

20 April 2021

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000456-01
Commercial Name	Rusch TracFlex Plus Phonation Set, Cuffed Rusch TracFlex Plus Set, cuffed Rüsck TracFlex Plus Tracheostomy Tube with Subglottic Suction Set, Cuffed Ruschcare TracFlex Plus Phonation Set, Cuffed
Product Code/Lot Number	Refer to Appendix 2

Dear Customer

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action (FSCA) for the above listed product, refer to Appendix 2 for a list of product codes and lots impacted. This recall is an amendment to a recent recall reference EIF-000456 and is an expansion in the scope of lots subject to the recall. If you did not receive a copy of the original recall letter, it is because we have identified that you had only received products from the expanded scope of products involved, and did not receive any affected lots that were included in the original recall scope.

Regardless, if you had originally responded to the initial notification, or are just receiving notification for the first time, Teleflex requests that you complete and sign the attached response form (Appendix 1) confirming that you had been notified of this action and took the required action.

Description of the problem & immediate actions required

Teleflex is initiating a Field Safety Corrective Action for the above-mentioned products due to reports that the Tracheostomy cuff folded over the cannula tip of the Tracflex Plus Tracheostomy product, resulting in an obstruction of the cannula and reduced oxygen flow. If the defect is present, and is not recognised prior to use, adverse health consequences such as desaturation may result from the use of the device for Tracheostomy patients in a hospital or homecare setting.

Our records indicate you have received products that are subject to this Field Safety Advisory Notification.

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

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	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 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.
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. 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, refer to Appendix 2 for the list of impacted codes & lots, 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: Sales Assistants
FAX: +31 (0) 88 00 215 10

Telephone: +31 (0) 88 00 215 00
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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....., ***Global QA (Manufacturing)***

Appendix 1

Customer No

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000456-01

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +31 (0) 88 00 215 10

Email: productcomplaints.netherlands@teleflex.com

<input type="checkbox"/> 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.	<input type="checkbox"/> 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 _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<ul style="list-style-type: none"> 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 Safety Returns" 		

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

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	Phone/FAX
FORM COMPLETED BY:	Stamp
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Appendix 2

Appendix 2: EIF-000456-01 – Extended Product Scope

Product Code	Batch
121902-000070	KME20K2851
121902-000080	KME20K2854
121902-000090	KME20K2857
	KME20M2742
121902-000100	KME20K2858
121902-000110	KME20K2859
858005-000090	KME20M0200
	KME20M1460
	KME20M1462
121903-000060	17BT09
	19BT12
	19CT45
	19ET72
	19IT12
	19KT07
858002-000070	KME20K2852
121903-000050	16GT22
	19AT19
	19ET19
	19GT47
	19IT12
	19IT55
858002-000080	KME20K2853
858002-000090	KME20L0229
858002-000100	KME20K3325
121905-000090	KME20K2418
	KME20K3299
	KME20M1009
	KME20M0199
	KME20M1461
	KME20M1463
	KME20M3088