

Aug-2023

URGENT – FIELD SAFETY NOTICE

Type of Action	Advisory		
Teleflex Reference	EIF-000533		
Medline Reference	FSCA-23/02		
Commercial Name	Hudson RCI® AQUAPAK® Humidifier Adaptor		
Product Code	000-40F	003-40F	006-40F

To whom it may concern,

Teleflex Medical received a Field Safety Notice (FSN) from Medline; refer to Appendix 1. Medline has initiated the FSN for the above listed product codes of the Hudson RCI® AQUAPAK® Humidifier Adaptors due to 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.

Medline initiated the FSN as the Distributor of the impacted product. Teleflex Medical (Athlone, Ireland) is the Authorised Representative in Europe for the Hudson RCI® AQUAPAK® Humidifier Adaptors and Teleflex Medical (Morrisville, NC, United States) is the legal manufacturer. As the Authorised Representative in Europe, Teleflex Medical (Athlone Ireland) is notifying the Competent Authorities for the impacted regions.

If you have received the impacted product outlined in the above table, please refer to Medline’s specified actions as identified in Appendix 1.

Contact reference person

Should you require any further information or support concerning this issue, please refer to the contact details outlined in Appendix 1.

Teleflex is committed to providing high quality, safe and effective products. We regret any inconvenience this action may cause your operations.

The undersign confirms this notice has been notified to the appropriate Regulatory Authority.

For and on behalf of Teleflex Medical,

[Redacted Signature]

[Redacted Title] **VP Global QA (Manufacturing)**



Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY NOTICE

Medical Device Safety Advisory Notice

Châteaubriant, 21th August 2023

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-23/02
Lead Competent Authority Ref:	HPRA – CRN00DRQF
Product description:	Hudson RCI® AQUAPAK® Humidifier Adaptors
Action type:	Field Safety Notice
Product code :	000-40F, 003-40F, 006-40F

Ref. 000-40F



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 5).

Medline International France SAS

2 Rue René Caudron • Bâtiment 13F
Parc D'Affaires le Val Saint Quentin • 78960 Voisins-le-Bretonneux
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

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

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,

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-23/02

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-23/02 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: _____

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

Medline International France SAS

2 Rue René Caudron • Bâtiment 13F
Parc D'Affaires le Val Saint Quentin • 78960 Voisins-le-Bretonneux
Tel: +33 1 30 05 34 34 • Fax: +33 1 30 05 34 43
fr-customerservice@medline.com • fr.medline.eu
Commercial registry number: 408.537.249 R.C.S. Versailles

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

