Teleflex
MEDICAL

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

20 Feb 2014

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:	Recall	
TELEFLEX REFERENCE:	001/13	
COMMERCIAL NAME OF AFFECTED PRODUCTS:	**Catalog Number**	**Lot Number**
Rusch Bronchopart®	116200	**Ref Appendix 2**
Rusch Bronchopart®	116262	
Rusch Bronchopart® White	116201	
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.