Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

20th July 2017

URGENT - FIELD SAFETY NOTICE

Commercial Name	Percuvance® Percutaneous Surgical System
Teleflex Reference:	EIF-000167/EIF-000181/EIF-000184
Type of Action	**Recall**
Product code	**Lot/Batch**
PCVGG5	**Refer to Appendix 2**
PCVHCA5	
PCVJG5	
PCVMD5	
PCVSC5	
PCVSH3	

Dear Customer,

Details of affected devices
Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed product codes.

Description of the problem
For some of the recalled products, the security of the connection between the shaft and the tool tip may be compromised. If the connection is not secure, the tool tip may detach inside the patient. For certain other recalled lots of the products, the jaws of the tool tips may close abruptly, which could cause bleeding or tissue damage. Teleflex Medical is recalling these products in an effort to provide our customers and their patients the highest quality product possible.
Our records indicate that you have received product that is subject to this recall. We are now notifying our customers to take the following actions:

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 below 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: Shane Kenny
FAX:+353 (0) 1 4370773
Telephone: +353 (0)90 6460869
Email: Recalls.Intl@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 you or your patients. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex,

[redacted]

Padraig Hegarty VP, QA

Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000167/EIF-000181/EIF-000184

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 (0) 1 4370773 **Email:** Recalls.Intl@teleflex.com

☐ We confirm receipt of this FSN and 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 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.

COMMERCIAL NAME OF AFFECTED PRODUCTS:		
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 Action Returns"**

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

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

Appendix 2 – Percuvance ® Percutaneous Surgical System Recall

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
PCVGG5	73A1600103	PCVJG5	73G1600728	PCVSC5	73G1600390
	73B1600340		73H1600148		73H1600006
	73C1600290		73H1600507		73H1600357
	73C1600451		73H1600901		73H1600506
	73E1600256		73J1600061		73K1600471
	73G1600559		73J1600601		73L1600034
	73G1600726		73L1600024		73M1600327
	73H1600147		73L1600376	PCVSH3	73B1600168
	73H1600340		73L1600559		73B1700525
	73H1600900		73M1500035		73C1600057
	73J1600599		73M1500300		73C1600152
	73K1600501	PCVMD5	73D1600174		73C1600267
	73L1600558		73D1600587		73C1600327
	73M1500034		73E1600661		73D1600176
PCVHCA5	73A1600601		73F1600015		73D1600481
	73A1700239		73G1600729		73E1600001
	73C1600705		73H1600012		73E1600662
	73E1600177		73H1600149		73F1600520
	73E1600341		73H1600341		73F1600594
	73F1600411		73H1600902		73F1600697
	73F1600695		73J1600062		73G1600015
	73G1600727		73L1600025		73G1600177
	73H1600151		73L1600210		73G1600178
	73H1600342		73L1600445		73G1600557
	73H1600660		73M1500036		73G1600730
PCVJG5	73A1600104		73M1500302		73H1600567
	73B1600339	PCVSC5	73A1600602		73J1600182
	73C1600291		73C1600170		73M1600025
	73C1600454		73D1600483		73M1600026
	73D1600586		73D1600623		73M1600232
	73E1600257		73E1600174		73M1600233
	73G1600016		73F1600149		73M1600328
	73G1600558		73F1600206		