

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

16th March 2020

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000413
Commercial Name	Arrow Multiple-Lumen Catheter
Product Code:	Lot Number
COMO-27702	71F19L0900
CE-15802	71F19L1790
CV-12712-FR1	71F19L1885
DE-14702-KBAL	71F19L2688
DE-14702-UW1	71F19L1532
DE-26702-DK	71F19L0818
DK-24702-EK	71F19L0813
CO-14702-EK	71F19L0807

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 product referenced above due to a potential sterility issue. The product tray may be damaged; thus, the sterility of the device cannot be guaranteed. If the devices sterility is compromised and the product is used it could lead to infectious complications.

No complaints, patient injuries or deaths have been reported at this time.

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

Telephone: 0711 / 20 90 80 00

FAX: 0711/ 49 05 08 71

Email: recalls.de@teleflex.com

Product Management

Contact: Sabine Schewior

Email: sabine.schewior@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-000413

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 0 14370773 Email: recalls.intl@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 NOT 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 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

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<div><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 Safety Returns”</div>		

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

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