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

04th April 2019

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000338
Commercial Name	Lasertube (Rubber) Laser resistant tracheal tube, cuffed; Endotracheal tube for laser surgery
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.

Description of the problem & immediate actions required

Teleflex Medical is initiating a Field Safety Corrective Action for the above-mentioned products due to reports indicating that the laser guard foil partially separated and/or slightly detached at the edges. If the defect is present and is not recognised prior to use, adverse health consequences may result from the use of the device during laser therapy in the trachea and larynx including potential for mucosal cell trauma/bleeding, scarring, infection and pain. No patient injuries have been reported.

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,

Appendix 1

Customer No _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000338

RETURN COMPLETED FORM 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

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 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	