



Facility  
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Address  
Address  
ZipCode City  
Country

## URGENT: FIELD SAFETY NOTICE

### Medical Device Safety Advisory Notice

Châteaubriant, Date

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

#### Security information regarding RX Cassette Cover included in Medline's Sterile Procedure Trays

**Medline Reference:** FSN-25/04  
**MoH Reference:** N/A  
**Product description:** RX Cassette Cover included in Medline's Sterile Procedure Trays  
**Legal Manufacturer SRN:** FR-MF-000000676  
**Action type:** Field Safety Corrective Action  
**Product codes:** See [Table 1](#) below

**Table 1:** List of Medline's Sterile Procedure Trays which include the RX Cassette Cover concerned by this security information.

Reference	Lot Number
DGFBA334C	42645489
	43247026
	44361980
DGFBS590A	42650281
DGFCV050C	46324738
	46324740
DGFCV090E	42774001
	43581633

Reference	Lot Number
DGFCV332A	43118367
DGFEY147E	42656025
	42656029
DGFEY334A	44945530
DGFEY351	50136756
HGGAN086C	47008890
	47008893
HGGNE022H	45027562

Reference	Lot Number
HGGNE022H	45027563
HGGNE023C	45026982
HGGNE103A	45027537
	45027543
PGSAN086	45046714
ST01-DGFEY441	48942242
ST01-DGFEY484	50561989

**Medline International France SAS**

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Commercial registry number: 408.537.249 R.C.S. Versailles

**Quality & Regulatory Affairs Dept.**

5 Rue Charles Lindbergh • 44110 Châteaubriant

Tel : +33 (0)2 44 05 30 67

Tel : +33 (0)2 44 05 30 68

GMB-EU-FSN-FSCA-CHBT@medline.com



Dear Customer,

This letter is to advise you that Medline International France S.A.S. has initiated a Field Safety Corrective Action regarding the RX Cassette Cover, which are included in the Medline's Sterile Procedure Trays listed in **Table 1**.

#### **REASON FOR THE FSN:**

During Medline assembly process of Sterile Procedure Trays, operators have detected deep marks on the RX Cassette Cover item. After further inspection, these marks cannot be observed without unfolding the cassette cover. This defect can lead to the formation of holes that may cause a breach in the sterile barrier.

#### **POTENTIAL RISKS:**

This defect can lead to the formation of holes that may compromise the intended use of the item. The use of a defective RX Cassette Cover can compromise the sterile barrier, and/or increase the risk of patient infection.

#### **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 and promptly put on quarantine the concerned Medline Sterile Procedure Trays listed in **Table 1**.

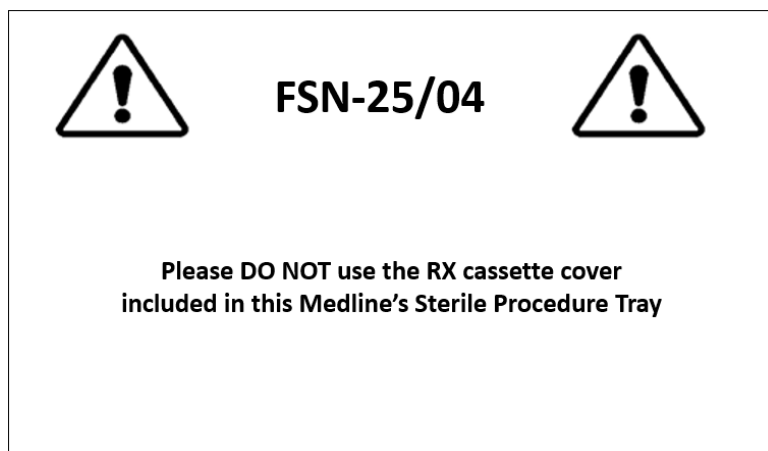
Step 3: Please complete the Acknowledgement Receipt (page 4) and return it by email as soon as possible, **but no later than March 21<sup>st</sup>, 2025**, and indicate the quantity of Medline's Sterile Procedure Trays in your stock, to receive the necessary quantity of "warning stickers".

Step 4: Your Medline sales representative will take in charge the relabelling of the affected products in your stock.

Step 5: Do not use the affected RX Cassette Cover from your Sterile Procedure Tray and remove it before use.

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 March 21<sup>st</sup>, 2025**.

**WARNING LABEL:**



As an alternative, Medline can supply single sterile covers under reference ICE4000.

Indeed, when using the Medline sterile procedure tray, a sterile unit cover can be used in order to proceed with the surgery in good conditions.

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-CHBT@medline.com**

**Medline Reference: FSN-25/04**

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than March 21<sup>st</sup>, 2025.**

The Medline's Sterile Procedure Trays which include the RX Cassette Cover, are listed in **Table 1.**

**Quantity of warning labels 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-25/04 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: \_\_\_\_\_

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