

**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.

<b>Item Code</b>	<b>Item Description</b>	<b>Lot Number beginning with</b>	<b>Expiration Date</b>
2841	Covidien Curity™ Eye Pad Oval	12, 13, 14, 15, 16	From 2017-02 through 2021-11
3339	Covidien Curity™ Sodium Chloride Dressing	14, 15, 16	From 2017-02 through 2019-11

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](mailto:ksa.ra@medtronic.com)

**Required Actions:**

1. Please quarantine and discontinue use of the affected item codes and lots listed above.
2. Please return affected product as follows:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased <b>directly</b> from Medtronic	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.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a <b>distributor</b>	Complete <b>all</b> fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

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

## Attachment A

Distinguish affected product by Item Code and Lot Number.

### Front of package

**Item code** REF 2841

**Item code** REF 3339

**Left Package (REF 2841):**  
COVIDIEN™  
**Curity™**  
Eye Pad  
Oval  
1-5/8" x 2-5/8" (4.2 cm x 6.7 cm)  
Comprese pour les yeux  
Ovales  
Augenkomprese, Oval  
Tamponcino per occhi, Ovali  
Almohadilla para ojos, Ovals  
Ögonkompress, Oval  
Met katoen gevuld ooggaasje, Ovaal  
Compressa ocular, Ovals  
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, AG62958733

**Right Package (REF 3339):**  
COVIDIEN  
*positive results for life®*  
**Curity™**  
Sodium Chloride Dressing  
6" x 6-3/4" (15.2 cm x 17.1 cm)  
Pansement au chlorure de sodium  
Natriumchloridverband  
Medicazione a base di cloruro di sodio  
Apósito impregnado en cloruro sódico  
Natriumchloridförband  
Natriumchloridverband  
Panso com cloruro de sódio  
Natriumchloridbånd  
Natriumchlorid-bandage  
Embiqaz ylaqoyigou vepiqou  
Kryti s chloridom sodnym  
Natrium-kloridos kitiizer  
Повязка с хлоридом натрия  
Opstrunek z chloridem sodu  
Sodium Chloride Pansement  
Bandage med natriumklorid  
Kryti s chloridom sodnym  
Pansement cu clorură de sodiu  
Прозрачная с натрием хлорид

STERILE  
Single use  
Do not use if package is opened or damaged  
CE 0123

STERILE  
Single use  
CE 0123

96  
FPO  
(01)20884527016669

### Back of package

**Lot number** LOT 15M000000

**Expiration Date** 2020-12