Medline International Germany GmbH – Medline Str. 1-3 – D-47533 Kleve
Account Number:

August, 10th 2021

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Medline Sterile Procedure Trays including DRENOFAST Draining systems

Medline reference:	**FSN 21-11**
MoH reference:	
Product Description:	**Medline Sterile Procedure Trays including DRENOFAST Draining systems**
Action Type	**Safety Advisory Notice Only**

Dear Customer,

This letter is to advise you that Medline has issued a field safety notice related to Medline Sterile Procedure Trays including DRENOFAST draining systems.

Although no serious injuries have been reported to Medline, the manufacturer of the DRENOFAST draining systems from the supplier Iberhospitex has issued a Field Safety Notice to inform users on the risks of miss-use.
Please take note of the following warnings that have been included in the DRENOFAST Information for use.

CONTRAINDICATIONS:
Catheters should not come into contact with tissue or organs that can be damaged by the vacuum system.
Drenofast should not be used in areas such as the brain, intestine, peritoneum, bone marrow or cavernous bone.

Medline International Germany GmbH
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Tel: +49 2821 7510 0 • Fax: +49 2821 7510 7802
de-customerservice@medline.com • de.medline.eu

Regulatory Affairs
gmb-eu-fsn-fsca-kleve@medline.com
Tel: +49 (0) 2821 7510 7210 • Fax: +49 (0) 28 21 7510 7822

Geschäftsführer/Legal Director: James D. Abrams • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 204

In case of use close to the dura mater and the possible risk of rupture: systematically check the condition of the dura mater and the compatibility of the desired depression.
Do not use the Drenofast bottle without vacuum and do not puncture the bellows.

The list of Sterile Procedure Trays containing DRENOFAST Draining systems are listed in TABLE 1 in the acknowledgment form.

The relevant competent authorities have been informed of this safety notice.
Please proceed to the following page to acknowledge receipt of this notice.

Please contact us at the email provided below if you have any questions.
Yours sincerely,

Kenneth Smith
Sr. Manager Regulatory Affairs, Medline Europe

This urgent safety information is only addressed to facilities that have received the products concerned.

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

Reference: FSN-21/11

Please complete the acknowledgment form and send it back by either fax or email as soon as possible, but no later than August 30th, 2021.

TABLE 1

Sterile Procedure Trays Concerned	Iberhospitex - DRENOFAST Draining systems Description

☐ I have read and I understand the instructions provided. I acknowledge receipt of the FSN-21/11 by signing this document and returning it to Medline.

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, that distributed any affected products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline at the address listed above:

Date:	
Account Number:	
Name:	
Position:	
Facility or Business Entity:	
Address:	
City:	
Telephone:	
Fax:	
Signature:	

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