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-000403		
Commercial Name			Rusch TracFlex Plus Set, cuffed TracFlex Plus PDT Set RuschCare TracFlex Plus Set, cuffed		
Product Code					**Lot Number**
121903-000070	121903-000080	121903-000090	121903-000100	121903-000110	See Appendix 2 for a list of product codes and lots in scope
121904-000070	121904-000080	121904-000090	858003-000070	858003-000080	
858003-000090	858003-000100	858003-000110			

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 during use. The root cause has been identified & corrective action taken.

For product in situ in patients:

- If the cuff requires further inflation or deflation during use it may be necessary to inspect the inflation line, ensuring that cuff inflation line is not kinked, to permit this to happen.
- If the deflation issue occurs during removal of the device, the attending clinician may intervene by pinching the inflation line open to allow the cuff to be deflated.
- If, during the removal of the tracheostomy tube, the cuff has not deflated despite recommended interventions, 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: Sales Assistants **Telephone:** +31 (0) 088 00 215 00
FAX: +31 (0) 88 00 215 10 **Email:** productcomplaints.netherlands@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,

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Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000403

RETURN COMPLETED FORM BY IMMEDIATELY TO:

FAX: +31 (0) 88 00 215 10 **Email:** productcomplaints.netherlands@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-000403

Product Code with Commerical Name	Lot Number						
121903-000070 Rusch TracFlex Plus Set, cuffed	15LT22	16AT06	16CT16	16FT22	16HT22	16HT26	16JT16
	17AT15	17BT22	17CT29	17FT34	17HT30	17JT12	17KT19
	17LT39	18LT04	19HT17	19HT37	19HT45	19IT55	19JT48
	19JT67	19KT07	19KT08	19KT09	19JT25		
121903-000080 Rusch TracFlex Plus Set, cuffed	15FT05	15HT06	15KT21	15LT22	16BT06	16CT16	16DT19
	16ET15	16GT22	16HT22	16HT26	16IT16	16JT16	16JT27
	16LT04	17AT15	17DT21	17IT09	17KT19	17LT14	18BT11
	19DT26	19ET08	19ET11	19GT15	19GT40	19HT65	19IT37
	19IT55	19JT25	19JT41	19KT17			
121903-000090 Rusch TracFlex Plus Set, cuffed	15FT24	15HT11	15JT16	15LT22	16AT06	16BT06	16CT16
	16DT19	16ET15	16FT22	16GT22	16IT16	16JT16	16JT27
	16KT04	16KT10	17BT22	17DT11	17DT15	17FT34	17GT28
	17HT30	17IT09	17JT13	17KT19	18LT04	19AT19	19BT08
	19ET35	19ET56	19HT30	19HT73	19IT37	19JT25	19JT30
	19JT59	19JT67					
121903-000100 Rusch TracFlex Plus Set, cuffed	15FT05	15HT06	16AT06	16BT06	16DT19	16GT22	16GT26
	16HT26	16JT16	16JT27	16LT04	17CT29	17FT34	17KT19
	18LT18	19BT04	19BT19	19GT15	19GT47	19IT37	19JT41
121903-000110 Rusch TracFlex Plus Set, cuffed	16GT26	16KT10	17AT15	17GT28	18LT18	19BT19	19JT48
121904-000070 TracFlex Plus PDT Set	17KT27						
121904-000080 TracFlex Plus PDT Set	15IT03	16BT14	16DT19	16GT21	16JT22	17ET28	17IT21
	17JT06	18CT20	19AT19	19ET11	19GT07		

Appendix 2 - Product Codes and Lots in scope of EIF-000403

Product Code with Commerical Name	Lot Number						
121904-000090 TracFlex Plus PDT Set	15FT14	15IT20	15JT19	16BT06	16DT23	16FT05	16GT21
	16JT16	17BT16	17HT15	17IT29	17KT18	17LT14	18BE05
	18BT08	18GT06	18KT21	19AT14	19AT19	19ET35	19HT08
	19JT70	19KT07					
858003-000070 RuschCare TracFlex Plus Set, cuffed	15LT22	16FT22	17HT30	18LT25	19HT17	19KT08	19KT09
858003-000080 RuschCare TracFlex Plus Set, cuffed	15IT12	15JT16	15LT22	16AT13	16DT19	16ET15	16GT22
	16IT16	16JT16	16JT27	17AT15	17DT21	17JT12	17LT14
	18LT24	19BT03	19DT26				
858003-000090 RuschCare TracFlex Plus Set, cuffed	15GT18	15JT16	15KT21	15LT22	16AT06	16CT16	16DT19
	16ET15	16GT22	16GT26	16JT16	16JT27	16KT04	16LT04
	17BT22	17DT15	17FT34	17GT28	17HT30	17IT09	17JT13
	17KT19	19AT19	19BT19	19ET35	19IT37	19JT41	
858003-000100 RuschCare TracFlex Plus Set, cuffed	15FT24	15HT11	16AT06	16AT13	16BT06	16ET15	16GT22
	16IT16	16JT16	16JT27	17CT29	17DT11	17FT34	17GT28
	17HT30	17KT19	19BT03	19BT19	19ET72	19GT15	
858003-000110 RuschCare TracFlex Plus Set, cuffed	15JT16	16AT06	16BT06	16JT16	17DT21	17GT28	17KT19
	18LT24	19AT19	19IT55				