Ref 50052655

Date: 9 February 2016

URGENT FIELD SAFETY NOTICE

Commercial name of the product: ProcedurePak® containing umbilical clamps IFKR08 (supplier reference HEF02128)
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. We are writing to let you know about a Field Safety Notice (FSN) regarding umbilical clamps IFKR08 (Supplier ref code: HEF02128). Mölnlycke Health Care includes their umbilical clamps in some of the ProcedurePak® trays and kits that are provided to you.

About the problem
Mölnlycke Health Care has received over a relatively short period of time similar complaints for a specific clamps batch number. Those product complaints have been assessed and based on this Mölnlycke Health Care has decided to make an Advisory Notice. The potential risk of the failure, broken clamp, is identified on the picture.

About the potential risk to health
If the clamp is not in place when the umbilical cord has been cut, this can lead to blood loss for the baby and need for a transfusion.

What you need to do
1. Please use the attached list to identify all unused ProcedurePak® trays or kits at your facility that contain this specific batch of umbilical clamps.
2. Please affix a copy of this advisory notice to each product and make sure that its contents are brought to the attention of all relevant personnel to check the product before use.
3. At the point of use the customer is required to not use the umbilical clamp included in the trays or kits. Remove and scrap the umbilical clamp from the tray.
4. 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.
5. 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.
6. Please contact your Mölnlycke Health Care representative to obtain any additional support in order to be able to manage this situation e.g. if replacement of the affected component is needed.

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: Anette Stenson (vigilance@molnlycke.com) or +46 31 722 31 66

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 apologies for any inconvenience.

Sincerely,

[redacted]

[redacted]

CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Anette Stenson, Head of Vigilance
Mölnlycke Health Care,
Box 130 80, SE-402 52
Göteborg, Sweden

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

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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 : _____