Medtronic
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USA
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URGENT FIELD SAFETY NOTICE
Devon™ Light Glove

January DD, 2017

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

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling its Covidien Devon™ Light Gloves and non-sterile sub assembly kits that contain the Devon™ Light Glove. All lot numbers beginning with 630XXXXXXX and lower are affected.

Customers have reported that, on rare occasion, the Devon™ Light Glove may split upon application to the Devon™ Light Handle Adapter. Some of the reported splits resulted from difficult application of the Light Glove to the Handle Adapter. More recently, clinicians have reported finding splits in the Light Glove following surgery completion, where no difficulty in application of the Light Glove was encountered or finding splits directly out of the package. A split in the Light Glove causes a breach in the sterile field and can increase the potential for infection. Medtronic has received notice of two patient adverse events (infection) in which Light Glove splits were found at the conclusion of surgery.

Medtronic requests that you quarantine and return any unused products of the item codes listed on Attachment A. Unused products should be returned as described in the Required Actions section below. If you have distributed the Devon™ Light Glove products listed on Attachment A, please promptly forward the information from this letter to those recipients. All unused products must be returned.

This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: XXXXX@Medtronic.com

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Required Actions:

1. Please quarantine and discontinue use of the affected item codes listed on Attachment A.
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.

Please forward this Field Safety Notice to all those who need to be aware of it within your organisation and to all persons and/or organisations where these devices have been transferred.

Medtronic is committed to providing you with the most up-to-date and relevant information with respect to the use of our products. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (XXX) XXX-XXXX.

Sincerely,

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

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Attachment A: Affected Item Codes

Item Number	Description
31141784	K-1960-S STANDARD MINI-KIT
31140208	3611 FLEXBL LITE GLOVE 1EA/PKG
31140216	3613 LITE GLV-FLEXIBLE 3EA/PKG
31140257	3612 LITE GLV-FLEXIBLE 2EA/PKG
571711	NS-3600-B LITE GLOVE 1000/CASE

Attachment B

Distinguish affected product by Item Code