REF: 50064341

Mölnlycke®

Date: 03 May 2017

URGENT FIELD SAFETY NOTICE

Commercial name of the product:	Barrier® Sets
Codes:	60611-01, 60612-01, 60614-01, 60615-05, 60205-01, 60302-01, 698780-08, 699175-08, 699180-08
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 Barrier® Sets.

Mölnlycke has identified a potential safety issue. During an investigation of a product complaint, micro holes has been detected after immersion test on some of Barrier® Sets.
Despite that all Barrier® Sets are produced in a clean environment and then sterilised we cannot guarantee a sterile package. Mölnlycke is taking this matter seriously and is now performing a **recall** concerning the devices listed in the attached document.

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

About the potential risk to health
A sterile device is aimed at keeping the operative field as sterile as possible and prevent postoperative infection. The packaging provides a microbial barrier and allows aseptic presentation of the product unit at the point of use. As a sterile product cannot be guaranteed there is a risk for possible contamination, which may lead to infection.

What you need to do

1. Please use the attached list to identify and isolate all affected, unused Barrier® Sets 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 Barrier® Sets, 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) trom 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: …… (vigilance@molnlycke.com) or +46 31 352 3733

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

Sincerely,

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CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

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

Fax +46 31 722 34 00
E-mail: viqilance@molnlyck.ecom

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Product code	Batch/LOT	Quantitv Quarantined (pieces/travs)

1 have read this Field Safety Notice, understand the actions required and have acted accordingly.
If you area distributor: 1 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 : . . . .