URGENT MEDICAL DEVICE RECALL
Covidien Curity™ Eye Pad, Curity™ Eye Pad Oval, Kerlix™ Super Sponge Saline Dressing, Curity™ Wet Dressing, Curity™ Sodium Chloride Dressing and Curity™ Saline Dressing

March 3, 2017

Attention: Risk Management Director and O.R. Materials Management
Distributors of affected product

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of Covidien Curity™ eye pad, Curity™ eye pad oval, Kerlix™ super sponge saline dressing, Curity™ wet dressing, Curity™ sodium chloride dressing and Curity™ saline dressing. This voluntary recall is being conducted due to the potential for the sterile packaging to be compromised. The use of products with this condition may result in a potentially increased risk for infection. There have been no reports of infection associated with this issue.

Medtronic requests that you quarantine and return any unused products of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Item Description</th>
<th>Lot Number beginning with</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>03201</td>
<td>Covidien Curity™ Eye Pad</td>
<td>12, 13, 14, 15, 16</td>
<td>From 2017-02 through 2021-11</td>
</tr>
<tr>
<td>2841</td>
<td>Covidien Curity™ Eye Pad Oval</td>
<td></td>
<td></td>
</tr>
<tr>
<td>91650</td>
<td>Covidien Curity™ Eye Pad</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3337</td>
<td>Covidien Curity™ Wet Dressing</td>
<td>14, 15, 16</td>
<td>From 2017-02 through 2019-11</td>
</tr>
<tr>
<td>3338</td>
<td>Covidien Kerlix™ Super Sponge Saline Dressing</td>
<td>*Exclude lots 16J098062 16J098162</td>
<td></td>
</tr>
<tr>
<td>3339</td>
<td>Covidien Curity™ Sodium Chloride Dressing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3606*</td>
<td>Covidien Curity™ Saline Dressing</td>
<td>16J098262</td>
<td></td>
</tr>
</tbody>
</table>

If you have distributed the sterile Covidien Curity™ eye pad, Curity™ eye pad oval, Kerlix™ super sponge saline Dressing, Curity™ wet dressing, Curity™ sodium chloride dressing and Curity™ saline dressing products listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

This voluntary recall affects only the item codes and lots listed above.
This action is being taken with the knowledge of the FDA and other regulatory authorities. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Post Market Vigilance at: Mansfield.productmonitoring@Covidien.com

The FDA can be contacted to report any adverse events experienced with the use of these products:
- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail)
- Call FDA 1-800-332-1088

**Required Actions:**
1. Please quarantine and discontinue use of the affected item codes and lots listed above.

2. Please return affected product as follows:

<table>
<thead>
<tr>
<th>Customer with inventory:</th>
<th>Customer with Zero Inventory</th>
<th>Where to send the completed form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchased DIRECTLY from Medtronic</td>
<td>Ship affected product with RGA# provided by Customer Service (800) 882-5878 to: Medtronic Attn: Field Returns Department 195 McDermott Road North Haven, CT 06473 USA</td>
<td>Complete form and check the box indicating “no inventory”. Fax form to 800-895-6140 or email it to <a href="mailto:Feedback.customerservice@Covidien.com">Feedback.customerservice@Covidien.com</a></td>
</tr>
<tr>
<td>Purchased from a Distributor</td>
<td>Complete ALL fields on the form and contact your Distributor directly to arrange for return of product.</td>
<td>Complete form and check the box indicating “no inventory”. Fax form to 203-492-7719 or email to <a href="mailto:FCAMITG@Covidien.com">FCAMITG@Covidien.com</a></td>
</tr>
</tbody>
</table>

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service at (800) 882-5878.

Sincerely,

Subu Mangipudi
Vice President, Quality
Patient Monitoring and Recovery
Medtronic
Attachment A

Distinguish affected product by Item Code and Lot Number.

Front of package

Curity™ Eye Pad
Oval
1-5/8" x 2-5/8" (4.2 cm x 6.7 cm)
Compresse pour les yeux
Ovales
Augenkompress, Oval
Tamponcino per occhi, Oval
Almohadilla para ojos, Ovales
Gypokompress, Oval
Met katoen geredoogdoozeg, Ovaal
Compressa ocular, Oval

Made in USA

© 2011 Covidien, Made in USA.
Covidien Inc., 15 Hampshire Street,
Mansfield, MA 02048 USA.
Covidien Ireland Limited, IDA
Business & Technology Park, Tullamore.
AG2290733

Item code

Kerlix™
Super Sponge Saline Dressing

Directions for use:
Wet to dry - Apply at room temperature.
Hot - Follow instructions on
Curity™ Wet Dressings Heater.
Cold - Refrigerate as needed.

Made in USA

© 2011 Covidien. Made in USA.
Covidien, Inc., 15 Hampshire Street,
Mansfield, MA USA.
AG2290863

Item code

Back of package

Lot number

LOT
15M000000

Expiration Date

2020-12

Page 3 of 4

© 2017 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. ECO73029
RECALLED PRODUCT RETURN FORM
Covidien Curity™ Eye Pad, Curity™ Eye Pad Oval, Kerlix™ Super Sponge Saline Dressing, Curity™ Wet Dressing, Curity™ Sodium Chloride Dressing and Curity™ Saline Dressing
PLEASE COMPLETE THIS FORM

Date: 
Name of Person Completing this Form: 
Title: 
Direct Phone #: 
Email 

How did the account purchase this product? (Please complete ONLY A or B)
Direct from Medtronic (Complete A):  
From a Distributor (Complete B): 

A. Direct Customers:
Account Name: 
Primary Account #: 
Account Address:  
City: 
State:  Zip Code: 

B. From a Distributor:
Distributor: 
Customer Information:
Customer Name: 
Address: 
City:  
State:  Zip: 

RETURN INVENTORY TO: Medtronic, Attn: Field Returns Dept., 195 McDermott Road, North Haven, CT 06473 USA
Return Goods Authorization (RGA) #: ____________ (please include once received from Customer Service)

No Inventory (Please check): 

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Lot Number</th>
<th>Qty</th>
<th>Case or Each</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I acknowledge receipt of the Covidien Curity™ eye pad, Curity™ eye pad oval, Kerlix™ super sponge saline dressing, Curity™ wet dressing, Curity™ sodium chloride dressing and Curity™ saline dressing

(Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:
Product purchased directly from Medtronic: feedback.customerservice@Covidien.com or fax to (800)-895-6140.
Product purchased through distributor: FCA MITG@Covidien.com or fax it to (203) 492-7719.