Teleflex

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

January-2023

URGENT – FIELD SAFETY NOTICE

Type of Action	**Recall**
Teleflex Reference	EIF-000527
Commercial Name	Rüsch EndoGuide T PVC
Product Code	503110-000060 & 503100-000060
Batch/Lot Number	Refer to Appendix 2

Dear Customer,

Details of affected devices
Teleflex Medical Europe Limited has initiated a voluntary Field Safety Corrective Action ("FSCA") for the above listed products; refer to Appendix 2 for Unique Device Identifier ("UDI") and lot number information.

Description of the problem & immediate actions required
This voluntary FSCA for the above-listed products has been initiated due to a potential for the plug to detach from the tip of the EndoGuide T Size 6.

In the event that the plug detaches from the EndoGuide T the exposed wire may damage any of the anatomy through which the device passes. If the plug were to detach during use, the plug may fall into the airway. Either of these events require remediation by a clinician.

As of 14-December-2022 Teleflex have received no complaints related to the detaching of the plug from the EndoGuide T Size 6.

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

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 immediately check your inventory for product within the scope of this FSCA. Users should cease use and distribution of affected product and immediately quarantine the affected product.
2. If you have impacted product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and contact Teleflex Customer Service by calling the phone number provided below. Teleflex Customer Service will issue a Return Goods Authorisation (RGA) number to you. Write the (RGA) number into the respective field in the Acknowledgement Form and promptly return this form to the e-mail address below.

3. If you do not have impacted product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and return the form to Teleflex at the contact details provided.
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 impacted product. Each of your customers is then required to complete the Acknowledgement Form and return it to you.
2. We request that you immediately check your inventory for impacted product. Cease use and distribution of impacted product and immediately quarantine the affected product. You may then return all product in scope.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined in actions 1 and 2 of this Action List Number 2. Upon completion of your actions, please forward the completed Acknowledgement Form to the e-mail address below. **Important** - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.
4. Please be aware that all European Economic Area/Switzerland, United Kingdom (EEA/CH/UK) and Turkey (TR) 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 Customer Service by return e-mail to the e-mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/UK/TR area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Customer Service at the contact information below.

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. Please 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: Customer Service **Telephone:** 0711 / 20 90 80 00
Email: recalls.de@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We regret any inconvenience this action may cause your operations. If you have any other questions, please contact your local Teleflex sales representative or Teleflex Customer Service.

The undersign confirms this notice has been notified to the appropriate Regulatory Authority.

For and on behalf of Teleflex,

[redacted]
[redacted] ***Global QA (Manufacturing)***

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Appendix 1

Customer No _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000527

RETURN COMPLETED FORM IMMEDIATELY TO:

E-mail: recalls.de@teleflex.com

☐ We confirm receipt of this FSN and completion of the required actions contained therein. We further confirm that our inventory **does NOT** include products impacted by this Field Action.	☐ We confirm receipt of this FSN and completion of the required actions contained therein. We further confirm our inventory **DOES** include products impacted 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 Goods Authorisation No** _____

Complete this Acknowledgement Form and return the completed form immediately using the contact information above.

Product code	Lot/batch number	Quantity returning
Important - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.		

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

Note: Non-FSCA product returns should be processed per standard product return processes.

INSTITUTION NAME (E.G., NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**PHONE/FAX/E-MAIL**
FORM COMPLETED BY	**STAMP**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

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Appendix 2: Product in scope of EIF-000527

Product Code	Batch	UDI Information (Unit Level)
503100-000060	KME21F0192	(01)14026704735140(17)230528(10)KME21F0192
503100-000060	KME21F1411	(01)14026704735140(17)230528(10)KME21F1411
503100-000060	KME21F1654	(01)14026704735140(17)230528(10)KME21F1654
503110-000060	KME21F1490	(01)14026704735157(17)230528(10)KME21F1490
503100-000060	KME21F1912	(01)14026704735140(17)230528(10)KME21F1912
503100-000060	KME21F1990	(01)14026704735140(17)230528(10)KME21F1990
503100-000060	KME21F2337	(01)14026704735140(17)230528(10)KME21F2337
503100-000060	KME21G0432	(01)14026704735140(17)230628(10)KME21G0432
503110-000060	KME21G0599	(01)14026704735157(17)230628(10)KME21G0599
503100-000060	KME21G1140	(01)14026704735140(17)230628(10)KME21G1140
503100-000060	KME21G1748	(01)14026704735140(17)230628(10)KME21G1748
503110-000060	KME21G1989	(01)14026704735157(17)230628(10)KME21G1989
503100-000060	KME21G2086	(01)14026704735140(17)230628(10)KME21G2086
503110-000060	KME21G2196	(01)14026704735157(17)230628(10)KME21G2196
503110-000060	KME21G2627	(01)14026704735157(17)230628(10)KME21G2627
503100-000060	KME21J2004	(01)14026704735140(17)230828(10)KME21J2004
503100-000060	KME21K0335	(01)14026704735140(17)230928(10)KME21K0335
503100-000060	KME21K0693	(01)14026704735140(17)230928(10)KME21K0693
503100-000060	KME21K1097	(01)14026704735140(17)230928(10)KME21K1097
503100-000060	KME21K1380	(01)14026704735140(17)230928(10)KME21K1380
503110-000060	KME21K1671	(01)14026704735157(17)230928(10)KME21K1671
503110-000060	KME21L1135	(01)14026704735157(17)231028(10)KME21L1135
503100-000060	KME21M2531	(01)14026704735140(17)230528(10)KME21M2531
503100-000060	KME21M2813	(01)14026704735140(17)230828(10)KME21M2813
503100-000060	KME21M2529	(01)14026704735140(17)230528(10)KME21M2529
503110-000060	KME21M2532	(01)14026704735157(17)230628(10)KME21M2532
503110-000060	KME22B2867	(01)14026704735157(17)240128(10)KME22B2867
503100-000060	KME22C0046	(01)14026704735140(17)240228(10)KME22C0046
503100-000060	KME22C3310	(01)14026704735140(17)240228(10)KME22C3310
503100-000060	KME22D2403	(01)14026704735140(17)240328(10)KME22D2403
503100-000060	KME22D2998	(01)14026704735140(17)240328(10)KME22D2998
503100-000060	KME22E0999	(01)14026704735140(17)240428(10)KME22E0999
503100-000060	KME22G0292	(01)14026704735140(17)240628(10)KME22G0292
503110-000060	KME22G1741	(01)14026704735157(17)240628(10)KME22G1741
503110-000060	KME22K0630	(01)14026704735157(17)240928(10)KME22K0630

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