



Date: 23 February 2016

URGENT FIELD SAFETY NOTICE

Commercial name of the product: ProcedurePak® kits and trays containing umbilical clamps (IFKR21)
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) regarding ProcedurePak® kits and trays containing umbilical clamps (ref code: IFKR21).

About the problem

Mölnlycke Health Care has through our product complaint system become aware of situations where the umbilical clamp included in our ProcedurePak® trays/kits may have been used incorrectly. If used improper i.e. both hooks in the clamp are not in place the clamp may reopen. The risk of incorrect usage may be related to that an Instruction for Use was not provided for the umbilical cord clamp.

The product complaints have been assessed and based on this Mölnlycke Health Care has decided to make an Advisory Notice.

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.

What you need to do

1. Please use the attached list to identify all concerned, unused ProcedurePak® trays or kits at your facility that contain umbilical clamps (ref code: IFKR21).
2. Please affix a copy of this Advisory Notice and the provided Instruction For Use 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 Instructions 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: 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,

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

Ref – 50053846

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

NAME : _____

POSITION : _____

HOSPITAL/INSTITUTE : _____

CITY : _____

POSTCODE / ZIP : _____

COUNTRY : _____

HOSPITAL CONTACT TELEPHONE NUMBER : _____

EMAIL ADDRESS : _____

SIGNATURE : _____

DATE : _____

