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

Company Name
Address
Address
ZIP City

Einschreiben-Rückschein

Kleve, Date

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 regarding Aortic Root Cannula included in Medline Sterile Procedure Trays

Medline Reference:	**FSN-25/03**
MoH Reference:	**N/A**
Product description:	**Aortic Root Cannula included in Medline Sterile Procedure Trays**
Legal Manufacturer SRN:	**US-MF-000019977**
Action type:	**Field safety corrective action**
Product codes:	**See details in Table 1 (page 4)**

Dear Customer,

This letter is to advise you that Medtronic has initiated a Recall regarding Aortic Root Cannula included in Medline Sterile Procedure Trays listed in **Table 1,** (page 4).

The Medtronic Field Safety Notice is available on the Bfarm website under the reference 03912/25.

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Geschäftsführer/Legal Director: Hervé Bertrand Million, Jochen Helmut Günther Hein • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 204

www.medline.eu/de

REASON FOR THE FSCA:

Please find the description of the problem announced by Medtronic:
"During the manufacturing process, unexpected loose material in the male luer used in the aortic root cannula was identified."

POTENTIAL RISKS:

Please find the potential risks announced by Medtronic:
"The potential for harm exists given the failure mode and the affected rate of 5% related to the identified scope. The potential harms when identified prior to use is procedure delay while another cannula is located. If this is not identified prior to use, and the clinician uses the cannula, the potential harms is stroke (reversible and irreversible.)"

ACTIONS REQUIRED:

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

Step 2: Urgently physically check your stock to promptly put on quarantine the concerned Medline Sterile Procedure Trays listed in **Table 1**.

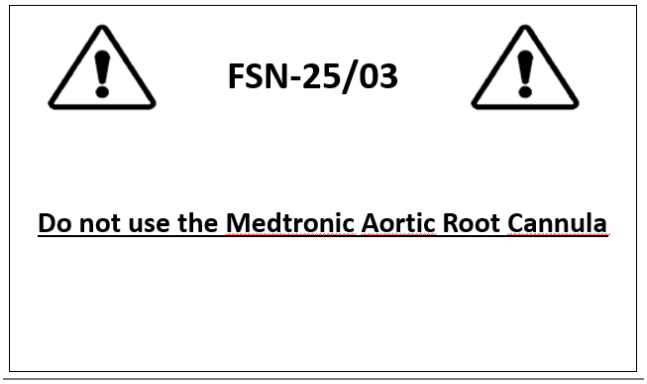
Step 3: Complete the acknowledgement form and indicate the quantity of impacted trays in your stock, to receive the necessary quantity of "warning stickers" to be placed on each Medline Sterile Procedure Trays. Then, return the acknowledgement form by email as soon as possible, **but no later than 17th March 2025**.

Step 4: Please put a "warning sticker" on each concerned Products in your stock and then release them.
If required, Medline staff are available to label the concerned Products.

Step 5: Do not use the affected Product from your Sterile Procedure Tray and remove it before use in the operating room.

Step 6: If you no longer have any of the impacted products in stock, please complete the Acknowledgment Receipt *(page 4)* and return it by email as soon as possible **but no later than 17th March 2025**.

WARNING STICKER:



Thank you for your cooperation; 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,

Audrey Barraud,
Quality Director, Medline Europe

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-25/03

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than 17th March 2025**.

Table 1: The Medline Sterile Procedure Trays which include the Aortic Root Cannula concerned by this notification are listed in the below table:

Reference	Lot Number
HGGCV118G	976900
HGGCV118F	947149
	952164
	956646
	958464
HGGCV116F	950175

Quantity *(in eaches)* of stickers needed: _____

By completing and signing the document, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-25/03 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: _____