



Date: 2015-11-04

**URGENT FIELD SAFETY NOTICE**

**Commercial name of the product:** BARRIER® EasyWarm®  
**Type of action:** Advisory Notice  
**Attention:** Theatre Manager, Distributor  
**Details of affected devices:** See List provided

**Dear Customer**

At Mölnlycke Health Care, patient safety is our highest priority. Therefore we are writing to inform about a Field Safety Notice (FSN) related to our BARRIER® EasyWarm® products.

**About the problem**

Mölnlycke Health Care BARRIER® EasyWarm® product contains warmers to provide heat. According to a stability study the warmers have passed its intended performance for all time points except for 3,5 years, where the product did not give sufficient amount of heat. Based on this Mölnlycke Health Care gives an Advisory Notice that products that are 2 years old or older should be scrapped and will be replaced free of charge by Mölnlycke Health Care.

**About the potential risk to health**

The BARRIER® EasyWarm® product does not give sufficient amount of heat according to the shelf life stated on the packaging.

**What you need to do**

1. Please use the attached list to identify all affected, unused BARRIER® EasyWarm® products at your facility.
2. Please make sure that everyone knows not to use BARRIER® EasyWarm® products that are two years old or older. Those products should be scrapped and replaced free of charge by Mölnlycke Health Care.
3. Please complete the attached Confirmation form and **e-mail/fax back** per its instructions – even if you no longer have any affected BARRIER® EasyWarm® products. We need to be sure that all our customers have received this communication.
4. If you have forwarded any BARRIER® EasyWarm® products to other healthcare institutions, please send them a copy of this letter and along with the list of affected products.

**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](mailto:vigilance@molnlycke.com)) or +46 (0) 31 722 3166

Mölnlycke Health Care confirms that this notice has been notified to the appropriate Regulatory Agency.

Thank you for your time and attention, and we apologize for any inconvenience.

Sincerely,

Thomas Pettersson  
Global Vigilance Manager

Eiler Anderson  
Global Director of Regulatory Affairs (acting)

## CONFIRMATION FORM

**PLEASE COMPLETE AND RETURN THIS FORM TO:**

Anette Stenson  
Mölnlycke Health Care,  
Box 130 80, SE-402 52  
Göteborg, Sweden

Fax +46 (0) 31 722 34 00  
E-mail: [vigilance@molnlycke.com](mailto:vigilance@molnlycke.com)

**Ref - 50052635**

I have read this Field Safety Notice and I understand the actions required.

NAME : \_\_\_\_\_

POSITION : \_\_\_\_\_

HOSPITAL/INSTITUTE : \_\_\_\_\_

CITY : \_\_\_\_\_

COUNTRY : \_\_\_\_\_

HOSPITAL CONTACT TELEPHONE NUMBER : \_\_\_\_\_

EMAIL ADDRESS : \_\_\_\_\_

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

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

## Details of affected devices

### Instruction

This instruction concerns all products delivered prior to November 9th 2015

Products that are more than two years old needs to be scrapped but will be replaced free of charge by Mölnlycke Health Care.

### **How to identify if the product needs to be scrapped or not**

Deduct one year from the expiry date on the label of the product. If the “new” date has already passed, the product needs to be scrapped.

### **Example**

The label below has an expiry date of June 2016; 2016-06. After deducting one year from this date, the new date is June 2015. As this date has passed, the product needs to be scrapped.

