

URGENT FIELD SAFETY NOTICE
Devon™ Light Glove

October X, 2016

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

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a labeling update for specific item codes of Covidien Devon™ Light Gloves.

Customers have reported that on rare occasion (complaint rate less than 2/100,000 or 0.0017%), the Devon™ Light Glove may split upon application to the Devon™ Light Handle Adapter. A subset of these splits reportedly resulted from a difficult application of the glove to the handle adapter. A split in the glove can potentially lead to a breach in the sterile barrier between the glove and the handle adapter. While there have been no reports of serious injury associated with these rarely occurring splits, Medtronic is adding the following statement to the Devon™ Light Glove Instructions for Use in order to help OR staff ensure that the sterile field is maintained.

After application, inspect the Light Glove for barrier integrity.

Actions required by you:

- Please promptly forward this information to all customers you have distributed the affected devices listed on Attachment A.
- The list of items on Attachment A includes the single sterile item codes and the bulk non sterile item code.

This action is being taken with the knowledge of the (insert applicable Competent Authority).

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-XXX.

Sincerely,



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

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

The image shows the packaging for COVIDIEN Devon Light Glove. On the left, the COVIDIEN logo and 'Devon Light Glove' branding are visible, along with multilingual descriptions: 'Leuchtenschutz', 'Copripugnatura per lampada', 'Cobertor de luz', 'Lamphandtagsskydd', 'Overtrek voor lamphandgreep', 'Suporte para luzes', 'Valon suojus', 'Lampehandske', 'Κάλυμμα λαβής φωτός', and 'Lampholder'. On the right, a 'REF 31140208' label is highlighted with a red box and labeled 'Item number'. Below it, a 'LOT XXXXXXXXXXXXX' label is highlighted with a red box and labeled 'Lot number'. A 'Use by YYYY-MM-DD' label is also present. A box icon with the number '100' indicates the quantity. At the bottom, a barcode area is enclosed in a dashed pink box, containing 'GTIN - FPO' (0110884527011704) and 'EXP/LOT - FPO' (17YYMMDDN0XXXXXXXXXX). A large diagonal watermark 'Approved - Uncirculated Version' is overlaid on the image.

URGENT FIELD SAFETY NOTICE

**Acknowledgement and Receipt Form—Response is Required
Devon™ Light Glove**

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Covidien Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

I have read and understand the instructions provided and acknowledge receipt of the Urgent Field Safety Notice regarding the Devon™ Light Glove device by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

Name: (print) Signature: Date:

If you have any questions regarding this Urgent Field Safety Notice, please contact your Medtronic representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO: Insert Email address or Insert Fax Telephone Number