



Date: 2016-03-15

URGENT FIELD SAFETY NOTICE - AMENDED

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, were 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.
3. Please, immediately scrap products on the list if they are more than two years old. If the product are on the list but not yet two years old, either scrap or if still to be used attach the FSN to each of the affected products. Mölnlycke Health Care will ensure replacement free of charge for any scrapped products in accordance with these recommendation .
4. Please complete the attached Confirmation form and **e-mail/fax back** per its instructions – **even if you have already done this once, so we can be sure that all our customers have received and understood this amended communication.**
5. 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) 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,

A handwritten signature in black ink, appearing to read "Anette Stenson".

Anette Stenson
Global Vigilance Manager

CONFIRMATION FORM II

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

Ref - 50052635

I have read this **amended** 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 – UPDATED

BARRIER® EasyWarm®: 629900

Instruction

This instruction concerns all products delivered prior to November 9th 2015 with the following batch numbers:

MATERIAL	MATERIAL DESCRIPTION	BATCH
629900-00	Active Self Warming Blanket 92x152 cm	14446501
629900-00	Active Self Warming Blanket 92x152 cm	14426502
629900-00	Active Self Warming Blanket 92x152 cm	14426501
629900-00	Active Self Warming Blanket 92x152 cm	14466502
629900-00	Active Self Warming Blanket 92x152 cm	14486501
629900-00	Active Self Warming Blanket 92x152 cm	14466502
629900-00	Active Self Warming Blanket 92x152 cm	14506501
629900-00	Active Self Warming Blanket 92x152 cm	15026502
629900-00	Active Self Warming Blanket 92x152 cm	15086502
629900-00	Active Self Warming Blanket 92x152 cm	15116501
629900-00	Active Self Warming Blanket 92x152 cm	15106501
629900-00	Active Self Warming Blanket 92x152 cm	15186501

629900-00	Active Self Warming Blanket 92x152 cm	15196502
629900-00	Active Self Warming Blanket 92x152 cm	15186502
629900-00	Active Self Warming Blanket 92x152 cm	15326502
629900-00	Active Self Warming Blanket 92x152 cm	15336502

Please, immediately scrap products on the list if more than two years old. If the product are on the list but not yet two years old, please choose if scrap or attach the FSN to each of the affected products. Mölnlycke Health Care will ensure replacement free of charge.

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.

