** all storage and usage locations to confirm if you have any units of the affected item codes and lot numbers in your possession. [Exhibit A](#) outlines the lot formatting convention found on the gown labeling and explains how to identify affected gowns and the manufacturing date.

Distributors – In the event your company has included affected gowns as components in convenience kits, we advise that you assess the impact of this recall on those kits.

2. **SEGREGATE and QUARANTINE** all gowns on-hand that are confirmed to be affected by lot number per [Exhibit A](#).
3. **RETURN** the enclosed acknowledgment form either by facsimile (614-495-5651) or email (GMB-CardinalSurgicalGownRecall@cardinalhealth.com) and indicate the product code, lot and quantity of product you've quarantined. Please respond even if you are not affected by this recall.
4. **NOTIFY** any customers to whom you may have distributed or forwarded product affected by this recall. You may include a copy of this recall notice with your customer notification.
5. **CONTACT** the appropriate Cardinal Health Customer Service group, Mondays – Fridays between 8 AM and 5 PM EST, to arrange for **return and credit/replacement** of affected product:
 - Hospital – (800) 964-5227
 - Federal Government – (800) 444-1166
 - Distributor – (800) 635-6021
 - All Other Customers – (888) 444-5440
6. **CUSTOMERS** that did not receive affected gowns directly from Cardinal Health should return them through the location where they purchased them.



Cardinal Health 200, LLC
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cardinalhealth.com

In the event you have experienced quality problems or adverse events related to the affected gowns, contact the appropriate Cardinal Health Customer Service group listed in #5 above.

Report any adverse events associated with the use of these gowns to the FDA:

- Online @ <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (return completed form via email or facsimile)
- Call (800) 332-1088

We sincerely apologize for the hardship this product hold and recall has caused your staff and patients.

Sincerely,

A handwritten signature in black ink that reads "D Linden Barber".

D. Linden Barber
SVP, Regulatory Affairs

Attachment (1)

EXHIBIT A – IDENTIFICATION OF AFFECTED SURGICAL GOWN LOTS

The affected bracketing is all product manufactured between September 1, 2018 and January 10, 2020.

In order to determine the date of manufacture, refer to the lot number formatting below:

Single-Sterile Lot Format: YYMRJXXX	Bulk Non-Sterile Lot Format: XXXYRPQ
<u>Where:</u>	<u>Where:</u>
YY – Last two digits of the year ('18 or '19)	XXX – Elapsed days of year <ul style="list-style-type: none"> • If made in 2018, “244” or greater is affected OR • If made in 2019, any value is affected; see below for year made identifier
M – Month in alpha code <ul style="list-style-type: none"> • If made in 2018 – <ul style="list-style-type: none"> ○ “J” for September ○ “K” for October ○ “L” for November OR ○ “M” for December • If made in 2019, any value is affected 	Y – Last character of year gown was made (2018 or 2019)
R – Product revision or suffix	R – Product Revision
P – Facility code is letter “J”	P – Facility code is letter “J”
XXX Sequential Number - Monthly reset	Q – Plant shift identifier; this identifier was added during the affected time period and therefore older product may <u>not</u> contain this digit in the lot number

Note: Single-sterile and bulk non-sterile Cardinal Health™ Non-Reinforced Surgical Gowns, Cardinal Health™ Fabric-Reinforced Surgical Gowns and RoyalSilk® Non-Reinforced Surgical Gowns manufactured prior to 2018 are not affected by this recall.