

Date:

FIELD SAFETY NOTICE

Commercial name of the product: Barrier Extremity Drape 230x315cm
Type of action: Return of the Device
Attention: Theatre Manager, Distributor

Details on affected devices:

Product Code	Batch Number
60213-00	12167258

Description of the problem:

It has been identified that Extremity Drape products manufactured as batch 12167258 may have a defect on the primary packaging in the form of a cut mark. This cut mark may have pieced through the packaging, resulting in a compromise in sterility if used during a Surgical Procedure.

Actions to be taken by the user:

1. Please identify and isolate all affected unused product at your facility.
2. Please complete the attached Confirmation form/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. If you have forwarded any affected product to any other healthcare institutions, please forward a copy of this letter and fax back containing affected serial numbers to those institutions.
5. Mölnlycke Health Care will arrange for collection and replacement of the product from your facility.

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

Vigilance: Caroline Price (vigilance@molnlycke.com) or +44 (0)161 777 2646

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,



Caroline Price
Vigilance Associate



Global Director of Regulatory Affairs

PLEASE COMPLETE AND RETURN THIS FORM TO:

Caroline Price, Vigilance Associate
Mölnlycke Health Care
2 Omega Drive
Irlam
Manchester
M44 5BJ

Tel: +44 (0)161 777 2679
Fax: +44 (0)161 621 2045
E-mail: vigilance@molnlycke.com

Ref - 50038347

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

NAME : _____
POSITION : _____
EMAIL ADDRESS : _____
SIGNATURE : _____
DATE : _____
HOSPITAL/INSTITUTE : _____
COUNTRY : _____
HOSPITAL CONTACT TELEPHONE NUMBER : _____