

25<sup>th</sup> March 2020

**URGENT – FIELD SAFETY NOTICE**

Type of Action				Recall				
Teleflex Reference				HRA00077				
Commercial Name				Langston® Dual Lumen Catheter				
Product Code:	Lot Numbers:							
5540	651278	653053	654340	655465	657030	658250	659362	660590
	651457	653319	654514	655738	657243	658438	659443	660717
	651920	653443	654657	655869	657517	658541	659630	660823
	652097	653565	654889	656191	657627	658671	659855	660910
	652176	653776	654890	656533	657680	658824	660075	661139
	652459	653863	655128	656554	657866	658984	660199	661257
	652628	654010	655287	656727	658018	659122	660288	661474
	652777	654190	655460	656801	658151	659217	660397	662824

Dear Customer,

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed product codes and lots.

**Description of the problem & immediate actions required**

As of the date of this letter Vascular Solutions LLC, a subsidiary of Teleflex, has received eight reports that the inner lumen of the Langston Dual Lumen catheter has separated from the device hub during or after a powered contrast injection. A power injection through an affected device could result in the inner lumen separating from the device and remaining in the patient, which would require an immediate intervention to retrieve the inner lumen to prevent injury or risk of embolization. An immediate intervention could also potentially be required to address vessel dissection or perforation, or attendant physiologic effects, though this has not been reported. Additionally, the strain relief adjacent to the catheter hub may simultaneously rupture when the inner lumen separates, thereby exposing medical, nursing or other staff to contrast or contrast/blood mixture dispersed under pressure, with the potential risk of infection.

Although there have been no reports of patient or clinician injury related to this matter, Teleflex is voluntarily recalling the affected Langston Dual Lumen catheters due to the potential risk of harm.

Our records indicate that you have received products that are subject to this recall.

**Depending on your device location please adhere to the following action list:**

Device location	Action List Number
Medical facilities	<b>1</b>
Distributors	<b>2</b>

**Action list number 1 – Medical facilities**

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective

field in the Acknowledgement Form and return this form immediately to Customer Service.

3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

#### **Action list number 2 – Distributors**

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then 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.
4. 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.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, 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 of this Field Safety Corrective Action.

#### **Transmission of this Field Safety Notice**

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider interventional cardiologists, cardiac catheterization labs, clinicians, end users, 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:** Shane Kenny

**FAX:** +353 0 14370773

**Telephone:** +353 0 90 64608769

**Email:** recalls.intl@teleflex.com

Please be advised that all 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 apologise 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,**

*Padraig Hegarty*

Padraig Hegarty, VP Global Quality Assurance (Manufacturing)

Appendix 1

Customer No  
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## FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

**PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED**

Ref. HRA-00077

RETURN COMPLETED FORM IMMEDIATELY TO:  
FAX: +353 0 14370773      Email: recalls.intl@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and have 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 have 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 is stopped. All products are put on hold and the amount below will be returned. <b>Return Authorisation No:</b> _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
5540		
<ul style="list-style-type: none"> <li>• Include a copy of the <b>completed Acknowledgement Form</b> in the returns package with the returned units</li> <li>• Ensure the <b>RAN number</b> is clearly visible on the returns package</li> <li>• Please label returns as <b>“Field Safety Returns”</b></li> </ul>		

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

<b>INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)</b>	
<b>INSITIUTION ADDRESS</b>	<b>Phone/FAX</b>
<b>FORM COMPLETED BY:</b>	<b>Stamp</b>
PRINT NAME: _____  SIGNATURE: _____	
<b>DATE</b>	