

## 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](mailto: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 Manager

Steven Dowdley  
Global Director of Regulatory Affairs

**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

**Ref - 50044784**

NAME/POSITION : \_\_\_\_\_

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

CITY/COUNTRY : \_\_\_\_\_

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

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

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

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