

URGENT FIELD SAFETY NOTICE

Covidien Curity™ All Purpose Gauze Sponges, Curity™ X-Ray Detectable Laparotomy Sponges, Kerlix™ X-Ray Detectable Laparotomy Sponges, Vistec™ X-Ray Detectable Sponges

March 14, 2016

**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 Covidien Curity™ all-purpose gauze sponges, Curity™ X-Ray detectable laparotomy sponges, Kerlix™ X-Ray detectable laparotomy sponges and Vistec™ X-Ray detectable sponges. This Field Safety Corrective Action (FSCA) is being conducted due to the potential for the sterile barrier to be compromised at the package seal. The use of products with this condition may result in a potentially increased risk for infection. There have been no reports of serious injury associated with this issue.

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

If you have distributed the sterile Curity™, Kerlix™ or Vistec™ products listed on Attachment A, 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 on Attachment A. Lot numbers not included in Attachment A are not affected by this FSCA.

Required Actions:

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

COVIDIEN IRELAND
COMMERCIAL LTD

CORRESPONDENCE
ADDRESS:

BLOCK G, GROUND FLOOR
CHERRYWOOD SCIENCE & TECHNOLOGY PARK
LOUGHLINSTOWN
DUBLIN 18
IRELAND

+353(1) 438-1600(T)
WWW.COVIDIEN.COM

	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 and e-mail it to audrey.doyle@medtronic.com or fax to 01 439 3039. Upon receiving your form, 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 & 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 & contact your Distributor directly to arrange for return of product.	Complete form & 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

This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA).

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information detailed above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative Françoise Soldo by telephone at 33 (0)670 756 301 or by e-mail at francoise.soldo@medtronic.com.

Sincerely,



Subu Mangipudi
Vice President, Quality Assurance
Patient Monitoring and Recovery
Medtronic



Audrey Doyle
RA Specialist,
Email: audrey.doyle@medtronic.com

Attachment A
List of Affected Item Codes and Lot Numbers.

Item Number	Item Description	Lot Number
397310	Curity™ Gauze Sponges, 16 ply 4" x 4" (10.2 cm x 10.2 cm), Sterile 10's in Soft Pouch	All lots beginning with 110000037462 through Lot 120002259962
4034	Kerlix™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 16" x 17" (40.6 cm x 43.2 cm)	All lots beginning with 110000142862 through lot 130002191062X
8047	Curity™ All Purpose Sponges, Non-woven, 4 Ply, Soft Pouch, 4" x 4" (10.2 cm x 10.2 cm)	All lots beginning with 110000233562 through lot 120002651262X
4031	Kerlix™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 17" x 26" (43.2 cm x 66 cm)	All lots beginning with 110000311162 through lot 15J101262X
4037	Kerlix™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 8" x 32" (20.3 cm x 81.3 cm)	All lots beginning with 110000311262 through lot 15G162262X
6022	Curity™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 18" x 18" (45.7 cm x 45.7 cm)	All lots beginning with 110000463762 through lot 15K235262
6056	Curity™ X-Ray Detectable Laparotomy Sponges, Tray Pack, 8" x 36" (20.3 cm x 91.4 cm)	All lots beginning with 110001358162 through lot 15C033262X
6522	Curity™ X-Ray Detectable Laparotomy Sponges, Soft Pouch Pack, 18" x 18" (45.7 cm x 45.7 cm)	All lots beginning with 110000161662 through lot 15G255462X
6534	Curity™ X-Ray Detectable Laparotomy Sponges, Soft Pouch Pack, 12" x 12" (30.5 cm x 30.5 cm)	All lots beginning with 110000476162 through lot 15J070162X
6545	Curity™ X-Ray Detectable Laparotomy Sponges, Soft Pouch Pack, 4" x 18" (10.2 cm x 45.7 cm)	All lots beginning with 110001420362 through lot 15C151862X
6556	Curity™ X-Ray Detectable Laparotomy Sponges, Soft Pouch Pack, 8" x 36" (20.3 cm x 91.4 cm)	All lots beginning with 100000055262 through lot 15B223462X
7319	Vistec™ X-Ray Detectable Sponges, 16 Ply, 8" x 4" (20.3 cm x 10.2 cm)	All lots beginning with 100000010062 through lot 15J162962X
7321	Vistec™ X-Ray Detectable Sponges, 24 Ply, 8" x 4" (20.3 cm x 10.2 cm)	All lots beginning with 100000009962 through lot 15J163262X

Attachment B

Sample Label - Distinguish affected product by Item Code and Lot Number.

COVIDIEN™

REF 8047

Curity™

All Purpose Sponges

Non-woven, 4 Ply, Soft Pouch
4" x 4" (10.2 cm x 10.2 cm)

Compresses universelles

Non tissées, 4 plis,
pâche souple

Universalkompressen
Vlies, 4-lagig, weicher Beutel

Compresso multilasa
Non tessute, a 4 strati, busta soffice

Compressas multilasa
Ne tīnāruotas, 4 ragas, baltas šlaidas

Universella kompresser
Fiber, 4 skikt, mjukt påse

Universelle doppere
Non-woven, 4-lags, zachle zak

Compressas multilases
Molekulāras, 4 kamadas,
Baltā mada

STERILE EO

REFP

**Do not use if
package is opened
or damaged**

Single use

CE
0123

© 2011 Covidien. Made in USA.
Covidien Inc, 15 Hampshire Street,
Mansfield, MA 02048 USA. Covidien
Ireland Limited, IDA Business & Technology
Park, Tullamore. AG62958245

10

FPO

(01)10884521060494

URGENT MEDICAL DEVICE Field Safety Corrective Action

Covidien Curity™ All Purpose Gauze Sponges, Curity™ X-Ray Detectable Laparotomy Sponges,
Kerlix™ X-Ray Detectable Laparotomy Sponges, Vistec™ X-Ray Detectable Sponges

VERIFICATION FORM

PLEASE COMPLETE THIS FORM IN ITS ENTIRETY

14 March 2016

Customer Contact Details	Medtronic Contact Details
Hospital Name: Covidien/Medtronic Account Number:	To: Medtronic
Collection Address: Department: Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	Address: Block G, Ground Floor, Cherrywood Technology Park, Loughlinstown, Dublin 18
Telephone:	Telephone: 01 4381609
Fax:	Fax: 01 439 3039
E-mail:	E-mail: audrey.doyle@medtronic.com

Item Codes: Refer to attachment A of the Urgent Field Safety Notice.

Please list the quantity of affected product at your facility, if you have no inventory, please tick the box below.

No Inventory (Please check)

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Boxes) Please specify

- **Please complete this form and return it to Medtronic even if you have no affected inventory**

Information for the courier:

Number of parcels to collect: _____

Weight: < 45kg > 45kg

By signing this form I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding-specific production lots of the Covidien Curity™ All Purpose Gauze Sponges, Curity™ X-Ray Detectable Laparotomy Sponges, Kerlix™ X-Ray Detectable Laparotomy Sponges and Vistec™ X-Ray Detectable Sponges dated 14 March, 2016

Customer Name: (Please Print)	Signature:	Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- **This action is being taken with the knowledge of the Irish Competent Authority, The Health Products Regulatory Authority (HPRA).**