

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**FAX:** 0711 / 49 05 06 08**Telephone:** 0711/ 20 90 80 00**Email:** recalls.de@teleflex.com**Product Manager:****Contact:** Sabine Schewior**Email:** sabine.schewior@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,

[Redacted Signature]

[Redacted Title]