Medline International France SAS
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www.medline.com/fr

URGENT: FIELD SAFETY NOTICE

Medical Device Safety Advisory Notice

Châteaubriant, 10th October 2018

For the attention of: the Pharmacist responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Medline Sterile Procedure Trays

Medline reference:	**FSN-18/12**
Description:	Medline Sterile Procedure Trays containing a Kocher clamp.
Product Codes and lots concerned:	See details in the **table** of the Acknowledgment receipt

Dear Customer,

This letter is to inform you of an urgent safety notification concerning Medline sterile procedure trays including "kocher" clamps. Its objective is to remind customers on the recommendations of use and to inform you that there were no information for use included in the trays manufactured from June 2018 to October 2018.

Recommendations for Use:

The "kocher" clamps used for maternity procedures of newborns require visual inspection during use if they are used to clamp the umbilical cords (see Appendix – Operating instructions).
Other devices such as Barr clamps have a locking system that does not require monitoring

Actions required:

- Thank you for communicating the information for use to all user services of the sterile procedure trays listed in the table of the acknowledgement form BELOW.
- Thank you for providing users with the information for use (attached), missing from the kits manufactured between 2018-06 and 2018-10

Exemple étiquette  2018-06

Instruction for Use will be included in the new productions.

Please return the acknowledgement form by fax or by email no later than October 31, 2018

Yours Sincerely,
Quality and Regulatory Affairs Dept.

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Acknowledgement receipt to be faxed to the following Fax: XXXXXXXXX or E-mail: XXXXXXXXXX

Please complete this form and return to Medline by either fax or email as soon as possible, but **not later than October 31st, 2018**.

Reference: FSN-18/12

Table:
For your facility, the references of Sterile Procedure Trays concerned by this notification are:

Reference
xxxxxxxx
xxxxxxxx
xxxxxxxx

☐ I have read and understand the instructions provided by Medline and acknowledge receipt of the FSN-18/12 regarding the Medline Sterile Procedure Trays by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

Date:

Name:

Position:

Facility:

Address:

City:

Telephone:

Fax:

Signature:

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Annex

EN - When/if used to clamp umbilical cords and as this device is not lockable, the effectiveness of the clamp must be monitored during the full period of clamping.

FR - Lorsque la pince de Kocher est utilisée pour clamper les cordons ombilicaux et s'agissant d'une pince sans verrouillage, son système de fermeture doit être contrôlé visuellement tout le temps de l'utilisation.

DE - Wenn die Komponente zum Klemmen von Nabelschnüren verwendet wird, muss die Wirksamkeit der Klemme während der gesamten Dauer der Klemmung überwacht werden, da sie nicht verschließbar ist.

NL - Als de component wordt gebruikt om de navelstreng af te klemmen, moet de effectiviteit van de klem gedurende de gehele procedure van de klemming gecontroleerd worden, omdat deze niet kan worden afgesloten.

ES - Cuando se utilice el dispositivo para clampar el cordón umbilical, como el bloqueo no es fijo, la efectividad de éste debe estar bajo vigilancia durante su uso.

PT - Quando serve para a fixação do cordão umbilical, e não sendo um dispositivo fechado, a eficácia do grampo tem de ser monitorizado durante o period completo de fixação.

NO - Dersom klemmen blir brukt på navlestreng, gjør vi oppmerksom på at klemmen er ikke låsbar og at den må overvåkes kontinuerlig under bruk.

DA - Når / hvis anvendt til at klemme navlestrengen og klemmen ikke er ikke låsbar, skal klemmen overvåges under den fulde periode den anvendes.

IT - Qualora usato per il clampaggio dei cordoni ombelicali, poiché questo dispositivo non è bloccabile, l'efficacia del morsetto deve essere monitorata durante tutto il periodo del clampaggio.

Doc. # IFU-18-10/00

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