



URGENT: FIELD SAFETY NOTICE (Removal)

EVENT #: 2020-02735

Specific product codes and lots of:

- **Cardinal Health™ Non-Reinforced Surgical Gowns**
- **Cardinal Health™ Fabric-Reinforced Surgical Gowns**
- **RoyalSilk® Non-Reinforced Surgical Gowns**

24 January 2020

Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health is voluntarily initiating a field safety corrective action for 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 field safety corrective action.

Issue Description

Cardinal Health is conducting this field safety corrective action because the affected gowns were manufactured at locations that did not maintain proper environmental conditions as required by law, were not registered with the U.S. Food and Drug Administration (FDA) and were not qualified by Cardinal Health. As a result, Cardinal Health cannot provide assurances that the affected gowns 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 field safety corrective action 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		



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ASG9541EL	AAMI 3 FABRNF SURGGWN XL LONG 2 TWL		
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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		
9585N	AAMI 3 NONREINF SURG GOWN 3XL BNS	Bulk Non-Sterile	XXXXXJ or XXXXXJX
ASG9515	AAMI 3 NON-REINF SURG GOWN LG 2 TWL	Single-Sterile	XXXXJXXX
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		
95995N	AAMI 3 NON-RNF SURG GOWN 3XL LONG	Bulk Non-Sterile	XXXXXJ or XXXXXJX
9575ELNA	AAMI 3 NONRNF SURG GWN 2XL XLNG BNS		
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	Single-Sterile	XXXXJXXX
9578	ROYALSILK 2XLARGE		
95998	ROYALSILK 3XLARGE/XLONG	Bulk Non-Sterile	XXXXXJ or XXXXXJX
95998N	ROYALSILK 3XLARGE/XLONG NS		
9518	ROYALSILK LARGE	Single-Sterile	XXXXJXXX
9548	ROYALSILK XLARGE		

Cardinal Health's records indicate you may have received product associated with this field safety corrective action. Please follow the directions outlined in the **Required Actions** section on the next page.



Required Actions:

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 explains how to identify affected gowns.

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

2. **Review, complete, sign and return** the enclosed Acknowledgement Form by following the directions on the Form.
3. **Return** product labeled as shown in Exhibit A or contact your local sales representative to facilitate return of the affected gowns. Your local sales representative will inform you of either product replacement or credit options.
4. **Share** this notice with others in your facility who need to be aware of this removal. Contact other facilities that may have received units of affected lots.
5. **Maintain awareness** of this notice until all affected product has been returned to Cardinal Health.
6. **Keep** a copy of this notice with affected product until returned to Cardinal Health.

Cardinal Health is notifying the appropriate regulatory authorities of this voluntary field safety corrective action. We request that you contact Cardinal Health if you have experienced quality problems or adverse events. We sincerely apologize for any hardship this field action may have caused your staff and patients.

Sincerely,
xxx

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 field safety corrective action.