

Arrow International  
 c/o Teleflex Medical  
 IDA Business & Technology Park  
 Dublin Road, Athlone  
 Westmeath, Ireland

09 July 2020

**URGENT – FIELD SAFETY NOTICE**

Type of Action		Recall	
Teleflex Reference		EIF-000431	
Commercial Name		Arrow® Cannon and Epidural Devices	
Product Name	Product Code	Lot Number	
Arrow Single Shot Epidural Anesthesia Kit	AK-03000-S	13F17J0230	
Cannon II Plus Replacement Hub Set	CAR-02400	13F19J0153	
Cannon II Plus Replacement Hub Set	CAR-02400	23F17H0547	
Arrow TheraCath® Epidural Catheter	EC-05000	13F18C0518	
NextStep Retrograde Replacement Hub Set	NRH-15192	13F19H0454	

**Dear Customer,**

Arrow International has voluntarily issued a Field Safety Notice for the product codes and lot numbers listed above.

**Description of the problem & immediate actions required**

Arrow International, a subsidiary of Teleflex, is voluntarily recalling the product referenced above because the product lidstock contains a labelling error. The lidstock states the incorrect expiration date for the product. This issue could result in use of a device that is expired which could potentially lead to an increased risk of infection or other complications. Sterility, biocompatibility, safety, or efficacy of the kits and their components are not assured beyond the correct expiration date.

Our records indicate 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	<b>1</b>
Distributors	<b>2</b>

**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:** Shane Kenny

**FAX:** +353 0 14370773

**Telephone:** +353 0 90 64608769

**Email:** [recalls.intl@teleflex.com](mailto:recalls.intl@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 Arrow International,*

*Padraig Hegarty*

*Padraig Hegarty VP, QA (Manufacturing)*

Appendix 1

Customer No  
\_\_\_\_\_

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

**PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED**

Ref. EIF-000431

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 0 14370773

Email: [recalls.intl@teleflex.com](mailto: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 <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>	