Arrow International
c/o Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

20th June 2018

URGENT - FIELD SAFETY NOTICE

Commercial Name of Affected Product:		Arrow® HANDS-OFF® Thermodilution Catheter	
Type of action:		**Recall**	
Arrow Reference:		**EIF-000289**	
Product Code	**Lot/Batch Numbers**	**Product Code**	**Lot/Batch Numbers**
AH-05000	16F17L0046	AH-05050	16F18A0027
	16F17M0006		16F18B0015
	16F17M0023		16F18C0035
	16F17M0054		16F18D0033
	16F18B0024	AH-05050-D	16F17M0005
	16F18C0070		16F18A0034
	16F18C0113		16F18A0078
	16F18D0032		16F18C0058
	16F18D0050		
	16F18D0073		

Dear Customer,

Details of affected devices
Arrow International is recalling the product referenced above because the packaging may not be sealed. If the packaging is compromised in this manner, the sterility of the product cannot be guaranteed. If a non-sterile product is used, there is potential for infection to occur. No patient injuries have been reported related to this issue.

Description of the problem
Arrow International is recalling the product referenced

Our records indicate your facility has received product in scope of this field safety notice.

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 the affected product batch and quarantine immediately.

2. If you do not have stock in scope of this field action as referred to above, then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.

3. If you have stock from the affected product as referred to above, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned below 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 Customer Service.

5. Teleflex (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 International that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.

3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Arrow International.

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 International.

Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Arrow International distribute directly will be notified by Arrow.

Arrow International
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 to 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)90 6460869
FAX: +353(0)1 4370773
E-mail: Recalls.intl@teleflex.com

Arrow International 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,

[redacted]

Padraig Hegarty VP, QA

Appendix 1

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

Customer No. _____

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000289

RETURN COMPLETED FORM IMMEDIATELY TO:

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

☐ 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 is stopped. All products are put on hold and the amount below will be returned. **Return Authorisation No _____**

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	EIF-000289 - Arrow® HANDS-OFF® Thermodilution Catheter	
PRODUCT NUMBER	**LOT NUMBER**	**QUANTITY (Returning)**

- 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 return immediately by using the fax number or e-mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**Phone / Fax**
FORM COMPLETED BY:	**Stamp**
PRINT NAME:_____ **SIGNATURE:_____**	
DATE	