Medtronic
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North Haven, CT 06473
USA
www.medtronic.com

URGENT FIELD SAFETY NOTICE

Curity™ Eye Pad Oval and Curity™ Sodium Chloride Dressing

March, 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.

Item Code	Item Description	Lot Number beginning with	Expiration Date
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 Competent Authority in your Country. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: NordicRA@covidien.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:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased **directly** 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 **distributor**	Complete **all** 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.

Sincerely,

Sebnem Yavas Hoffsten
Regulatory Affairs Manager Nordic Countries
Medtronic

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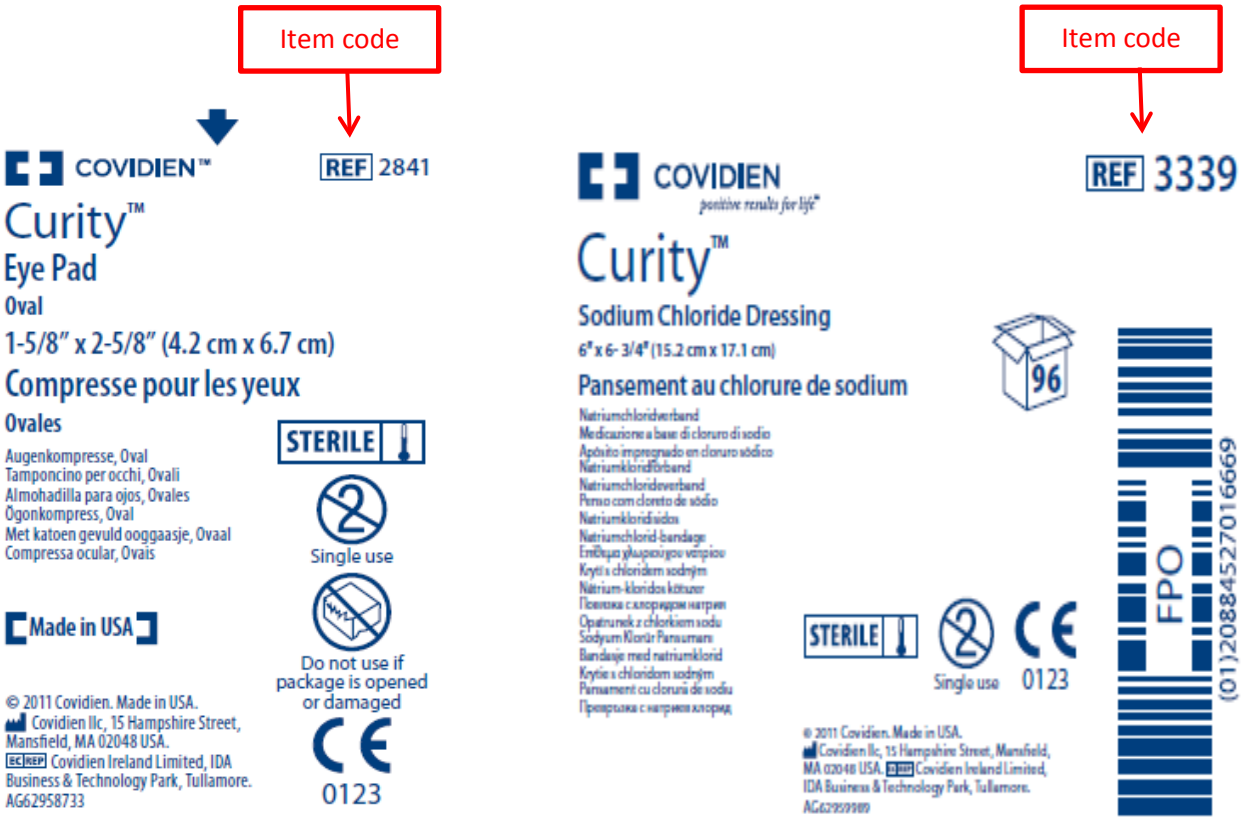
Attachment A

Distinguish affected product by Item Code and Lot Number.

Front of package



Back of package