Teleflex MEDICAL

ARROW INTERNATIONAL

[insert local affiliate or distributor address]

XX February, 2009

Urgent
Field Safety Notice

Commercial Name of Affected Product:	30/40/50 CC IAB Catheters 30/40/50 CC IAB Volume Connectors
FSCA Identifier:	***[Reference number assigned by Natio Competent Authority]***
Type of action:	PRODUCT RECALL

AFFECTED PRODUCT CODES:

IAB-04830-U	IAB-04840-U	IAB-05840-U
IAB-05830-LWS	IAB-05830-U	IAB-05840-LWS
IAB-06830-U	IAB-06840-U	IAB-R950-U
IAB-S730C	IAB-S840C	IAK-02691
IAK-02692	IAK-02693	

This Field Safety Notice has been provided to you in English.
This notice will follow in your own language.

Dear Cardiac Care Customer,

1. Details on affected devices

Teleflex Medical, through its subsidiary Arrow International, has issued a voluntary recall for specific lots of the products identified above. The lot numbers affected are printed in Appendix A of this letter.

2. Description of the problem

Arrow International has become aware through a small number of customers that the blue connector for the 40cc IAB is not properly recognized by the Arrow Intra-Aortic Balloon Pump (IABP) system. A fault in the connector of the pump tubing assembly may result in the volume setting on the pump defaulting to 2.5 cc's or 5 cc's (depending on IABP model) rather than the appropriate 30, 40, or 50 cc volume.

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If the incorrect volume is pumped and this is not recognized while IABP therapy is allowed to be continued at this volume, poor or no augmentation support will result, reducing the therapeutic efficacy and increasing the risk of ischemic events. Further, even in the presence of anticoagulation, the lack of movement of the IAB may increase the risk of thrombus development on the surface of the IAB. Therefore, Teleflex Medical, through its subsidiary Arrow International, has initiated a voluntary recall of these products. The Food and Drug Administration has been notified of this action.

3. Advise on action to be taken by Medical Staff

In order to provide the highest level of quality product to our customers, we are notifying our Customers to take the following action:

RECALL INSTRUCTIONS:

- Examine stock and quarantine all affected product immediately.
- Please print and complete the attached Recall Acknowledgement Form in Appendix C and fax back to Arrow Customer Services (number located on the form) who will contact you to arrange return of the product.
- Return any affected product freight collect, along with the original completed Recall Acknowledgement & Stock Status Form.
- Report all adverse incidents related to the affected products to the National Competent Authority and Teleflex Medical.

If you are a distributor, communicate this recall notice to your customers who received product within the scope of this recall by providing a copy of this recall notification to them. Also provide a copy of the Acknowledgement Form. This form should be completed in its entirety, signed and returned to you (the Distributor). As a Distributor, it is your responsibility to provide Teleflex Medical/Arrow International with a certification that all of your consignees have been contacted under this recall.

Or

MITIGATION DIRECTIONS:

For patients currently undergoing therapy please follow the mitigations described in Appendix B.

In circumstances where alternate IAB Catheters/adaptors or other forms of therapy are not available,contact Arrow International to obtain replacement tubing and implement the mitigations described in Appendix B until replacement Pump Tubing Assemblies are received. Arrow International will provide replacement Pump Tubing Assemblies within 7-10 days that will correct this potential defect. Replacement tubing can be ordered from Arrow International customer service by calling XXXXXX (Monday -Friday 8.30 -5.00pm) and request 30cc (Part Number IAK-02696), 40cc (Part Number IAK-02695), and 50cc (Part Number IAK-02693) Pump Tubing Assemblies.

Further information may be found at the company's website, www.arrowintl.com.

If you have any other questions, please feel free to contact your local sales representative or the Arrow International Customer Service, which is available at:

[insert local contact phone number here]

We strive to supply Cardiac Care Products of the highest quality and reliability. We regret any inconvenience caused by this issue and we thank you for your continued support.

4. Teleflex Medical/Arrow International Action

Teleflex Medical/Arrow International 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 need any further information or support concerning this issue, please contact:

[Insert local contact person name & details]

This recall is voluntary and all relevant Regulatory Agencies have been notified of this action. Teleflex Medical/Arrow International apologizes for any inconvenience caused by this issue.

[redacted]
Director, RA/QA
Kernen Facilities (Germany)

Attachments:

Appendix A: Lot numbers affected by this recall
Appendix B Mitigation Directions
Appendix C: Acknowledgement Form

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APPENDIX A

ARROW INTERNATIONAL 30/40/50 CC IAB Catheters

LOT NUMBERS INCLUDED IN SCOPE OF RECALL

2009	
Product Number	Lot/Serial Number
IAB-04840-U	MF8124304 MF9014426 MF9014444 MF9014446 MF9014447
IAB-05830-LWS	MF8124308 MF8124409
IAB-05830-U	MF8124064 MF8124307 MF8124408
IAB-05840-LWS	MF8124179 MF8124202 MF8124309 MF8124340 MF8124410 MF8124411
IAB-05840-U	MF8124345
IAB-06830-U	MF8124413 MF8124414
IAB-06840-U	MF8124162
IAB-R950-U	MF8124297
IAB-S730C	MF8124198 MF8124282
IAB-S840C	MF8103165

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2008	
Product Number	Lot/Serial Number
IAB-04830-U	MF6079580 MF6100954 MF7033668 MF7086558 MF7086984 MF7097225 MF7097426 MF7118000 MF7118001 MF7128557 MF8018922
IAB-04840-U	MF6090318 MF6111511 MF7065955 MF7076255 MF7086556 MF7097114 MF7097115 MF7097226 MF7097227 MF7097228 MF7097427 MF7097470 MF7097471 MF7107861 MF7107862 MF7118045 MF7118046 MF7128470 MF7128508 MF8018724 MF8018813 MF8018996 MF8124303 MF8124304
IAB-05830-LWS	MF6090321 MF6122057 MF7044419 MF7076250 MF7086674 MF7107863 MF7118002

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2008	
	MF7128359
	MF7128561
	MF8018727
	MF8018849
	MF8019095
	MF8039848
	MF8039849
	MF8039991
	MF8040484
	MF8050805
	MF8050981
	MF8061206
	MF8061268
	MF8061335
	MF8061416
	MF8072073
	MF8082285
	MF8082394
	MF8082505
	MF8082506
	MF8092785
	MF8092999
	MF8103156
	MF8113922
	MF8114009
	MF8124160
IAB-05830-U	MF6122058
	MF7065640
	MF7076257
	MF7076378
	MF7097392
	MF7118003
	MF7118004
	MF7118219
	MF7128387
	MF7128471
	MF7128504
	MF7128505
	MF8018907
	MF8018997
	MF8030122
	MF8039664
	MF8039878
	MF8040324
	MF8040325

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2008	
	MF8040638
	MF8050911
	MF8061125
	MF8061176
	MF8061334
	MF8061500
	MF8061615
	MF8071782
	MF8072074
	MF8082267
	MF8082584
	MF8092783
	MF8092784
	MF8093000
	MF8093001
	MF8103155
	MF8103262
	MF8103263
	MF8124064
	MF8124178
IAB-05840-LWS	MF7044497
	MF7054982
	MF7076013
	MF7086515
	MF7086964
	MF7097339
	MF7097388
	MF7107535
	MF7128358
	MF7128419
	MF7128466
	MF8018705
	MF8018706
	MF8018707
	MF8018725
	MF8018726
	MF8018729
	MF8018846
	MF8018847
	MF8018848
	MF8018924
	MF8018925
	MF8018998
	MF8018999
	MF8019101

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2008
MF8019102
MF8029111
MF8029166
MF8029167
MF8029168
MF8029256
MF8029257
MF8029258
MF8039704
MF8039705
MF8039706
MF8039707
MF8039709
MF8040286
MF8040326
MF8040543
MF8040641
MF8050720
MF8050721
MF8050722
MF8050806
MF8050912
MF8050913
MF8050982
MF8050995
MF8050996
MF8061126
MF8061177
MF8061185
MF8061405
MF8061406
MF8061457
MF8061501
MF8071783
MF8071784
MF8071785
MF8071786
MF8071853
MF8071854
MF8071864
MF8072072
MF8082151
MF8082395
MF8082396
MF8082397
MF8092764

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2008	
	MF8092786
	MF8093003
	MF8103157
	MF8103158
	MF8103640
	MF8113837
	MF8113838
	MF8113839
	MF8113840
	MF8113949
	MF8113950
	MF8124161
	MF8124179
	MF8124202
IAB-05840-U	MF7065606
	MF7076012
	MF7076021
	MF7086462
	MF7086736
	MF7107536
	MF7107537
	MF7107694
	MF7107696
	MF7118048
	MF7118049
	MF7118050
	MF7118151
	MF7118221
	MF7118222
	MF7128472
	MF7128506
	MF7128507
	MF8018908
	MF8019033
	MF8019034
	MF8019035
	MF8019104
	MF8029191
	MF8029433
	MF8029434
	MF8039774
	MF8040251
	MF8040287
	MF8050764
	MF8050812

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2008	
	MF8050966 MF8061267 MF8061413 MF8071676 MF8071863 MF8082268 MF8082507 MF8093002 MF8103280 MF8103416 MF8103571 MF8113836 MF8113919 MF8113951
IAB-06830-U	MF8039760 MF8039772 MF8040252 MF8040485 MF8040486 MF8040639 MF8050723 MF8050807 MF8050914 MF8061336 MF8061458 MF8061616 MF8061617 MF8071677 MF8071855 MF8082154 MF8082586 MF8092763 MF8093004 MF8103159 MF8103160 MF8103264 MF8103265 MF8103417 MF8124181 MF8124203
IAB-06840-U	MF8029428 MF8029506 MF8029508

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2008	
	MF8030125 MF8030126 MF8039646 MF8039647 MF8039762 MF8039851 MF8040487 MF8040640 MF8050724 MF8061127 MF8061503 MF8071787 MF8072071 MF8082286 MF8082508 MF8093047 MF8103162 MF8103418 MF8103642 MF8113920 MF8114010 MF8124162
IAB-R950-U	MF7076413 MF7086743 MF7097191 MF8092738 MR8039844
IAB-S730C	MF7012650 MF7065398 MF7076011 MF7086585 MF7086981 MF7097060 MF7097473 MF7107623 MF7117871 MF7128553 MF8018756 MF8018814 MF8019001 MF8019036 MF8029114 MF8029190
	MF8039773

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2008	
	MF8039989 MF8040133 MF8050762 MF8050763 MF8050985 MF8051093 MF8061455 MF8071620 MF8082323 MF8082324 MF8082325 MF8092832 MF8103260 MF8124197 MF8124198
IAB-S840C	MF6090326 MF6101289 MF7012817 MF7065399 MF7065882 MF7076380 MF7086744 MF7097061 MF7097113 MF7097319 MF7097474 MF7118038 MF7118039 MF7128469 MF7128554 MF7128555 MF7128556 MF8018842 MF8018976 MF8019000 MF8019100 MF8029244 MF8029295 MF8029296 MF8029509 MF8039793 MF8039794 MF8039988 MF8040431
	MF8040432

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2008	
	MF8040433
	MF8040445
	MF8040601
	MF8040602
	MF8040603
	MF8050760
	MF8050761
	MF8050986
	MF8050987
	MF8050988
	MF8051091
	MF8051092
	MF8061324
	MF8061325
	MF8061456
	MF8071619
	MF8071627
	MF8071628
	MF8071789
	MF8071849
	MF8072043
	MF8082319
	MF8082320
	MF8082321
	MF8082322
	MF8092737
	MF8092833
	MF8092870
	MF8092871
	MF8092872
	MF8092873
	MF8103163
	MF8103164
	MF8103165
	MF8103166
	MF8103167
	MF8103168
	MF8103568
	MF8103569

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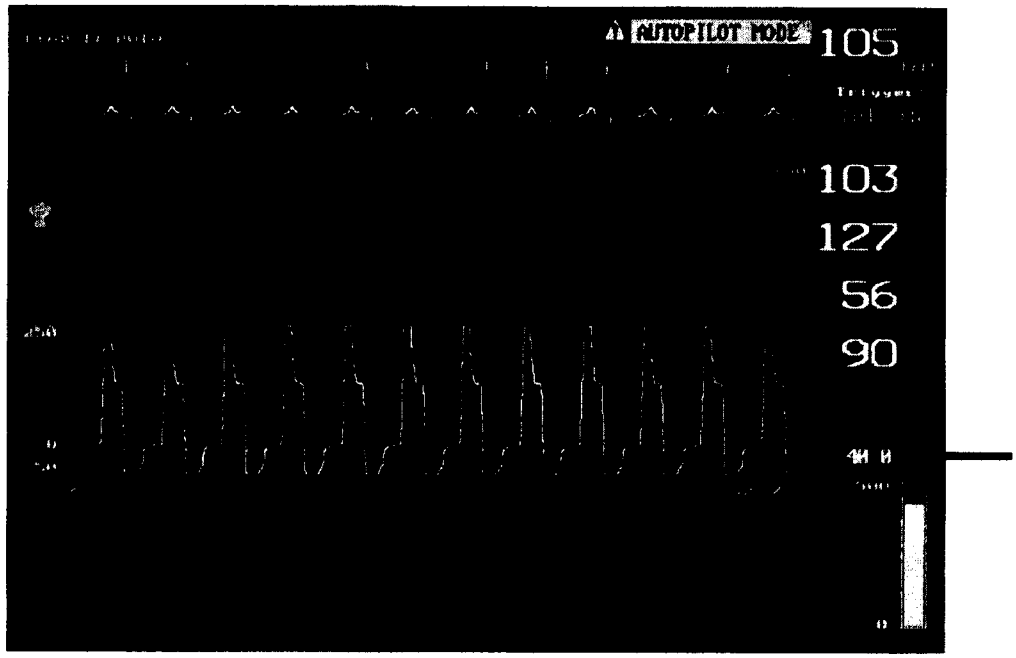
APPENDIX B

ARROW INTERNATIONAL 30/40/50 CC IAB VOLUME CONNECTORS

MITIGATION DIRECTIONS

When setting up and using the unit follow all instructions in the Operator's Manual.

1. As stated in the Operator's Manual (See pages: 5-4 to 5-11 and 6-4 for ACAT1; 5-3 to 5-11 and 6-13 for AutoCAT 2 rev.2.21 and 5-3 to 5-11 and 6-13 for AutoCAT 2 rev 2 23.) this issue can be recognized immediately by verifying the VOLUME SETTING displayed on the screen of the ACAT 1 Plus and AutoCAT 2 Series IABP Console. The currently set volume of the IAB balloon pump catheter is shown in the Lower Right Area of the display, below the Hemodynamic values and above the HE tank bar graph. As soon as the IAB Volume connector is securely connected, the volume of the corresponding IAB catheter and connector should be properly displayed in the area shown. The IAB volume is also printed on the recorder strip.



When setting up the IABP console for use, ensure that the following steps are completed.

2. ***Verify*** that all connections are made properly. This includes the ECG cables, Arterial Pressure connections (AP) and the IAB volume connector. (See pages: 5-4 to 5-11 and 6-4 for ACAT1; 5-3 to 5-11 and 6-13 for AutoCAT 2 rev.2.21 and 5-3 to 5-11 and 6-13 for AutoCAT 2 rev.2.23).

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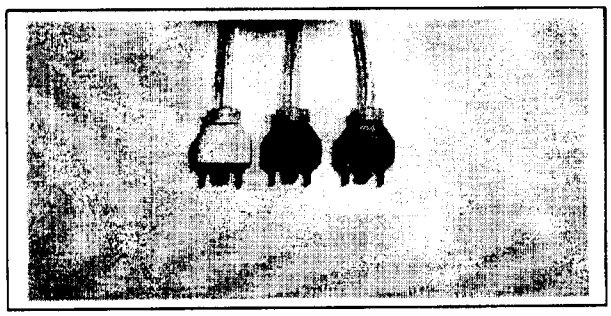
3. ***Verify*** that after the IAB connector of the IAB pump tubing assembly is attached to the IABP console, the volume setting is correct for the corresponding connector that is listed below. The volume settings are as follows for the each color coded connector below:

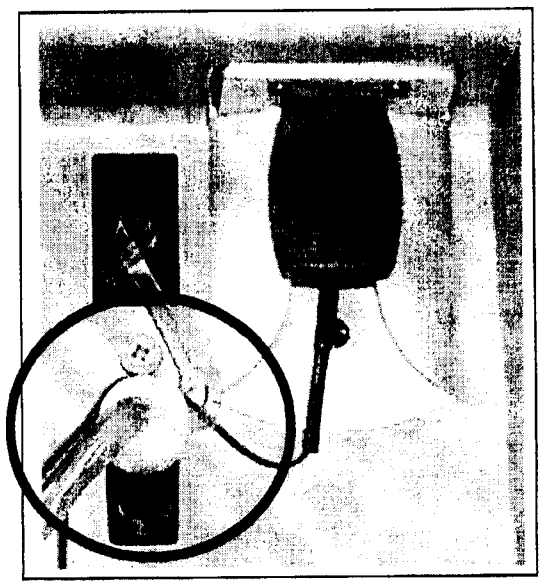
    a. ***White Connectors: 30cc***
    b. ***Blue Connectors: 40 cc***
    c. ***Orange Connectors: 50 cc***



4. If the volume is properly displayed, no further action is required. ***Set the AUG Alarm (see section 8b below)***: When the augmentation alarm is set and the Augmentation falls below the set limit, the IABP console will alert the clinician with an audible alarm and a screen message that states "AUG BELOW SET LIMIT". This alarm will alert the clinician when the level of augmentation is not being provided to the patient. If this alarm occurs, the clinician should assess the patient and the IABP and verify that the IAB volume setting is set to the correct level. The IAB volume, that is shown on the screen and recorder should be verified as per your hospital policy, but at least every 2 hours as described in the operator's manual.

5. If the volume is NOT properly displayed and reads 2.5cc on the AutoCAT 2 Series or 5.0cc on the ACAT 1 Series;

    a. ***Disconnect and Reconnect the IAB Pump Tubing Assembly connector*** making sure the IAB pump tubing assembly connector is fully seated in the receptacle.



b. ***Verify the IAB volume setting on the IABP.*** If it is showing the correct volume, no further action is required.

6. If the IAB volume is still ***INCORRECT***, you should replace the IAB Pump Tubing assembly with a tubing assembly of the same volume size.

   a. ***DISCONNECT*** the IAB pump tubing assembly at the QUICK CONNECT on the balloon.
   b. ***REPLACE*** with another appropriate size pump tubing assembly. Pump Tubing Assembly may be ordered from Arrow using 30cc (Part Number IAK-02696), 40cc (Part Number IAK-02695), and 50cc (Part Number IAK-02693).
   c. ***RECONNECT*** to IABP and verify IAB volume setting is correct, as described above.

WARNING:

Use of an incorrectly sized IAB pump tubing assembly can result in under or over delivery of Helium to the IAB. This may reduce cardiac support or increase the risk of Helium embolism in the event of a leak in the IAB. This can also increase the risk of thrombus formation on the IAB balloon catheter that is implanted in the patient. If the thrombus formation is somehow dislodged from the catheter, it could potentially cause end organ damage or neurological deficits (i.e., stroke or transient ischemic attack).

Ensure that if an alternative pump tubing assembly is used, that it is the same volume as the pump tubing assembly that it is replacing.

7. If replacing the IAB pump tubing assembly with an assembly that does NOT correct the problem, change to another IABP console and notify your local Biomedical support staff or contact Teleflex Medical/Arrow IABP Worldwide Service.

8. Once pumping has been started:

   a. ***Assess*** the AP waveform and note that Augmentation is present during IAB inflation. If the IAB volume is very low, Augmentation may not be present or may be very low. (See pages 5-14 to 5-18 and 9-15 to 9-18 for ACAT1; 6-16 to 6-18 and 8-20 to 8-22 for AutoCAT 2 rev.2.21; 6-18 and 8-24 to 8-26 for AutoCAT 2 rev2.23 for AP waveform/Timing assessment and assessment of augmentation).

b. ***Set the AUG Alarm***: The augmentation alarm when set will alert the clinician with an audible alarm and a screen message that states "AUG BELOW SET LIMIT". This alarm will alert the clinician that the proper augmentation/pressure is no being delivered to patient. To set the augmentation alarm:
   i. ***Press AP SELECT***
   ii. ***Press AP Alarm***
   iii. ***TURN AP Alarm ON***
   iv. ***Verify AUG Alarm is selected***
   v. ***Set AUG AP Alarm to appropriate value based on patient condition and hospital protocol.***
   vi. ***See pages 10 to 11 for ACAT1; 3-33 to 3-34 for AutoCAT 2 rev.2.21 and 3-34 and 3-35 for AutoCAT 2 rev.2.23 for further information on the AP Alarm***

9. Refer to the operator's manual for proper operation of the IABP.

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APPENDIX C

ARROW INTERNATIONAL 30/40/50 CC IAB VOLUME CONNECTORS

RECALL ACKNOWLEDGEMENT AND STOCK STATUS FORM

Immediate Attention Requested

Please check the appropriate box and return this form by Fax XXXXXX immediately.

☐ We have no inventory within the scope of this recall.

☐ 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.

☐ Due to lack of available product we have chosen to use the affected product and follow the mitigations described in Attachment B of the Recall Letter Dated: XX February 2009.

Return Authorization Number:_____

Contact Arrow Customer Service at ***[insert local contact phone number]*** for a Return Authorization Number.

(Print Name)	**(Date)**
(Signature)	**(Telephone Number)**
(Institution Name)	**Alternate Mailing Address**
(Institution Street Address)	**(Street Address)**
(Institution City, State, Zip)	**(City, State, Zip)**
(Country)	**(Country)**

All product details are to be completed on page 2 of this form.

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QUANTITY	CATALOG NUMBER	LOT NUMBER