



Date: 09 July 2018

URGENT FIELD SAFETY NOTICE

Commercial name of the product: Mölnlycke® Procedure trays
Type of action: Product recall
Attention: Theatre Manager
Details of affected devices: For more details – see attached list of affected devices

Dear Customer,

At Mölnlycke, patient safety is our highest priority. We are writing to inform you about a Field Safety Corrective Action (FSCA) regarding one component manufactured by B. Braun Surgical, S.A. Mölnlycke has recently been informed by B. Braun Surgical that they are performing a recall on a component which Mölnlycke includes in some of the Mölnlycke® Procedure trays that are provided to you.

The reason for this recall is because B. Braun Surgical, S.A has detected that some units of their component have a potential packaging integrity issue and as a consequence the product sterility could be compromised.

In accordance with B. Braun Surgical FSN, Mölnlycke has decided to recall all Mölnlycke® Procedure trays with affected component.

If you have any affected Mölnlycke® Procedure trays in your inventory from the list, we ask you to return them and **not use** them.

What you need to do

1. Please use the attached list to identify and isolate all affected, unused Mölnlycke® Procedure trays at your facility.
2. Please complete the attached confirmation form and **e-mail/fax** back per its instructions. Even if you no longer have any concerned Mölnlycke® Procedure tray, Mölnlycke needs to be sure all customers are aware of the situation.
3. Mölnlycke will contact you and arrange for collection of the product(s) from your facility, as soon as you return the confirmation form. Mölnlycke will issue a credit for the goods returned.
4. 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.
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.

In addition Mölnlycke 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.

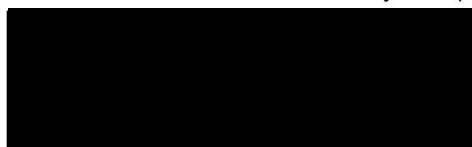
Any questions?

Please contact your local Mölnlycke 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 confirms that this FSN has been notified to the appropriate Regulatory Agencies. Thank you for time and attention, and Mölnlycke apologises for any inconvenience.

Sincerely,



Linda Magnusson,
Global Product Complaints Manager

CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Linda Magnusson, Global Product Complaints Manager
Mölnlycke Health Care,
Box 130 80, SE-402 52
Gothenburg, Sweden

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

Ref – 2018-06 (01)

Product code	Batch/LOT	Quantity Quarantined (trays)

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 : _____

UPLIFT ADDRESS IF APPLICABLE: _____

SIGNATURE : _____

DATE : _____