



February 2, 2009

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[WWW.ARROWINTL.COM](http://WWW.ARROWINTL.COM)

## Urgent Medical Device Recall

**30/40/50 CC IAB Volume Connectors**  
**MANUFACTURER: Arrow International PRODUCTS**  
**AFFECTED: 30/40/50 CC IAB Catheters PRODUCT**  
**CODES:**

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

Dear Cardiac Care Customer,

Arrow International has issued a voluntary recall for specific products identified above. 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. The lot numbers for these affected products are printed on Appendix A of this letter.

Arrow 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. 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, Arrow International has initiated a voluntary recall of these products. The Food and Drug Administration has been notified of this action.

Hospitals should complete the attached Recall Acknowledge Form and take the following actions: **RECALL INSTRUCTIONS:**

- (1) Check your stock for the products included within the scope of the recall. Cease use and distribution, and quarantine all affected product immediately.**
- (2) Contact Arrow's Customer Service Department at 800-523-8446, or if calling outside the US 1-919-361-4062, 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 and immediately fax back to Arrow International. This will allow us to document your receipt of this letter and the amount of product you have on hand for return.**
- (4) Return any affected product freight collect, along with the original completed Recall Acknowledgement & Stock Status Form.**

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 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.

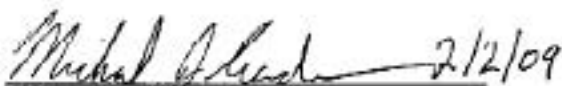
In circumstances where alternate IAB Catheters/adaptors or other forms of therapy are not available, contact Arrow International to obtain replacement tubing and implement the mitigations described in Appendix B until replacement Pump Tubing Assemblies are received. Affected product should only be used 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 by calling 1-800-523-8446 or if calling from outside the USA, 1-919-361-4062 (Monday - Friday, 8:00 am to 5pm Eastern Standard Time) 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](http://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:

**1-800-523-8446 In the US or 1-919-361-4062**  
**Outside the US**

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.



Michael J. Grader  
Vice President Global Regulatory Affairs / Quality Assurance