Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland
06th Sept 2019

URGENT - FIELD SAFETY ADVISORY NOTICE

Commercial Name of Affected Product:	Rüsch® DispoGrip Single-Use Standard Laryngoscope Handles
Type of action:	**Advisory Notice**
Teleflex Reference:	**EIF-000369**
Product code	**Lot/Batch**
88800	1810011

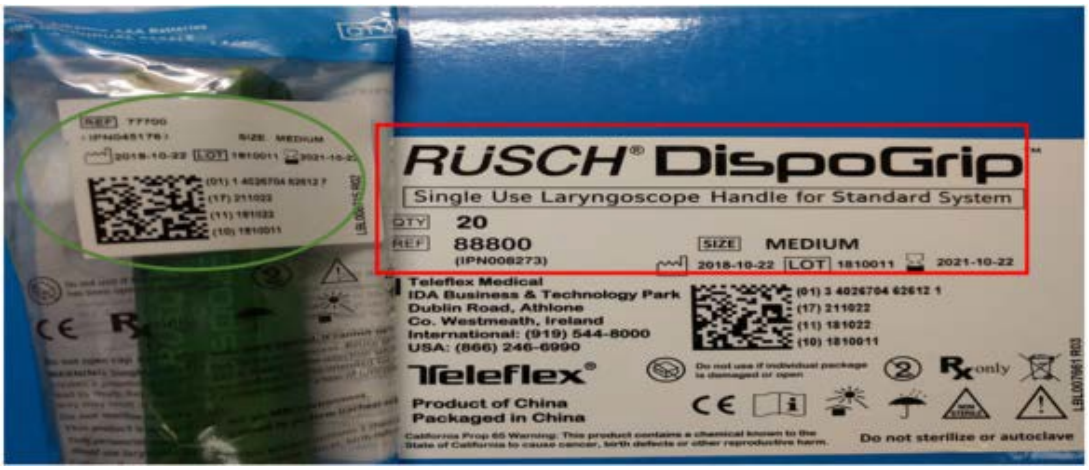
Dear Customer,

Teleflex is issuing a Field Safety Advisory Notification for the above listed product.

Description of the problem & immediate actions required
Teleflex Medical is issuing a Field Safety Advisory Notice for the product referenced above due to a labelling error on the outer blue box containing 20 individually packaged and labelled units per box.
Some boxes may be labelled as containing Rüsch DispoGrip Single-Use Standard Laryngoscope Handle (product code 88800), when they may in fact contain Rüsch DispoLED Single-Use Fiber Optic Laryngoscope Handle (product code 77700) see image below. Units are packaged in individual colour-coded pouches in accordance with their size, in this case a blue pouch, and labelled with the correct product code and lot number.

- Devices are labelled in individual pouches with the correct product code, lot number and product size.
- The error (labels containing product code 888000, asdisplayed below) is on the blue box only.

Pouch label **Box label**



No patient injuries have been reported related to this issue.
Our records indicate that you have received products that are subject to this correction.
We are now notifying our customers to take the following actions:

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities	**1**
Distributors	**2**

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.

Teleflex
Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

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.
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 Telephone: +31 0 088 00 215 00
FAX: 088 00 215 10 Email: Productcomplaints.netherlands@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize 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

…….