

28 Oct, 2010

URGENT FIELD SAFETY NOTICE

Commercial Name of Affected Product:	Single shot epidural kits, Venous access kits and arterial line kits
Type of action:	Market Withdrawal

AFFECTED PRODUCT: See Appendix 1

Dear Customer,

1. Details of affected devices

Teleflex Medical, through its subsidiary Arrow International, Inc. ("Arrow") has issued a voluntary recall for products in the attachment.

2. Description of the problem

Some of the outer trays used in the packaging of the above products were found to have cracks. Therefore, the packaging may have been compromised and sterility of the product cannot be guaranteed. If non-sterile product is used, there is a potential for infection to occur.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

Advice on action to be taken by Medical Staff

1. If you have no affected stock, please indicate so on the Recall Acknowledgement form and fax to your local Teleflex Medical Customer Service/Sales Rep as indicated on the Acknowledgement Form (Appendix 2)
2. If you do have stock, please contact your local Teleflex Medical Customer Service/Sales Rep (or Distributor) as indicated on the attached Acknowledgement Form for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the enclosed Recall Acknowledgement & Stock Status Form.
3. Complete the enclosed Recall Acknowledgement & Stock Status Form providing detail on product under your control within the scope of this Field Safety Action and immediately email the completed form to **[insert local contact details]** This will allow us to document your receipt of this letter and the amount of product you have on hand for return.
4. Your local Teleflex Medical Customer Service/Sales Rep (or Distributor) will coordinate the product return with you.
5. Teleflex Medical Customer Service can credit your account when the product is returned.

Instruction for Distributors of affected product

If you are a distributor, Teleflex Medical requires that you communicate this field safety corrective action notice to your customers who received product within the scope of this field safety corrective action by providing:

- A copy of this Field Safety Notice to them.
- A copy of the Acknowledgement Form (Appendix 2)

The Acknowledgement Form is required to be completed in its entirety, signed and returned to you (the Distributor).

As a Distributor, it is your responsibility to provide Teleflex Medical with confirmation that all of your consignees have been contacted under this field safety corrective action. Please forward the completed Acknowledgement Form to **[insert local contact details]**

4. Teleflex Medical

Teleflex Medical is notifying any potentially affected Customers, Teleflex Medical employees and Distributors of this Field Safety Notice.

5. 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.

6. Contact reference person

Should you require any further information or support concerning this issue, please contact:

For Customer Service
[insert local contact details]

For Product Specific Queries:
[insert local contact details]

This field safety corrective action is voluntary and all affected competent authorities have been advised of this Field Safety Corrective Action.

Teleflex Medical 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 at **[insert local contact details]**

Signed by:



VP Quality Assurance & Regulatory Affairs, EMEA
Attachments as follows:

Appendix 1
Appendix 2

Affected Part and Lot Numbers
Acknowledgement Form

Appendix 1
ARROW INTERNATIONAL, INC.
PRODUCTS AND LOTS NUMBERS AFFECTED BY CRACKED TRAYS

Product SKU (Code)	Description
AK-03000	Single Shot Epidural Anesthesia Kit
AK-04050	Internal Jugular Puncture Kit with Blue FlexTip® Catheter
AK-04150-E	Pediatric Jugular Puncture Kit
AK-04510	Arterial Line Kit
AK-04550	Vessel Catheterization Kit
AK-04550-A	Vessel Catheterization Kit
AK-04650-E	Central Venous Catheterization Kit
AK-04660	Central Venous Catheterization Kit
AK-04800	Jugular Puncture Kit
AM-03000	Single Shot Epidural Anesthesia Kit
AP-08100	Epidural Catheterization Kit with FlexTip Plus® Epidural Catheter
ASK-03000-CHUQ	Access Tray
ASK-03000-CHUQ1	Access Tray
ASK-03001-KC	Epidural Anesthesia Kit
ASK-03001-KC1	Epidural Anesthesia Kit
ASK-04001-GFH	Access Tray
ASK-04001-SLE	Prep Tray
ASK-04001-SUH	Access Tray
ASK-04001-UHC	Access Tray
ASK-04001-VCU	Nerve Block Prep Tray
ASK-04100-AMC	Arterial Catheterization Kit
ASK-04120-VBH	Radial Artery Catheterization Kit
ASK-04500-HF	QuickFlash® Radial Artery/Arterial Line Catheterization Kit
ASK-04550-TG	Vessel Catheterization Kit
BH-03000	Single Shot Epidural Anesthesia Kit
CC-04100	Arterial Catheterization Kit
DH-03000	Single Shot Epidural Anesthesia Kit
FS-04510	Arterial Catheterization Kit
HF-04020-1	Radial Artery Catheterization Kit with Sharps Safety Features
HH-03000	Epidural Anesthesia Kit
KC-03000	Single Shot Epidural Anesthesia Kit
MMC-04001-1	Arterial Access Tray
NH-05501	Epidural Catheterization Kit with FlexTip Plus® Catheter
NS-04100	Arterial Catheterization Kit
PW-04100	Arterial Catheterization Kit
SA-03001	Single Shot Epidural Anesthesia Kit
SH-03001	Single Shot Epidural Anesthesia Kit

Product Number	Lot Number	
AK-03000	RF0020735	
	RF0035260	
	RF0048279	
	RF0074386	
	RF5033131	
	RF5043814	
	RF5054886	
	RF5072941	
	RF5107406	
	RF5118270	
	RF6011018	
	RF6045801	
	RF6079491	
	RF6081233	
	RF6103625	
	RF7018712	
	RF7020460	
	RF7054076	
	RF7089370	
	RF7091000	
	RF7124568	
	RF8020964	
	RF8045881	
	RF8072854	
	RF8083651	
	RF8097339	
	RF8123912	
	RF9042571	
	RF9086457	
	RF9125787	
	AK-04050	RF0018975
		RF0022666
		RF0063422
RF0087612		
RF5107030		
RF5119129		
RF5129996		
RF6012024		
RF6034966		
RF6046200		
RF6068548		
RF6079525		
RF6081311		
RF6103626		
RF6127038		
RF7019125		
RF7032328		
RF7065841		
RF7090233		

Product Number	Lot Number	
	RF7102114	
	RF7124570	
	RF8020116	
	RF8020746	
	RF8033340	
	RF8057411	
	RF8072077	
	RF8084420	
	RF8108025	
	RF8122236	
	RF8123291	
	RF9014648	
	RF9039391	
	RF9042572	
	RF9070841	
	RF9097328	
	RF9114810	
	AK-04150-E	RF0022667
		RF0033740
		RF0046478
		RF0060733
		RF0077188
		RF0088407
		RF5096037
		RF5106234
		RF5107292
		RF5118200
RF5118780		
RF5120565		
RF6011373		
RF6022682		
RF6034425		
RF6045659		
RF6046109		
RF6056924		
RF6068239		
RF6070321		
RF6080609		
RF6080850		
RF6081520		
RF6081708		
RF6104136		
RF6104601		
RF6115551		
RF6116665		
RF6126992		
RF6127587		
RF7018408		
RF7019248		

Product Number	Lot Number
	RF7019349
	RF7020641
	RF7029585
	RF7031002
	RF7032409
	RF7054068
	RF7054442
	RF7066512
	RF7077049
	RF7077980
	RF7088148
	RF7089033
	RF7090321
	RF7101971
	RF7102066
	RF7102169
	RF8016471
	RF8016662
	RF8017377
	RF8020057
	RF8020145
	RF8032058
	RF8043583
	RF8044115
	RF8057399
	RF8060575
	RF8069060
	RF8071107
	RF8084932
	RF8107598
	RF8108167
	RF8122713
	RF9016397
RF9028165	
RF9030309	
RF9031619	
RF9042926	
RF9043901	
RF9056771	
RF9069749	
RF9073047	
RF9084363	
RF9086547	
RF9100268	
RF9109832	
RF9114301	
RF9126957	
AK-04510	RF0010114
	RF0018132

Product Number	Lot Number
	RF0018136
	RF0019643
	RF0021353
	RF0033300
	RF0034146
	RF0046480
	RF0046481
	RF0048286
	RF0050653
	RF0074357
	RF0075298
	RF0075818
	RF0087266
	RF0088221
	RF0088410
	RF8020974
	RF8031688
	RF8032978
	RF8043751
	RF8045887
	RF8056218
	RF8057412
	RF8058042
	RF8060183
	RF8068874
	RF8071805
	RF8083442
	RF8085102
	RF8095660
	RF8096096
	RF8097344
	RF8109477
	RF8110962
	RF8111746
	RF8122816
	RF9014694
	RF9016821
	RF9028787
	RF9030080
	RF9030930
	RF9030931
	RF9031616
	RF9043905
	RF9043906
	RF9056711
	RF9057855
	RF9069064

Product Number	Lot Number
	RF9073049
	RF9073283
	RF9084368
	RF9100470
	RF9101082
	RF9101137
	RF9101623
	RF9112089
	RF9112769
	RF9112997
	RF9114268
	RF9125843
	RF9127306
AK-04550	RF0010265
	RF0018842
	RF0022005
	RF0022669
	RF0034147
	RF0035268
	RF0048287
	RF0059345
	RF0062443
	RF0087619
	RF8028881
	RF8031667
	RF8045033
	RF8045886
	RF8057927
	RF8069061
	RF8070645
	RF8071944
	RF8083671
	RF8095448
	RF8095827
	RF8108233
	RF8110473
	RF8112162
	RF8119849
	RF9016806
	RF9028387
	RF9030312
	RF9043419
	RF9043907
	RF9055441
	RF9068560
	RF9071697
	RF9071851

Product Number	Lot Number
	RF9084369
	RF9100405
	RF9112397
	RF9126906
AK-04550-A	RF0019447
	RF8043582
	RF9072630
AK-04650-E	RF0019520
	RF0021354
	RF0046482
	RF0046961
	RF0063424
	RF5117904
	RF6022525
	RF6023560
	RF6023566
	RF6045757
	RF6057357
	RF6079772
	RF6092792
	RF6104795
	RF6105161
	RF6127332
	RF6127674
	RF7018942
	RF7031005
	RF7031998
	RF7054159
	RF7077028
	RF7090472
	RF7091001
	RF7112897
	RF7124307
	RF8016370
	RF8020798
	RF8029139
	RF8045217
	RF8056796
	RF8058001
	RF8071697
	RF8072284
	RF8083910
	RF8095863
	RF8108791
	RF8110833
	RF9016136
	RF9044809

Product Number	Lot Number
	RF9072425
	RF9083735
	RF9085743
	RF9113835
AK-04660	RF0034148
	RF0046483
	RF0061650
	RF0063020
	RF0075819
	RF0087771
	RF5117911
	RF5129632
	RF6023024
	RF6057559
	RF6092439
	RF6104845
	RF7018862
	RF7032229
	RF7054430
	RF7077080
	RF7089171
	RF7102397
	RF8016283
	RF8029410
	RF8033120
	RF8045315
	RF8057243
	RF8058270
	RF8083403
	RF8097345
	RF8122721
	RF9044663
	RF9055442
	RF9084406
	RF9097333
	RF9114824
	AK-04800
RF0021355	
RF0035270	
RF0048289	
RF0075820	
RF0087622	
RF8020975	
RF8045579	
RF8072078	
RF8072511	
RF8084428	

Product Number	Lot Number
	RF8096134
	RF8108839
	RF8111695
	RF8123388
	RF9016822
	RF9030939
	RF9039585
	RF9055444
	RF9073109
	RF9083736
	RF9097334
	RF9101715
	RF9126227
	RF0021939
	RF0059446
	RF0088369
	RF5129734
AM-03000	RF6057409
	RF6116605
	RF7088733
	RF8071779
	RF8123969
	RF9070874
	RF9100154
	RF9114379
	RF0058668
	RF0059099
AP-08100	RF8095615
	RF9055826
	RF9085255
ASK-03000-CHUQ	RF7125131
	RF8044816
	RF9056379
	RL8088126
ASK-03000-CHUQ1	RL8118762
	RF0076695
	RF9056277
	RF9071611
	RF9113177
ASK-03001-KC	RF9127313
	RL8067536
ASK-03001-KC1	RL8088127
	RF0019736
ASK-04001-GFH	RL8128948
	RF0019576
	RF0050476
	RF0063762

Product Number	Lot Number
ASK-04001-SLE	RF9043945
ASK-04001-SUH	RF0018516
	RF0022619
	RF0035227
	RF0062121
	RF0076516
	RF9015142
	RF9028180
	RF9057183
	RF9086014
	RF9109959
ASK-04001-UHC	RF9114930
	RL8129036
	RF0018444
	RF0048049
	RF0088324
	RF8057019
	RF8084220
	RF8123782
	RF9031837
	RF9084607
ASK-04001-VCU	RF9097370
	RF9101531
ASK-04100-AMC	RF9068430
	RF9071290
	RF0035352
ASK-04120-VBH	RF0062123
	RF9127596
ASK-04500-HF	RL8067738
	RL8128952
	RF0018785
	RF0034659
	RF0062342
	RF0087349
	RF0088181
	RF8096686
	RF8109019
	RF8110769
	RF8123605
	RF9015145
	RF9028427
RF9056742	
RF9068200	
RF9072648	
RF9097171	
RL8067689	
ASK-04550-TG	RF0021830

Product Number	Lot Number
	RF0047072
	RF0061718
	RF0075460
	RF8107597
	RF9016396
	RF9030308
	RF9042394
	RF9068856
	RF9069987
	RF9085877
	RF9100222
	RF9126420
BH-03000	RF0019618
	RF0047612
	RF0060793
	RF0087742
	RF8031875
	RF8057376
	RF8084126
	RF8110915
	RF8123973
	RF9043981
	RF9044684
	RF9068606
	RF9085979
	RF9100926
RF0019630	
CC-04100	RF0035146
	RF0062164
	RF0063964
	RF0088343
	RF4121260
	RF5012171
	RF5022620
	RF5022694
	RF5022936
	RF5023056
	RF5043795
	RF5044244
	RF5054841
	RF5060136
	RF5072938
	RF5083080
	RF5084506
	RF5095700
	RF5106236
	RF5118583

Product Number	Lot Number
	RF6012260
	RF6022847
	RF6033756
	RF6034434
	RF6035286
	RF6057003
	RF6068210
	RF6070336
	RF6080902
	RF6081546
	RF6093300
	RF6104481
	RF6115675
	RF6116613
	RF6127345
	RF6127983
	RF7018330
	RF7020221
	RF7032233
	RF7054012
	RF7054686
	RF7065398
	RF7076855
	RF7077581
	RF7088648
	RF7089293
	RF7090478
	RF7101417
	RF7112432
	RF7113766
	RF7124960
	RF8015963
	RF8020094
	RF8029171
	RF8031984
	RF8033220
	RF8044241
	RF8045487
	RF8056874
	RF8057384
	RF8068362
	RF8071384
	RF8083492
	RF8085126
	RF8096691
	RF8109018
	RF8110511

Product Number	Lot Number
	RF8110923
	RF8123490
	RF9015797
	RF9027384
	RF9028781
	RF9030798
	RF9044347
	RF9056860
	RF9057865
	RF9060300
	RF9071990
	RF9101135
	RF9112313
	RF9112770
	RF9114303
	RF9125231
DH-03000	RF0019622
	RF0020877
	RF0075585
	RF8032658
	RF8056830
	RF8072009
	RF8119791
	RF9027240
	RF9043983
	RF9068609
	RF9071992
FS-04510	RF9100168
	RF9112897
	RF0020943
	RF0033155
	RF0059261
	RF0062162
	RF0075661
	RF8033219
	RF8045501
	RF8070634
	RF8119793
RF8124055	
RF9030633	
RF9068315	
RF9071039	
RF9085981	
RF9101233	
RF9126921	
HF-04020-1	RF0017630
	RF0021276

Product Number	Lot Number	Product Number	Lot Number	Product Number	Lot Number
	RF0047810		RF9126884		RF6033757
	RF0075670		RF0010249		RF6034356
	RF8045172		RF8045051		RF6045750
	RF8045506		RF8072024		RF6057353
	RF8056833		RF8095226		RF6057883
	RF8069627		RF8096907		RF6068372
	RF8071319		RF8107879		RF6068635
	RF8110927	MMC-04001-1	RF8110959		RF6070561
	RF9015802		RF8119801		RF6079358
	RF9030635		RF9014498		RF6080954
	RF9056019		RF9028895		RF6081473
	RF9068611		RF9060351		RF6082032
	RF9071050		RL8067569		RF6093231
	RF9086007		RL8077782		RF6104147
	RF9097842		RF9044688		RF6116038
	RF9100852		RF9057542		RF6116779
	RF9114874		RL6123752		RF7018345
	RF0034516	NH-05501	RL8118743		RF7020079
	RF0076550		RL9019412		RF7029684
	RF8045507		RL9029591		RF7031136
	RF8069628		RF0021271		RF7031694
	RF8072014	NS-04100	RF0035169		RF7042757
	RF8085134		RF0059455		RF7043349
	RF8096832		RF0062166		RF7054836
HH-03000	RF8119796		RF0076519		RF7066014
	RF9031152		RF0087520		RF7066675
	RF9057640		RF5012173		RF7077586
	RF9070896		RF5012263		RF7088649
	RF9073140		RF5022525		RF7089181
	RF9112779		RF5022640		RF7090486
	RF9126209		RF5022884		RF7101953
	RF0019721		RF5033202		RF7102163
KC-03000	RF0019727		RF5043960		RF8015969
	RF0062036		RF5044137		RF8016893
	RF0076951		RF5044415		RF8029175
	RF7032320		RF5054655		RF8031766
	RF7055209		RF5055028		RF8033221
	RF7088801		RF5060314		RF8044245
	RF7101703		RF5072320		RF8045307
	RF7102262		RF5084106		RF8057233
	RF8017549		RF5095841		RF8068375
	RF8056557		RF5106237		RF8072081
	RF8084129		RF5107230		RF8083722
	RF8119798		RF5118615		RF8097203
	RF9015804		RF6011424		RF8107887
	RF9057951		RF6012258		RF8111833
	RF9099001		RF6022392		RF811833

Product Number	Lot Number
	RF9014775
	RF9027307
	RF9042699
	RF9068374
	RF9085995
	RF9101133
	RF9112853
	RF9114302
	RF9125236
	RF8029429
PW-04100	RF8031774
	RF8043868
	RF8057234

Product Number	Lot Number
SA-03001	RF8021034
	RF8069022
	RF8108468
	RF8123597
	RF9028904
	RF9056328
	RF9097652
	RF9101076
	RF0017728
	RF0022606
SH-03001	RF0059476
	RF0075693
	RF8057235

Product Number	Lot Number
	RF8071390
	RF8083724
	RF8096352
	RF8109029
	RF8122700
	RF9027311
	RF9032220
	RF9056916
	RF9060668
	RF9084115
	RF9097727
	RF9100901
	RF9114878

Acknowledgement Form

Immediate Attention Requested

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT AND STOCK STATUS FORM
Medical Device Field Safety Corrective Action Concerning Teleflex Medical, through its subsidiary Arrow International, Inc. ("Arrow") Products

Single shot epidural kits, Venous access kits and arterial line kits

RETURN COMPLETED FORM IMMEDIATELY TO: **[insert local contact details]**

Please check the appropriate box and return this form by Fax to the number above.

<input type="checkbox"/> We have no inventory within the scope of this recall.	<input type="checkbox"/> We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities.
	<input type="checkbox"/> Please credit our account once you have received the returns

Please print product numbers clearly.

Product Number	Lot Number	Quantity (unit)

Print Name/Title _____

Date _____

Signature _____

Telephone Number _____

Institution Name _____

Address _____

City, State, Zip Code _____

Return Authorisation
No _____

Customer No
