

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

09 October 2013

**URGENT
 FIELD SAFETY NOTICE**

COMMERCIAL NAME OF AFFECTED PRODUCTS:				TRANSRADIAL ARTERY ACCESS KIT
TYPE OF ACTION:				RECALL
ARROW REFERENCE:				EV1308-082
PART NUMBER				LOT NUMBER
AA-10407-1	AA-10411-1	AA-10507-1	AA-10511-1	Refer to Appendix 1 for list of lots
AA-10524-1	AA-10607-1	AA-10611-1	AA-10624-1	
AA-15511-3	AA-15511-S	AA-15611-3	AA-15611-S	

Dear Customer,

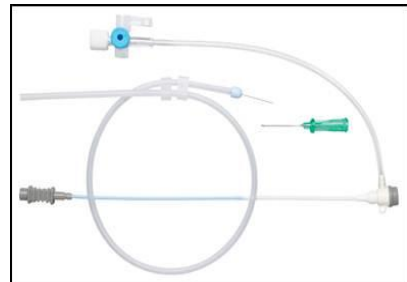
1. Details of affected devices

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

2. Description of the problem

Arrow is recalling the products referenced in the Appendix 1 as there is a risk that the introducer needles packaged within the kits can be partially or fully occluded.

If an occluded needle is used on a patient, there is risk of delay in treatment and/or adverse event requiring medical intervention.



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 fax number below.
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:

Contact: Hélène Sauvage **Telephone:** +44 (0)1494 532761
FAX: +44(0)1494 524650 **E-mail:** orders.uk@teleflex.com

Product Specific Queries:

Contact: Ian Mellors **Phone:** +44 (0) 1494-532761
Email: ian.mellors@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.

For and on behalf of Arrow International, Inc.,

Padraig Hegarty

Padraig Hegarty
Senior Director, QA

Appendix 1

PART #	LOT #	PART #	LOT #	PART #	LOT #	PART #	LOT #	LOT #
AA-10407-1	RF1093923	AA-15511-S	RF0021262	AA-15511-S	RF8097142	AA-15611-S	RF1070730	RF9014646
	RF2056874		RF0022395		RF8109405		RF1071062	RF9027938
	RF2057003		RF0033719		RF8119837		RF1071206	RF9030870
	RF2072322		RF0046459		RF8122732		RF1071757	RF9056723
AA-10411-1	RV2096427		RF0059652		RF9014645		RF1082042	RF9069105
AA-10507-1	RF1093924		RF0062416		RF9027936		RF1082374	RF9070830
	RF2071408		RF0087577		RF9030868		RF1082709	RF9085114
	RF2071428		RF0088503		RF9043881		RF1082956	RF9085720
	RF2082733		RF0091088		RF9057834		RF1093937	RF9086531
	RF2083221		RF0092144		RF9073033		RF1094515	RF9100255
	RF2083578		RF0104465		RF9085142		RF1105690	RF9112368
	RF2107659		RF0115903		RF9101704		RF1105980	RF9114142
	RF2108238		RF0117682		RF9109533		RF1117682	RF9127372
	RF2110742		RF1011172		RF9114143		RF1128383	RV0018374
RV2069822	RF1019756		RF9127374		RF2010467		RV0018375	
AA-10511-1	RF1093925	RF1022056	RF2108243	RF2010868	RV0018376			
	RF2071407	RF1035112	AA-15611-3	RV2095276	RF2019197			
	RF2072700	RF1045951	RV2096130	RF2019759	RV0018927			
	RF2083574	RF1057481	RF0018142	RF2021612				
	RF2095165	RF1060013	RF0021263	RF2022115				
	RF2108519	RF1069507	RF0022652	RF2022510				
RV2069824	RF1070880	RF0046461	RF2033301					
AA-10524-1	RF2108830	AA-15511-S	RF0048269	AA-15611-S	RF2033811			
	RV2096435	RF1071354	RF0062419		RF2044703			
AA-10607-1	RF2071409	RF1071798	RF1082959	RF0087575	RF2045176			
	RF2082876	RF1082959	RF1083632	RF0087845	RF2045513			
	RF2083917	RF1083632	RF1093936	RF0089041	RF2046241			
	RF2107371	RF1093936	RF1094910	RF0092014	RF2056688			
	RF2111224	RF1094910	RF1105983	RF0104466	RF2057702			
	RV2069823	RF1105983	RF1106517	RF0115587	RF2058443			
AA-10611-1	RF2071405	RF2010359	RF2010359	RF0117454	RF2058727			
	RF2083576	RF2010675	RF2010675	RF0129193	RF2060013			
	RF2084732	RF2019230	RF2019230	RF1010343	RF2060748			
	RF2096244	RF2021565	RF2021565	RF1011171	RF2069110			
	RF2096785	RF2033341	RF2033341	RF1023132	RF2071228			
	RF2109094	RF2044756	RF2044756	RF1033969	RF2072265			
	RF3013490	RF2045508	RF2045508	RF1034279	RF2083790			
	RV2069826	RF2071172	RF2071172	RF1035009	RF2084674			
AA-10624-1	RF2071406	RF2071836	RF1045491	RF8095420	RF8096588			
	RF2083454	RF2072114	RF1046643	RF8097143	RF8097143			
	RF2083577	RF2083300	RF1046962	RF8108474	RF8108474			
	RV2069827	RF2084734	RF1060349	RF8110519	RF8110519			
AA-15511-3	RF2107374	RF2108240	RF2108240	RF1068720	RF8111258			
	RF2108239	RF2119659	RF2119659	RF1069509	RF8119838			
	RV2095275	RF8095418	RF8095418	RF1069978	RF8122734			
	RV2096154	RF8095817	RF8095817	RF1070556				

Customer No. _____

Appendix 2

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

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

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +44(0)1494 524650

E-mail: orders.uk@teleflex.com

<input type="checkbox"/> Our inventory does NOT 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. Return Authorisation No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	TRANSRADIAL ARTERY ACCESS KIT	
PRODUCT NUMBER	LOT NUMBER	QUANTITY

- 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 send back to Arrow immediately by using the fax number or e-mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	
FORM COMPLETED BY:	TITLE/ROLE
DATE	