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

06 May 2020

URGENT - FIELD SAFETY NOTICE

Type of Action			Recall		
Teleflex Reference:			EIF-000409		
Commercial Name			Rüsch TracFlex Plus Tracheostomy Tube with Subglottic Suction Set, Cuffed		
Product Code					Batch/Lot Number
121905-000070	121905-000080	121905-000090	121905-000100	121905-000110	See Appendix 2 for a list of product codes and lots in scope
858005-000070	858005-000080	858005-000090	858005-000100	858005-000110	

Dear Customer,

Teleflex has voluntarily issued a recall for the above listed products.

Description of the problem & immediate actions required

Teleflex is recalling the product referenced above due to reports indicating the inability to inflate and/or deflate the tracheostomy tube cuff when the adjustable flange connector is locked.
We have identified the root cause.

For product in situ in patients:

- If the cuff requires further inflation or deflation during use it may be necessary to unlock the adjustable flange connector in order to permit this to happen.
- If the deflation issue occurs during removal of the device, the attending clinician may intervene by unlocking the adjustable flange connector, which may permit the cuff to be deflated.
- If, during the removal of the tracheostomy, the cuff has not deflated despite unlocking the adjustable flange connector, caution should be exercised as this may cause a reopening of the tracheostomy stoma.

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**
Home Setting	**3**

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. Where inventory indicates that you may have product within the scope of this FSCA that is in situ in patients, ensure that the attending clinician is urgently informed of this issue and of the advice in this Field Safety Notice.
3. 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.
4. 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.
5. 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.

Action list number 3 – Home Setting

1. Carefully check unused product you have in storage using the list of product codes and lots listed above. This product should not be used, quarantine/segregate the product immediately.
2. If you do have unused product: Complete 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 unused product: Complete 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 from whom you received product) will issue a credit note upon receipt of the returned affected product.
5. A copy of this notice should be provided to attending clinicians so that they can follow the guidance outlined in the **Description of the problem & immediate actions required** section above.

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: Nicole Morawiec **Telephone:** +41 (0) 31 818 40 90

FAX: +41 (0) 31 818 40 93 **Email**: info.ch@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-000409

RETURN COMPLETED FORM BY IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93 **Email:** info.ch@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. **Return Authorisation No _____**

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

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

- 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: _____ **SIGNATURE: _____**	
DATE	

Appendix 2 - Product Codes and Lots in scope of EIF-000409

Product Code	Lot Number
121905-000070	18FG10
	18LT11
	19ET82
	19IT07
	19IT12
121905-000080	18FG10
	18LT11
	19ET35
	19ET38
	19ET56
	19GT30
	19GT40
	19GT64
	19IT12
121905-000090	18FT13
	18KT30
	19DT26
	19DT29
	19ET19
	19FT19
	19GT30
	19GT64
	19HT65
	19IT37
121905-000100	18FG10
	18LT11
	18LT13
	19DT26
	19ET19
	19ET56
	19HT08
121905-000110	18FT13
	18KT30
	18LT11
	18LT13
	19ET19
	19IT12
	19JT25
858005-000070	18FT13
	18LT25
	19IT12

Product Code	Lot Number
858005-000080	18FT13
	18LT24
	19ET56
	19GT23
	19GT64
858005-000090	18FT13
	18LT24
	19GT07
	19GT30
858005-000100	18FT13
	19ET56
	19HT08
858005-000110	18FT13
	19IT12