Ref: 50048919
Date 04.02.2015

URGENT FIELD SAFETY NOTICE

Commercial name of the product:	Wound-EL Dressing Electrode 15x15cm (10x10cm)
Type of action:	**Return of the device**
Attention:	Health Care Professional
Details of affected device:	Please find attached report.

Description of the problem

During internal quality control at Mölnlycke Health Care, it has been found that a low number of packaging of the Wound-EL Dressing Electrode is insufficiently sealed. Although this defect should be visible to the user, if unnoticed, this could lead to the use of an unsterile product.

Mölnlycke Health Care has assessed the issue and advises the health care professional not to use the Dressing Electrode and return the device.

Actions to be taken by the user

1. Please identify and isolate all affected unused products at your facility.
2. Please complete the attached Confirmation form and **email/fax back** per its instructions. This step is required to confirm receipt of communications with all customers.
3. Return the attached response form **even if no recalled product is in inventory.**
4. Mölnlycke Health Care will arrange for collection and replacement of the product from your facility.
5. If you have forwarded any affected product to any other healthcare institutions, please forward a copy of this letter and fax/email back containing affected serial numbers to those institutions.

Please contact your local Mölnlycke Health Care Customer Service or Account Manager if you have any questions or concerns regarding this notification. You may also contact:

Global Vigilance Group: Ineke Boek (vigilance@molnlycke.com) or +44 (0)161 621 3964

Mölnlycke Health Care also confirms that this notice has been notified to the appropriate Regulatory Agency. Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,

Thomas Pettersson
Global Vigilance Manager

Caroline Allen
Global Director of Regulatory Affairs

Ref: 50048919
Date 04.02.2015

PLEASE COMPLETE AND RETURN THIS FORM TO:

Ineke Boek, Vigilance Associate
Mölnlycke Health Care
Unity House
Medlock Street
Oldham
UNITED KINGDOM
OL1 3HS
Tel: +44 (0)161 621 3964
Fax: +44 (0)161 621 3966
E-mail: vigilance@molnlycke.com

Ref – 50048919

Product code	Batch/LOT	Quantity Quarantined (pieces/trays)

NAME : _____

POSITION : _____

EMAIL ADDRESS : _____

SIGNATURE : _____

DATE : _____

HOSPITAL/INSTITUTE : _____

POSTCODE: _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____