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

NHS SUPPLY CHAIN RUGBY
VALLEY POINT
VALLEY DRIVE
CV21 1TN RUGBY

Kleve, 23. Juni 2025

URGENT: FIELD SAFETY NOTICE
Medical Device Recall

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

Recall for Sterile surgical procedure drape and Sterile Drape Packs

Medline Reference:	**FSN-25/02**
MoH Reference:	**N/A**
Product description:	**Sterile surgical procedure drape and Sterile Drape Packs**
Legal Manufacturer SRN:	**FR-MF-000000676**
Action type:	**Recall**
Product codes:	**See Appendix 1 (page 4)**

Dear Customer,

This letter is to advise you that Medline International France S.A.S. has initiated a Recall regarding Sterile surgical procedure drape and Sterile Drape Packs, listed in **Appendix 1,** *(page 4).*

REASON FOR THE RECALL:

During final visual inspection, a small hole was found near the seal of the header bag pouch, close to the Tyvek portion of the pouch.

POTENTIAL RISKS:

Damaged packaging can compromise the sterility of the product. If holes in the packaging were to go unrecognized, there is an increased risk of infection.

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Additionally, there is a potential risk for a non-sterile device to be placed within the sterile field or a non-sterile device to be used within a sterile procedure. This could lead to contamination of a sterile field and/or a potential risk for patient infection to occur.

ACTIONS REQUIRED:

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

Step 2: Urgently physically check your stock to promptly put on quarantine and discard the impacted products listed in **Appendix 1**.
Products that have green stickers are not impacted by this recall and can safely be used. These products with a green sticker, which belonged to the batches involved in this FSN, have been inspected or reworked using another source of sterilization bag to ensure their compliance.

Step 3: Please complete the Acknowledgment Receipt *(page 4)* and indicate the number of units discarded in your stock. Then, return it by email as soon as possible **but no later than 18th July 2025**.

Step 4: 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 18th July 2025**.

Step 5: Once Medline has received your completed and signed Acknowledgment Receipt, if any actions are required to replace the discarded units or if additional financial compensation is needed, please contact your Medline representative

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-25/02

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than 18th July 2025**.

The products concerned by this recall are listed in Appendix 1 *(page 4).*

By completing and signing the document, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-25/02 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:	NHS SUPPLY CHAIN RUGBY _____
Position:	_____
Facility or Business Entity:	_____
Address:	_____
City:	RUGBY _____
Medline Account Number:	5544452G _____
Telephone:	_____
Email address:	_____
Signature:	_____

Appendix 1

See below the list of impacted products and lots. Please check the stock physically and discard products **without green sticker.**

Reference	Lot Number	Quantities discarded (in eaches)
DYJPEADSSM1	24GAC013	
DYJPEHEDSM2	24GAC009	
	24GAC028	
DYJPEOBPSM	24FAC018	
	24GAC007	
DYNJPE9010SM	24GAC011	
	24GAC014	
	24GAC016	
	24GAC017	
ES10116CE	24JAZ205	
	24KAZ207	
ES29024CE	24JAZ214	
	24KAZ217	
ES29081CE	24HAZ269	
	24JAE669	
	24JAE670	
	24KAE746	
ES29095CE	24FAZ218	
	24HAZ217	
	24JAZ215	
	24KAZ218	
ES29105CE	24KAZ219	
	24KAZ241	
ES29106CE	24KAZ220	
ES29114CE	24KAZ221	
ES29186CE	24JAZ216	
	24KAZ222	
S7444CE	24GAC007	
SM29419CE	24JAES690	
TB29367CE	24KAE727	
TB29419CE	24JAES693	
	24KAES763	