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Teleflex MEDICAL

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

4 May, 2010

URGENT
FIELD SAFETY NOTICE

Commercial Name of Affected Product:	Arrow 4 Fr Peripherally Inserted Central Catheter (PICCs) Kits
Type of action:	PRODUCT RECALL

AFFECTED PRODUCT:

Refer to attached Product Listing – Appendix A

Dear Customer,

1. Details of affected devices

Teleflex Medical, through its subsidiary Arrow International, Inc. ("Arrow") has issued a voluntary recall for products in Appendix A. Our records indicate you have received product included in the scope of this recall.

2. Description of the problem

Teleflex Medical has received complaints regarding the PICC catheter fitting too tightly in the "kit supplied" peelable sheath. In some cases, clinicians have been unable to insert the catheter through the peelable sheath during the insertion procedure. If the catheter will not pass through the sheath, the clinician is required to place a guide wire back into the sheath, remove the sheath, and place another sheath that the catheter will pass through. This may delay the procedure and/or increase the need for a repeat procedure. Risks associated with delay and/or repeat procedure may include bleeding and infection.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

We are notifying our customers to take the following actions:

Advice on action to be taken by Medical Staff

1. If you have no affected stock, please indicate same on the Recall Acknowledgement form and fax or email the form to your local Teleflex Medical Customer Service/Sales Representative as indicated on the Acknowledgement Form.

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2. If you do have affected stock, please indicate on the Recall Acknowledgement & Stock Status form whether you wish to:

   a) return your stock for replacement, b) return your stock for credit.

   - If you are returning stock for replacement or credit, contact Teleflex Medical Customer Service at **[insert fax or email address of Customer Service here]** for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the enclosed Recall Acknowledgement & Stock Status Form.

3. Complete the enclosed Recall Acknowledgement & Stock Status Form and immediately fax or email the completed form to Teleflex Medical Customer Service at **[insert fax or email address of Customer Service here]**. This will allow us to document your receipt of this letter and the amount of product you have on hand for replacement product, or credit.

4. Your local Teleflex Medical Customer Service/Sales Representative will coordinate the product return with you.

Instruction for Distributors of affected product

If you are a distributor, Teleflex Medical requires that you communicate this field safety corrective action notice to your customers who received affected product by providing:

- A copy of this Field Safety Notice to them.

The Acknowledgement Form is required to be completed in its entirety, signed and returned to you (the Distributor).

As a Distributor, it is your responsibility to provide Teleflex Medical with confirmation that all of your consignees have been contacted under this field safety corrective action. Please forward the completed Acknowledgement Form to **[insert fax or email address of Customer Service here]**.

4. Teleflex Medical

Teleflex Medical is notifying any potentially affected Customers, Teleflex Medical employees and Distributors of this Field Safety Notice.

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.

6. Contact reference person

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

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For Customer Service
[insert name and contact details of Customer Service Manager here]

For Product Specific Queries:

[insert name and contact details of appropriate Sales Manager here]

This field safety corrective action is voluntary and all affected competent authorities have been advised of this Field Safety Corrective Action.

Teleflex Medical 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, please contact your local sales representative or Customer Service at **[insert telephone number of Customer Service here].**

Signed by:

_____

[redacted]
VP Quality Assurance & Regulatory Affairs, EMEA

Attachments as follows:

Appendix A *Acknowledgement Form & Product Listing*

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FAX TO/EMAIL: Customer Service

Teleflex MEDICAL

[Insert Fax or Email Here]

RECALL acknowledgement and stock status form

Immediate Attention Requested – Medical Device Recall 4 Fr. PICC Kits

Please check the appropriate box(s) and return this form by Fax/Email as provided above.

☐ We have no inventory within the scope of this recall.

☐ We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities. When the product is received by Arrow International, please (select one):

☐ Credit our account

☐ Provide an equivalent replacement (may take 6-8 weeks for replacements)

Product Number	Lot Number	Qty (each)
ASK-01451-BMH	RF8060214	
	RF8096384	
ASK-05041-CHC	RF8109279	
	RF9056727	
ASK-05041-CHC1	RF9069677	
	RF9096408	
ASK-05041-CHM	RF8057827	
	RF8068899	
ASK-05041-HMC	RF8068662	
	RF8083994	
	RF8108545	
	RF9043625	
	RF9056403	
	RF9085278	
	RF9096560	
ASK-05041-QV	RF9097395	
ASK-07041-BMH	RF9031839	
	RF9096784	
	RL8108648	
CN-05041-LW	RF8069608	
	RF9056127	
	RF9070920	
	RL9019402	
MSO-01451-UCL	RF9057410	

Product Number	Lot Number	Qty (each)
MSO-01451-UCL	RF9084460	
	RL8118758	
	RL9029477	
MTO-01451-RH	RL9019228	
PL-05041	RF8071766	
	RF9109677	
PR-04041-HPX	RF8072920	
	RF8109646	
PR-05041	RF8056742	
	RF8068423	
	RF8069651	
	RF8071677	
	RF8095208	
	RF8095832	
	RF8108465	
	RF9028902	
	RF9043449	
	RF9056132	
	RF9060506	
	RF9085153	
	RF9086357	
PR-05041-HP	RF8072840	
	RF8083508	
	RF8084926	

Product Number	Lot Number	Qty (each)
PR-05041-HP	RF8107907	
PR-05041-HPX	RF8071099	
	RF8072981	
	RF9015967	
	RF9057607	
	RF9097057	
PR-05041-LW	RF8057252	
	RF8072743	
	RF8083529	
	RF8108466	
	RF8110585	
	RF9031472	
	RF9044054	
	RF9060502	
	RF9097058	
PR-05041-MW	RF8057253	
	RF8060216	
	RF8095834	
	RF8108467	
	RF8110586	
	RF9016412	
	RF9031473	
	RF9044055	
	RF9069045	

Product Number	Lot Number	Qty (each)
PR-05041-MW	RF9071244	
	RF9085152	
	RF9086354	
	RF9100412	
	RF9109679	
PR-05041-T	RF8068845	
	RF8107962	
PR-05042	RF8068846	
	RF8107963	
	RF8122680	
	RF9016413	
	RF9044057	
	RF9073297	
PR-05541-HPX	RF8124014	
PR-07041-PTSP	RF8068850	
	RF8071679	
	RF8107965	
	RF8110358	
	RF9042708	
	RF9072922	
RJ-01451-W	RF8068664	
	RF8096774	
	RF8123596	
	RF9060298	

Complete this Acknowledgement Form and immediately fax to Arrow International at the number given above.

Print Name/Title _____ Date _____ Institution Name _____

Signature _____ Telephone Number _____ Address _____