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

14th January 2019

URGENT - FIELD SAFETY NOTICE

Commercial Name	Percuvance® Percutaneous Shaft 29cm Percuvance® Percutaneous Shaft 36cm
Teleflex Reference:	**EIF-000322**
Type of Action	**Recall**
Product code	**Lot/Batch Number**
PCVSH3	Refer to Appendix 2 for a list of lots impacted
PCVSHL3	

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 voluntarily recalling these products because there is potential for a piece of the distal tip on the Percuvance® shaft to become deformed and possibly break off during use. If a piece did break off it could compromise the functionality and security of the tool tip. Should this occur during use, surgical intervention may be required.

Our records indicate you have received products that are 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 batches 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,

Padraig Hegarty

Padraig Hegarty
VP Global QA (Manufacturing)

Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000322

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:	**Percuvance® Percutaneous Shaft 29cm Percuvance® Percutaneous Shaft 36cm**	
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	

Appendix 2 - EIF-000322

Product Code	Product Name	Lot/Batch Number
PCVSH3	**Percuvance® Percutaneous Shaft 29cm**	73A1700531 73B1700180 73F1700583 73F1700584 73F1700585 73H1700728 73J1600394 73J1700072 73J1700073 73J1700074 73J1700554
PCVSHL3	**Percuvance® Percutaneous Shaft 36cm**	73A1700535 73B1600170 73B1700073 73B1700523 73B1700646 73C1600058 73C1600706 73D1600482 73F1600086 73G1600207 73G1600468 73G1600573 73G1700041 73G1700311 73G1700577 73H1600509 73H1700513 73H1700526 73H1700531 73H1700532 73J1700100 73J1700553 73M1600016 73M1600027 73M1600231