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

Chateaubriant 3rd December 2021

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

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

SECURITY INFORMATION for the removable L-connector for Medline MED-SOFT Liner

Medline reference: **FSN-21/15**
MoH reference: **R2123307**
Product description: **Removable L-connector for Medline MED-SOFT Liner**
Action type: **Safety advisory notice**
Product codes: **See tables below**

Reference	Lot number
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	670210**813** to 670211**101**
OR929K	670210**802** to 670211**014**

Reference	Lot number
OR53926	670210**727** to 670210**818** 670211**029**
DYNDSCL3000	670210**715** to 670210**811** 670210**830** 670210**918** to 670211**108**
OR53929	670210**813** to 670211**025**
OR54916	670210802
OR916K	670210**809** to 670211**020**
OR939K	670210**727** 670210**914** to 670211**014**
OR926K	670210**718** to 670211**014**
OR936K	670210**825** to 670211**022**

Dear Customer,

This letter is to advise you that Medline has initiated a field safety notice regarding the removable L-connector of Medline MED-SOFT Suction System.

Although no serious incidents have been reported, Medline identified a potential risk of malfunction of the MED-SOFT liner related to the removable L-connector, pre-connected to the patient port of the liners. Some of these removable L-connectors may prevent the MED-SOFT liner from performing the intended suction operation.

The origin of the problem is the total or partial blockage of the removable L-connector in the corner of the elbow. The measures implemented to remediate this defect are the reinforcement of controls during the production (connectors and liners)

[redacted]

The removable L-connector pre-assembled onto the MED-SOFT liner is a non-essential accessory, and the functionality of the liner is therefore not impaired if the liner is used without the removable L-connector. Therefore, it can be removed prior to the use of the liner.

As stated in the directions for use shown in Figure 1, when the liner is installed, its correct functioning should be systematically checked by testing the aspiration (see instruction H).

Directions for set up and use

A. Remove liner from its packaging and then pull the liner down in order to extend and straighten out.
B. Insert proper sized soft liner into the coinciding sized hard outer reusable canister. Connect tubing from the suction regulator (or other vacuum source) to the port underneath the canister bracket.
C. Press down on the liner lid in order to make sure that you have securely sealed the liner and outer canister.
D. Attach red tubing from vacuum source to the Vacuum Port (1) on the soft liner lid.
E. Securely cap off Tandem Port (3) and Accessory Port (4).
F. Attach patient tubing to the Patient Port (2) on the soft liner lid.
G. Confirm all unused ports are securely capped off prior to initiating suction.
H. Ensure that the vacuum has been created and the soft liner is fully inflated.
I. The system is ready for use

Figure 1: Instructions for use of MED-SOFT system

Actions required:

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

Step 2: When fitting and using the MED-SOFT suction liners affected by this advisory, if the suction does not work properly, then the removable L-connector that is pre-connected to the liner patient port may be the cause.

Step 3: If the suction does not work after the test in step 2, remove the L-connector and connect the patient suction tubing directly to the patient port and check for the correct vacuum:

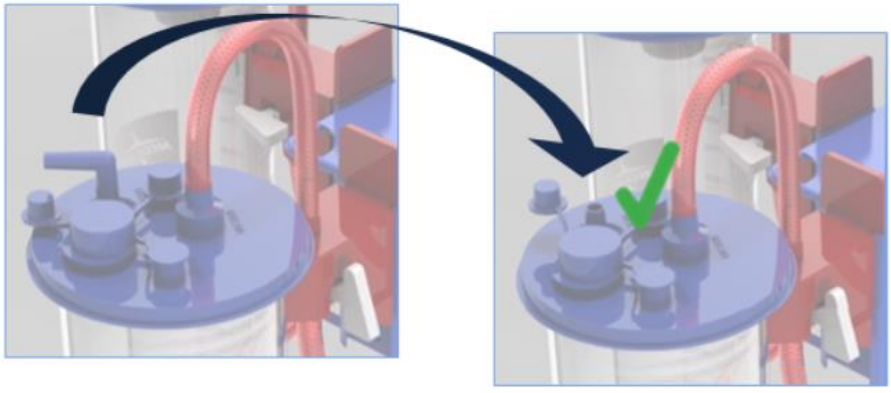

Figure 2: Remove the removable L-connector

Until the end of March 2022, the deliveries with the MED-SOFT liner affected by this field safety notice will be identified with a label on the carton:

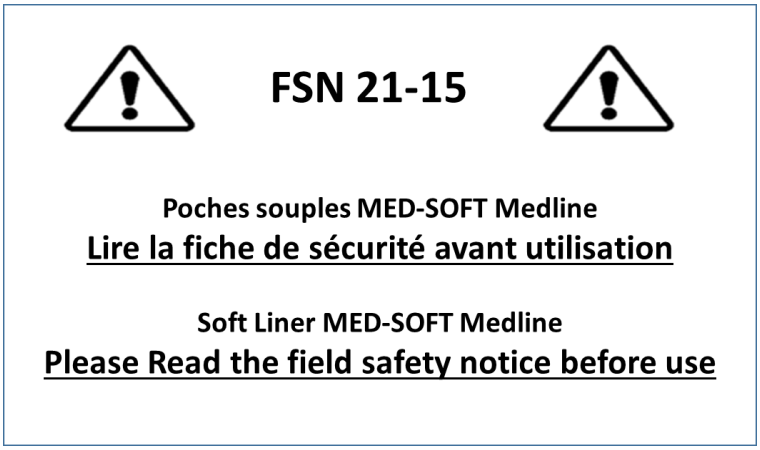

Figure 3: Warning Label on the carton

We thank you for your cooperation and apologize 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,

[redacted]

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

Please fax or email the acknowledgement receipt to: +49 2821 7510 7822 or gmb-eu-ra-kleve@medline.com

Reference: FSN-21/15

Please complete the acknowledgement form and send it back by either fax or email as soon as possible, but no later than 30 December 2021.

Table 1: Removable L-connector for MED-SOFT liner Medline concerned by this notification are listed in the below table:

Reference	Lot number
DYNDSCL1000	670210**802** to 670210**805** 670210**903** to 670211**102**
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OR936K	670210**825** to 670211**022**

☐ I have read and I understand the instructions provided. I acknowledge receipt of the FSN-21/15 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: _____
Email address: _____
Signature: _____