



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

Kleve June 25, 2021

## ***URGENT: FIELD SAFETY NOTICE*** ***Medical Device Safety Advisory Notice***

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

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### **SECURITY INFORMATION of Medline Sahara Absorbent OR Table Sheet**

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**Medline reference:** FSN 21-08  
**Product Description:** Medline Sahara Absorbent Operating Room (OR) Table Sheet  
**Action Type** Safety Advisory Notice Only

Product codes concerned
DYND4060SBE
DYND4090SBE
QSS01
DYKQSUITEL2CEA
DYKQSUITEL2CEASB
DYKQSUITEL3CEA
DYKQSUITEL4CEA
DYKQS01
DYKQSC01

#### **Medline International Germany GmbH**

Medline-Straße 1-3 • 47533 Kleve

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de-customerservice@medline.com • de.medline.eu

Geschäftsführer/Legal Director: James D. Abrams • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 204

#### **Regulatory Affairs**

gmb-eu-ra-kleve@medline.com

Tel: +49 (0) 2821 7510 7210 • Fax: +49 (0) 28 21 7510 7822





Dear Customer,

This letter is to advise you that Medline has issued a field safety notice related to Medline's Sahara Absorbent OR Table Sheet shown in the figure below.



Figure 1: Medline Sahara Absorbent Operating Room (OR) Table Sheet

Although no serious injuries have occurred, Medline received some user reports relating to patients slipping when the operating table is inclined (i.e. Trendelenburg or Reverse Trendelenburg position). Medline recommends users to secure patients to the operating table using straps or other appropriate means before inclining the operating table. The Sahara Table Sheet is intended to optimise efficiency in the OR by protecting the OR table from fluids, while also protecting the patient from skin damage (due to maceration). The sheet material contains properties to help keep the table sheet in place during use, however it is not intended to secure patients to the operating table.

The Instructions for Use (IFU) have been updated with the appropriate warnings and precautions. The updated instructions and all related product information can be accessed at [www.medline.eu](http://www.medline.eu).

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.





Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822  
or send by email to: [gmb-eu-fsn-fsca-kleve@medline.com](mailto:gmb-eu-fsn-fsca-kleve@medline.com)

**Reference: FSN-21/08**

Please complete the acknowledgment form and send it back by either fax or email as soon as possible, but no later than July 23rd, 2021.

Table 1:

Medline Sahara Absorbent OR Table sheets concerned by this notification are listed in the below table.

Code
DYND4060SBE
DYND4090SBE
QSS01
DYKQSUITEL2CEA
DYKQSUITEL2CEASB
DYKQSUITEL3CEA
DYKQSUITEL4CEA
DYKQS01
DYKQSC01

I have read and I understand the instructions provided. I acknowledge receipt of the FSN-21/08 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:	
Account Number:	
Name:	
Position:	
Facility or Business Entity:	
Address:	
City:	
Telephone:	
Fax:	
Signature:	

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