

**URGENT FIELD SAFETY NOTICE**  
**Devon™ Light Glove**

January 09th, 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 Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Regulatory Affairs at: [Christine.Aldenbeck@medtronic.com](mailto:Christine.Aldenbeck@medtronic.com)

**Devon™ Light Glove  
Field Safety Corrective Action (FSCA)  
Cover Letter**

January 9<sup>th</sup>, 2017

Dear Valued Customer:

This cover letter is to advise you that Medtronic is recalling all lots of former 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.

You will find all the details in the official communication, Field Safety Notice, here attached.

With this cover letter we also want to provide you with more practical details about this FSCA:

Please review the information provided to determine if notification of this FSCA needs to be reported to your local Competent Authority. For the custom kits that you have assembled and distributed to your customers using the affected Light Glove, we ask that you notify your customers of this FSCA. Your customers should reply to you regarding the kits you produced, not to Medtronic. Once all your customers have responded to this action you should complete the appropriate returns verification form & forward it to Medtronic at: [Christine.Aldenbeck@medtronic.com](mailto:Christine.Aldenbeck@medtronic.com). Review and determine if notification of this FSCA may need to be reported to your local Competent Authority.

For product that you purchased directly from Medtronic, please respond to Medtronic using the attached form. All kit packer customers must reply to Medtronic via this form, WHETHER you have affected, unused product at your site OR NOT.

Your response is vital to our monitoring of the effectiveness of this recall.

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative, Henri Laitervo, at +31 6 53 92 69 18, [henri.laitervo@medtronic.com](mailto:henri.laitervo@medtronic.com)

We sincerely apologize for any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



## Required Actions:

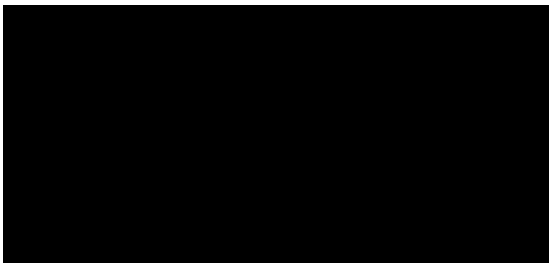
1. Please quarantine and discontinue use of the affected item codes listed on Attachment A.
2. Please return affected product as follows:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased <b>directly</b> 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"	<u><a href="mailto:Christine.Aldenbeck@medtronic.com">Christine.Aldenbeck@medtronic.com</a></u>

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 Henri Laitervo at +31 6 53 92 69 18 [henri.laitervo@medtronic.com](mailto:henri.laitervo@medtronic.com)

Sincerely,



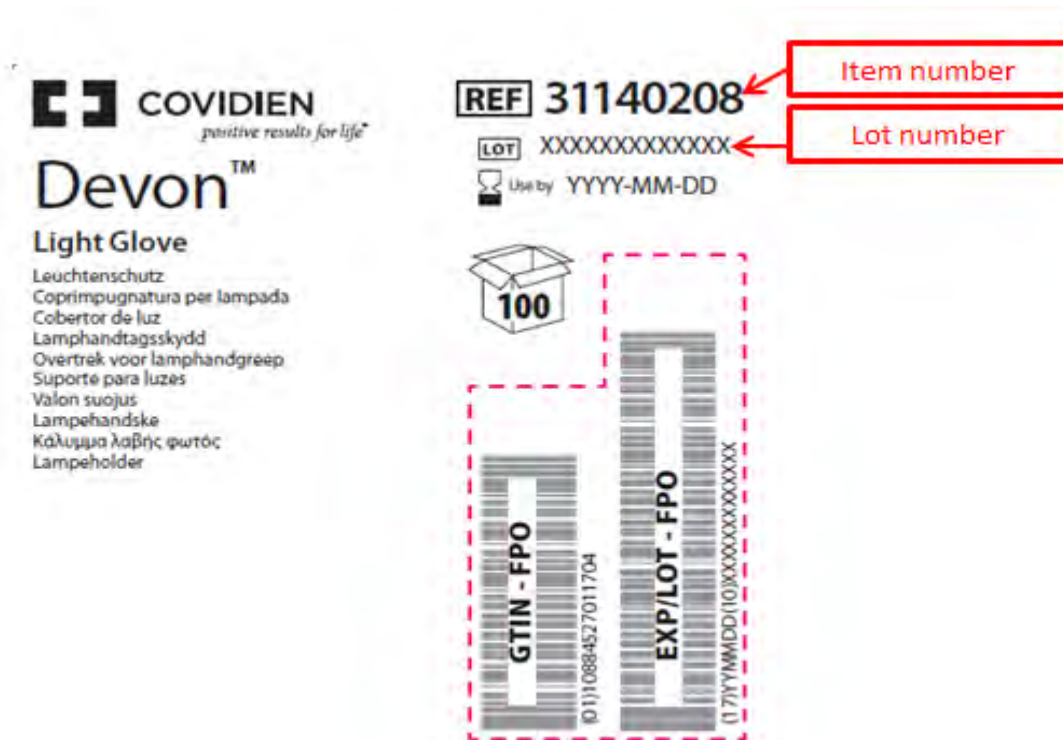
Medtronic

## 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



## Urgent Field Safety Notice

### Address

Sales Division

Sales Division

Lohmann & Rauscher GmbH & Co.KG

Westerwaldstr. 4 · D-56579 Rengsdorf

Kurzz. Tel.: 99-XXXX/ Fax: 99-XXXX

Email: xxxx.xxxx@de.LRmed.com

Date

## Urgent Field Safety Notice

### due to increased potential for infection during surgical procedure

#### Covidien Devon™ Light Glove in KitPack® OP-Setsystems

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about following Field Safety Corrective Action (FSCA) of Covidien/Medtronic for the following product:

#### Covidien Devon™ Light Glove

Covidien Devon™ Light Gloves is a disposable cover used in operating rooms and similar settings to cover the handles of surgical lights.

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.

The products were integrated in our KitPack® OP-Setsystems.

In terms of patient safety, not to stop the work in the operation theatre as well as to guarantee the patient care following corrective actions has to be performed:

- Do not use the Devon™ Light Glove in the KitPack. Please discard it before you start your surgery.
- We will add on our setsystems in our warehouses following additional label: Attention! Do not use the Covidien Devon™ Light Glove. Discard it.

The other components of KitPack® OP-Setsystems are not affected and can be used as usual. Of course, we will recommend you alternatives to the Devon™ Light Glove if necessary, in order to best bridge a possible supply bottleneck.

Our responsible authority agreed with this procedure.

Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

If you have delivered the product to third parties, please forward a copy of that information to them.

We thank you in advance for your cooperation and apologize for any inconvenience.

Yours truly,  
Lohmann & Rauscher GmbH & Co KG  
i.V. / On behalf of    i.V. / On behalf of

XXXXYY  
Sales department

XXXXYY  
Regional Vigilance Officer

Attachment:  
Urgent Field Safety Notice – due to increased potential for infection during surgical procedure

**Urgent Field Safety Notice!**

**Date**

due to increased potential for infection during surgical procedure

**(via Fax to 02634 - 99 xxxx)**

**Sender:** Lohmann & Rauscher GmbH & Co. KG  
Westerwaldstr.4  
D-56579 Rengsdorf

**Addressee:** Adresse  
Xxx  
xxx  
& all users who use the below mentioned products.

**Description:** Urgent Field Safety Notice – due to increased potential for infection during surgical procedure

**Covidien Devon™ Light Glove in KitPack® OP-Setsystems**

Product	REF	Lot
KitPack XXXX	XXX	XXXXX

**If necessary please add a L&R contact person**

**Corrective Actions:**

We ask you not to use the contained Covidien Devon™ Light Glove anymore.

Please **discard** the contained Covidien Devon™ Light Glove in the KitPack® OP-Setsystems.

Please inform your employees who use the product of this Field Safety Notice and confirm to us that the product is not used anymore.

The undersigned confirms (please tick):

- that he does not use the Covidien Devon™ Light Glove
- that he has informed all involved persons about this urgent field safety notice
- that he does not possess the above mentioned products anymore,
- that he has not given the above mentioned products to third parties,
- that if he has given the above mentioned products to third parties, he has informed the third parties about this urgent field safety notice not to use the Covidien Devon™ Light Glove ,

Date / Signature : \_\_\_\_\_

Printed Name: \_\_\_\_\_

Position: \_\_\_\_\_

Department / Institution: \_\_\_\_\_

Phone and Email: \_\_\_\_\_