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_PRComplaints@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.

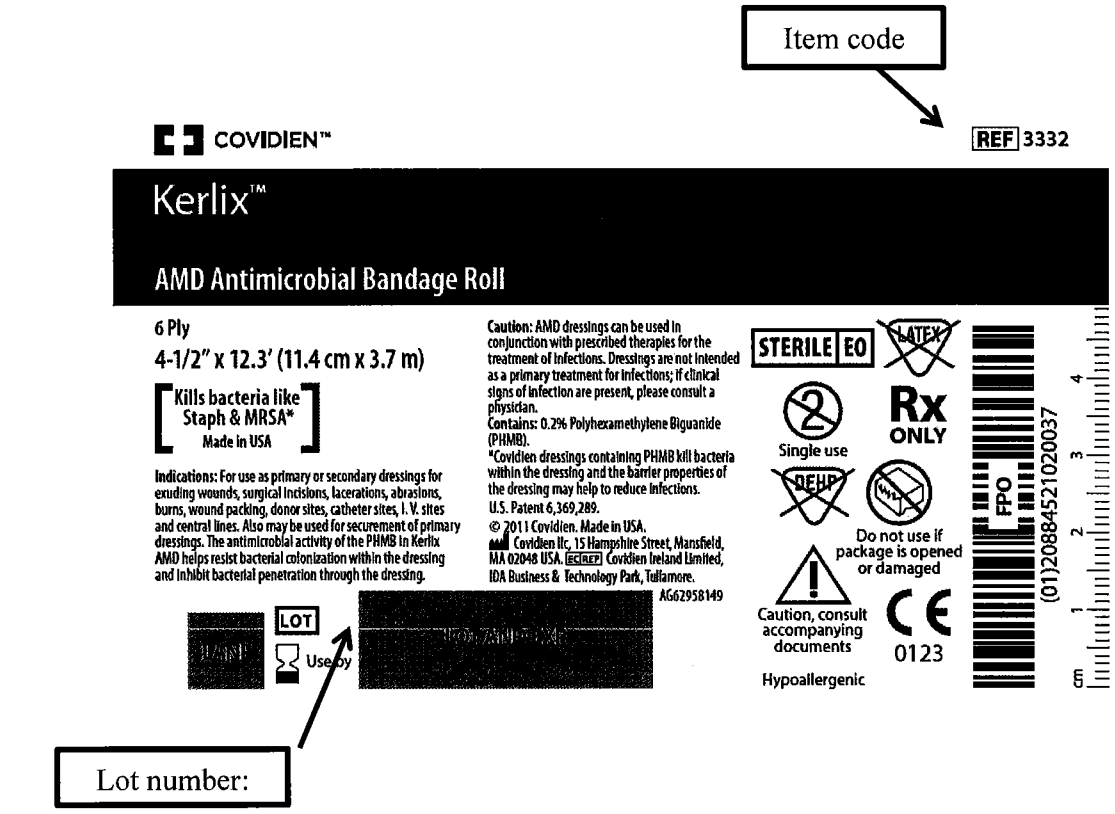
We regret any inconvenience caused by this voluntary recall. Cardinal Health is committed to patient safety and appreciates your prompt attention to this matter. If you have any questions regarding this letter, then please contact (800) 292-9332.

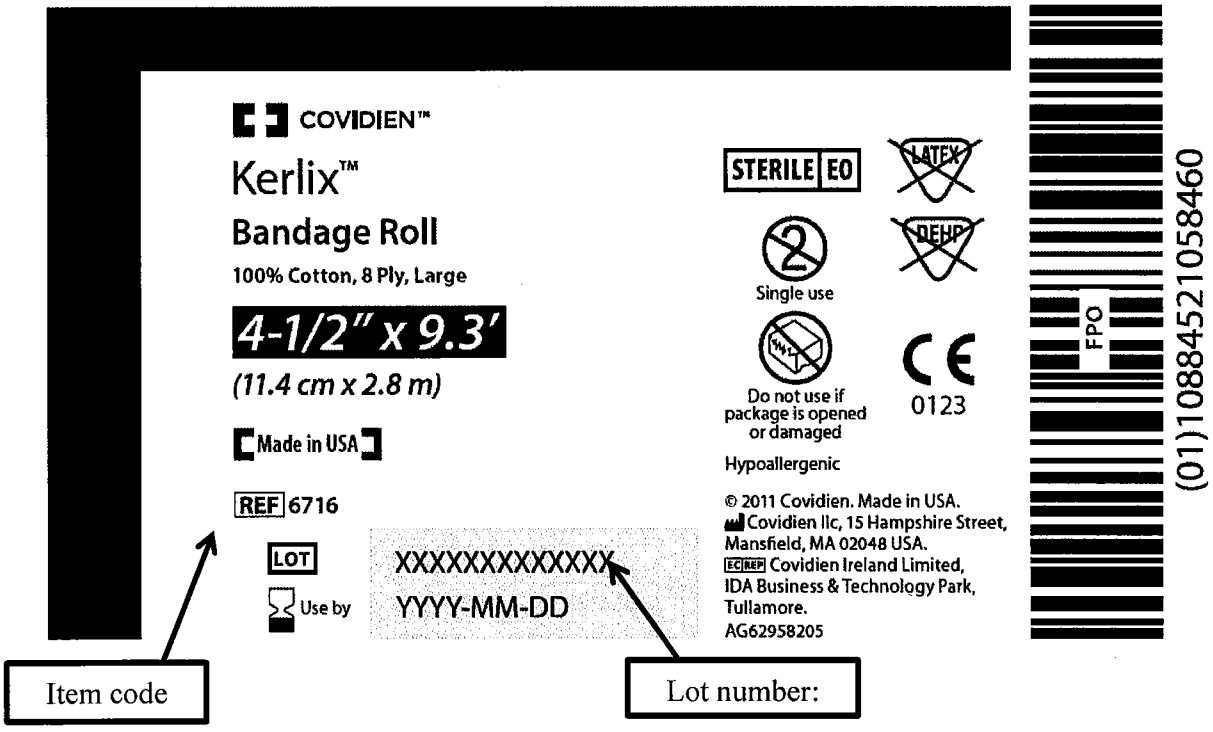
Sincerely,

Stephanie Shield

Stephanie Shield
Director, Manufacturing Quality
Attachments (2)

Attachment A





CardinalHealth

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
ACTWGT: 1.00 LB MAN
CAD: 0399834/CAFE3210

BILL SENDER

TO ATTN RECALL COORDINATOR/MATL MGMT
MEDICAL SPECIALTIES DISTRIBUTION
800 TECHNOLOGY CTR DR
STOUGHTON MA 02072

REF: 1000000733

PO: PATIENT RECOVERY RECALL - 2018

FedEx Express

J181118042001uv

551C1/3309/104C

TRK# 0201 4518 5038 5587

THU - 02 AUG 3:00P
STANDARD OVERNIGHT

01 NZWA

02072
MA-US BOS