



Cardinal Health
 15 Hampshire Street
 Mansfield, MA 02048

cardinalhealth.com

URGENT: MEDICAL DEVICE RECALL

August 1, 2018

Attention: Risk Management Director and Operating Room Materials Management

Dear Valued Customer:

The purpose of this letter to advise you that Cardinal Health is recalling specific Covidien™ production lots of **Kerlix™ AMD, Kerlix™ and Dermacea™ bandage and gauze rolls**¹.

Issue Description

This voluntary recall is being conducted due to a small percentage of product that has the potential to have an open seal or a pinched seal defect in the primary flexible sealed pouches, which could result in a sterility breach of the product. Use of product containing this type of seal defect may lead to infection due to potential break in the sterile barrier. Cardinal Health is not aware of any reports of injury or harm attributed to this issue.

As a result, Cardinal Health is initiating this recall on the following Covidien™ item codes and lot numbers:

Item Code	Item Description	Affected Lots
3332	KERLIX™ AMD Antimicrobial Large Roll, 6 Ply, 4.5" x 4.1 yd	18D180962, 18D181062, 18E029462, 18E029562, 18E070762, 18E131262, 18E131362, 18E131462, 18E166662, 18E167362, 18E223462, 18E223362, 18F054362, 18E222662, 18F034762, 18F034662, 18F035562, 18F072862, 18F072662, 18F072962, 18F123062, 18F122562, 18F122662
6715	KERLIX™ 100% Bandage Cotton Large Roll, 4-1/2" x 4-1/8 yd, 6 Ply, Sterile	18D181262, 18D181162, 18E029662, 18E029762, 18E029862, 18E029962, 18E030062, 18E030162, 18E030262, 18E030362, 18E070962, 18E071062, 18E071162, 18E071262, 18E071362, 18E071462, 18E071562, 18E071662, 18E131562, 18E131962, 18E132062, 18E132162, 18E131662, 18E131762, 18E131862, 18E166762, 18E167462, 18E166862, 18E166962, 18E167562, 18E167162, 18E167062, 18E167762, 18E167662, 18E167262, 18E222762, 18E223162, 18E223062, 18E222962, 18E222862, 18E223662, 18E223562, 18E224062, 18E223962, 18E223862, 18E223762, 18F035862, 18F034962, 18F034862, 18F035262, 18F035162, 18F035062, 18F035362, 18F035962, 18F035762, 18F035462, 18F089262, 18F036262, 18F036162, 18F036062, 18F073062, 18F072762, 18F123262, 18F123162, 18F158462, 18F158362, 18G004562

¹ On July 31, 2017, Cardinal Health announced that it had completed the acquisition of the Patient Care, Deep Vein Thrombosis and Nutritional Insufficiency business from Medtronic, which includes the Covidien Kerlix™ and Dermacea™ branded products. See <https://is.gd/Vle4SI>.



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7880	KERLIX™ Gauze Large Roll, 4-1/2" x 4-1/8 yd, 6 Ply, Sterile	18E030462, 18E223262, 18F122962
6716	KERLIX™ 100% Bandage Cotton Large Roll, 4-1/2" x 9.3', 8 Ply, Sterile	18E071762, 18E072262, 18E072362, 18E132262, 18E132362
441103	DERMACEA™ Fluff Roll, 6 Ply, 4.5 Inch x 4.1 yd, Stretched, Sterile	18D180662, 18E070362, 18E222362, 18F072362
441106	DERMACEA™ Fluff Roll, 6 Ply, 4.5 Inch x 4.1 yd, Stretched, Sterile	18D180762, 18D180862, 18E029062, 18E029162, 18E029262, 18E029362, 18E070662, 18E070462, 18E070562, 18E130962, 18E131062, 18E166462, 18E166562, 18E131162, 18E222562, 18E222462, 18F034562, 18F034462, 18F034362, 18F072562, 18F072462, 18F122462, 18F122362

Actions Required

1. Immediately stop using affected product.
2. Return the enclosed acknowledgment form via fax to 847-689-9101 or 614-652-9648, whether or not you have affected product, as Cardinal Health is required to confirm receipt of this notification from you, and to prevent further notices.
3. Notify any customers to whom you may have distributed product affected by this recall.
4. Contact the appropriate Customer Service group to arrange for credit and return of any affected product you may have:
 - Hospital 800-964-5227
 - Federal Government 800-444-1166
 - Distributors—800-635-6021
 - All other customers 888-444-5440

Cardinal Health is taking this action with the knowledge of the U.S. Food and Drug Administration ("FDA") and other regulatory authorities.

In the event you have experienced quality problems or adverse events related to the products listed above, send an email to: GMB_PRCComplaints@cardinalhealth.com. In addition, you may report product-related adverse events to the FDA by calling (800) 332-1088 or submitting a MedWatch Voluntary Reporting Form online at <https://is.gd/R4OABV>.

We regret any inconvenience caused by this voluntary recall. Cardinal Health is committed to patient safety and appreciates your prompt attention to this matter. If you have any questions regarding this letter, then please contact (800) 292-9332.

Sincerely,

Stephanie Shield
 Director, Manufacturing Quality
 Attachments (2)

Attachment A

Item code



REF 3332

Kerlix™
AMD Antimicrobial Bandage Roll

6 Ply
4-1/2" x 12.3' (11.4 cm x 3.7 m)

Kills bacteria like Staph & MRSA*
Made in USA

Indications: For use as primary or secondary dressings for exuding wounds, surgical incisions, lacerations, abrasions, burns, wound packing, donor sites, catheter sites, I. V. sites and central lines. Also may be used for securement of primary dressings. The antimicrobial activity of the PHMB in Kerlix AMD helps resist bacterial colonization within the dressing and inhibit bacterial penetration through the dressing.

Caution: AMD dressings can be used in conjunction with prescribed therapies for the treatment of infections. Dressings are not intended as a primary treatment for infections; if clinical signs of infection are present, please consult a physician.
Contains: 0.2% Polyhexamethylene Biguanide (PHMB).
*Covidien dressings containing PHMB kill bacteria within the dressing and the barrier properties of the dressing may help to reduce infections.
U.S. Patent 6,369,289.
© 2011 Covidien. Made in USA.
Covidien Inc, 15 Hampshire Street, Mansfield, MA 02048 USA. ~~CE/REACH~~ Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

STERILE EO ~~LATEX~~
Single use ~~DEHP~~
Do not use if package is opened or damaged
Caution, consult accompanying documents
Hypoallergenic

Rx ONLY
CE 0123

(01)20884521020037



Lot number:

COVIDIEN™
Kerlix™
Bandage Roll
100% Cotton, 8 Ply, Large
4-1/2" x 9.3'
(11.4 cm x 2.8 m)
Made in USA

REF 6716

LOT
Use by

XXXXXXXXXXXXXX
YYYY-MM-DD

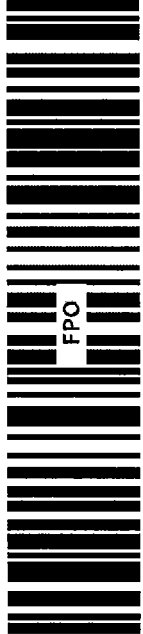
STERILE EO ~~LATEX~~
Single use ~~DEHP~~
Do not use if package is opened or damaged
Hypoallergenic

CE 0123

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Covidien Inc, 15 Hampshire Street, Mansfield, MA 02048 USA.
~~CE/REACH~~ Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.
AG62958205

Item code

Lot number:



(01)10884521058460



RECALL ACKNOWLEDGMENT FORM

SUPPLIER: Covidien
 RECALL DATE: 08/01/2018
 FILE#: EVENT-2018-01563

Your response to this recall notice is required

Please fax this form to 614-652-9648 or email to GMB-fieldcorrectiveaction@cardinalhealth.com to acknowledge your receipt of the recall. Please respond even if you do not have recalled product on hand.

- We have affected inventory within our possession **AND** will contact the appropriate customer service group for credit/replacement. Quantity on hand: _____
- We have no affected inventory within our possession.

Print name of person completing this form _____
 Print Institution Name, City, State, Zip _____
 (IF DIFFERENT FROM LABEL BELOW) _____

 Email address _____
 Phone number _____
 Fax number _____

THIS IS NOT A PRODUCT RETURN LABEL
 FOR PRODUCT RETURNS— PLEASE FOLLOW INSTRUCTIONS ON THE ENCLOSED NOTICE

ORIGIN ID: FEPA (800) 292-9332
 REGULATORY MANAGEMENT
 CARDINAL HEALTH
 3651 BIRCHWOOD DR
 WAUKEGAN, IL 60085
 UNITED STATES US

SHIP DATE: 01AUG18
 ACT WT: 1.00 LB MAN
 CAD: 0399834/CAT/FE3210

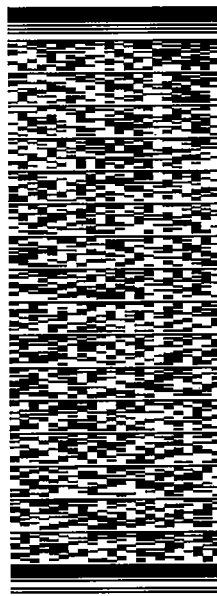
BILL SENDER

TO **ATTN: RECALL COORDINATOR/MATL MGMT**
MEDICAL SPECIALTIES DISTRIBUTION
800 TECHNOLOGY CTR DR

STOUGHTON MA 02072

P.O. PATIENT RECOVERY RECALL - 2018

REF: 100000733



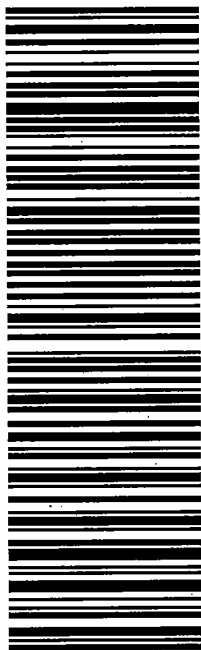
J181118042001uv

TRK# 0201
4518 5038 5587

THU - 02 AUG 3:00P
 STANDARD OVERNIGHT

01 NZWA

MA-US
02072 BOS



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