

Arrow International Inc. ("Arrow")  
 c/o Teleflex,  
 IDA Business & Technology Park  
 Dublin Road, Athlone  
 Co. Westmeath, Ireland

24 May 2013

**URGENT  
 FIELD SAFETY NOTICE**

<b>COMMERCIAL NAME OF AFFECTED PRODUCTS:</b>		Central Venous Catheter Kits
<b>TYPE OF ACTION:</b>		Recall
<b>ARROW INTERNATIONAL INC. ("ARROW") REFERENCE:</b>		ZD1304-066
<b>Material</b>	<b>Lot Numbers</b>	
EU-25703-EK	Refer to Appendix 1	
EU-26702-EK		
GU-24730		

Dear Customer,

**1. Details of affected devices**

Arrow International, Inc. ("Arrow") has initiated a voluntary Field Safety Corrective Action for the above listed products.

**2. Description of the problem**

Arrow has issued a voluntary recall for the above listed products due to misplacement of the ECG Marker on the Spring Wire Guide, which may result in misplacement or mis-positioning of the CVC. The likelihood of such an occurrence leading to patient injury or harm has been determined as negligible. There have been no reported incidents to date relating to injury or harm for this issue.

**3. 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 affected product 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 2) and return the form to the fax number or e-Mail-address mentioned there.
3. If you have stock from the affected product as referred to in Appendix 1, mark the according checkbox on the Acknowledgement form (Appendix 2). Contact customer service by calling the phone number mentioned in section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 2' for all products in your possession and under control. Return this form immediately to the fax number below or provide a completed copy to your local Sales Representative.
5. Arrow (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 Arrow that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to the following fax number: **07151 406 – 566**
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Arrow distribute directly will be notified by Arrow.
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 Arrow.

**4. Arrow International Inc. (“Arrow”)**

Arrow informs all customers, employees of Arrow and distributors on this Field Action.

**5. Transmission of this Field Safety Notice**

This notice should be passed on 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

**6. Contact reference person**

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

**Customer Specific Queries:**

**Horst Erbe**

Tel.: 07151 / 406 – 431

Mobil: 0172 / 74 33 713

e-mail: [horst.erbe@teleflex.com](mailto:horst.erbe@teleflex.com)

**Product Specific Queries:**

**Herr Alexander Krebs**

Tel.: 07151 / 406 – 186

Mobil: 0172 / 77 36 254

e-mail: [alexander.krebs@teleflex.com](mailto:alexander.krebs@teleflex.com)

Arrow is committed to providing high quality, safe and effective products. We sincerely apologize 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 at [horst.erbe@teleflex.com](mailto:horst.erbe@teleflex.com)

**For and on behalf of Arrow International, Inc.,**



*International VP Quality Assurance & Regulatory Affairs*

**Appendix 1**

Material	Batch	Material	Batch	
<b>EU-25703-EK</b>	ZF1091215	<b>GU-24730</b>	ZF1125277	ZF2087969
	ZF1102228		ZF2027459	ZF2098229
	ZF1125535		ZF2028131	ZF2098517
	ZF2027729		ZF2028529	ZF2099299
	ZF2030062		ZF2030483	ZF2100225
	ZF2052409		ZF2038940	ZF2111937
	ZF2075410		ZF2039846	ZF2123098
	ZF2086543		ZF2041157	ZF2124299
	ZF2112222		ZF2041721	ZF3014689
	ZF3014502		ZF2052654	
<b>EU-26702-EK</b>	ZF1079824		ZF2053468	
	ZF1091277		ZF2064164	
	ZF2015961		ZF2064641	
	ZF2038944		ZF2064974	
	ZF2052743		ZF2075229	
	ZF2076298		ZF2076435	
	ZF2100807		ZF2087102	

## FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

**PRODUCT FIELD ACTION BY ARROW INTERNATIONAL INC.  
IMMEDIATE ATTENTION REQUIRED**

**RETURN COMPLETED FORM IMMEDIATELY TO:  
[horst.erbe@teleflex.com](mailto:horst.erbe@teleflex.com) or by fax on +07151 406 – 566**

<input type="checkbox"/> Our inventory does <b>NOT</b> include products affected by this Field Action.	<input type="checkbox"/> 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.  <b>Return Authorisation No</b> _____
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**PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.**

<i>COMMERCIAL NAME OF AFFECTED PRODUCTS:</i>			Central Venous Catheter Kits					
PRODUCT NUMBER	LOT - #	Qty	PRODUCT NUMBER	LOT - #	Qty	PRODUCT NUMBER	LOT - #	Qty
<b>EU-25703-EK</b>			<b>EU-26702-EK</b>			<b>GU-24730</b>		

**Complete this Acknowledgement form and send back to Arrow immediately by using the fax number or e-mail address above.**

Print Name/Title	Date
Signature	Telephone Number
Institution Name	Address
Address	City, Zip Code