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

Facilty
Service
Address
Address
Zip Code City
Country

URGENT: FIELD SAFETY CORRECTIVE ACTION
Recall

Kleve, 20th June 2022

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

Recall regarding Medline MED-SOFT liners

Medline reference : **FSCA-22/07 (Extension of FSN-21/15, replacing FSCA-22/05)**
MoH Reference: N/A
Product description : Medline MED-SOFT liners
Action type: Recall
Product codes : See Table 1 below

Table 1: Product codes and batches affected by this voluntary recall

Product Codes	Lot number of MED-SOFT Liner
DYNDSCL1000	670210**802** to 670210**805** 670210**903** to 670211**102**
DYNDSCL1500	670210**714** to 670210**805** 670210**819** to 670210**828** 670210**909** to 670211**025**
OR1910PG	670210**729** to 670210**924**
OR1920PG	670210**717** to 670211**029**
OR1930	670210**802** to 670210**825**
OR1930PG	670210**724** to 670210**809** 670210**819** to 670210**827** 670210**908** 670210**920** to 670211**112**
OR53916	**670210727 and** 670210**813** to 670211**101**
OR929K	670210**802** to 670211**014 and 670211116**

Product Codes	Lot number of MED-SOFT Liner
OR53926	670210**727** to 670210**818** 670211**029 and 670211109**
DYNDSCL3000	670210**715** to 670210**811** 670210**830** 670210**918** to 670211**108**
OR53929	670210**813** to 670211**025 and 670211027**
OR54916	670210802
OR916K	670210**809** to 670211**020**
OR939K	670210**727** 670210**914** to 670211**014**
OR926K	670210**718** to 670211**014 and 670211116**
OR936K	670210**825** to 670211**022**

Medline International Germany GmbH
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Regulatory Affairs
gmb-eu-fsn-fsca-kleve@medline.com
Tel: +49 (0) 2821 7510 7528 • Fax: +49 (0) 28 21 7510 7822

Dear customer,

Medline initiated an inspection of L-connectors to replace defective connectors used with the MED-SOFT liner through FSN-21/15 and FSCA-22/05. However, the implementation of the FSCA-22/05 has been difficult to execute. Therefore, Medline is initiating a voluntary recall on the Medline MED-SOFT liner lots listed in Table 1. This FSCA-22/07 cancels and replaces the FSCA-22/05 and the FSN-21/15.

REASON FOR FSCA-22/07:

The origin is a moulding issue of the removable L-connectors in the patient port of the MED-SOFT liners, which only affects cavity number 1 of the molding. As a result, the removable L- connector with the number "1" may be fully or partially blocked in the corner of the elbow which may impact suction when using the liner.

CORRECTIVE ACTIONS:

Medline has identified and implemented corrective actions to address this defect and has strengthened controls during the manufacturing process to prevent further product defects.

New deliveries of MED-SOFT suction liners are not affected by this FSCA, as the corrective actions have been implemented.

ACTIONS REQUIRED :

1. Check your inventory immediately. If you have the references with the affected lots listed in Table 1, please quarantine them.

2. Please discard all affected products in your facility and return the attached acknowledgement of receipt form duly completed, indicating the quantity of discarded products.

3. Even if you no longer have any of the products concerned in stock, please complete and return the acknowledgement form below as soon as possible, by email, and **no later than 30th June 2022**.

When we receive your completed acknowledgement form, please indicate if you would like to be refunded for the defective products or if you would like to receive a replacement order of products free of charge from customer services.

We thank you for your cooperation and Medline apologizes for the inconvenience caused. The relevant competent authorities have been informed of this field safety corrective action. 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,

xxx

Medline Europe

This urgent safety information is only addressed to facilities that have received the products concerned.

2 **Medline International Germany GmbH**
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Acknowledgement of receipt to be returned by email to the following address gmb-eu-fsn-fsca-kleve@medline.com

Medline reference: FSCA-22/07

Please complete and return the acknowledgement of receipt form as soon as possible by email **and no later than 30th June 2022.**

Table 1: Product codes and batches affected by this voluntary recall

Product Codes	Med-SOFT liners lots	Quantity discarded
DYNDSCL1000	670210802 to 670210805 670210903 to 670211102	
DYNDSCL1500	670210714 to 670210805 670210819 to 670210828 670210909 to 670211025	
OR1910PG	670210729 to 670210924	
OR1920PG	670210717 to 670211029	
OR1930	670210802 to 670210825	
OR1930PG	670210724 to 670210809 670210819 to 670210827 670210908 670210920 to 670211112	
OR53916	**670210727 and** 670210813 to 670211101	
OR929K	670210802 to 670211014 **and 670211116**	

Product Codes	Med-SOFT liners lots	Quantity discarded
OR53926	670210727 to 670210818 670211029 **and 670211109**	
DYNDSCL3000	670210715 to 670210811 670210830 670210918 to 670211108	
OR53929	670210813 to 670211025 **and 670211027**	
OR54916	670210802	
OR916K	670210809 to 670211020	
OR939K	670210727 670210914 to 670211014	
OR926K	670210718 to 670211014 **and 670211116**	
OR936K	670210825 to 670211022	

By completing and signing this document, I confirm that I have read and understood the instructions provided, and that all MED-SOFT liners have been discarded. I acknowledge receipt of this FSCA-22/07 by returning this completed and signed acknowledgement to Medline. I also agree to further distribute and communicate this important information within my facility as required.

If you distribute these products to other facilities or departments within your institution, please send a copy of this communication to them.

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

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:

☐ I would like to be refunded.

☐ I would like to receive a replacement order of products free of charge.

Date:	
Customer-Nr.:	
Name:	
Position:	
Faciliy or Business Entity:	
Addresse:	
City:	
Telephone:	
Email adress:	
Signature:	

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