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

10th 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: 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, Global QA (Manufacturing)

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: +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

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	

Appendix 2 - Product codes and Lots in Scope

Product Code	Lot Number	Product Code	Lot Number
102004-000040	14151	102004-000060	15411
	14161		15421
	14171		15431
	14211		15441
	14231		15451
	14271		15461
	14281		15471
	14321		15501
	14441		16031
	14461		16061
	14501		16081
	14511		16091
	15031		16101
	15051		16131
	15091		16151
	15101		16161
	15251		16171
	15271		16181
	15411		16191
	16051		16201
	16071		16221
	16101		16231
	16161		16241
	16171		16251
	16201		16261
	16231		16281
	16271		16291
	16291		16301
	16301		16311
	16311		16351
	16361		16361
	16381		16371
	16401		16381
	16421		16391
	16431		16421
	16451		16431
	16481		16441
	16501		16451
	16511		16461
	17021		16471
	17031		16481
	17051		16501
	17071		17021
	17091		17031
	17111		17041
	17121		17051
	17161		17061
	17181		17081

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	17201		17101
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	17261		17121
	17271		17131
	17281		17161
	17351		17171
	17371		17181
	17461		17191
	18021		17201
	18031		17221
	18061		17231
	18101		17251
	18121		17261
	18161		17271
	18201		17281
	18351		17291
	18361		17301
	18401		17361
102004-000050	14151		17381
	14161		17411
	14171		17421
	14201		17431
	14211		17441
	14231		17451
	14261		17461
	14271		17471
	14291		17481
	14451		17491
	14461		17501
	14491		18021
	14511		18031
	15041		18041
	15081		18051
	15091		18061
	15101		18071
	15131		18091
	15161		18101
	15201		18111
	15211		18121
	15221		18131
	15241		18141
	15251		18151
	15361		18161
	15381		18171
	15391		18201
	15411		18221
	15431		18231

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Product Code	Lot Number	Product Code	Lot Number
102004-000050	15441	102004-000060	18241
	15461		18251
	15491		18281
	15501		18301
	16041		18311
	16051		18381
	16061		18401
	16081		18411
	16091		18421
	16111		18431
	16121		18441
	16141	102004-000070	14161
	16161		14171
	16171		14201
	16191		14211
	16201		14231
	16221		14261
	16231		14301
	16241		14311
	16251		14361
	16261		14431
	16281		14481
	16291		14491
	16301		15041
	16351		15051
	16361		15081
	16371		15091
	16381		15121
	16391		15131
	16401		15161
	16421		15171
	16431		15201
	16441		15221
	16451		15241
	16471		15261
	16481		15371
	16501		15411
	16511		15421
	17021		15501
	17041		16031
	17051		16071
	17061		16111
	17071		16151
	17081		16161
	17091		16181
	17101		16201
	17121		16221
	17131		16241

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102004-000050	17161	102004-000070	16251
	17171		16271
	17181		16281
	17191		16291
	17201		16301
	17211		16351
	17231		16361
	17271		16371
	17281		16381
	17301		16391
	17311		16401
	17361		16421
	17371		16441
	17391		16461
	17421		16471
	17431		16481
	17441		17061
	17451		17071
	17461		17161
	17471		17191
	17481		17211
	17491		17221
	17501		17251
	17511		17271
	18021		17291
	18031		17301
	18041		17311
	18051		17381
	18061		17391
	18071		17411
	18081		17471
	18091		17481
	18101		17511
	18111		18021
	18121		18081
	18131		18091
	18141		18151
	18151		18161
	18171		18211
	18191		18241
	18201		18291
	18231		18381
	18241		18411
	18271		18421
	18351		18431
	18361		18441
	18381	102004-000080	14151
	18401		14161

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102004-000050	18421	102004-000080	14201
	18431		14281
	18441		14301
	14141		14321
	14161		14431
	14171		14491
	14201		14511
	14211		15041
	14231		15371
	14261		15441
	14271		16071
	14281		16131
	14291		16191
	14301		16221
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	15311		18301
	15361		18411
	15371		

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