Ref: 50062004

Date: 20 January 2017

URGENT FIELD SAFETY NOTICE

Commercial name of the product: ProcedurePak® trays containing Light Handle Cover (Devon™ Light Glove)
Component code: 2301760-00
Type of action: Field Safety Notice
Attention: Theatre Manager, Distributor
Details of affected devices: For more details – see attached list of affected devices

Dear Customer,
At Mölnlycke Health Care, patient safety is our highest priority. We are writing to inform you about a Field Safety Corrective Action (FSCA) regarding Light Handle Cover (Devon™ Light Glove), supplied by Medtronic. Mölnlycke Health Care includes their Light Handle Cover in some of the ProcedurePak® trays that are provided to you.

You may have received a FSN (50058318) from Mölnlycke Health Care in October 2016, with information that Medtronic updated the IFU of the component. Medtronic has since been made aware of two patient adverse events and decided to recall this product.

Medtronic´s 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 after surgery completion, where no difficulty in application of the Light Glove was encountered or finding splits directly out of the package. Medtronic has received notice of two patient adverse events (infection) in which Light Glove splits were found at the conclusion of surgery.

If you have any affected ProcedurePak® trays in your inventory, we ask you **not to use them** and to follow the instructions below.

About the potential risk to health
A split in the Light Glove causes a breach in the sterile field and can increase the potential for infection.

What you need to do
1. Please use the attached list to identify and isolate all affected, unused ProcedurePak® trays at your facility.
2. Please affix a copy of this Field Safety Notice to each product and make sure that its contents are brought to the attention of all relevant personnel.
3. At the point of use the user is required to remove the Light Handle Cover from the ProcedurePak® and **discard the Light Handle Cover.** Then replace with Barrier® single packed sterile version that will be provided to you.
4. Please complete the attached Confirmation form and **e-mail/fax** back per its instructions. Even if you no longer have any concerned ProcedurePak® trays, Mölnlycke Health Care needs to be sure that all customers are aware of the situation.
5. Mölnlycke Health Care will contact you to arrange Barrier® single packed sterile replacement product to be shipped to you, as soon as you return the confirmation form.
6. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly.
7. If you are a distributor, please inform your customers by sending them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly and return the confirmation form to you.

In addition, Mölnlycke Health Care appreciates your help in collecting data on product complaints and/or incidents related to the concerned products. Please, follow the reporting procedures established by your facility.

Any questions?
Please contact your local Mölnlycke Health Care Customer Service or Account Manager if you have any questions or concerns regarding this FSN. You may also contact:

Vigilance: Linda Magnusson (vigilance@molnlycke.com) or +46 31 352 3733
Mölnlycke Health Care confirms that this notice has been notified to the appropriate Regulatory Agencies.
Thank you for your time and attention. Mölnlycke Health Care apologies for any inconvenience.

Sincerely,

Mölnlycke®

CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Linda Magnusson, Global Product Complaints Manager
Mölnlycke Health Care,
Box 13080, SE-402 52
402 52 Gothenburg, Sweden

Fax +46 31 722 34 00
E-mail: vigilance@molnlycke.com

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Product code	Batch/LOT	Quantity discarded (pieces)

I have read this Field Safety Notice, understood the actions required and have acted accordingly.
If you are a distributor: I return the completed confirmation form and by that ensure that the end users have received the Field Safety Notice and acted accordingly.

PLEASE COMPLETE ALL SECTIONS

NAME : _____

POSITION : _____

HOSPITAL/INSTITUTE : _____

SERVICE/ DEPARTMENT : _____

CITY : _____ POSTCODE / ZIP : _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

EMAIL ADDRESS : _____

DELIVERY ADDRESS IF APPLICABLE : _____

SIGNATURE : _____

DATE : _____