



**Medline International Germany GmbH**  
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[www.medline.com/de](http://www.medline.com/de)

Medline International Germany GmbH - Wilhelm-Sinsteden-Str. 5-7 - D-47533 Kleve

Customer Number:

Kleve, 27<sup>th</sup> October 2017

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

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

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**SECURITY INFORMATION of Medline Fluid Management – MED-SOFT 3-liter suction liners**

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**Medline reference:** FSN-17/06  
**Description:** Medline Fluid Management – MED-SOFT 3-liter liners  
**Product Codes concerned:** DYNDSC3000, OR1930PG, OR936K and OR939K

Dear Customer,

Medline International France has identified a potential risk when MED-SOFT 3-liter liners are filled to their maximum capacity, notably in high liquid intensive surgical procedures (during Urology surgical procedures or Arthroscopy surgical procedures for example), and used with a strong vacuum. At the end of the suction procedure, when disconnecting the red vacuum tube from the liner, the accessory cap can potentially come off, immediately or later, leading to the possibility of exposure to contaminated fluids.

**References and Lots Concerned**

Liner Reference	Description	Lots Concerned
DYNDSC3000	3L MED-SOFT Liner	6701701xxxx up to and including 6701710xxxx
OR1930PG	3L MED-SOFT Liner + MED-GEL	
OR936K	3L MED-SOFT Liner + 6mm x 1.80m Tubing	
OR939K	3L MED-SOFT Liner + 6mm x 3m Tubing	



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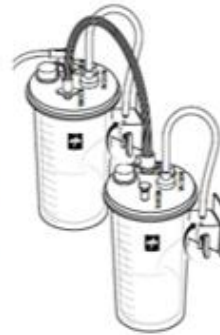
**Action:**

Read this Field Safety Notice carefully and communicate the precautions to the other users and concerned parties in your facility. Medline propose the following options:

1. Continue to use the Medline MED-SOFT 3-liter liners under the conditions that the liners are not filled to their maximum capacity:
  - a) when using a single/parallel configuration : fill the liner until the first accordion flange (see yellow mark in below diagram)
  - b) when using a tandem/series configuration, the liquid goes automatically from one liner to the next one. Fill the last liner until the first accordion flange (see yellow mark in below diagram), or
2. Use the 12-liter canister for fluid intensive procedures, i.e. (urology and arthroscopy), or
3. Return the Medline MED-SOFT 3-liter liners and receive alternative liners.



**1.a) SINGLE/PARALLEL**



**1.b) TANDEM/SERIE**

Yours Sincerely,  
Quality and Regulatory Affairs Dept.



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**Acknowledgement receipt to be faxed to the following Fax: +49 2821 7510 7822 or  
E-mail: [gmb-eu-ra-kleve@medline.com](mailto:gmb-eu-ra-kleve@medline.com)**

Please complete this form with your option and return to Medline by either fax or email as soon as possible, but **not later than November 17th, 2017**.

**Reference: FSN-17/06**

**Case 1.a)** I have read and understand the instructions provided by Medline: I will continue to use the Medline MED-SOFT 3-liter liners, and acknowledge receipt of the FSN-17/06.

**Case 1.b)** I have read and understand the instructions provided by Medline: I will use the tandem configuration and request Medline to provide the tandem tubes, and acknowledge receipt of the FSN-17/06.

REF	Quantity of Medline MED-SOFT 3-liter liners in stock	Quantity of tandem tubes requested (DYNDTND)
<b>DYNDSC3000</b>		
<b>OR1930PG</b>		
<b>OR936K</b>		
<b>OR939K</b>		

**Case 2)** I have read and understand the instructions provided Medline: I will use the 12-liter canister configuration, and acknowledge receipt of the FSN-17/06.

REF	Quantity of Medline MED-SOFT 3-liter liners in stock	Quantity of 12-Liter liners required for replacement (65651-120 or OR12L)
<b>DYNDSC3000</b>		
<b>OR1930PG</b>		
<b>OR936K</b>		
<b>OR939K</b>		

**Case 3)** I have read and understand the instructions provided Medline and I request the replacement of the liners, and acknowledge receipt of the FSN-17/06.

REF	Quantity of Medline MED-SOFT 3-liter liners to be replaced
<b>DYNDSC3000</b>	
<b>OR1930PG</b>	
<b>OR936K</b>	
<b>OR939K</b>	

I also agree to further distribute and communicate this important information within my facility as required.

Date:  
Customer Number:  
Name:  
Position:  
Facility:  
Address:

Telephone:  
Fax:  
Signature: