

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

11th June 2020

## URGENT – FIELD SAFETY NOTICE

Type of Action		Recall		
Teleflex Reference:		EIF-000426		
Commercial Name		Arrow® FlexTip Plus(R) Epidural Kit with NRFit(R) connector		
Product Code				Batch/Lot Number
ASK-05500-NRON	AT-05501-NRF	EJ-05400-NRON	OT19HBPSS	See Appendix 2 for a list of product codes and lots in scope
OT19TKPSS	OU-05500-NRON	TU-05500-NRON	UM-05400-NRF	

Dear Customer,

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

### Description of the problem & immediate actions required

Arrow International, a subsidiary of Teleflex, is voluntarily recalling the above product codes and lots due to receipt of nine complaints reporting that the rotatable collar on the filter of the epidural catheter had detached, causing a leak. If a leak presents during use, an alternative filter may be required, or the catheter may need to be removed and replaced with a new kit.

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

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities	1
Distributors	2

### Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.

3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

**Action list number 2 – Distributors**

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then 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.
4. 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.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, 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 of this Field Safety Corrective Action.

**Transmission of this Field Safety Notice**

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation 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.

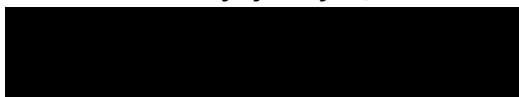
**Contact reference person**

Should you require any further information or support concerning this issue, please contact:

**Customer Service:****Contact:** Customer Service**FAX:** 0711 / 49 05 08 71**Telephone:** 0711 / 20 90 80 00**Email:** recalls.de@teleflex.com

Please be advised that all 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 apologise 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,***



**FIELD SAFETY CORRECTIVE ACTION**  
**ACKNOWLEDGEMENT FORM**

**PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED**  
Ref. EIF-000426

**RETURN COMPLETED FORM IMMEDIATELY TO:**  
**FAX: 0711 / 49 05 08 71      Email: recalls.de@teleflex.com**

<input type="checkbox"/> We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does <b>NOT</b> include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory <b>DOES</b> 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. <b>Return Authorisation No:</b> _____
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**PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY**

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<ul style="list-style-type: none"><li>• Include a copy of the <b>completed Acknowledgement Form</b> in the returns package with the returned units</li><li>• Ensure the <b>RAN number is clearly visible</b> on the returns package</li><li>• Please label returns as <b>“Field Safety Returns”</b></li></ul>		

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

<b>INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)</b>	
<b>INSITIUTION ADDRESS</b>	<b>Phone/FAX</b>
<b>FORM COMPLETED BY:</b>	<b>Stamp</b>
<b>PRINT NAME:</b> _____	
<b>SIGNATURE:</b> _____	
<b>DATE</b>	

**Appendix 2**

<b>Product Code:</b>	<b>Lot Number:</b>
ASK-05500-NRON	71F19K1049
ASK-05500-NRON	71F19K2042
ASK-05500-NRON	71F19L0977
ASK-05500-NRON	71F19M1319
ASK-05500-NRON	71F20A0805
ASK-05500-NRON	71F20A0812
ASK-05500-NRON	71F20A0813
AT-05501-NRF	71F19M0710
EJ-05400-NRON	71F19J0604
EJ-05400-NRON	71F19K1653
EJ-05400-NRON	71F19K2501
EJ-05400-NRON	71F19M0326
EJ-05400-NRON	71F20A1819
EJ-05400-NRON	71F20A2040
OT19HBPSS	71F18K1579
OT19TKPSS	71F18F1429
OT19TKPSS	71F18J2111
OT19TKPSS	71F20A1078
OT19TKPSS	71F20A1614
OU-05500-NRON	71F20A0044
UM-05400-NRF	71F19E2019
TU-05500-NRON	71F19K2043
TU-05500-NRON	71F19L0359
UM-05400-NRF	71F19L0269
UM-05400-NRF	71F19L2068