



Date: 5 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. So 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 clamp failure 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.
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

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

Christina Lewing
Global Director of Regulatory Affairs

CONFIRMATION FORM

PLEASE COMPLETE AND RETURN THIS FORM TO:

Thomas Pettersson, Global Vigilance Manager
Mölnlycke Health Care,
Box 130 80, SE-402 52
Göteborg, Sweden

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

Ref – 50052655

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 : _____

Country	Product	LOT	Product Name	Material group code	Material group description	Date of Manufacture	Expiry date
FR/CH/Fl/G	37004318-00	B15069	DELIVERY TRAY	12400	Delivery	20/05/2015	22/05/2018
FR/CH	37002195-02	C14186	SET CORDON	12523	Obstetric Others	20/11/2014	22/11/2017
FR/CH	37002195-02	C15031	SET CORDON	12523	Obstetric Others	11/03/2015	11/03/2018
FR/CH	37002195-02	C15056	SET CORDON	12523	Obstetric Others	24/04/2015	27/04/2018
FR/CH	37002195-02	C15090	SET CORDON	12523	Obstetric Others	30/06/2015	01/07/2018
FR/CH/GB	37004318-00	C15107	DELIVERY TRAY	12400	Delivery	19/08/2015	20/08/2018
CH	GCM11542-ECH	C15110	GEBURTENSET	12400	Delivery	28/08/2015	27/08/2018