

29th May 2012

**URGENT
FIELD SAFETY NOTICE**

COMMERCIAL NAME OF AFFECTED PRODUCTS:	RUSCH Macintosh Laryngoscope Disp. Metallic Kit – All Sizes
TYPE OF ACTION:	Market Withdrawal
Lot Numbers	Part Numbers
041511	670160-0000**
021512	

Dear Customer,

1. Details of affected devices

Teleflex acting as Distributor on behalf of M. A. Arain & Brothers (Pvt) Ltd. has issued an **extension** to the voluntary Field Action for the above listed products.

2. Description of the problem

Teleflex, acting as Distributor has become aware, through M. A. Arain & Brothers (Pvt) Ltd that some of the coil springs in the battery compartment were improperly engaged during manufacturing. It will most likely be discovered before the application but it may happen during intubation.

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 from the affected lot number and quarantine all products from the affected lot number immediately.
2. If you do not have stock from the affected part or lot numbers as referred to in above table then mark the according checkbox on the Acknowledgement form (see Appendix 1) and send the form to the fax number or e-Mail-address mentioned there.
3. If you have stock from the affected part/lot numbers as referred to in above table, mark the according checkbox on the Acknowledgement form (see Appendix 1). Contact customer service by calling the phone number mentioned in section 6 and you will be given 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 for return and send this information immediately to the following fax number: **+44(0)1494 524650** or provide a completed copy to your local Sales Representative. This helps us to confirm your notification and to register the amount of products under your control.
5. Agree the return of the affected product with the Teleflex Customer Service (or your local dealer).
6. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Instruction for Distributors of affected product

If you are a distributor, provide this field safety notice to all of your customers which have received product of the Field Actioned part or lot numbers. Send the customers the following documents:

- A copy of this Field Safety Notice
- A copy of the Acknowledgement Form (see Appendix 1)

The Acknowledgement form has to be filled in completely by your customer and returned to you.

As a Distributor you are required to confirm to Teleflex that you have informed all of your customers affected by the Field Action. Please forward the completed Acknowledgement Form (Appendix 1) to the following fax number: **+44(0)1494 524650**

Please be advised that all European Economic Area/Switzerland (EEA/CH and Turkey) Member State Competent Authorities to which Teleflex distribute directly will be notified by the Authorised Representative for M. A. Arain & Brothers (Pvt) Ltd.

If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH and Turkey 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.

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:

For Customer Service:	For Product Specific Queries:
Contact: Hélène Sauvage Telephone: +44 (0)1494 532761 FAX: +44(0)1494 524650 E-mail: orders.uk@teleflex.com	Contact: Duncan Bass Phone: +44 (0) 7423453978 Email: duncan.bass@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 at **orders.uk@teleflex.com**

If you have further questions please feel free to contact our customer service or sales representatives.

For and on behalf of Teleflex,

Úna Whiskey-Crowe
Complaints Manager, EMEA

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

**RETURN COMPLETED FORM IMMEDIATELY TO: orders.uk@teleflex.com or by
fax on +44(0)1494 524650**

<input type="checkbox"/> Our inventory does not include products affected by this Field Action.	<input type="checkbox"/> Our inventory does include products affected by this Field Action. The use and further distribution of the affected products is stopped. All product is put on hold and the amount below will be returned.	
Return Authorisation No: _____	<input type="checkbox"/> Replacement	<input type="checkbox"/> Credit note

PLEASE PRINT QUANTITY NUMBERS CLEARLY

Commercial name of affected products:	RUSCH Macintosh Laryngoscope Disp. Metallic Kit – All Sizes		
Lot Numbers:	041511		
	021512		
Part Number:	670160-0000**		
Part Number	Lot Number	Quantity	
Complete this form and return to Teleflex immediately by using the fax number or e-mail address above.			
Print Name / Title		Date	
Signature:		Telephone #	
Institution Name		City	
Address		Address	