www.medline.com/de

Medline International Germany GmbH
Wilhelm-Sinsteden-Straße 5 – 7
D-47533 Kleve
Tel: +49 (0) 2821 – 7510 – 0
Fax: +49 (0) 2821 – 7510 – 7802

Regulatory Affairs
gmb-eu-ra-kleve@medline.com
Quality Department
Tel: +49 (0) 2821 – 7510 – 7528
Fax: +49 (0) 2821 – 7510 – 7804

Medline International Germany GmbH - Wilhelm-Sinsteden-Str. 5-7 - D-47533 Kleve

Kleve, 20th. Januar 2017

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

For the attention of: the Pharmacist responsible for medical device vigilance and the Biomedical Engineering Department.

Object: SECURITY INFORMATION of Covidien Devon™ Light Gloves used in Sterile Procedure Trays manufactured by Medline International France

Medline reference:	FSCA-17/01
Description:	Sterile Procedure Trays containing Devon™ Light Gloves
Product Codes concerned:	See details in the **table 1** below.

Dear Customer,

This letter is to advise you that Medtronic is recalling all lots of former Covidien Devon™ Light Gloves included in Medline Sterile Procedure Trays.

Medtronic's customers have reported that, on rare occasions, the Devon™ Light Glove may split upon application to the Devon™ Light Glove. 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 list of Sterile Procedure Trays delivered to your facility is mentioned in Table 1.

Lots that are not concerned:
Sterile Procedure Trays with Lot numbers that start with 10…. greater than 108976 are not concerned.
Sterile Procedure Trays with Lot numbers that start with 6 or 7…. greater than 711209 are not concerned.

REF

Actions to be taken :

Step 1)
Please urgently check your stock and promptly put on quarantine the concerned Sterile Procedure Trays listed in Table 1.

Step 2)
As soon as Medline is informed on the quantity of Sterile Procedure Trays concerned, (indicated in the acknowledgement form to be returned) Medline will send you 'warning' labels, and Medline requests you to put the label on each of the Sterile Procedure Trays concerned still in your stock. Please indicate your address and how many 'warning' stickers you require. Medline will send you labels in sufficient quantity to be applied visibly on the concerned Sterile Procedure Trays.
The 'warning' sticker is to inform the concerned users that the Devon™ Light Glove included has to be removed from the Sterile Procedure Tray. The other components in the Sterile Procedure Tray can be used safely.

Step 3)
Please complete and send back the enclosed attachment by either fax or email as soon as possible, but **not later than February 14th, 2017** with information about the quantity in stock and where to send the required amount of 'warning' labels.

Step 4)
The Sterile Procedure Trays can be released and used once they have been labelled with a 'warning' sticker.

Step 5)
Discard all Devon™ Light Gloves that have been removed from the used Sterile Procedure Trays.

All stock of your trays currently in our warehouses, will be labelled with the 'warning' label.
New production of Sterile Procedure Trays previously containing Devon™ Light Glove will be manufactured with an alternative Light Glove.

Yours sincerely

Sabine Koroma
Vigilance specialist
Quality and Regulatory Affairs Department
On behalf of Medline Int. Germany GmbH

Please send this Acknowledgement receipt
before 14th February 2017 to RA Kleve:

Fax: +49 2821 7510 7822 or
E-mail: gmb-eu-ra-kleve@medline.com

Reference: FSCA-17/01

Table 1:
Sterile Procedure Trays references delivered to your hospital which are concerned by this notification

REF

Sterile Procedure Trays with Lot numbers that start with **10….** greater than **108976** are not concerned.

Sterile Procedure Trays with Lot numbers that start with **6 or 7….** greater than **711209** are not concerned.

☐ I acknowledge the receipt of the notification relative to the FSCA-17/01.

☐ I confirm that our stock has been checked and the following Sterile Procedure Trays contain the Covidien Devon™ Light Glove. This component will be discarded before use of the Sterile Procedure Tray.

REF	LOT	Quantity on stock

Number of warning labels required and delivery address if it differs from letterhead: .....

☐ I have read and understand the instructions provided and acknowledge receipt of the FSCA-17/01 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.

Date:

Name:

Position:

Facility:

Address:

Country

Customer Number:

Telephone:

Fax/Email:

Signature: