Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland
01st November2019

URGENT - FIELD SAFETY NOTICE

Type of Action			Advisory Notice		
Teleflex Reference:			EIF-000378		
Commercial Name			Rusch TracFlex Plus Phonation Set, Cuffed Ruschcare TracFlex Plus Phonation Set, Cuffed		
Product Code	**Batch/Lot Number**	**Product Code**	**Batch/Lot Number**	**Product Code**	**Batch/Lot Number**
121902-000070	17AT21 17CT20 17JT06	**121902-000100**	17BT03 17BT09 17GT28 17JT12 19BT11 19DT26 19FT51	**858002-000080**	17BT03 19BT12 19ET19 19FT51 19HT30
121902-000080	17BT03 17GT28 17JT18 17JT25 19BT11	**121902-000110**	17BT03 17BT16 17CT20 17GT28	**858002-000090**	17AT21 17BT03 18FT46 19BT08 19ET82 19HT17
121902-000090	17BT03 17ET20 17GT28 17JT13 17JT25 19DT26 19ET82 19GT64	**858002-000070**	17AT21 17JT06	**858002-000100**	17BT03 19ET56 19HT17
				858002-000110	17BT03

Dear Customer,

Teleflex Medical has voluntarily issued a Field Safety Advisory Notification for the above listed products.

Description of the problem & immediate actions required
Teleflex Medical is issuing a Field Safety Advisory Notice for the product referenced above as there is insufficient information outlined in the IFU with regards to Tracheostomy Tube warnings during positive pressure ventilation. In the event these products are used during positive pressure ventilation, it may lead to an inadequate seal with an exaggerated leak and therefore, a risk of a break in ventilation requiring medical intervention.
Teleflex Medical are updating the IFU to include additional information on Tracheostomy Tube warnings.

Our records indicate you have received products that are subject to this Field Safety Advisory Notification.

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**
Home Setting	**3**

Action list number 1 – Medical facilities
Our records indicate your facility has received product in scope of this advisory notice. Please provide this Advisory Notice to all those who need to be aware of it within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

Action list number 2 – Distributors
If you are a distributor, provide this field safety notice to all your customers who have received product in scope of this Field Action. There is no further action required.

If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below. 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.

Action list number 3 – Home Setting
Our records indicate you have received product in scope of this advisory notice. Please provide this Advisory Notice to all those who need to be aware of it within your home setting and place a copy with affected product. There is no further action required.

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
FAX: +41 (0) 31 818 40 93
Telephone: +41 (0) 31 818 40 90
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)