Cardinal Health 200, LLC
3651 Birchwood Drive
Waukegan, IL 60085

cardinalhealth.com

URGENT MEDICAL DEVICE RECALL

EVENT #: 2020-02735 Presource® Packs

February 25, 2020

Presource® Procedure Packs Containing Cardinal Health™ Non-Reinforced Surgical Gown; Cardinal Health™ Reinforced Surgical Gown and RoyalSilk® Non-Reinforced Surgical Gown

Dear Valued Customer:

Cardinal Health recently initiated a voluntary recall and correction for specific production lots of Presource® Procedure Packs containing the recalled Cardinal Health™ Non-Reinforced Surgical Gowns, Cardinal Health™ Fabric-Reinforced Surgical Gowns and/or RoyalSilk® Non-Reinforced Surgical Gowns . For more information related to that recall, visit www.cardinalheath.com/surgicalgownrecall..

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Upon further review, Cardinal Health is initiating an expansion to the Presource® Procedure Pack recall for specific lots of Presource® Packs produced between September 1, 2018 and February 19, 2020.

Issue Description

Cardinal Health is conducting this recall because the Presource® Packs contain the recalled Cardinal Health™ Non-Reinforced Surgical Gowns, Cardinal Health™ Fabric-Reinforced Surgical Gowns and/or RoyalSilk® Non-Reinforced Surgical Gowns. Cardinal Health initiated the surgical gown voluntary 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 U.S. Food and Drug Administration ("FDA"), were not qualified by Cardinal Health and were comingled with properly manufactured gowns. As a result, Cardinal Health cannot assure that the identified item codes and lot numbers are sterile. An inadequately sterilized surgical gown could compromise a sterile field and increase the risk of a surgical site infection. At this time, Cardinal Health also cannot provide assurances that components in Presource® kits that contain the recalled gowns are sterile.

Our records indicate you may have received Presource® Packs identified as part of the recall expansion containing the recalled gown(s) and lot number(s). Please reference the enclosed report identifying your facility's packs, along with the corresponding lot numbers that are affected by this recall expansion action. Please be aware that the packs identified on the enclosed report are affected in addition to the packs contained within the original Presource® Procedure Pack recall notification dated January 31, 2020 your facility should have received.

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 per enclosed report identifying your facility's packs. Exhibit A outlines how to identify affected packs and the lot number.

2. **SEGREGATE and QUARANTINE** all packs on-hand that are confirmed to be affected by lot number per attached report identifying your facility's packs.

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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 11 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 packs directly from Cardinal Health should return them through the location where they purchased them.

In the event you have experienced quality problems or adverse events related to the affected packs, 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 continue to work closely with the FDA to address this issue. Please report surgical gown and procedure pack shortage issues you are encountering to the FDA at deviceshortages@fda.hhs.gov and to Cardinal Health.

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

Sincerely,

D. Linden Barber
SVP, Regulatory Affairs

Attachment (1)

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EXHIBIT A – IDENTIFICATION OF AFFECTED PRESOURCE® SURGICAL PROCEDURE PACKS

Case Label

Pack Label