



Date: 14 February 2017

URGENT FIELD SAFETY NOTICE

Commercial name of the product: ProcedurePak® trays containing Syringe 100ml 3parts Cath. tip Conc. W/LS Adapter (BD Plastipak™ Syringe, Catheter tip with Luer slip adaptor)

Type of action: Field Safety Notice

Attention: Theatre Manager, Distributor

Details of affected devices: For more details – see attached list of affected devices

Dear Customer,

At Mölnlycke Health Care, patient safety is our highest priority. We are writing to inform you about a Field Safety Corrective Action (FSCA) regarding Syringe 100ml 3parts Cath. tip Conc. W/LS Adapter supplied by BD (Becton Dickinson International). Mölnlycke Health Care includes their 100ml Plastipak Catheter Tip (CT) syringe in some of the ProcedurePak® trays that are provided to you.

BD is conducting a field safety corrective action for all lots of BD 100ml Plastipak Catheter Tip (CT) syringe labelled with a 5 years expiration date. During internal routine stability tests, BD has identified leakage past stopper failures which start at the 2 year time point. No adverse event has been reported for this issue at this time.

If you have any affected ProcedurePak® trays in your inventory, we ask you **not to use them** and to follow the instructions below.

About the potential risk to health

There is an increased risk of leakage past the stopper starting at 18 months after production. In exceptional cases, this might result in delay in therapy, under dosing of the patient or exposure of clinicians or patients to drugs.

What you need to do

1. Please use the attached list to identify and isolate all affected, unused ProcedurePak® trays at your facility.
2. Please affix a copy of this Field Safety Notice to each product and make sure that its contents are brought to the attention of all relevant personnel.
3. At the point of use the user is required to remove the Syringe 100ml 3parts Cath. tip Conc. W/LS Adapter from the ProcedurePak® and **discard it**. Then replace with single packed sterile version that will be provided to you.
4. Please complete the attached Confirmation form and **e-mail/fax** back per its instructions. Even if you no longer have any concerned ProcedurePak® trays, Mölnlycke Health Care needs to be sure that all customers are aware of the situation.
5. Mölnlycke Health Care will contact you to arrange single packed sterile replacement product to be shipped to you, as soon as you return the confirmation form.
6. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly.
7. If you are a distributor, please inform your customers by sending them a copy of this Field Safety Notice together with the list of concerned products. Make sure they act accordingly and return the confirmation form to you.

In addition, Mölnlycke Health Care appreciates your help in collecting data on product complaints and/or incidents related to the concerned products. Please, follow the reporting procedures established by your facility.

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: Linda Magnusson (vigilance@molnlycke.com) or +46 31 352 3733

Mölnlycke Health Care confirms that this notice has been notified to the appropriate Regulatory Agencies. Thank you for your time and attention. Mölnlycke Health Care apologies for any inconvenience.

Sincerely,

A handwritten signature in blue ink that reads 'Linda Magnusson'.

Linda Magnusson,
Global Product Complaints Manager



CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Linda Magnusson, Global Product Complaints Manager
 Mölnlycke Health Care,
 Box 13080, SE-402 52
 402 52 Gothenburg, Sweden

Fax +46 31 722 34 00
 E-mail: vigilance@molnlycke.com

Ref – 50062911

Product code	Batch/LOT	Quantity discarded (pieces)

I have read this Field Safety Notice, understood the actions required and have acted accordingly.
 If you are a distributor: I return the completed confirmation form and by that ensure that the end users have received the Field Safety Notice and acted accordingly.

PLEASE COMPLETE ALL SECTIONS

NAME : _____

POSITION : _____

HOSPITAL/INSTITUTE : _____

SERVICE/ DEPARTMENT : _____

CITY : _____ POSTCODE / ZIP : _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

EMAIL ADDRESS : _____

DELIVERY ADDRESS IF APPLICABLE : _____

SIGNATURE : _____

DATE : _____