



Medline International Germany GmbH
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Regulatory Affairs
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www.medline.com/de

FIELD SAFETY NOTICE

Medical Device Safety Advisory Notice

Kleve, December 9th, 2019

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

SECURITY INFORMATION of Fluid collection pouches with graduations

Medline reference: FSN-19/08
MoH reference:
Description: Fluid collection pouches with graduations used on maternity drapes
Product Codes concerned: See annex 1

Dear Customer,

This letter is to inform you on a security information concerning fluid collection pouches with graduations included in the product references listed in [Annex 1](#).

Issues:

An incident was reported to Medline International France concerning a graduated fluid collection pouch used on a maternity drape. The graduation scale on the fluid collection pouches are approximate and in the case of this incident the healthcare professional did not make a correct diagnostic. This would lead to a possible underestimated quantity of fluids loss (blood in particularly), which can lead to inappropriate care and discomfort.

Medline International France, would like to inform you that fluid collection pouches are not measuring devices, they are used to provide healthcare professional an indication on the loss of patient fluids. In any case, external calibrated weighing scales should be used for a precise reading.

To reduce the risk of miss-use, Medline has placed a warning label on products containing graduated fluid collection pouch. This will accompany the concerned products until the information can be included in an Instruction For Use (IFU) – see [Annex 2](#).

The graduation scale is to be used as an indication; however, Medline is in progress of modifying the graduation scale to improve the precision.

Photo of the graduated fluid collection pouch concerned:





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Actions to be taken:

1. Urgently check your stock and promptly put in quarantine the concerned products listed in Annex 1.
2. Complete the acknowledgement form by either fax or email as soon as possible, but not later than January 17th, 2020 and indicate the quantity of products in stock, to receive the necessary "warning stickers".
3. Put a "warning sticker" on each concerned product in your stock, release the labelled products and refer to Annex 2 for the IFU.

The relevant competent authorities are informed of this safety notice.

We apologize for the inconvenience caused.

Yours Sincerely,
Kenneth Smith
International Quality and Regulatory Affairs Manager.

PS: This safety information is only addressed to facilities that had received the concerned products.



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**Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822
or send by email to: gmb-eu-ra-kleve@medline.com**

Medline reference: FSN-19/08

Please complete and send back the enclosed acknowledgment form by either fax or email to Medline as soon as possible, but no later than **January 17th, 2020**.

Medline International France references concerned by this notification are listed in [Annex 1](#).

Quantity of warning labels required: _____

I have read and understood the security information provided by Medline and I acknowledge receipt of the FSN-19/08.

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

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected products to other facilities, please distribute this notification to customers and confirm us that your customers have been notified.

Date: _____

Customer Number: _____

Name: _____

Position: _____

Facility: _____

Address: _____

City: _____

Telephone: _____

Fax: _____

Signature: _____



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ANNEX 1 – List of products concerned

Product Code	Description
4576CE	UNDER-BUTTOCKS DRAPE W/2 POUCHES, DETACH,96X120CM
AGBMA081B	SET D'ACCOUCHEMENT / MATERNITY
AGBMA122A	BEVALLING SET
DG29556	TROUSSE ACCOUCHEMENT AVEC DEUX POCHE DE RECUEIL / MATERNITY
DG29565	PACK ACCOUCHEMENT / MATERNITY
DGFMA051D	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA142A	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA164E	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA168B	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA318A	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA330A	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA333	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA334B	TROUSSE ACCOUCHEMENT / MATERNITY
DGFMA339A	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA462	TR ACCOUCHEMENT POCHE + PLAT / MATERNITY
DGFMA465A	TROUSSE ACCOUCHEMENT 3 / MATERNITY
DGFMA468	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA528	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA531	TROUSSE COMPOSITE ACCOUCHEMENT / MATERNITY
DGFMA535	PACK ACCOUCHEMENT POUR E PISIO / MATERNITY
DGFMA574	TROUSSE ACCOUCHEMENT 6 / MATERNITY
DGFMA575	TROUSSE D'ACCOUCHEMENT / MATERNITY
DGFMA576	TROUSSE ACCOUCHEMENT / MATERNITY
DGFMA578	PACK ACCOUCHEMENT / MATERNITY
DGFMA587	TROUSSE ACCOUCHEMENT 5 / MATERNITY
DGFMA588	PACK ACCOUCHEMENT POUR E PISIO / MATERNITY
DGFMA591	TROUSSE ACCOUCHEMENT 4 / MATERNITY
DGFMASP04C	TROUSSE D'ACCOUCHEMENT DOUBLE / MATERNITY
DMFMA037	TROUSSE D'ACCOUCHEMENT / MATERNITY
DMFMA044	TROUSSE ACCOUCHEMENT / MATERNITY
SPTE-4576	DRAPE, PE, U-BUTTOCK W/2 FCP&1GAUGE,
1395433-7	TROUSSE ACCOUCHEMENT AVEC INST / MATERNITY
1414562-10	TROUSSE D'ACCOUCHEMENT N° 10 / MATERNITY
1442668-9	TROUSSE ACCOUCHEMENT COMPLETE / MATERNITY
1436317-4	TROUSSE ACCOUCHEMENT / MATERNITY
1444726-2	TROUSSE ACCOUCHEMENT / MATERNITY
1444728-2	TROUSSE ACCOUCHEMENT / MATERNITY




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ANNEX 2 – Information for Use



(nfr) Under buttocks drape, with graduated pouch
Champ sous fessier, avec poche graduée

- The graduated pouch of this device is a visual indicator to assist in the evaluation of patient's blood loss. It is not a measuring device, blood loss should be precisely measured using a calibrated weighing scale.
- La poche graduée de ce dispositif est un indicateur visuel pour aider à l'évaluation de la perte de sang du patient. Ceci n'est pas un instrument de mesure, la perte de sang doit être mesurée avec précision par un dispositif de mesure étalonné.
- De gradatie van de opvangzak van dit stultliaken, is een visueel hulpmiddel om het bloedverlies van de patiënt te evalueren. Het is echter geen meetinstrument. De exacte hoeveelheid bloedverlies dient gemeten te worden met een gekijkte weegschaal.

 Medline International France SAS,
5 rue Charles Lindbergh, 44110 Châteaubriant, France

 **CE2797**
Medical Device