Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Endotracheal Tube Connector
Manufacturer	Teleflex
Country of Origin	Ireland
Reference	Refer to the below attachment
Reason of Alert	NHRA initiates this FSN 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.
Action should be taken	For more information about the necessary action for the recall please contact the Authorized Representative Gulf Corporation for Technology at quality@gctbahrain.com.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2023 0020 **03/12/2023**

Teleflex

Teleflex LLC
3015 Carrington Mill Blvd.
Morrisville, NC 27560

May-2023

URGENT MEDICAL DEVICE RECALL

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 LLC has initiated a voluntary recall 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 recall 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.

Teleflex

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 recall. 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 recall.

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 recall. **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 fax it to *1-855-419-8507*, including "Attn: Customer Service", or e-mail it to recalls@teleflex.com. This will allow us to document the amount of affected product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) number and will provide instructions for the return of affected products to Teleflex.
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 recall 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 recall notice when completing this form.
4. 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.

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Customer Service using the contact information below or may also be reported to the FDA's MedWatch Adverse Event Reporting program either by phone at 1-888-INFO-FDA (1-888-463-6332) or online at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization 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 organization.

Contact reference person

Should you require further information or support concerning this issue, please contact Customer Service via email, phone, or FAX using the details provided below. Customer Service hours of operation are 8am–7pm EST.

Customer Service:
Contact: Customer Service
FAX: 1-855-419-8507
Telephone: 1-866-396-2111
Email: Recalls@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.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, Global QA (Manufacturing)