Teleflex

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

May-2023

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall Notice
Teleflex Reference	EIF-000537
Product Code & Batch/Lot Number	Refer to Appendix 2
Commercial Name	
TOP Endotracheal tube with Cuff	RUSCHELIT® Preformed Nasal Tracheal Tube, Two Eyes without Cuff
Slick Set ® Cuffed Endotracheal Tube and Stylet Set, oral/nasal	RUSCHELIT® Safety Clear Tracheal Tube, oral/nasal
Slick Set ® Uncuffed Endotracheal Tube and Stylet Set, oral/nasal	Safety Clear Tracheal tube (without Cuff)
Flexi-Set Cuffed Endotracheal Tube and Stylet Set, oral/nasal	RUSCHELIT® Preformed Oral Tracheal Tube, Cuffed, Oral, Murphy Eye
Flexi-Set Uncuffed Endotracheal Tube and Stylet Set, oral/nasal	AGT Orotracheal tube
Preformed AGT Oral Endotracheal Tube uncuffed/plain - Murphy	RUSCHELIT® Preformed Nasal Tracheal Tube, Cuffed, Nasal, Murphy Eye
Preformed AGT Nasal Endotracheal Tube uncuffed/plain - Murphy	AGT Nasotracheal tube
Endotracheal Tube oral/nasal uncuffed/plain - Murphy	RUSCHELIT® Safety Clear Plus Tracheal Tube, oral/nasal, Cuffed
Preformed AGT Oral Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff	RUSCHELIT® Super Safety Clear Microlaryngeal Tube, oral/nasal
Preformed AGT Nasal Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff	RUSCHELIT® Super Safety Clear Tracheal Tube, oral/nasal, Cuffed
Endotracheal Tube oral/nasal Magill, High Volume, Low Pressure Cuff	Flexiset Super Safety Clear Tracheal Tube, oral/nasal with Cuff and Insertion Aid
Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff	RUSCHELIT ® Safety Clear Tracheal Tube, oral/nasal, Murphy
RUSCHELIT ® Safety Clear Tracheal Tube, oral/nasal, Magill	Super Safety Clear Tracheal tube
RUSCHELIT® Preformed Oral Tracheal Tube, Two Eyes without Cuff	ENDOSOFT Tracheal tube

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 product code and lot number information.

Description of the problem & immediate actions required

This voluntary FSCA has been initiated due to reports of disconnection of the 15mm connector from the endotracheal tube (ET tube) for the affected products. There is the possibility of oxygen desaturation and in that event any immediate and long-term health consequences are dependent on the degree and duration of desaturation, which may include serious injury or death.

Where patients are undergoing mechanical ventilation in either the operating room or critical care settings, the ventilation devices to which the affected products are connected are designed to alarm immediately upon a disconnection in the breathing circuit, alerting the clinician to reattach the connector. Additional standards of care such as pulse oximetry also alert clinicians to desaturation within seconds of its occurrence, again permitting prompt reattachment of the connector.

For product in situ, Teleflex advises clinical staff to ensure the 15 mm connector is seated firmly in the ET tube to prevent disconnection during use per the product instructions for use. Should disconnection occur, reconnect the two components promptly and securely in the manner described in the product instructions for use. Clinical staff may wish to consider replacing the device, making sure to evaluate on a case by case basis the risks associated with extubation and reintubation.

As of 14-April-2023, Teleflex received 173 complaints reporting connector issues for products in scope of this field correction. Of these 173 complaints, 10 reported injury, including eight reports of patient desaturation, and three reports of patient death. Two complaints reported that the patient deaths were unrelated to the disconnection of the device and one complaint reported that it was impossible to determine whether the device contributed to the patient death.

The initial investigation has identified that the disconnection results from intermittent cross-contamination of the 15mm connector with trace amounts of silicone oil. Although this does increase the lubricity of the connection, this does not present additional expected risks.

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 affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and contact Teleflex Customer Service by calling the phone number provided below.
3. If you do not have affected 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 a copy of 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 affected product. **Cease use and distribution of, 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: Sales Assistant **Telephone:** +31 (0) 088 00 215 00
Email: productcomplaints.netherlands@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,
...

Teleflex

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000537

RETURN COMPLETED FORM IMMEDIATELY TO:

E-mail: productcomplaints.netherlands@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.

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	