Medline International France
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh
44110 Châteaubriant

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice

Châteaubriant, Date

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

Field Safety Notice for Hudson RCI® AQUAPAK® Humidifier Adaptors distributed by Medline

Medline Reference:	**FSN-23/08**
Competent Authority Ref:	**TBD**
Product description:	**Hudson RCI® AQUAPAK® Humidifier Adaptors**
Action type:	**Field Safety Notice**
Product code :	**000-40F, 003-40F, 006-40F**

Figure 1: Example of sterile adaptor, ref. 000-40F

Dear Customer,

This letter is to advise you that Teleflex has initiated a field safety notice regarding the Hudson RCI® AQUAPAK® Humidifier Adaptors distributed by Medline. The adaptors are sold individually or with AQUAPAK® Sterile Water. The references of the adaptors concerned are provided in **Annex 1 (Page 4)**.

REASON FOR THE FIELD SAFETY NOTICE:

Teleflex Medical Europe, LTD has issued a field safety notice for AQUAPAK® Humidifier Adaptors due to reports of cracking across the threaded section of the adaptor, potentially compromising the seal and causing leakage during use. Defective adaptors must be replaced which may cause a delay in the procedure. While containment and correction activities have been ongoing, Medline is notifying our customers in an abundance of caution.

ACTIONS REQUIRED:

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

Step 2: If using an adaptor from an affected lot, when removing the adaptor from its packaging and visually inspect it for damage. If you observe any cracking per the figure below, do not use and replace with another adaptor immediately. There is no need to discard/replace the sterile water reservoir.

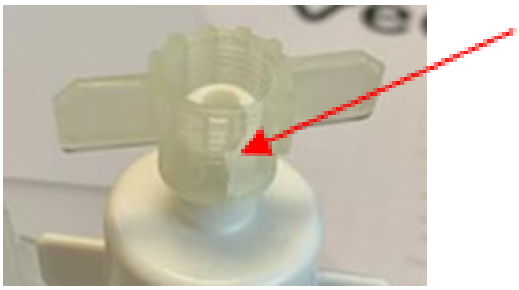

Figure 2: Example of a cracked adaptor

Step 3: Please complete the Acknowledgement Receipt (page 3) and return it by email as soon as possible, but no later than **September 15th, 2023**. For replacement of any cracked adaptors, please contact your Medline sales representative to request the quantity needed. As a result of Medline's correction and containment activities, all replacement adaptors received after April 18th, 2023 have been inspected and released by Medline.

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.

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel: +33 (0)2 44 05 30 68
gmb-eu-fsn-fsca-chbt@medline.com

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

Medline Reference: FSN-23/08

Field Safety Notice for Hudson RCI® AQUAPAK® Humidifier Adaptors distributed by Medline

Please complete and return the acknowledgement form and send it back by email as soon as possible, **but no later than 15th September, 2023**.

List of products concerned are listed in **Annex 1 (Page 4)**.

By completing and signing the document, I confirm that I have read and I understood the instructions provided, and that all impacted products have been discarded.

I acknowledge receipt of the FSN-23/08 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: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh • 44110 Châteaubriant
Tel: +33 (0)2 44 05 30 68
gmb-eu-fsn-fsca-chbt@medline.com

ANNEX 1

Part Number	Lot Number
003-40F	21B490
003-40F	22B232
003-40F	22B234
003-40F	22B238
003-40F	22B248
003-40F	22B249
003-40F	22B285
003-40F	22B286
003-40F	22B288
003-40F	22B290
003-40F	22B333
003-40F	22B369
003-40F	22B371
003-40F	22B373
003-40F	22B379
003-40F	22B381
003-40F	22B383
003-40F	22B385
003-40F	22B432
003-40F	22B434
003-40F	22B469
003-40F	22B470
003-40F	22B473
003-40F	22B474
003-40F	22B476
003-40F	22B479
003-40F	22B481
003-40F	22E096
003-40F	22E116
003-40F	22E117
003-40F	22E119
003-40F	22E156
003-40F	22E175
003-40F	22E176
003-40F	22E196
003-40F	23B001
003-40F	23B002
003-40F	23B003
003-40F	23B004

Part Number	Lot Number
006-40F	22E096
006-40F	22E116
006-40F	22E117
006-40F	22E119
006-40F	22E156
006-40F	22E157
006-40F	22E175
006-40F	22E176
006-40F	22E196
006-40F	23E001

Part Number	Lot Number
000-40F	11M19
000-40F	10M22

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Commercial registry number: 408.537.249 R.C.S. Versailles

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