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Medline International Germany GmbH –Medline Str. 1-3 - D-47533 Kleve
1740419A
Tosama Tovarna
Att. Vesna Rusnov Plaznik
Vir, Saranoviceva cesta 35
Domzale
1230
SLOVENIA

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Kleve, September 3rd 2020

For the attention of: the Pharmacist responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Sterile Procedure Trays containing Allmed XR gauze swabs with XR Threads

Medline reference:	FSN-20/02
MoH reference:	R2012530
Description:	Sterile Procedure Trays and containing Allmed XR gauze compresses
Product Codes concerned:	See Table 1 (Table will be adapted to the respective customer)

Dear Customer,

This letter is to advise you that the supplier “Allmed” has issued a field safety corrective action related to XR gauze swabs included in some Medline Sterile Procedure Trays.

There is a possible breaking or fraying of the XR thread used in the gauzes and theoretically, small pieces of thread could occur when the XR thread breaks or frays and this could lead to inflammation and/or granuloma formation when remaining in the body.

All lot numbers of Sterile Procedure Trays with the references mentioned in the acknowledgement form in Table 1 are concerned.

For the remaining packs available in our stock, “warning stickers” will be placed on each Sterile Procedure Tray.

Do not use the affected x-ray swabs from your Sterile Procedure Tray and discard them before use in the operating room. All other components from your Sterile Procedure Tray can be used, after a visual inspection to ensure the components have not been contaminated

Actions to be taken:

Could you please:

1. Urgently check your stock and promptly put on quarantine the concerned Sterile Procedure Trays listed in Table 1 (see: acknowledgement form).
2. Complete the acknowledgement form and return by either fax or email as soon as possible, but not later than September 30th 2020 and indicate the quantity of Sterile Procedure Tray in your stock, to receive the necessary quantity of “warning stickers” to be put on each Sterile Procedure Tray.
3. Put a “warning sticker” in the middle of each concerned Sterile Procedure Tray of your stock and on each box under the label.
4. Do not use the affected x-ray swabs from your Sterile Procedure Tray and remove them before use in the operating room. Before using the other components, make a visual inspection to ensure the components have not been contaminated with pieces from the XR thread.

Sticker details –



The relevant competent authorities are informed of this safety notice.

We apologize for the inconvenience caused.

Yours Sincerely,
Kenneth Smith
Quality and Regulatory Affairs Manager.

PS: This urgent safety information is only addressed to facilities that had received the concerned Sterile Procedure Trays.



Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822
or send by email to: gmb-eu-ra-kleve@medline.com

Medline reference: FSN-20/02

Please complete and send back the enclosed acknowledgment form by either fax or email to Medline as soon as possible, but no later than **September 30th, 2020**.

Table 1:

Sterile Procedure Trays concerned by this notification delivered to you are listed in the below table. Please mention the quantity of packs available in your stock and quantity of stickers required in the table below:

Item Number	Lot/Batch	Quantity Delivered	Quantity in Transit	Quantity stickers required
VGCBAA004	839634	15		
VGCBAA004	847039	18		
VGCBAA004	850939	24		
VGCBAA004	852583	6		
VGCCV001	839642	70		
VGCCV001	848869	12		
VGCCV001	851321	44		
VGCCV001	854078	22		
VGCCEN001	856286	16		
VGCCEN001	858076	32		
VGCCMA002	842854	32		
VGCCMA002	848603	24		
VGCCMA002	852588	8		
VGCCMA007	842851	256		
VGCCMA007	848445	160		
VGCCMA007	852263	240		
VGVBSS007	838809	168		
VGVBSS007	843459	24		
VGVBSS007	848033	36		
VGVBSS007	848526	168		
VGVR001	856287	24		
VGVR001	857131	84		



Total quantity of warning stickers required:

I have read and understood the security information provided by Medline and I acknowledge receipt of the FSN-20/02.

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, please distribute this notification to customers and confirm that your customers have been notified.

Date: _____

Customer Number: 1740419A _____

Name: _____

Position: _____

Facility: Tosama Tovarnasanitetnega materiala d.o.o. _____

Address: _____

City: Domzale _____

Telephone: _____

Fax: _____

Signature: _____