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

19th February 2016

URGENT FIELD SAFETY NOTICE

Commercial Name of Affected Product:	ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits
Type of action:	**Recall**
Arrow Reference:	EIF1507-33

Product Codes			
FiberOptix Ultra 8 IAB: 8Fr 30cc	IAB-05830-LWS	Ultra 8 IAB: 8Fr 30cc	IAB-05830-U
FiberOptix Ultra 8 IAB: 8Fr 40cc	IAB-05840-LWS	Ultra 8 IAB: 8Fr 40cc	IAB-05840-U
Insertion Tray 5800 and 6800 Series IAB	IAK-06845	UltraFlex IAB: 7.5Fr 30cc	IAB-06830-U
Insertion Tray for IAB-S730C	IAK-S7IT	UltraFlex IAB: 7.5Fr 40cc	IAB-06840-U
RediGuard IAB: 7Fr 30cc	IAB-S730C		
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 these products due to the possibility that the sheath body may become separated from the sheath hub. If the separation occurs, there is a potential for bleeding from the device. If bleeding is not addressed with prompt intervention, it may result in loss of significant blood volume or exsanguination. In addition, delay of treatment, interruption of treatment, or loss of IAB therapy can occur.

Arrow is recalling these lots 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 Service

Contact:	Shane Kenny	**Telephone:**	+353 (0)906460869
FAX:	+353 (0)1 4370773	**E-mail**:	Recalls.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.

Padraig Hegarty

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Padraig Hegarty – VP, QA

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref. EIF1507-33

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +353 (0)1 4370773 **E-mail**: Recalls.intl@teleflex.com

Please check applicable box:

☐ 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.	☐ 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. **Return Authorisation No _____**

Please CLEARLY print the below return information:

Name of Affected Products:	**ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits**	
Product Number	**Lot Number**	**Quantity (Returning)**

Return Instructions:

- 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:	