Ref 50052292

MÖLNLYCKE HEALTH CARE

Date: 26 October 2015

URGENT FIELD SAFETY NOTICE

Commercial name of the product: ProcedurePak® containing BD Plastipak syringes
Type of action: Advisory Notice
Attention: Theatre Manager, Distributor
Details of affected devices: See List provided

Dear Customer

At Mölnlycke Health Care, patient safety is our highest priority. So we are writing to let you know about a Field Safety Notice (FSN) issued by our supplier Becton Dickinson (BD). Mölnlycke Health Care includes their Plastipak syringes in some of the ProcedurePak® trays and kits that are provided to you.

About the problem
When certain drugs are stored in BD Plastipak syringes, there have been reports of decreased potency. These syringes are cleared for use in general purpose fluid aspiration / injection only. There is no potential risk of decreased drug potency if the syringes are used as intended, and not used for drug storage.

In their FSN, BD indicate that they will not withdraw these syringes and will continue to manufacture and distribute them. You can find out more in their FSN attached and on the BD website www.bd.com/alerts-notices.

About the potential risk to health
These syringes can be safely used as long as they are used for their intended use of medical fluid aspiration / injection and not for drug storage. Mölnlycke Health Care has assessed the risk of decreased potency as very low since syringes in ProcedurePak® trays and kits are intended to be used immediately.

What you need to do
1. Please use the attached list to identify all affected, unused ProcedurePak® trays or kits at your facility that contain BD Plastipak syringes.
2. Please make sure that everyone knows not to store drugs in the syringes.
3. Please complete the attached Confirmation form and **e-mail/fax back** per its instructions – even if you no longer have any affected ProcedurePak® trays or kits. Mölnlycke Health Care needs to be sure that all our customers have received this communication.
4. If you have forwarded any affected trays or kits to other healthcare institutions, please send them a copy of this letter together with the list of affected products, and make sure they act accordingly.

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: Eva Brunhage (vigilance@molnlycke.com) or +46 (0)31 722 32 62

Mölnlycke Health Care confirms that this notice has been notified to the appropriate Regulatory Agency.

Thank you for time and attention, and Mölnlycke Health Care apologises for any inconvenience.
Sincerely,

Thomas Pettersson
Global Vigilance Manager

Eiler Anderson
Global Director of Regulatory Affairs (acting)

CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Eva Brunhage, Global Vigilance Associate
Mölnlycke Health Care,
Box 130 80, SE-402 52
Göteborg, Sweden

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

Ref – 50052292

I have read this Field Safety Notice and I understand the actions required.

NAME : _____

POSITION : _____

HOSPITAL/INSTITUTE : _____

CITY : _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

EMAIL ADDRESS : _____

SIGNATURE : _____

DATE : _____