

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

20 Feb 2014

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:	Recall	Recall 001/13	
TELEFLEX REFERENCE:	001/13		
COMMERCIAL NAME OF AFFECTED PRODUCTS:		Catalog Number	Lot Number
Rusch Bronchopart®		116200	
Rusch Bronchopart®		116262	
Rusch Bronchopart® White		116201	Ref Appendix 2
Rusch One-lumen bronchial tube, right		115901	
Rusch Tracheopart®		116401	

Dear Customer,

1. Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed products.

2. Description of the problem

Teleflex is recalling the products referenced above as we have received complaints that the Rusch Bronchopart® (116200) may fail to achieve seal of the right lung due to the cuff inflating to one side. If a seal does not occur there is the potential for oxygen de-saturation and loss of volatile anaesthetics, requiring re-intubation of the patient.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

- 1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of affected product and quarantine immediately.
- 2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned there.
- 3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned in section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
- 4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
- 5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.

Teleflex

- 2. As a Distributor you are 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.
- 3. 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.
- 4. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

4. Teleflex

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

5. Transmission of this Field Safety Notice

This notice should be passed on 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

6. Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service: Contact: Shane Kenny FAX: +353 (0)1 4370773

Telephone: +353 (0)90 6460869 E-mail: <u>orders.intl@teleflex.com</u>

Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty Senior Director of Quality International.