URGENT FIELD SAFETY NOTICE
Curity™ Eye Pad Oval and Curity™ Sodium Chloride Dressing

March 12, 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 recalling specific item codes and production lots of Curity™ eye pad oval and Curity™ sodium chloride dressing products. This Field Safety Corrective Action (FSCA) 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>2841</td>
<td>Covidien Curity™ Eye Pad Oval</td>
<td>12, 13, 14, 15, 16</td>
<td>From 2017-02 through 2021-11</td>
</tr>
<tr>
<td>3339</td>
<td>Covidien Curity™ Sodium Chloride Dressing</td>
<td>14, 15, 16</td>
<td>From 2017-02 through 2019-11</td>
</tr>
</tbody>
</table>

If you have distributed the sterile Curity™ eye pad oval and Curity™ sodium chloride 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 FSCA affects only the item codes and lots listed above.

This action is being taken with the knowledge of the Saudi Food and Drug Authority. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: ksa.ra@medtronic.com

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### 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><strong>Purchased directly from Medtronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.</td>
<td>Complete form and check the box indicating “no inventory”</td>
<td>E-mail or fax the completed form to the Medtronic contact provided on the verification form.</td>
</tr>
<tr>
<td><strong>Purchased from a distributor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<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”</td>
<td>E-mail or fax the completed form to your Distributor &amp; to the Medtronic contact provided on the verification form.</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 at +966 56 355 5583

Sincerely,

Subu Mangipudi  
Vice President, Quality  
Patient Monitoring and Recovery  
Medtronic

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Attachment A

Distinguish affected product by Item Code and Lot Number.

Front of package

Item code

Curity
Eye Pad
Oval
1-5/8" x 2-5/8" (4.2 cm x 6.7 cm)
Compresse pour les yeux

STERILE

Do not use if package is opened or damaged

Made in USA

© 2011 Covidien. Made in U.S.A.
Covidien Inc., 15 Hampshire Street,
Warsaw, MA 02084 U.S.A.
Covidien Ireland Limited, IDA
Business & Technology Park, Tallaght.
AGA2587FJ

Back of package

Lot number

LOT 15M000000

Expiration Date

2020-12