Medline International France
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh
44 110 Châteaubriant

Facility
Service
Address
Address
ZipCode City
Country

URGENT: RECALL
Medical Device Safety Advisory Notice

Châteaubriant, Date

ATTENTION:
Pharmacist,
Risk Manager responsible for medical device vigilance,
The Biomedical/Engineering Department

Recall regarding Medline's Magnetic Instrument Drape

Medline Reference:	**FSCA-23/07**
MoH Reference:	**N/A**
Product description:	**Magnetic Instrument Drape**
Action type:	**Recall**
Product codes :	**Item : MDL1CE - Lot : GMD22W02**

Dear Customer,

This letter is to advise you that Medline has initiated a recall regarding Medline's Magnetic Instrument Drape, reference **MDL1CE**, lot number **GMD22W02**.

Reason for the Recall:

Medline is issuing this recall to inform customers about the potential for a weak seal that may cause a breach in the sterile barrier of the packaging of the Magnetic Instrument Drape **MDL1CE**, lot number **GMD22W02**.

No serious incidents have been reported to date, however Medline is recalling this lot in an abundance of caution.

Medline International France SAS
2 Rue René Caudron • Bâtiment 13F
Parc D'Affaires le Val Saint Quentin • 78960 Voisins-le-Bretonneux
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
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 68
gmb-eu-fsn-fsca-chbt@medline.com

POTENTIAL RISKS:

The product is used to transfer sterile metallic instruments during surgery, therefore the use of a non-sterile magnetic drape could lead to non-sterility of the sterile field and/or patient contacting instruments, resulting in an increased risk of infection.

ACTIONS REQUIRED:

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

Step 2: Urgently check your stock and promptly put on quarantine the concerned Magnetic Instrument Drape. (Item: **MDL1CE -** Lot: **GMD22W02**)

Step 3: Please discard all affected products in your facility and return by email as soon as possible, but not later than **September 1st, 2023** the attached acknowledgement form duly completed, indicating the quantity of discarded products.

Step 4: Please complete and return the acknowledgement form below by email as soon as possible, but not later than **September 1st, 2023** even if you no longer have any of the concerned products in stock. Medline will issue a credit for the goods destroyed.

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

The relevant competent authorities have been informed of this recall.

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,
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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gmb-eu-fsn-fsca-chbt@medline.com

Please email the Acknowledgement Receipt to the following email address: gmb-eu-fsn-fsca-chbt@medline.com

Medline Reference: FSCA-23/07

Please complete the acknowledgement form and send it back by email as soon as possible, **but no later than September, 1st 2023**.

Reference	Lot Number
MDL1CE	GMD22W02

Quantity *(in eaches)* **of product discarded:** _____

By completing and signing the document, I confirm that I have read and understood the instructions provided.
I acknowledge receipt of the FSCA-23/07 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: _____

Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

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