

Urgent Medical Device Recall Notification

ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits

February 11, 2016

To: Customer of Arrow International Products

Arrow International, Inc. (“Arrow”) has issued a voluntary recall for the product codes and lot numbers listed in the enclosed affected products list.

Product Code	Product Description	Lot
IAB-05830-LWS	Intra-Aortic Balloon Catheter Kit	Reference Enclosed List
IAB-05830-U	Intra-Aortic Balloon Catheter Kit	
IAB-05840-LWS	Intra-Aortic Balloon Catheter Kit	
IAB-05840-U	Intra-Aortic Balloon Catheter Kit	
IAB-06830-U	Intra-Aortic Balloon Catheter Kit	
IAB-06840-U	Intra-Aortic Balloon Catheter Kit	
IAB-S730C	Intra-Aortic Balloon Catheter Kit	
IAK-06845	Percutaneous Insertion Kit	
IAK-S7IT	Percutaneous Insertion Kit	

Arrow is recalling these products due to the possibility that the sheath body may become separated from the sheath hub. If the separation occurs, there is a potential for bleeding from the device. If bleeding is not addressed with prompt intervention, it may result in loss of significant blood volume or exsanguination. In addition, delay of treatment, interruption of treatment, or loss of IAB therapy can occur.

Arrow is recalling these lots in an effort to provide our customers and their patients with the highest quality product possible.

Our records indicate that you have received products that are subject to this voluntary recall. We are now notifying our customers to take the following actions:

1. If you have any products referenced in the attached enclosure, immediately discontinue use and quarantine those products appropriately.
2. To return product, complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507 Attn: Customer Service or email it to recalls@teleflex.com. 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 Authorization (RGA) Number and will provide instructions for the return of product to Arrow International.
3. If you have no affected stock, please complete the enclosed Recall Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email it to recalls@teleflex.com. This will allow us to document your receipt of this letter.



The U.S. Food and Drug Administration has been notified of this action.

Arrow International, Inc. 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 1-866-246-6990.

For and on behalf of Teleflex,

Karen Boylan

Karen Boylan
VP, Global RA/QA

Enclosure - Affected Product Codes and Lots, 3 pages

ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits

Page 1 of 3 – Affected Product Codes and Lots

Product Code	Lot
IAB-05830-LWS	18F14A0031
IAB-05830-LWS	18F14A0032
IAB-05830-LWS	18F14A0033
IAB-05830-LWS	18F14D0066
IAB-05830-LWS	18F14E0018
IAB-05830-LWS	18F14E0072
IAB-05830-LWS	18F14F0067
IAB-05830-LWS	18F14F0079
IAB-05830-LWS	18F14G0045
IAB-05830-LWS	18F14G0046
IAB-05830-LWS	18F14G0081
IAB-05830-LWS	18F14H0037
IAB-05830-LWS	18F14J0023
IAB-05830-LWS	18F14L0014
IAB-05830-LWS	18F14M0033
IAB-05830-LWS	18F15A0010
IAB-05830-LWS	18F15B0015
IAB-05830-LWS	18F15C0004
IAB-05830-LWS	18F15C0023
IAB-05830-LWS	18F15D0025
IAB-05830-LWS	18F15D0052
IAB-05830-LWS	18F15E0020
IAB-05830-LWS	18F15F0002
IAB-05830-LWS	18F15F0039
IAB-05830-LWS	18F15G0005
IAB-05830-LWS	18F15G0015
IAB-05830-LWS	18F15H0006
IAB-05830-LWS	18F15H0037
IAB-05830-LWS	18F15H0051
IAB-05830-LWS	18F15J0026
IAB-05830-LWS	18F15L0007
IAB-05830-LWS	18S14G0046
IAB-05830-LWS	18S15A0021
IAB-05830-U	18F14E0030
IAB-05830-U	18F14H0019
IAB-05830-U	18F14J0038
IAB-05830-U	18F14K0012
IAB-05830-U	18F14K0019
IAB-05830-U	18F15D0030
IAB-05830-U	18F15E0017
IAB-05840-LWS	18F14A0025
IAB-05840-LWS	18F14A0026

Product Code	Lot
IAB-05840-LWS	18F14A0030
IAB-05840-LWS	18F14A0049
IAB-05840-LWS	18F14A0050
IAB-05840-LWS	18F14A0051
IAB-05840-LWS	18F14A0054
IAB-05840-LWS	18F14A0057
IAB-05840-LWS	18F14A0066
IAB-05840-LWS	18F14A0067
IAB-05840-LWS	18F14D0045
IAB-05840-LWS	18F14E0004
IAB-05840-LWS	18F14E0006
IAB-05840-LWS	18F14E0016
IAB-05840-LWS	18F14E0017
IAB-05840-LWS	18F14E0052
IAB-05840-LWS	18F14F0017
IAB-05840-LWS	18F14F0047
IAB-05840-LWS	18F14F0049
IAB-05840-LWS	18F14F0080
IAB-05840-LWS	18F14G0003
IAB-05840-LWS	18F14G0004
IAB-05840-LWS	18F14G0021
IAB-05840-LWS	18F14G0037
IAB-05840-LWS	18F14G0055
IAB-05840-LWS	18F14G0056
IAB-05840-LWS	18F14G0068
IAB-05840-LWS	18F14G0070
IAB-05840-LWS	18F14G0071
IAB-05840-LWS	18F14G0076
IAB-05840-LWS	18F14H0009
IAB-05840-LWS	18F14H0030
IAB-05840-LWS	18F14H0054
IAB-05840-LWS	18F14H0055
IAB-05840-LWS	18F14H0060
IAB-05840-LWS	18F14H0061
IAB-05840-LWS	18F14J0003
IAB-05840-LWS	18F14J0005
IAB-05840-LWS	18F14J0037
IAB-05840-LWS	18F14K0006
IAB-05840-LWS	18F14M0001
IAB-05840-LWS	18F14M0014
IAB-05840-LWS	18F14M0032
IAB-05840-LWS	18F15A0005

Product Code	Lot
IAB-05840-LWS	18F15A0011
IAB-05840-LWS	18F15A0026
IAB-05840-LWS	18F15A0034
IAB-05840-LWS	18F15B0005
IAB-05840-LWS	18F15B0008
IAB-05840-LWS	18F15B0010
IAB-05840-LWS	18F15B0018
IAB-05840-LWS	18F15B0020
IAB-05840-LWS	18F15B0027
IAB-05840-LWS	18F15C0002
IAB-05840-LWS	18F15C0007
IAB-05840-LWS	18F15C0010
IAB-05840-LWS	18F15C0015
IAB-05840-LWS	18F15C0024
IAB-05840-LWS	18F15C0030
IAB-05840-LWS	18F15C0036
IAB-05840-LWS	18F15D0017
IAB-05840-LWS	18F15D0032
IAB-05840-LWS	18F15D0034
IAB-05840-LWS	18F15D0043
IAB-05840-LWS	18F15D0049
IAB-05840-LWS	18F15E0003
IAB-05840-LWS	18F15E0011
IAB-05840-LWS	18F15E0014
IAB-05840-LWS	18F15E0023
IAB-05840-LWS	18F15E0029
IAB-05840-LWS	18F15E0037
IAB-05840-LWS	18F15F0011
IAB-05840-LWS	18F15F0017
IAB-05840-LWS	18F15F0021
IAB-05840-LWS	18F15F0032
IAB-05840-LWS	18F15G0001
IAB-05840-LWS	18F15G0013
IAB-05840-LWS	18F15G0021
IAB-05840-LWS	18F15G0028
IAB-05840-LWS	18F15G0034
IAB-05840-LWS	18F15H0010
IAB-05840-LWS	18F15H0015
IAB-05840-LWS	18F15H0021
IAB-05840-LWS	18F15H0024
IAB-05840-LWS	18F15H0033
IAB-05840-LWS	18F15J0013

ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits

Page 2 of 3 – Affected Product Codes and Lots

Product Code	Lot
IAB-05840-LWS	18F15J0028
IAB-05840-LWS	18F15J0038
IAB-05840-LWS	18F15J0044
IAB-05840-LWS	18F15J0049
IAB-05840-LWS	18F15K0001
IAB-05840-LWS	18F15K0007
IAB-05840-LWS	18F15L0002
IAB-05840-LWS	18S14G0068
IAB-05840-LWS	18S14M0001
IAB-05840-LWS	18S15C0002
IAB-05840-U	18F14B0044
IAB-05840-U	18F14B0045
IAB-05840-U	18F14E0060
IAB-05840-U	18F14F0019
IAB-05840-U	18F14G0067
IAB-05840-U	18F14H0002
IAB-05840-U	18F14J0026
IAB-05840-U	18F15A0033
IAB-05840-U	18F15B0009
IAB-05840-U	18F15B0019
IAB-05840-U	18F15C0012
IAB-05840-U	18F15D0016
IAB-05840-U	18F15D0037
IAB-05840-U	18F15D0044
IAB-05840-U	18F15F0001
IAB-06830-U	18F13M0016
IAB-06830-U	18F14A0017
IAB-06830-U	18F14A0018
IAB-06830-U	18F14A0022
IAB-06830-U	18F14A0046
IAB-06830-U	18F14E0054
IAB-06830-U	18F14E0070
IAB-06830-U	18F14G0038
IAB-06830-U	18F14G0078
IAB-06830-U	18F14H0007
IAB-06830-U	18F14J0007
IAB-06830-U	18F14J0025
IAB-06830-U	18F14K0016
IAB-06830-U	18F15A0035
IAB-06830-U	18F15B0006
IAB-06830-U	18F15B0014
IAB-06830-U	18F15C0019

Product Code	Lot
IAB-06830-U	18F15E0028
IAB-06830-U	18F15F0016
IAB-06830-U	18F15G0007
IAB-06830-U	18F15H0009
IAB-06830-U	18F15H0035
IAB-06840-U	18F13M0017
IAB-06840-U	18F13M0019
IAB-06840-U	18F13M0021
IAB-06840-U	18F14A0012
IAB-06840-U	18F14A0013
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IAB-06840-U	18F14A0044
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IAB-06840-U	18F14B0042
IAB-06840-U	18F14B0043
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IAB-06840-U	18F14E0069
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IAB-06840-U	18F14J0027
IAB-06840-U	18F14J0051
IAB-06840-U	18F15A0008
IAB-06840-U	18F15A0015
IAB-06840-U	18F15A0023
IAB-06840-U	18F15B0003
IAB-06840-U	18F15B0007

Product Code	Lot
IAB-06840-U	18F15B0021
IAB-06840-U	18F15C0006
IAB-06840-U	18F15C0011
IAB-06840-U	18F15C0027
IAB-06840-U	18F15D0010
IAB-06840-U	18F15D0019
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IAB-06840-U	18F15E0012
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IAB-06840-U	18F15F0038
IAB-06840-U	18F15F0041
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IAB-S730C	18F14C0026
IAB-S730C	18F14C0027
IAB-S730C	18F14C0028
IAB-S730C	18F14E0039
IAB-S730C	18F14E0055
IAB-S730C	18F14E0058
IAB-S730C	18F14F0035
IAB-S730C	18F14F0038
IAB-S730C	18F14F0054



Immediate Attention Requested

Recall Acknowledgment Form for:

**ARROW® International Intra-Aortic Balloon Catheter Kits
and Percutaneous Insertion Kits**

Check the appropriate box and fax this form to 1-855-419-8507 or email it to recalls@teleflex.com.

- 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. When the product is received by Arrow International, Inc., please (select one):
 - Send replacements
 - Credit our account

Product Code	Lot Number	Quantity

Please print legibly.

(Print Name)	(Date)
(Signature)	(Telephone Number)
(Institution Name)	(Email Address)
(Institution Street Address)	<u>Alternate Mailing Address</u>
(Institution City, State, Zip)	(Street Address)
(Country)	(City, State, Zip)

Arrow International, Inc. Use Only

Received By:	Date: