
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 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. For more information related to that recall, visit www.cardinalhealth.com/surgicalgownrecall.

After reviewing the potential impact of this recall on Presource® Procedure Packs, Cardinal Health is initiating a voluntary recall on 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 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 action.

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.
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.



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

cardinalhealth.com

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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,

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

D. Linden Barber
SVP, Regulatory Affairs

Attachment (1)

EXHIBIT A – IDENTIFICATION OF AFFECTED PRESOURCE® SURGICAL PROCEDURE PACKS

Case Label



KIT DESCRIPTION
Cat. **SANCXXXAUC** Qty. **4**
Exp date **2021-04-01**
Mfg date **2019-12-03**
Lot # **999999**
Cty. Mtd. **NSC**

HOSPITAL NAME
Ship to: MIDWEST DISTRIBUTION CENTER
2101 WAUKEGAN RD
WAUKEGAN, IL 60085
Phone #: 847-578-9600

Region

STERILE EO

(11) 191203 (17) 210401 (10) 999999

Contents may be imported. See Article for country of origin.

CardinalHealth Cardinal Health
Waukegan, IL 60085 USA 1 CS-216-FRU

(01) 5088748815310 (240) 999999 0001

Pack Label



Presource™ STERILE EO C Product Not made with natural rubber latex

KIT DESCRIPTION **SANCXXXAUC**

HOSPITAL NAME

Contents:

2 MX TOWELABSORBENT	2 KH GOWN,SURGICAL	2 SYRINGE,20ML
1 NEEDLE,RS9	10 CN SPONGE,GAUZE	10 CN SPONGE
1 CN DOWNBAG	1 SCALPEL,SAFETY	1 MX BOWL
1 MX BOWL	2 TW BAG	8 CN CLAMP,TOWEL
1 DO KIT,PROBE COVER,WGEL	1 CUP,SPECIMEN	1 SYRINGE,10ML
2 SYRINGE,20CC	1 PK CLAMP,HEMOSTAT	1 PK CLAMP,HEMOSTAT
1 MARBER	3 SYRINGE,10ML	12 CN TOWEL,COTTON,BLUE
1 PK SCISSOR	1 CN BOWL,GUIDEWIRE	1 PAD,TRAY PROTECTOR
1 APPLICATOR,FREP	1 LABEL,SHEET OF 60 ASSORTED	1 MX DRAPE,FEMORAL ANGIOGRAPHY
1 CN NEEDLE,COUNTER	1 NEEDLE	2 SYRINGE,NEEDLE,1ML,20GX,1.7
1 CUP,VEDICINE,RED	1 KIT,R AURORA,ST,LUXE'S	1 MX COVER,BACK TABLE
1 CN GOWN,SURGICAL,WITDOWEL	2 MX DRAPE,THREE QUARTER SHEET	

Cardinal Health
Waukegan, IL 60085 USA
cardinalhealth.com/presource
packmanager.com
800.964.5227

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EXP DATE 2021-04-01
MFG DATE 2019-12-03
LOT # 999999
QUANTITY ONE
CATALOG SANCXXXAUC

All components of U.S. origin unless otherwise denoted by alphanumeric codes adjacent to the component.
H=HEXED I=CANBODIA O=D-MEXICO T=TAIWAN,RCH D=DOMINICAN REPUBLIC
P=PAKISTAN

NOTE: Ensure that all assembled connections are secure.
Store at controlled room temperature per USP (15-30 C/59-86 F).
Doc #521646

CardinalHealth™ 1

Contents of the unopened, undamaged package are sterile with the following caution: contents of foil packets, bottles, and ampoules, including liquids, gels, and pastes have not been terminally sterilized by Cardinal Health and therefore may not be sterile. Refer to unit package of components to confirm sterile condition. Do not re-sterilize the kit or any of its contents. Avoid contact with open flames and high intensity heat sources as the contents of this package may burn if exposed to a flame or extremely hot object. Caution: Federal (USA) law restricts this kit to sale by or on the order of a physician. Directions: Use Hospital's Standard Procedure. Cardinal Health, Waukegan, IL 60085.

Format CS-215-FRK
STK1UPRED