

19<sup>th</sup> July 2016

**URGENT FIELD SAFETY NOTICE**

<b>Commercial Name of Affected Product:</b>	RUSCH - Catheter for radiation measurement	
<b>Type of action:</b>	<b>Recall</b>	
<b>Teleflex Reference:</b>	EIF-000054	
	<b>Product Code</b>	<b>Lot</b>
	<b>333464-000180</b>	<b>15471</b>

Dear Customer,

**Details of affected devices**

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

**Description of the problem**

The catheters' shaft and funnel may not be bonded completely. A correct bonding between the catheter shaft and funnel is essential to ensure that the three lumens remain separated. Should the bonding be compromised, there may be a connection between the different lumens and the device may not function as intended. The clinical end-user may be provided with inaccurate radiation measurement readings which could result in an inaccurate diagnosis and also prompt an inaccurate therapeutic strategy. There may be a need for repeated medical intervention and a repeated exposure to radiation.

**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, 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 the fax number below or provide a completed copy to your local Sales Representative.
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.
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 the fax number below.
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.

#### **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 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: Horst Erbe**

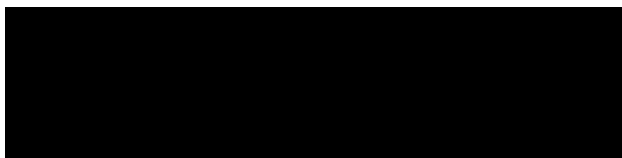
**FAX: 49 (0)7151 406-566**

**Telephone: 49 (0) 7151 406 431**

**E-mail: horst.erbe@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,***



Appendix 1

Customer No: \_\_\_\_\_

## FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref. EIF-000054

### Acknowledgement Form

**URGENT ATTENTION REQUIRED**

Return completed form immediately to:

FAX: +353 (0)1 4370773

E-mail: Recalls.intl@teleflex.com

Please check applicable box:

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does <b>NOT</b> include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory <b>DOES</b> include products affected by this Field Action. The use and further distribution of the affected products has been stopped. All products are on hold and the quantity stated below will be returned.
<div style="border: 2px solid red; padding: 5px; display: inline-block;">           Return Authorisation No _____         </div>	

Please CLEARLY print the below return information:

Name of Affected Products:	<i>RUSCH - Catheter for radiation measurement</i>	
Product Number	Lot Number	Quantity (Returning)
333464-000180	15471	

**Return Instructions:**

- Please label product returns as "Field Action Returns".
- Include a copy of this form (including RAN Number) with product returns. Returns excluding ALL necessary documentation CANNOT be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
	Phone Number:
Form completed by:	
Print Name :	Institution Stamp:
Signature :	
Date:	