

16 March 2016

## URGENT - FIELD SAFETY NOTICE

<b>Type of Action:</b>	<b>Recall</b>
<b>Teleflex Reference:</b>	EIF-000004
<b>Kidney Transplant Catheter</b>	

Product Code	Lot	
<b>621600200, UK621600200</b>	15AE01	15DE15
	15AE04	15DE17

Dear Customer,

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

### **Description of the problem**

Teleflex are recalling the products referenced above following receipt of reports that a leak was identified in the catheter during the infusion of perfusion fluid into a deceased kidney donor. A leak in the kidney transfusion catheter may lead to perfusion fluid loss, hypovolemia and inadequate perfusion of the donated organ and thereby compromise its viability.

### **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 the affected product batch 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 below.
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.
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.

**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:** H el ene Sauvage

**FAX:** +44 (0)1494 524650

**Telephone:** +44 (0)1494 532761

**E-mail:** [orders.uk@teleflex.com](mailto:orders.uk@teleflex.com)

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 Teleflex.

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,***

*Karen Boylan*

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**Karen Boylan VP, Global RA/QA**

**Appendix 1**

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

**FIELD SAFETY CORRECTIVE ACTION**

Teleflex Ref. EIF-000004

**Acknowledgement Form**

**URGENT ATTENTION REQUIRED**

**Return completed form immediately to:**

**FAX:** +44 (0)1494 524650

**E-mail:** [orders.uk@teleflex.com](mailto:orders.uk@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: 1px solid red; padding: 5px; display: inline-block;"><b>Return Authorisation No</b> _____</div>

**Please CLEARLY print the below return information:**

<b>Name of Affected Products:</b>	Kidney Transplant Catheter		
<b>Product Number (Size)</b>	<b>Lot Number</b>	<b>Quantity (Returning)</b>	

**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.

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