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

25th October 2017

URGENT - FIELD SAFETY NOTICE

Commercial Name			Percuvance® Percutaneous Surgical System		
Teleflex Reference:			EIF-000216		
Type of Action			Recall		
Product code			Lot/Batch		
Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
PCVJG5	73E1700794	PCVMD5	73E1700796	PCVGG5	73E1700793
	73G1700271		73G1700273		73G1700272
	73G1700515		73H1700083		73H1700082
	73H1700081	PCVHCA5	73E1700798		73H1700247
	73H1700367		73H1700084	PCVSC5	73H1700569

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
Teleflex is recalling these products because the jaws of the tool tip may break, causing a fragment of the tool tip to fall off during use. If breakage occurs during a procedure, additional operating time or enlargement of the incision may be required to retrieve the fragment from the patient. If the fragment cannot be retrieved easily, additional complications could occur. Teleflex Medical has not received any reports of patient injuries or deaths relating to the recalled products.
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: Sales Assistants
FAX: 088- 00 215 10
Telephone: 088-00 215 25
Email: Productcomplaints.Netherlands@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,

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Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000216

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: 088-00 215 10 **Email:** productcomplaints.Netherlands@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:	**Percuvance® Percutaneous Surgical System**	
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**
FORM COMPLETED BY:	**Stamp**
PRINT NAME:_____ **SIGNATURE:**_____	
DATE	