Medtronic

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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

3 March 2017

Attention: Risk Management Director and O.R. Materials Management and 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.

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

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.

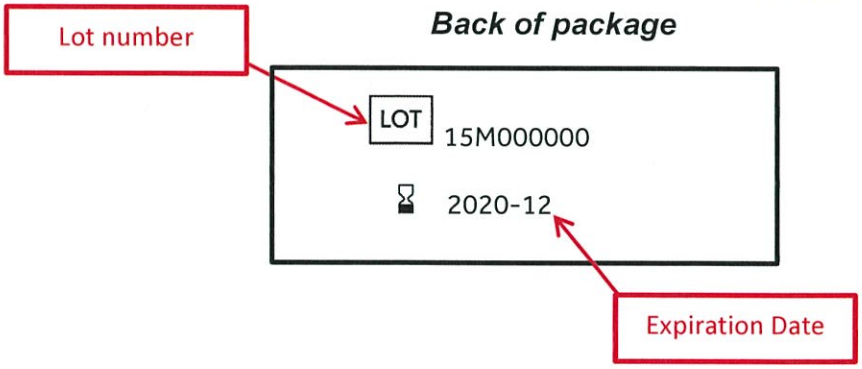
This voluntary recall affects only the item codes and lots listed above.

Attachment A

Distinguish affected product by Item Code and Lot Number.

Front of package

Back of package



Required Actions:

1. Please quarantine and discontinue use of the affected item code and lots listed.

2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" and revert back to your local Medtronic Representative.

3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

  Please complete the Covidien Curity Recalled Return Form (attached) and return to your local Medtronic representative together with affected units if any.

- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

  Please complete the Covidien Curity Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Sincerely,

[redacted]

Diana Teo
QA Supervisor
Medtronic

cc: Chairman Medical Board and relevant Head of Departments

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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

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**By E-mail:**
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Even if you have no affected stock to returned, please complete this form and table; return to your local Medtronic contacts stated above

Please tick (either one) only:

☐ No, no affected inventory to be returned.

☐ Yes, affected inventory to be returned

Item code	Product Description	Lot number	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Recall regarding 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 by signing below:

Name: _____ (print) Signature: _____ Date: _____