Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland

14 September 2020

# URGENT - FIELD SAFETY NOTICE

| Type of Action | Recall |
|---|---|
| **Teleflex Reference:** | EIF-000439 |
| **Commercial Name** | Rusch TracFlex Plus Phonation Set, Cuffed<br>Ruschcare TracFlex Plus Phonation Set, Cuffed |
| **Product Code / Lot Number** | **See Appendix 2 for a list of product codes and lots in scope.** |

Dear Customer,

Teleflex Medical has voluntarily issued a recall for the product codes and lot numbers listed above. All affected lot numbers are listed within **Appendix 2**.

**Description of the problem & immediate actions required**
Teleflex Medical is recalling the above-mentioned products following receipt of two complaints reporting a leak in the cuff. The issue was identified prior to use during the pre-use integrity check as outlined in the IFU therefore there was no patient involvement. In the unlikely event that a user does not perform the pre-use check per IFU, and a cuff leak is present, it may lead to an inadequate seal and a risk of a break in ventilation requiring medical intervention.

Our records indicate you have received products that are subject to this recall.

**Depending on your device location please adhere to the following Action list:**

| Device location | Action List Number |
|---|---|
| **Medical facilities** | **1** |
| **Distributors** | **2** |

**Action list number 1 – Medical facilities**

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

**Action list number 2 – Distributors**

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.

2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

**Teleflex**
Teleflex informs all customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

**Transmission of this Field Safety Notice**
This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this notice until all required actions have been completed in your organisation.

**Contact reference person**
Should you require any further information or support concerning this issue, please contact:

**Customer Service:**

**Contact:** Shane Kenny
**FAX:** +353 0 14370773
**Telephone:** +353 0 90 64608769
**Email**: recalls.intl@teleflex.com

Please be advised that all Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologise for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

***For and on behalf of Teleflex,***

*Padraig Hegarty*

**Padraig Hegarty VP, QA (Manufacturing)**

Appendix 1

Customer No. _____

# FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

**PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED**

**Ref. EIF-000439**

**RETURN COMPLETED FORM BY IMMEDIATELY TO:**

**FAX:** +353 (0) 1 4370773 **Email:** Recalls.Intl@teleflex.com

| | |
|---|---|
| ☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action. | ☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned.<br><br>**Return Authorisation No** _____ |

**PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.**

| **COMMERCIAL NAME OF AFFECTED PRODUCTS:** | | |
|---|---|---|
| **PRODUCT NUMBER** | **LOT NUMBER** | **QUANTITY (Returning)** |
| | | |
| | | |
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| | | |
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| | | |

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package.
- Please label returns as "**Field Action Returns"**

**Complete this Acknowledgement form and return immediately by using the fax number or e-mail address above.**

| **INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)** | |
|---|---|
| | |
| **INSTITUTION ADDRESS** | **Phone / Fax** |
| | |
| **FORM COMPLETED BY:** | **Stamp** |
| **PRINT NAME:**_____<br><br>**SIGNATURE:**_____ | |
| **DATE** | |

## Appendix 2

| Product Codes | Lots in Scope | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **121902-000070** | 17AT21 | 17CT20 | 17JT06 | 19KT07 | 19LT20 | | | |
| **121902-000080** | 17BT03 | 17GT28 | 17JT18 | 17JT25 | 19BT11 | 19JT67 | 19KT42 | 19LT20 |
| **121902-000090** | 17BT03 | 17ET20 | 17GT28 | 17JT13 | 17JT25 | 19DT26 | 19ET82 | 19GT64 |
| | 19KT10 | 19KT17 | 19LT23 | 19LT39 | | | | |
| **121902-000100** | 17BT03 | 17BT09 | 17GT28 | 17JT12 | 19BT11 | 19DT26 | 19FT51 | 19JT67 |
| | 19KT26 | 19LT20 | | | | | | |
| **121902-000110** | 17BT03 | 17BT16 | 17CT20 | 17GT28 | 19JT67 | | | |
| **858002-000070** | 17AT21 | 17JT06 | 19JT67 | | | | | |
| **858002-000080** | 17BT03 | 19BT12 | 19ET19 | 19FT51 | 19HT30 | 19JT67 | 19KT18 | 19LT23 |
| **858002-000090** | 17AT21 | 17BT03 | 18FT46 | 19BT08 | 19ET82 | 19HT17 | 19KT10 | 19LT38 |
| **858002-000100** | 17BT03 | 19ET56 | 19HT17 | 19JT67 | 19LT23 | | | |
| **858002-000110** | 17BT03 | 19LT20 | | | | | | |