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

07th January 2020

URGENT – FIELD SAFETY NOTICE

Type of Action		**RECALL**	
Teleflex Reference		**EIF-000396**	
Commercial Name		**Arrow® PICC, EPIDURAL CATHETER, DRAPE, CONTINUOUS NERVE BLOCK NEEDLE; CVC, PSI, EPIDURAL NEEDLE and SPINAL NEEDLE Kits**	
Product code	**Lot Number**	**Product code**	**Lot Number**
AB-00150 AB-17080-N AB-17110-N AB-17140-N AB-18080-N AB-18110-N AB-18140-N AK-05000 AM-05500 AN-05505 ASA-25090-S ASK-00002-1A ASK-04200-UPM	See Appendix 2 for a list of product codes and lots in scope	ASK-05060-CHO1 ASK-05400-CA1 ASK-05500-CAN ASK-05560-WH ASK-09801-UPM ASK-17019-MSC CK-02220 EC-05000 EU-05052-HPMSB JH-05500 PR-35052-HPHNM SL-05500 YC-02220	See Appendix 2 for a list of product codes and lots in scope

Dear Customer,
Arrow International has voluntarily issued a Field Safety Notice for the product codes and lot numbers listed above.

Description of the problem & immediate actions required
Arrow International, a subsidiary of Teleflex, is voluntarily recalling the product referenced above because the product lidstock contains a labelling error. The lidstock states the incorrect expiration date for the product.
This issue could result in use of a device that is expired which could potentially lead to an increased risk of infection or other complications; sterility, biocompatibility, safety, or efficacy of the kits and their components are not assured beyond the correct expiration date.

No complaints or patient injury has been reported pertaining to this issue at this time. Only product codes and lot combinations referenced in Appendix 2 are impacted by this recall.

Our records indicate you have received products that are subject to this field action. We are now notifying our customers to take the following actions:

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities	**1**
Distributors	**2**

Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
3. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Action list number 2 – Distributors

1. Provide this Field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. 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 Teleflex.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation 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: Customer Service
Telephone: +43 0 1 402 4772 DW 94
FAX: + 343 0 1 402 4772 DW 77
Email: qualityAT@teleflex.com

Please be advised that all Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologise 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,

Padraig Hegarty

Padraig Hegarty VP, QA (Manufacturing)

Appendix 1

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

Customer No _____

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000396

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: + 343 0 1 402 4772 DW 77 **Email**: qualityAT@teleflex.com

☐ We confirm receipt of this FSN and have 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 have 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

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 Safety Returns"**

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

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

Appendix 2 – Product codes and lots in scope

Product Code	Lot Number
AB-00150	13F16B0155
AB-17080-N	13F18J0654 13F16H0046 13F16F0210 13F16E0106 13F16C0107
AB-17110-N	13F16G0226 13R16G0226 13F16F0079
AB-17140-N	13F16F0190 13F16C0045
AB-18080-N	13F16H0048 13F16F0007 13F16B0181
AB-18110-N	13F16F0189 13F16C0046
AB-18140-N	13F16H0292
AK-05000	13F18A0451
AM-05500	13F18A0745
AN-05505	13F18H0836 13F17L0441 13R17L0441
ASA-25090-S	13F18A0715
ASK-00002-1A	13F18G0481 13F18H0652 13F18K0645
ASK-04200-UPM	13F18H0209
ASK-05060-CHO1	13F18A0547
ASK-05400-CA1	13F18A0527
ASK-05500-CAN	13F18K0740
ASK-05560-WH	13F18A0714
ASK-09801-UPM	13F18G0475 13F18F0729
ASK-17019-MSC	13F18B0063
CK-02220	13F18A0713 13F18B0394
EC-05000	13F18D0313
EU-05052-HPMSB	13F18G0925
JH-05500	13F18A0719
PR-35052-HPHNM	13F18A0540
SL-05500	13F17H0053
YC-02220	13F18A0593