

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

31st July 2015

URGENT FIELD SAFETY NOTICE

Commercial Name of Affected Product:		ARROW® International PICC Kits with Peel-Away Sheath Component	
Type of action:		Recall	
Arrow Reference:		1505-07	
Product	Product	Product	Product
ASK-02041-SEH1	CA-05052-HP	CDC-34052-VPS	EU-05552-HPMSB
ASK-04001-DU4	CA-05052-HPX	CDC-35041-VPS	FR-04041
ASK-04052-AC	CDC-02041-MK1A	CDC-35052-VPS	FR-04041-CF
ASK-05041-LM4	CDC-04041-HPK1A	CDC-35541-VPS	FR-05041
ASK-05052-SFL	CDC-04052-HPK1A	CDC-35552-VPS	FR-05041-CF
ASK-05541-MS2	CDC-05041-HPK1A	EU-04041-HP	FR-05541-CF
ASK-05541-MS3	CDC-05052-HPK1A	EU-04041-HPMSB	PI-01451-LS
ASK-15552-LM2	CDC-05541-HPK1A	EU-04052-HPMSB	PI-01451-LS5
ASK-15552-MS3	CDC-05542-PK1A	EU-05041-HPMSB	PK-01451-WS
ASK-35041-JHVA	CDC-05552-HPK1A	EU-05052-HPMSB	PK-01451-WSSP
CA-05041-HP	CDC-15552-HPK1A	EU-05541-HP	UK-05041-HPMIN
CA-05041-HPX	CDC-34041-VPS	EU-05541-HPMSB	
Lot Numbers:		Refer to Appendix 2	

Dear Customer,

Details of affected devices

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

Description of the problem

Arrow is recalling certain lots of the products referenced above due to the possibility that the catheter peel-away component hub tabs may prematurely detach when the practitioner begins to peel apart the sheath body from the catheter. Although the issue does not pose a significant risk to the patient, it may cause a delay of treatment when placing the catheter.

Arrow is recalling these products in an effort to provide our customers and their patients with the highest quality product possible.

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 1) and return the form to the fax number or e-Mail-address mentioned there.
3. If you have stock from the affected product, mark the according checkbox on the Acknowledgement form (Appendix 1). 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 1' 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.

Arrow International Inc. ("Arrow")

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

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

Contact reference person



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

Customer Contact: Shane Kenny
FAX: +353 (0)1 4370773

Telephone: +353 (0)90 6460869
E-mail: orders.intl@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.

Karen Boylan

Karen Boylan VP, Global RA/QA

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION
Teleflex Ref. 1505-07

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +353 (0)1 4370773

E-mail: orders.intl@teleflex.com

Please check applicable box:

<input type="checkbox"/> We confirm receipt of this FSN and 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 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 has been stopped. All products are on hold and the quantity stated below will be returned.
<div style="border: 2px solid red; padding: 5px; display: inline-block;"> Return Authorisation No _____ </div>	

Please CLEARLY print the below return information:

Name of Affected Products:	ARROW® International PICC Kits with Peel-Away Sheath Component	
Product Number	Lot Number	Quantity (Returning)

<p>Return Instructions:</p> <ul style="list-style-type: none"> • Please label product returns as "Field Action Returns". • Include a copy of this form (including RAN Number) with product returns. Returns excluding ALL necessary documentation CANNOT be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
	Phone Number:
Form completed by:	
Print Name :	Institution Stamp:
Signature :	
Date:	

Attachment 2

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
ASK-02041-SEH1	23F14H0517	CA-05052-HPX	23F14J0077	CDC-05052-HPK1A	23F15F0662	EU-04041-HP	71F14M0678	FR-04041-CF	71F15A1660
	23F14L0941		23F15C2282		23F14H0328		71F15A0395		71F15B1938
	23F14B1232	CDC-05541-HPK1A	23F14D0456		23F14C0598		71F15C0214		71F15D0235
	23F15A1523		23F14C0059	23F14F1505	71F15D0053		71F14L1345		
ASK-04001-DU4	23F14A1779	CDC-02041-MK1A	23F14E1213		23F14K1025		71F15D1075		71F15D1077
	23F14G1295		23F14G1470		23F15B0400		23F14C0576		71F15E0455
	23F14J0973		23F14H1111	CDC-05542-PK1A	23F14F1507	EU-04041-HPMSB	23F14F0115	FR-05041	71F14K1571
	23F14M0791		23F14J0613		23F14M0440		23F14G1130		71F14F1786
ASK-04052-AC	23F15A1171		23F15A0149		23F14F0364	EU-04052-HPMSB	23F14F0504	71F14G1690	
ASK-05041-LM4	23F14H0848	CDC-05552-HPK1A	23F15D0507		23F14L0838	EU-05041-HPMSB	23F14D0713	FR-05041-CF	71F14F1844
	23F14F0370		23F14J1512		23F14H0331		23F14C0575		71F14E2043
	23F15C2435		23F15C0302		23F15B0401		23F14D0724		71F14K0639
	23F14L0090		23F15B0399		23F15D0938		23F14E1493		71F15B1937
ASK-05052-SFL	23F14G1072	CDC-04041-HPK1A	23F14C1096	CDC-15552-HPK1A	23F15D0313	EU-05052-HPMSB	23F14F0716		71F14L0577
	23F14M0774		23F14H1112		23F14D0281		23F14M1010		71F14L1347
	23F15D0622		23F14C0640	CDC-34041-VPS	23F14E1325		23F15D1420		71F15A1302
ASK-05541-MS2	23F14H0920	CDC-34052-VPS	23F14F1497		23F14G0091		71F14H0351		71F15B0662
	23F14J1382		23F15A1857		23F14D0282		71F14H0947		71F15D0681
	23F15A0038		23F15D0830		23F14H0498		71F14G0365		71F14J1860
ASK-05541-MS3	23F15C1236		23F14G1471		23F14H1312		71F14H1396	71F14F1785	
ASK-15552-LM2	23F14E1373	CDC-04052-HPK1A	23F14M0038		23F14D0285	EU-05541-HP	71F14J0869	FR-05541-CF	71F15A0300
	23F14E1124		23F14J1312	CDC-35041-VPS	23F14B1144		71F14K0082		71F15C2011
	23F14F0441		23F15A1604		23F14G0095		71F14F1358		23F14J0437
	23F14G1226	23F15B2002		23F14H1314	71F14K0622		23F14K0406		
	23F15B0065	23F15E1025		23F14E1469	71F14K1332		23F14B0935		
	23F14J1546	23F14A1419		23F14E1261	71F15A1289		23F14H1535		
23F14L0882	23F14C0643	CDC-35052-VPS	23F14J1390	71F15C1137	23F15A0278				
ASK-15552-MS3	23F15C1237		23F14F1504		23F14E1262		71F15A1984	23F15D0907	
ASK-35041-JHVA	23F14H0301	CDC-05041-HPK1A	23F14J0221		23F14H0510		71F15B0638	23F14F0326	
CA-05041-HP	23F14E1093	CDC-35541-VPS	23F14J1513		23F14B1128	EU-05541-HPMSB	71F15D0272	PI-01451-LS5	23F14K1016
	23F14J0415		23F14L1144		23F14C0473		71F15A0152		23F14G1587
	23F14B0844		23F14E0791		23F14D0308		71F14M0141		23F15A1813
	23F14L0810	23F14E0406		23F14J1391	71F15D1059		23F14D0042		
	23F14K1361	23F14E1215	CDC-35552-VPS	23F14F0780			23F14D0217	PK-01451-WS	23F15D0284
	23F14M0484	23F14G1458		23F14H0512			23F14D1125		23F14J0358
CA-05041-HPX	23F14L0187	CDC-05052-HPK1A	23F15D1232		71F14K0081		23F14B1013	PK-01451-WSSP	23F14F0106
	23F15D0881		23F14J0617		71F14J1087	EU-05552-HPMSB	23F14F0510		23F15A0388
CA-05052-HP	23F14J1048	EU-04041-HP	23F14K0537		71F14K0628	FR-04041	71F14K1569	UK-05041-HPMIN	23F15D0046
	23F14J0076		23F15A0695		71F14L0323		71F15D0052		71F14G0670
	23F15D0882		23F14L1146		71F15D0234		71F14J1086		71F14K1035
	23F15F0193		23F15C0992		71F14L0762	FR-04041-CF	71F14H0374		71F14K0409
			23F15A0691		71F15B0648				71F14K1198