

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

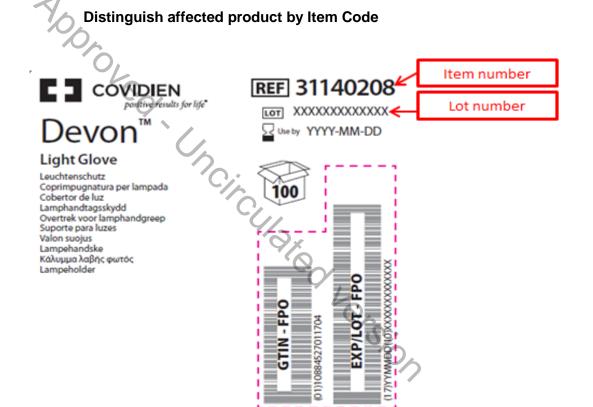
Page 1 of 3

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| ltem Number | Description | | |
|----------------|-------------------------------------|--|--|
| 31141784 | K-1960-S STANDARD MINI-KIT | | |
| 31140208 | 3611 FLEXBL LITE GLOVE 1EA/PKG | | |
| 31140216 | 3613 LITE GLV-FLEXIBLE 3EA/PKG | | |
| 31140257 | 0257 3612 LITE GLV-FLEXIBLE 2EA/PKG | | |
| 571711 | NS-3600-B LITE GLOVE 1000/CASE | | |

Attachment A: Affected Item Codes

Attachment B



Page 2 of 3

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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 #: | 0 ₁ | | |
| Email: | · OL | | |
| Account Name: | <u> </u> | | |
| Covidien Account Number: | 0 | | |
| Account Address: | | Circ | |
| City: | Zip Code: | | |
| I have read and understand the i regarding the Devon™ Light Glo | | | e Urgent Field Safety Notice |
| 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 N | lotice, please contact your Medt | ronic representative. |
| PLEASE EMAIL OR FAX THIS ACKNO | WLEDGEMENT TO: <mark>Inseri</mark> | <u>:</u> Email address or Insert Fax Tele | phone Number |