REF: 50056535



Date: 13 Sep 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: The product contained within this delivery.

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 affix a copy of this Advisory Notice 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.
- 2. 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.

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:

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

In Singapore, only Caesarean Section Pack, model 97048892-15 and GEH C-Section Pack, model 97070069-01 which contain umbilical clamp are affected. There could be other model of Procedure Pack affected globally, please contact our vigilance personnel, Naila Khalid for futher details to confirm if your pack contains the affected umbilical clamp.

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

