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

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY CORRECTIVE ACTION
Medical Device Safety Advisory Notice

Châteaubriant, 19th May 2023

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

Security Information regarding Turkuaz Ultrasound Gel included in Medline Sterile Procedure Trays

Medline Reference:	**FSCA-23/03**
MoH Reference:	**N/A**
Product description:	**Turkuaz Ultrasound Gel included in Medline Sterile Procedure Trays**
Action type:	**Field Safety Corrective Action**
Product codes :	**See details in the Table 1 of the acknowledgment form** *(Table will be adapted to each customers)*

Dear Customer,

This letter is to advise you that Medline has initiated a field safety corrective action regarding the Ultrasound Gel manufactured by Turkuaz included in Medline Sterile Procedure Trays.

REASON FOR THE FSCA:

During an inspection performed by Medline, they observed a breach regarding the sterility of the Turkuaz Ultrasound Gel.

Although no serious incidents have been reported, the sterility of the gel cannot be guaranteed.
Therefore, Medline has decided to perform a field safety corrective action FSCA-23/03 regarding the Turkuaz Ultrasound Gel included in Medline Sterile Procedure Trays.

POTENTIAL RISKS:

The use of this Ultrasound Gel could lead to a potential risk of infection for the patient.

CORRECTIVE ACTIONS:

Medline has taken the decision to stop distributing the Turkuaz Ultrasound Gel and is currently looking for an alternative Gel.

ACTIONS REQUIRED:

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

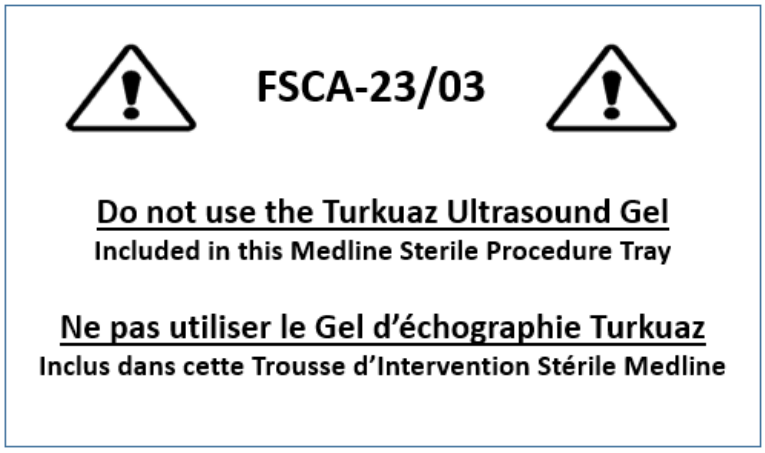
Step 2: Urgently check your stock and promptly put on quarantine the concerned sterile procedure trays listed in Table 1 *(see: acknowledgement form adapted to each customer)*.

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 not later than **June 2nd, 2023**.

Step 4: Place a "warning sticker" in the middle of each concerned Sterile Procedure Tray of your stock and on each box under the label.

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

WARNING STICKER:



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Tel: +33 (0)2 44 05 30 68
gmb-eu-fsn-fsca-chbt@medline.com

We thank you for your cooperation and 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,

Kenneth Smith
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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Please email the Acknowledgement Receipt to the email address: GMB-EU-FSN-FSCA-CHBT@medline.com

Medline Reference: FSCA-23/03

Please complete the acknowledgement form and send it back by email as soon as possible, **but no later than 2nd June 2023**.

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

Reference	Lot Number

Reference	Lot Number

Reference	Lot Number

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 FSCA-23/03 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: _____

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Item Number	Lot/Serial
ZGZAN012B	937130
	948017
ZGZBA133E	237930
	247811
	253919
	928334
	934581
	940667
ZGZBA152A	236461
	240542
	248191
	926764
	934345
ZGZBA174A	238670
	239796
	927244
ZGZCV010E	240462
	241915
	932840
	937536
	941363
ZGZMA073A	238827
	246511
	937213
	938178
	940031
	942209