



Date: 22 September 2017

URGENT FIELD SAFETY NOTICE

Commercial name of the product: Mölnlycke® Procedure trays containing Maternity Pad
Codes: 2300491-00 (component code)
Type of action: Product recall
Attention: Theatre Manager, Distributor
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 Maternity Pad supplied by Synergy Health (UK) Limited. Mölnlycke includes their Maternity Pad in some of the Mölnlycke® Procedure trays that are provided to you.

Mölnlycke has been informed by the supplier Synergy Health (UK) Limited that they are recalling one specific code and production lot of Maternity Pads. Synergy Health (UK) Limited is conducting this recall due to small amounts of debris found in finished packaged products, originated from sources including Synergy packaging equipment and incoming goods. The products are sterilized following packaging, nonetheless Synergy is asking Mölnlycke to recall all the trays containing this component.

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

About the potential risk to health

According to Synergy Health (UK) Limited this incidental debris is unlikely to present a hazard to patients or users. Nonetheless, Synergy Health is recalling these products as they do not meet their quality standards. There have been no reports of serious injury associated with these issues.

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 apologies for any inconvenience.

Sincerely,

A handwritten signature in blue ink that reads "Linda Magnusson".

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 – 50065926

Product code	Batch/LOT	Quantity Quarantined (pieces/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 : _____

Field Safety Notice: Ref 50065926

Affected Batch numbers for Fannin Healthcare

Product name	Product number	Batch number
C-Section Pack - UCHG Galway	97005644-04	17334614