



Date: 24 October 2016

### URGENT FIELD SAFETY NOTICE

**Commercial name of the product:** ProcedurePak® trays containing Light Handle Cover (Devon™ Light Glove)  
**Type of action:** Field Safety Notice  
**Attention:** Theatre Manager, Distributor  
**Details of affected devices:** See List Provided

**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 ProcedurePak® trays containing Light Handle Cover (Devon™ Light Glove).

Mölnlycke Health Care has been informed by the supplier Medtronic that some of their 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, Mölnlycke Health Care 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.*

**What you need to do**

1. Please use the attached list to identify and isolate all affected, unused ProcedurePak® trays or kits at your facility.
2. Please affix a copy of this Field Safety Notice (FSN) to each ProcedurePak® trays or kits and make sure that its contents is brought to the attention of all relevant personnel to read before use.
3. Please complete the attached Confirmation form and **e-mail/fax** back per its instructions – even if you no longer have any concerned ProcedurePak® trays or kits. Mölnlycke Health Care needs to be sure that all customers have received this communication.
4. If you have forwarded any affected products to your internal healthcare institutions, please send them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly.
5. 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.

**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: Anette Stenson ([vigilance@molnlycke.com](mailto:vigilance@molnlycke.com)) or +46 31 722 31 66

Mölnlycke Health Care confirms that this notice has been sent to the appropriate Regulatory Agencies. Thank you for your time and attention. Mölnlycke Health Care apologies for any inconvenience.

Sincerely,



### CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Anette Stenson, Global Director Post Market Quality  
Mölnlycke Health Care,  
Box 130 80, SE-402 52  
Göteborg, Sweden

Fax +46 31 722 34 00  
E-mail: [vigilance@molnlycke.com](mailto:vigilance@molnlycke.com)

Ref – 50058318

I have read this Field Safety Notice, understand 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 : \_\_\_\_\_

SIGNATURE : \_\_\_\_\_

DATE : \_\_\_\_\_