Vascular Solutions
c/o Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

21st August 2019

URGENT - FIELD SAFETY ADVISORY NOTICE

Commercial Name of Affected Product:	**TrapLiner™ Catheter**
Type of action:	**Advisory Notice**
Reference:	**VSI HRA00068**
Product code	**Lot/Batch**
5567	**641224**

Dear Customer,

Details of affected devices

Teleflex on behalf of Vascular Solutions (*a Teleflex company*) has voluntarily issued an advisory notice for the above product code and lot number.

Description of the problem

The purpose of this letter is to inform our customers of a hub labelling inaccuracy present in one lot of the 7F version of TrapLiner catheters, **Model 5567**. The units in **Lot 641224** are 7F catheters; however, they likely bear a hub marking that incorrectly indicates that they are size 8F. As a result, the hub indicates a size one French unit larger than the actual size of the device.

The box and pouch labels are unaffected and correctly describe the devices in Lot 641224. Reliance on the hub-marked French size may result in incompatibility and device exchange, causing a delay in procedure.

No patient injury has been reported pertaining to this issue. Product code and lot combinations not referenced above are not impacted by this notification.

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

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF
Our records indicate your facility has received product in scope of this advisory notice. Please provide this Advisory Notice to all those who need to be aware of it within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT
If you are a distributor, provide this field safety notice to all your customers who have received product in scope of this Field Action. There is no further action required.

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: Shane Kenny
FAX: +353(0)1 4370773
Telephone: +353 (0)90 6460869
E-mail: Recalls.Intl@teleflex.com

Teleflex International 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,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)