REF: 50056535

Date: 28 July 2016

URGENT FIELD SAFETY NOTICE

Commercial name of the product:	ProcedurePak® kits and trays containing umbilical clamps (IFKR21 & 2305123-00)
Type of action:	Advisory Notice
Attention:	Theatre Manager, Distributor
Details of affected devices:	See List Provided (All batches are affected)

Dear Customer,
At Mölnlycke Health Care, patient safety is our highest priority. So we are writing to let you know about a Field Safety Corrective Action (FSCA) regarding ProcedurePak® kits and trays containing umbilical clamps (ref: IFKR21 & 2305123-00).

About the problem
Mölnlycke Health Care has through our product complaint system become aware of situations where the umbilical clamp included in our ProcedurePak® kits and trays may have been incorrectly used due to a lack of adequate instructions for use. You may have received an Advisory FSN (50053846) from Mölnlycke Health Care previously, where we issued an IFU to be used with the umbilical clamps. We have since been made aware that this IFU maybe improved to include further instruction to ensure correct usage of the clamps.
If the clamp is used incorrectly i.e. both hooks in the clamp are not engaged the clamp may reopen.

To ensure correct usage

1. Rotate the umbilical cord clamp with the open side of the lock towards you, so that you can see the locking hooks.
2. Place the (thick) umbilical cord towards the ring end
3. Both hooks must be correctly positioned, check carefully that both hooks are securely clicked into place. Incorrect enagement of the hooks can cause the clamp to open.

This product is intended for single use only.

About the potential risk to health
If the clamp is not in place correctly when the umbilical cord has been cut, this can potentially lead to blood loss for the baby if not monitored regularly.

What you need to do

1. Please use the attached list to identify and isolate all affected, unused ProcedurePak® trays or kits at your facility that contain umbilical clamps.
2. Please affix a copy of this Advisory Notice and to each ProcedurePak® trays or kits and make sure that its contents is brought to the attention of all relevant personnel to read before use.
3. At the point of use the customer is required to follow the provided Instruction For Use with the umbilical clamp. The product is safe to use when clamped properly.
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 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 concerned 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: Naila Khalid (vigilance@molnlycke.com) or +44 161 621 3965

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,

Anette Stenson
Head of Vigilance

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.

PLEASE COMPLETE ALL SECTIONS

NAME : _____

POSITION : _____

HOSPITAL/INSTITUTE : _____

SERVICE/ DEPARTMENT : _____

CITY : _____ POSTCODE / ZIP : _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

EMAIL ADDRESS : _____

UPLIFT ADDRESS IF APPLICABLE : _____

SIGNATURE : _____

DATE : _____