

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: Nicole Morawiec

Telephone: +41 (0) 31 818 40 90

FAX: +41 (0) 31 818 40 93

E-mail: nicole.morawiec@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, QA

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: +41 (0) 31 818 40 93

Email: nicole.morawiec@teleflex.com

<input type="checkbox"/> 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.	<input type="checkbox"/> 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 _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Percuvance® Percutaneous Surgical System	
PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<ul style="list-style-type: none"> 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 – Percuance® 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	73B1600168	
	73H1600340		73L1600559	73B1700525	
	73H1600900		73M1500035	73C1600057	
	73J1600599		73M1500300	73C1600152	
	73K1600501		73D1600174	73C1600267	
	73L1600558		73D1600587	73C1600327	
	73M1500034		73E1600661	73D1600176	
	PCVHCA5		73A1600601	PCVMD5	73F1600015
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	PCVSC5	73M1500302	73H1600567	
	73B1600339		73A1600602	73J1600182	
	73C1600291		73C1600170	73M1600025	
	73C1600454		73D1600483	73M1600026	
	73D1600586		73D1600623	73M1600232	
	73E1600257		73E1600174	73M1600233	
	73G1600016		73F1600149	73M1600328	
	73G1600558		73F1600206		