Teleflex Medical Europe Ltd
IDA Business & Technology Park
Dublin Road, Athlone
Westmeath, Ireland

XX th August 2020

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	HRA00079
Commercial Name	Langston® Dual Lumen Catheter
Product Code / Lot Number	**See Appendix 2 for a list of product codes and lots in scope.**

Dear Customer,

This letter is to inform you that Vascular Solutions LLC, part of Teleflex, is expanding the scope of our voluntary recall of the Langston® Dual Lumen Catheter to include Models 5515, 5545, and 5550, as well as additional lots of Model 5540. The lot numbers outlined in this recall notice are being voluntarily recalled in addition to the lot numbers in the recall notice you may have already received in March 2020. All affected lot numbers are listed within **Appendix 2**.

Description of the problem & immediate actions required

As of the date of this letter, Teleflex has received two additional reports that the inner lumen of the Langston Dual Lumen catheter, including one for Model 5550, has separated from the device hub during use. A power injection, or forceful hand 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 additional Langston Dual Lumen catheters that may be affected due to the potential risk of harm. This voluntary recall affects Model Numbers 5515, 5540, 5545, and 5550 related to the lot numbers listed in **Appendix 2**.

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	1
Distributors	2

Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA (**Appendix 2**). 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
Telephone: +353 0 90 64608769
FAX: +353 0 14370773
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 _____

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. HRA00079

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 0 14370773 Email: recalls.intl@teleflex.com

☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory **DOES** 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. **Return Authorisation No:** _____

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package
- Please label returns as **"Field Safety Returns"**

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

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

Appendix 2

Product Codes	Lots in scope of HRA00079							
5515	635806	638111	640206	644140	648701	654130	654143	656020
	658252	659635	661470	665301	670376	672728	677058	
5545	634357	638547	638819	645111	649740	650126	650127	655647
	657411	659802	661790	666866	668503	672219	673313	675001
5550	632704	633668	635885	637973	640204	644096	656792	658273
	659555	659856	660597	663767	666755	669593	672481	676528
5540	666438	666559	666966	667151	667164	667465	667832	667835
	667936	668094	668095	668303	668305	668701	668703	668771
	668934	669190	669199	669402	669591	669602	669737	670144
	670299	670503	670586	670865	671004	671202	671427	671633
	671743	671948	672130	672349	672660	672813	672894	673021
	632018	632019	632020	633211	633647	633929	634247	634423
	635207	635208	635209	635280	635541	635542	635805	635861
	636284	636471	636709	636898	636901	637384	637388	637832
	637945	638198	638323	638953	639414	639516	639892	640034
	640459	640676	640938	641060	641222	641543	641679	642031
	642178	642373	642520	642928	643051	643376	643542	643835
	643874	644015	644573	644650	645031	645032	645118	645360
	645481	645482	646106	646108	646110	646247	646640	646641
	646879	647014	647206	647370	647482	647697	647786	648043
	648210	648337	648481	648603	648780	648963	649078	649315
	649456	649584	649729	650018	650023	650369	650560	650606
	650765	650873	650991	651163	651278	651457	651524	651829
	651920	652097	652176	652459	652628	652777	653053	653319
	653443	653565	653776	653863	654010	654190	654340	654514
	654657	654889	654890	655128	655287	655460	655645	655738
	655869	656191	656533	656554	656727	656801	657030	657243
	657517	657627	657680	657866	658018	658151	658250	658438
	658541	658671	658824	658984	659122	659217	659362	659443
	659630	659855	660075	660199	660288	660397	660590	660717
	660823	660910	661139	661257	661474	661707	661863	662053
	662133	662265	662493	662642	662824	662903	663039	663138
	663281	663344	663790	663791	663854	664087	664236	664449
	665098	665099	665234	665303	666067	666332		