



Ref: 50044784
Date: 17/02/14

FIELD SAFETY NOTICE

Commercial name of the product: Mölnlycke ProcedurePak®
Type of action: Advice regarding use of the device
Attention: Theatre Manager, Distributor

Details on affected devices: See list provided.

Description of the problem:

Mölnlycke Health Care has received the attached Field Safety Notice from BD Medical, for the **BD Plastipak™ 50ml Luer-Lok Syringe with Syringe Pumps**. This syringe is supplied to Mölnlycke Healthcare from BD Medical and is included in the referenced batches of ProcedurePak trays.

Please be advised that this Field Safety Notice supersedes any prior communication regarding this issue (please disregard any prior communications that you may have received).

The BD Field Safety Notice is included with this communication.

Actions to be taken by the user:

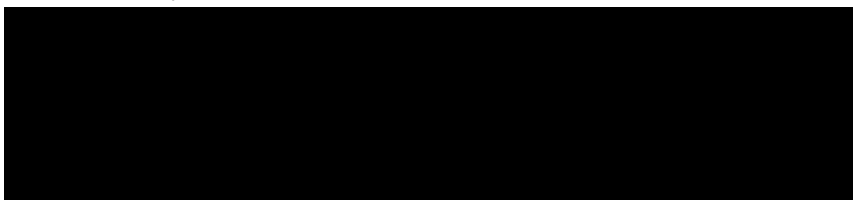
1. Please identify and isolate all affected unused product at your facility.
2. **Please affix a copy** of this advisory notice to each tray and make sure that its contents are brought to the attention of all relevant personnel
3. **Please complete the attached Confirmation form and email/fax back per its instructions with 10 days.** This step is required to confirm receipt of communications with all customers.
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.

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,



Vigilance Manager

Global Director of Regulatory Affairs



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PLEASE COMPLETE AND RETURN THIS FORM TO:

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

Tel.: +44 (0)161 777 2646
Fax: +44 (0)161 621 2045
e-mail: vigilance@molnlycke.com

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NAME/POSITION : _____

EMAIL ADDRESS : _____

CITY/COUNTRY : _____

HOSPITAL/INSTITUTE : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

SIGNATURE : _____

DATE : _____