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

February-2024

URGENT – FIELD SAFETY NOTICE

Type of Action:	**Recall – Removal**			
Product Name(s):	**Arrow® QuickFlash® Radial Artery Catheterisation Kits and Sets & Arrow® QuickFlash® Radial Artery/Arterial Line Catheterisation Kit**			
Teleflex Reference:	**EIF-000556**			
Product Codes:	AK-04220	ASK-04220-FMH1	ASK-04220-HHC	ASK-04220-KSP
	ASK-04220-PSU	ASK-04220-UCL1	ASK-04500-AH	ASK-04500-HF-S
	NA-04220-S1A	NA-04220-X1A	RA-04220	RA-04220-W
Batch/ Lot Number:	**Refer to Appendix 2**			

Dear Customer,

Details of affected devices
Arrow International LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary Field Safety Corrective Action ("FSCA") for the above listed products; refer to Appendix 2 for Product Code, lot number and Unique Device Identifier information.

Description of the problem & immediate actions required.
Teleflex is initiating this voluntary FSCA for the above-mentioned products due to reports received indicating a potentially defective component.

The complaints received relate to resistance of the guidewire handle/chamber during use. The possible immediate health consequences of the component issue are arterial vasospasm and vessel injury arising from multiple arterial punctures with repeated attempts. Any long-range consequences would be contingent on the severity of any immediate consequences. If tested prior to use as directed by the information for use and good clinical practice, the component issue should be discovered. Nevertheless, Teleflex is recalling the products listed in Appendix 2.

As of 31-January-2024, a total of 194 complaints reporting resistance of the guidewire handle/chamber during use have been received for the products in scope of this Field Safety Notice. Of these 194 complaints, no complaints reported injury.

Our records indicate you have received products that are in scope of this FSCA.

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

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	**1**
Distributors	**2**

Action list number 1 – Medical facilities

1. We request that you immediately check your inventory for product within the scope of this FSCA. **Users should cease use and distribution of affected product and immediately quarantine the affected product.**
2. If you have affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and contact Teleflex Customer Service by calling the phone number provided below. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorisation (RGA) Number and will provide instructions for the return of products to Teleflex Medical.
3. If you do not have affected product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and return the form to Teleflex at the contact details provided.
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 a copy of this field safety notice to all customers who have received impacted product. Each of your customers is then required to complete the Acknowledgement Form and return it to you.
2. We request that you immediately check your inventory for affected product. **Cease use and distribution of, and immediately quarantine, the affected product.** You may then return all product in scope.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined in actions 1 and 2 of this Action List Number 2. Upon completion of your actions, please forward the completed Acknowledgement Form to the e-mail address below. **Important** - Please ensure you only list batch numbers in scope of this field safety notice when completing this form.
4. Please be aware that all European Economic Area/Switzerland, United Kingdom (EEA/CH/UK) and Turkey (TR) 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 Customer Service by return e-mail to the e-mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/UK/TR area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Customer Service at the contact information below.

Teleflex

Teleflex informs impacted 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: Cliodhna Coffey **Telephone:** +44 (0) 1494 532761
Email: Recalls.uk@teleflex.com

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.

The undersign confirms this notice has been notified to the appropriate Regulatory Authority.

For and on behalf of Teleflex,

Padraig Hegarty
Padraig Hegarty VP, Global QA (Manufacturing)

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000556

RETURN COMPLETED FORM IMMEDIATELY TO:

E-Mail: RECALLS.UK@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 completion of the required actions contained therein. We further confirm our inventory DOES include products impacted 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.

Complete this Acknowledgement form and return immediately by using the contact information above.

Product code	Lot/batch number	Quantity returning
Important - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.		

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units.
- Please label returns as **"Field Safety Returns EIF-000556".**

Note: Non FSCA product returns should be processed per standard product return processes.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**PHONE/FAX/e-mail**
FORM COMPLETED BY	**STAMP**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

Appendix 2: Product in scope of EIF-000556

Product Code	Batch	Unique Device Identifier
AK-04220	13F22E0436	(01)20801902190943(17)241031(10)13F22E0436
AK-04220	13F22H0360	(01)20801902190943(17)241031(10)13F22H0360
AK-04220	33F23E0375	(01)20801902190943(17)250430(10)33F23E0375
AK-04220	33F23K0032	(01)20801902190943(17)250430(10)33F23K0032
AK-04220	33F23J0443	(01)20801902190943(17)250831(10)33F23J0443
AK-04220	33F23L0862	(01)20801902190943(17)251130(10)33F23L0862
AK-04220	13F22L0105	(01)30801902121616 (17)241130(10)13F22L0105
AK-04220	13F23A0651	(01)30801902121616 (17)241130(10)13F23A0651
AK-04220	33F23C0100	(01)30801902121616 (17)241130(10)33F23C0100
AK-04220	33F23F0347	(01)30801902121616 (17)241130(10)33F23F0347
AK-04220	33F23E0501	(01)30801902121616 (17)250331(10)33F23E0501
AK-04220	33F23G0141	(01)30801902121616 (17)250430(10)33F23G0141
ASK-04220-FMH1	33F23B0525	(01)20801902111665(17)240331(10)33F23B0525
ASK-04220-FMH1	33F23H0100	(01)20801902111665(17)250331(10)33F23H0100
ASK-04220-HHC	33F23F0067	(01)20801902190851(17)250228(10)33F23F0067
ASK-04220-HHC	33F23K0278	(01)20801902190851(17)250331(10)33F23K0278
ASK-04220-HHC	33F23G0478	(01)20801902190851(17)250531(10)33F23G0478
ASK-04220-HHC	33F23H0101	(01)20801902190851(17)250531(10)33F23H0101
ASK-04220-KSP	33F23E0709	(01)20801902156406(17)250131(10)33F23E0709
ASK-04220-KSP	33F23H0102	(01)20801902156406(17)250131(10)33F23H0102
ASK-04220-KSP	33F23H0918	(01)20801902156406(17)250131(10)33F23H0918
ASK-04220-KSP	33F23J0607	(01)20801902156406(17)250228(10)33F23J0607
ASK-04220-PSU	33F23F0331	(01)40801902121446(17)250331(10)33F23F0331
ASK-04220-PSU	33F23G0663	(01)40801902121446(17)250430(10)33F23G0663
ASK-04220-UCL1	33F23F0801	(01)20801902159124(17)240831(10)33F23F0801
ASK-04220-UCL1	33F23C0726	(01)20801902159124(17)241130(10)33F23C0726
ASK-04220-UCL1	33F23H0320	(01)20801902159124(17)250228(10)33F23H0320
ASK-04500-AH	33F23E0731	(01)20801902114048(17)251130(10)33F23E0731
ASK-04500-AH	33F23H0103	(01)20801902114048(17)260131(10)33F23H0103
ASK-04500-AH	33F23H0395	(01)20801902114048(17)260228(10)33F23H0395
ASK-04500-HF-S	33F23F0202	(01)40801902118002(17)251130(10)33F23F0202
ASK-04500-HF-S	33F23H0104	(01)40801902118002(17)251231(10)33F23H0104
ASK-04500-HF-S	33F23H0396	(01)40801902118002(17)260228(10)33F23H0396
NA-04220-S1A	33F23J0671	(01)20801902139416(17)250228(10)33F23J0671
NA-04220-X1A	33F23F0704	(01)20801902136606(17)250228(10)33F23F0704
RA-04220	14F23B0041	(01)20801902180678(17)280131(10)14F23B0041
RA-04220	14F21L0189	(01)30801902193309(17)261031(10)14F21L0189
RA-04220	14F21L0190	(01)30801902193309(17)261031(10)14F21L0190
RA-04220	14F21L0250	(01)30801902193309(17)261130(10)14F21L0250
RA-04220	14F21L0251	(01)30801902193309(17)261130(10)14F21L0251
RA-04220	14F21L0252	(01)30801902193309(17)261130(10)14F21L0252
RA-04220	14F21L0253	(01)30801902193309(17)261130(10)14F21L0253
RA-04220	14F21M0130	(01)30801902193309(17)261231(10)14F21M0130
RA-04220	14F21M0131	(01)30801902193309(17)261231(10)14F21M0131
RA-04220	14F21M0205	(01)30801902193309(17)261231(10)14F21M0205
RA-04220	14F21M0206	(01)30801902193309(17)261231(10)14F21M0206
RA-04220	14F22A0044	(01)30801902193309(17)261231(10)14F22A0044
RA-04220	14F22A0123	(01)30801902193309(17)261231(10)14F22A0123
RA-04220	14F22A0124	(01)30801902193309(17)261231(10)14F22A0124
RA-04220	14F22A0143	(01)30801902193309(17)261231(10)14F22A0143

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Product Code	Batch	Unique Device Identifier
RA-04220	14F22A0144	(01)30801902193309(17)270131(10)14F22A0144
RA-04220	14F22B0163	(01)30801902193309(17)270131(10)14F22B0163
RA-04220	14F22B0164	(01)30801902193309(17)270131(10)14F22B0164
RA-04220	14F22B0175	(01)30801902193309(17)270228(10)14F22B0175
RA-04220	14F22C0017	(01)30801902193309(17)270228(10)14F22C0017
RA-04220	14F22C0018	(01)30801902193309(17)270228(10)14F22C0018
RA-04220	14F22C0019	(01)30801902193309(17)270228(10)14F22C0019
RA-04220	14F22C0020	(01)30801902193309(17)270228(10)14F22C0020
RA-04220	14F22C0021	(01)30801902193309(17)270228(10)14F22C0021
RA-04220	14F22C0022	(01)30801902193309(17)270228(10)14F22C0022
RA-04220	14F22C0216	(01)30801902193309(17)270228(10)14F22C0216
RA-04220	14F22C0284	(01)30801902193309(17)270228(10)14F22C0284
RA-04220	14F22C0346	(01)30801902193309(17)270331(10)14F22C0346
RA-04220	14F22C0347	(01)30801902193309(17)270331(10)14F22C0347
RA-04220	14F22D0023	(01)30801902193309(17)270331(10)14F22D0023
RA-04220	14F22D0024	(01)30801902193309(17)270331(10)14F22D0024
RA-04220	14F22D0110	(01)30801902193309(17)270331(10)14F22D0110
RA-04220	14F22D0217	(01)30801902193309(17)270430(10)14F22D0217
RA-04220	14F22D0291	(01)30801902193309(17)270430(10)14F22D0291
RA-04220	14S22D0218	(01)30801902193309(17)270430(10)14S22D0218
RA-04220	14F22E0016	(01)30801902193309(17)270531(10)14F22E0016
RA-04220	14F22E0173	(01)30801902193309(17)270531(10)14F22E0173
RA-04220	14F22E0215	(01)30801902193309(17)270531(10)14F22E0215
RA-04220	14F22F0003	(01)30801902193309(17)270531(10)14F22F0003
RA-04220	14F22F0062	(01)30801902193309(17)270531(10)14F22F0062
RA-04220	14F22F0208	(01)30801902193309(17)270531(10)14F22F0208
RA-04220	14F22F0209	(01)30801902193309(17)270531(10)14F22F0209
RA-04220	14F22F0210	(01)30801902193309(17)270630(10)14F22F0210
RA-04220	14F22F0212	(01)30801902193309(17)270630(10)14F22F0212
RA-04220	14F22F0335	(01)30801902193309(17)270630(10)14F22F0335
RA-04220	14F22F0336	(01)30801902193309(17)270630(10)14F22F0336
RA-04220	14F22G0297	(01)30801902193309(17)270731(10)14F22G0297
RA-04220	14F22G0298	(01)30801902193309(17)270731(10)14F22G0298
RA-04220	14F22G0325	(01)30801902193309(17)270731(10)14F22G0325
RA-04220	14F22G0326	(01)30801902193309(17)270731(10)14F22G0326
RA-04220	14F22H0078	(01)30801902193309(17)270731(10)14F22H0078
RA-04220	14F22H0079	(01)30801902193309(17)270731(10)14F22H0079
RA-04220	14F22H0250	(01)30801902193309(17)270731(10)14F22H0250
RA-04220	14F22J0078	(01)30801902193309(17)270831(10)14F22J0078
RA-04220	14F22J0079	(01)30801902193309(17)270831(10)14F22J0079
RA-04220	14F22J0080	(01)30801902193309(17)270831(10)14F22J0080
RA-04220	14F22J0081	(01)30801902193309(17)270831(10)14F22J0081
RA-04220	14F22J0082	(01)30801902193309(17)270831(10)14F22J0082
RA-04220	14F22J0083	(01)30801902193309(17)270831(10)14F22J0083
RA-04220	14F22J0257	(01)30801902193309(17)270930(10)14F22J0257
RA-04220	14F22K0182	(01)30801902210631(17)270930(10)14F22K0182
RA-04220	14F22K0183	(01)30801902210631(17)270930(10)14F22K0183
RA-04220	14F22K0184	(01)30801902210631(17)270930(10)14F22K0184
RA-04220	14F22K0185	(01)30801902210631(17)270930(10)14F22K0185
RA-04220	14F22K0223	(01)30801902210631(17)271031(10)14F22K0223

Appendix 2: Product in scope of EIF-000556

Product Code	Batch	Unique Device Identifier
RA-04220	14F22M0032	(01)30801902210631(17)271130(10)14F22M0032
RA-04220	14F22M0033	(01)30801902210631(17)271130(10)14F22M0033
RA-04220	14F22M0034	(01)30801902210631(17)271130(10)14F22M0034
RA-04220	14F22M0035	(01)30801902210631(17)271130(10)14F22M0035
RA-04220	14F22M0036	(01)30801902210631(17)271130(10)14F22M0036
RA-04220	14F22M0132	(01)30801902210631(17)271231(10)14F22M0132
RA-04220	14F23B0042	(01)30801902210631(17)280131(10)14F23B0042
RA-04220	14F23B0142	(01)30801902210631(17)280131(10)14F23B0142
RA-04220	14F23B0143	(01)30801902210631(17)280131(10)14F23B0143
RA-04220	14F23B0144	(01)30801902210631(17)280131(10)14F23B0144
RA-04220	14F23B0154	(01)30801902210631(17)280131(10)14F23B0154
RA-04220	14F23D0203	(01)30801902210631(17)280430(10)14F23D0203
RA-04220	14F23D0204	(01)30801902210631(17)280430(10)14F23D0204
RA-04220	14F23D0205	(01)30801902210631(17)280430(10)14F23D0205
RA-04220	14F23D0206	(01)30801902210631(17)280430(10)14F23D0206
RA-04220	14F23D0207	(01)30801902210631(17)280430(10)14F23D0207
RA-04220	14F23E0093	(01)30801902210631(17)280430(10)14F23E0093
RA-04220	14F23E0094	(01)30801902210631(17)280430(10)14F23E0094
RA-04220	14F23E0210	(01)30801902210631(17)280430(10)14F23E0210
RA-04220	14F23E0211	(01)30801902210631(17)280430(10)14F23E0211
RA-04220	14F23F0036	(01)30801902210631(17)280531(10)14F23F0036
RA-04220	14F23F0037	(01)30801902210631(17)280531(10)14F23F0037
RA-04220	14F23F0038	(01)30801902210631(17)280531(10)14F23F0038
RA-04220	14F23F0252	(01)30801902210631(17)280531(10)14F23F0252
RA-04220	14F23F0253	(01)30801902210631(17)280531(10)14F23F0253
RA-04220	14F23F0377	(01)30801902210631(17)280630(10)14F23F0377
RA-04220	14F23F0378	(01)30801902210631(17)280630(10)14F23F0378
RA-04220	14F23F0379	(01)30801902210631(17)280630(10)14F23F0379
RA-04220	14F23G0147	(01)30801902210631(17)280630(10)14F23G0147
RA-04220	14F23G0148	(01)30801902210631(17)280630(10)14F23G0148
RA-04220	14F23G0149	(01)30801902210631(17)280630(10)14F23G0149
RA-04220	14F23G0150	(01)30801902210631(17)280630(10)14F23G0150
RA-04220	14F23G0151	(01)30801902210631(17)280630(10)14F23G0151
RA-04220	14F23G0252	(01)30801902210631(17)280630(10)14F23G0252
RA-04220	14F23H0087	(01)30801902210631(17)280731(10)14F23H0087
RA-04220	14F23H0088	(01)30801902210631(17)280731(10)14F23H0088
RA-04220	14F23H0089	(01)30801902210631(17)280731(10)14F23H0089
RA-04220	14F23H0090	(01)30801902210631(17)280731(10)14F23H0090
RA-04220	14F23H0163	(01)30801902210631(17)280731(10)14F23H0163
RA-04220	14F23H0253	(01)30801902210631(17)280731(10)14F23H0253
RA-04220	14F23H0254	(01)30801902210631(17)280731(10)14F23H0254
RA-04220	14F23H0255	(01)30801902210631(17)280731(10)14F23H0255
RA-04220	14F23J0031	(01)30801902210631(17)280831(10)14F23J0031
RA-04220	14F23J0032	(01)30801902210631(17)280831(10)14F23J0032
RA-04220	14F23J0137	(01)30801902210631(17)280831(10)14F23J0137
RA-04220	14F23J0138	(01)30801902210631(17)280831(10)14F23J0138
RA-04220	14F23J0276	(01)30801902210631(17)280930(10)14F23J0276
RA-04220	14F23J0277	(01)30801902210631(17)280930(10)14F23J0277
RA-04220-W	13F22E0142	(01)30801902193316(17)270430(10)13F22E0142
RA-04220-W	13F22H0417	(01)30801902193316(17)270831(10)13F22H0417

Appendix 2: Product in scope of EIF-000556

Product Code	Batch	Unique Device Identifier
RA-04220-W	13F22J0586	(01)30801902193316(17)270930(10)13F22J0586
RA-04220-W	13F22M0442	(01)30801902193316(17)271231(10)13F22M0442
RA-04220-W	13F23C0015	(01)30801902193316(17)280331(10)13F23C0015
RA-04220-W	13F23J0017	(01)30801902193316(17)280930(10)13F23J0017
RA-04220-W	13F22F0124	(01)30801902202988(17)270531(10)13F22F0124
RA-04220-W	13F23B0363	(01)30801902202988(17)280131(10)13F23B0363
RA-04220-W	13F23H0010	(01)30801902202988(17)280731(10)13F23H0010
RA-04220-W	13F23J0013	(01)30801902202988(17)280831(10)13F23J0013
RA-04220-W	13F23K0001	(01)30801902202988(17)280930(10)13F23K0001

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