REF: 50057487

MÖLNLYCKE HEALTH CARE

Date: 29 September 2016

URGENT FIELD SAFETY NOTICE

Commercial name of the product:	ProcedurePak® kits and trays containing cohesive bandages (components 2303205-00 & 2301997-00)
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 inform you about a Field Safety Corrective Action (FSCA) regarding ProcedurePak® kits and trays containing cohesive bandages (ref: 2303205-00 Bandage 15cm 4,5m Cohesive Flesh & 2301997-00 Bandage 10cm 4,5m Cohesive Tan).

Mölnlycke Health Care identified an error with the label of the Insert Card of the above referenced products. The information on the label incorrectly states that the ProcedurePak® tray does not contain "Natural Rubber Latex". However, cohesive bandages within these trays do contain latex. The label should advise that the tray **does contain latex**.

Please ensure that the affected ProcedurePak® kits and trays are not used by/on anyone sensitive to latex. Any incidents related to the use of the affected products should be reported immediately to Mölnlycke Health Care.

About the potential risk to health
If the concerned product is used by a latex sensitive person an allergic reaction may follow.

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 are a distributor or have forwarded any affected trays or kits to other healthcare institutions, please send them a copy of this FSN together with the list of concerned products, make sure they act accordingly.

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) 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,

Anette Stenson
Global Director Post Market Quality

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

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I have read this Field Safety Notice, understand the actions required and have acted accordingly.
If you are a distributor: I confirm 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 : _____

UPLIFT ADDRESS IF APPLICABLE : _____

SIGNATURE : _____

DATE : _____