



**Mölnlycke**<sup>®</sup>

Date: 27 April 2017

## URGENT FIELD SAFETY NOTICE

**Commercial name of the product:** Brennen® Skin Graft Mesher  
**Codes:** 131600, 131601, 131602, 131603, 131604  
 131500, 131501, 131502, 131503, 131504, 131506  
**Type of action:** Field Safety Notice for Stop Usage and Tag as Out of Service  
**Attention:** Sterilization Services  
**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 regarding the Brennen® Skin Graft Mesher.

Mölnlycke has identified a potential safety issue. During an internal investigation, we detected failures in a sterilization validation for the Brennen Skin Graft Mesher. With the current sterilization instructions we cannot assure sterility of the mesher. Mölnlycke is taking this matter very seriously and is now performing a Field Safety Notification concerning the devices listed in the attached document.

We have identified you as a customer who has inventory of the Brennen Skin Graft Mesher. Based on that information, we request that you immediately STOP usage of those meshers and tag them with the supplied Tag #FSN 2017-03(03) until further guidance is provided.

### About the potential risk to health

Sterilization is aimed at assuring the device is free from contamination and to prevent postoperative infection risk. Our Medical Director and team have been monitoring this issue closely and their analysis indicates minimum probability of risk to patients. However, we recommend you follow the instructions below immediately with regard to your mesher device.

### What you need to do

1. Please ensure that all relevant staff are made aware of this Field Safety Notice.
2. Please apply Tag #FSN 2017-03(03) accompanying this letter to the Brennen Skin Graft Mesher(s) and **STOP usage** until further direction is made available. Alternatively, you may use appropriate labelling and/or quarantine measures under your own quality system.
3. Please complete the attached confirmation form and **e-mail/fax** back per its instructions. Even if you no longer have any Brennen Skin Graft Meshers, Mölnlycke needs to ensure all customers are aware of the situation.
4. If you have forwarded any affected devices to other healthcare institutions, please send them a copy of this Field Safety Notice together with the list of concerned products. Please ensure they act accordingly and return the confirmation form to you.
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. Please ensure they act accordingly and return the confirmation form to you.

Please continue to follow the reporting procedures established by your facility should you need to report any issues.

### Any questions?

Please contact your local Mölnlycke Customer Service or Account Manager if you have any questions or concerns regarding this Field Safety Notice. You may also contact:

Vigilance: Linda Magnusson ([vigilance@molnlycke.com](mailto:vigilance@molnlycke.com)) or +46 31 352 3733

Mölnlycke confirms this notice has been notified to the appropriate Regulatory Agencies.

Thank you for time and attention, and Mölnlycke apologies 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 13080, SE-402 52  
 402 52 Gothenburg, Sweden

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

**Ref – 2017-03(03)**

Product code	Serial Number	Product Tagged and Placed on Hold (please initial and date once completed)

I have read this Field Safety Notice, understand the actions required and have acted accordingly.  
If you are a distributor: I returned the completed confirmation form and ensured 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 : \_\_\_\_\_

DELIVERY ADDRESS IF APPLICABLE : \_\_\_\_\_

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

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