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

December 2021

# URGENT – FIELD SAFETY NOTICE

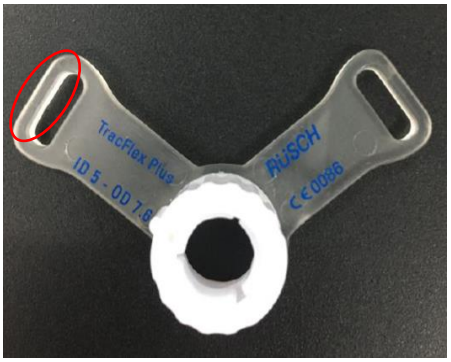
| | |
|---|---|
| **Type of Action** | **Advisory Notice** |
| **Teleflex Reference** | EIF-000493-01 |
| **Commercial Name** | RüschCare/ Rüsch TracFlex Plus, Paediatric Tracheostomy Tube Set |
| **Product Codes** | 121900-000050 |
| | 121900-000060 |
| | 858000-000050 |
| | 858000-000060 |

Dear Customer,

**Details of affected devices**

Teleflex has initiated a voluntary Field Safety Corrective Action for the TracFlex Plus Paediatric Tracheostomy tubes, refer to the above table for a list of product codes impacted.

**Description of the problem & immediate actions required**




Teleflex is initiating a voluntary Field Safety Corrective Action (FSCA) due to reports received indicating a break on the neckplate. Refer to the image for a guide to where the break may occur on the neckplate.

If the neckplate breaks during use, the neck band may become loose and/or detach from the neckplate. In this instance the immediate health consequences involve removing the affected tracheostomy tube and replacing with a new tracheostomy tube. A new tracheostomy tube and neckplate will allow the care provider to perform proper positioning and fixation of the tracheostomy tube with the neck band provided in the kit.

Product is suitable for continued use. Users are advised to adhere to the Instructions for Use for this product specifically, "*Avoid strong traction of the tube and the fixation flange as this can cause extubation and/or injury to the trachea.*" Following application of the neck band, care providers should check to ensure they can easily place two fingers between the neck band and the neck. This will ensure the neck band is not too tight. Always use the neck band supplied in the TracFlex Plus tracheostomy Tube set. Additional Rüsch® neck bands can be purchased separately, product reference 507800 Paediatric / 507900 Adult.

Our records indicate you have received products that are in scope of this Field Safety Notification.

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

| Device location | Action List Number |
|---|---|
| **Homecare Setting & Medical Facilities** | **1** |
| **Distributors** | **2** |

**Action list number 1 – Homecare Setting & Medical Facilities**

Our records indicate that you have received product in scope. Please read this notice carefully and adhere to the advice within.

Image 1, product without defect

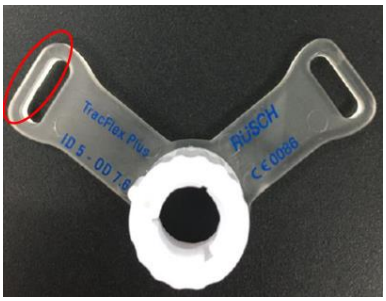



Image 2, product with defect


If the device is **in use**:

a) Visually inspect the neckplate to ensure that the area within the red circle on both sides is completely intact (like image 1).
b) Check the neck band to ensure it is not too tight. As a guide, an adult should be able to easily place two fingers between the neck band and the neck.
c) If the neck band is too tight, loosen until you can comfortably place two fingers under the neck band.
d) If a crack/break is present, like Image 2 above, the product should be replaced by whomever routinely supports this activity as soon as possible. In the interim, check the neck band to ensure it is not too tight. An overly tight neck band will exacerbate the issue.

If the device is **not in use**:

a) You may continue to use the product however be aware of this possible failure and inspect frequently when the product is in use.
b) Following product placement and subsequent neck band adjustments/swap outs, check the neck band to ensure it is not too tight. As a guide, an adult should be able to easily place two fingers between the neck band and the neck.
c) Always use the neck band supplied in the TracFlex Plus tracheostomy Tube set. Additional Rüsch® neck bands can be purchased separately, product reference 507800 Paediatric / 507900 Adult.

Please complete the acknowledgement form (Appendix 1) and return to Teleflex.

**Action list number 2 – Distributors**

1. Provide this field safety notice to customers who received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. Place a copy of this notice with the product.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the action outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.

**Teleflex**
Teleflex informs impacted 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 **Telephone:** +353 (0)86 3479154
**Email:** Recalls.Intl@teleflex.com

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,***

[redacted]

Teleflex

**Appendix 1**

**Customer No**
_____

# FIELD SAFETY CORRECTIVE ACTION
# ACKNOWLEDGEMENT FORM

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

**Ref. EIF-000493-01**

**RETURN COMPLETED FORM IMMEDIATELY TO:**

**E-Mail:** 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. |

**Complete this Acknowledgement form and return immediately by using the contact information above.**

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