Medline International Germany GmbH—Medline-Str. 1-3—D-47533 Kleve

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Kleve, Date

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

Security Information for Medline's Sterile Procedure Trays

Medline Reference: **FSN-23/10**
MoH Reference: **N/A**
Product description: **Medline's Sterile Procedure Trays**
Manufacturer SRN : **FR-MF-000000676**
Action type: **Field Safety Notice with Corrective Actions**
Product codes : **See Table 1 below**

Table 1: Lot numbers affected by this Field Safety Notice, FSN-23/10

Reference	Lot Number	Reference	Lot Number
HGGCV116F	976428	HGGCV118G	978660
HGGCV116F	978662	HGGCV118G	979483
HGGCV116F	980982	HGGCV120F	975989
HGGCV118G	976427	HGGCV120F	979484
HGGCV118G	976900	HGGCV120F	980246
HGGCV118G	978069	HGGCV121E	980940

Dear Customer,

This letter is to advise you that Medline has initiated a field safety notice with corrective actions regarding the Medline's Sterile Procedure Trays listed in **Table 1**.

Medline International Germany GmbH
Medline-Straße 1-3 • 47533 Kleve
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 7122 • Fax: +49 (0) 28 21 7510 7822

Geschäftsführer/Legal Director: James D. Abrams • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 202

www.medline.eu/de

REASON FOR THE FIELD SAFETY NOTICE:

Following an internal record review, Medline discovered that an Instruction For Use for Pennine Surgical Suction Probes was incorrectly placed in the IFU packet instead of the Non-Absorbable Surgical Suture, reference G850, for the Sterile Procedure Tray references listed in **Table 1**.
Although no serious incidents have been reported, in an abundance of caution, Medline is notifying customers of this error and is providing the correct IFU for the Non-Absorbable Surgical Suture, reference G850 that is contained within the packs.

POTENTIAL RISKS:

Information for proper usage is printed on the label as shown on the below **Figure 1**.

However, please notify users to take note that the following warning, which is mentioned in the IFU, is not included on the packaging label:
"*Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, SEIDE/SILK sutures should not be used where permanent retention of tensile strength is required as in fixation of vascular prostheses.*"

Figure 1: Photo of the component's packaging

CORRECTIVE ACTIONS:

Medline will include the correct IFU for Non-Absorbable Suture, reference G850, within existing stock of the pack references listed in **Table 1**. The correct IFU is also attached to this field safety notice, therefore please follow the instructions listed below under "actions required".

ACTIONS REQUIRED:

Step 1: Please take note of this safety information and inform all users in your facility.

Step 2: Urgently check your stock and promptly add the attached correct Instruction For Use in the concerned cases of the Medline's Sterile Procedure Trays listed in **Table 1**.

Step 3: Please complete the Acknowledgment Receipt *(page 4)* once step 2 is completed and return it by email as soon as possible, but **no later than December 22nd 2023**.

We thank you for your cooperation and Medline apologizes for the inconvenience caused.

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,

Brandi Panteleon
Sr. Director International Quality Assurance / Regulatory Affairs.

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

Please email the Acknowledgement Receipt to the following email address: GMB-EU-FSN-FSCA-KLEVE@medline.com

Medline Reference: FSN-23/10

Please complete the acknowledgement form and send it back by email as soon as possible, **but no later than 22nd December 2023**.

The concerned products are listed in the **Table 1** of the first page.

By completing and signing the document, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-23/10 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: _____
Name: _____
Position: _____
Facility or Business Entity: _____
Address: _____
City: _____
Medline Account Number: _____
Telephone: _____
Email address: _____
Signature: _____