



## Teleflex Incorporated Announces Worldwide Recall of ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits

March 11, 2016

WAYNE, Pa.--(BUSINESS WIRE)--Mar. 11, 2016-- Teleflex Incorporated (NYSE: TFX) announces worldwide recall of ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits. The Arrow® IAB is inserted in the aorta and provides mechanical circulatory support for cardiac patients, by inflating and deflating at different phases of the cardiac cycle to increase cardiac output and decrease the work of the heart.

Teleflex Incorporated announced today that the U.S. Food and Drug Administration (FDA) has classified the recall of ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits as a Class I recall. FDA defines a Class I recall as, "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

On 9-Feb-2016, Teleflex Incorporated initiated a worldwide recall of 47,140 units distributed to hospitals, clinics, and medical centers throughout the United States and globally. The ARROW® International Intra-Aortic Balloon Catheter Kits and Percutaneous Insertion Kits are being recalled because the sheath body may become separated from the sheath hub. If the separation occurs, the patient may bleed from the sheath. If bleeding is not promptly addressed, significant blood loss or exsanguination may occur. Interruption or loss of intra-aortic balloon pump treatment may also occur. At the time of the recall, there were 13 adverse events reported; including 6 serious injuries and 1 death.

Teleflex notified domestic distributors and customers via an Urgent Medical Device recall letter dated February 11, 2016. Consumers who have affected product should immediately discontinue use and return all affected product to Teleflex.

Teleflex has notified the FDA of this action.

See table below for affected product codes. A full list of affected lot numbers can be found in the appendix to this notification.

PRODUCTS AFFECTED	
Product Code	Lot
IAB-05830-LWS	
IAB-05830-U	
IAB-05840-LWS	
IAB-05840-U	
IAB-06830-U	Reference Appendix
IAB-06840-U	
IAB-S730C	
IAK-06845	
IAK-S7IT	

The original recall notice can be found at Teleflex's website: [http://www.teleflex.com/en/recall/Customer\\_letter\\_and\\_form\\_press\\_release.pdf](http://www.teleflex.com/en/recall/Customer_letter_and_form_press_release.pdf)

Consumers with questions may contact the company at 1-866-246-6990; 8am to 8pm, ET, Monday through Friday or at [recalls@teleflex.com](mailto:recalls@teleflex.com).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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  
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  
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  
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  
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  
IAB-06840-U 18F14A0015

IAB-06840-U	18F14A0016
IAB-06840-U	18F14A0044
IAB-06840-U	18F14A0047
IAB-06840-U	18F14B0042
IAB-06840-U	18F14B0043
IAB-06840-U	18F14D0068
IAB-06840-U	18F14E0005
IAB-06840-U	18F14E0007
IAB-06840-U	18F14E0031
IAB-06840-U	18F14E0053
IAB-06840-U	18F14E0069
IAB-06840-U	18F14F0030
IAB-06840-U	18F14F0031
IAB-06840-U	18F14F0066
IAB-06840-U	18F14G0020
IAB-06840-U	18F14G0039
IAB-06840-U	18F14G0066
IAB-06840-U	18F14H0003
IAB-06840-U	18F14H0010
IAB-06840-U	18F14H0023
IAB-06840-U	18F14H0024
IAB-06840-U	18F14H0056
IAB-06840-U	18F14J0006
IAB-06840-U	18F14J0016
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
IAB-06840-U	18F15B0021
IAB-06840-U	18F15C0006
IAB-06840-U	18F15C0011
IAB-06840-U	18F15C0027
IAB-06840-U	18F15D0010
IAB-06840-U	18F15D0019
IAB-06840-U	18F15D0045
IAB-06840-U	18F15E0002
IAB-06840-U	18F15E0012
IAB-06840-U	18F15F0008
IAB-06840-U	18F15F0028
IAB-06840-U	18F15F0038
IAB-06840-U	18F15F0041
IAB-06840-U	18F15G0016
IAB-06840-U	18F15G0027
IAB-06840-U	18F15H0005
IAB-06840-U	18F15H0020
IAB-06840-U	18F15H0032
IAB-06840-U	18F15H0041
IAB-06840-U	18F15J0007
IAB-06840-U	18F15J0010
IAB-06840-U	18F15J0021
IAB-06840-U	18F15J0029
IAB-06840-U	18F15J0039
IAB-06840-U	18F15J0056
IAB-06840-U	18F15K0016

IAB-06840-U	18F15K0032
IAB-06840-U	18F15L0001
IAB-06840-U	18F15L0010
IAB-S730C	18F14A0041
IAB-S730C	18F14C0003
IAB-S730C	18F14C0006
IAB-S730C	18F14C0021
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
IAB-S730C	18F14G0057
IAB-S730C	18F14G0077
IAB-S730C	18F14H0011
IAB-S730C	18F15B0023
IAB-S730C	18F15C0001
IAB-S730C	18F15C0008
IAB-S730C	18F15C0026
IAB-S730C	18F15D0028
IAB-S730C	18F15F0027
IAB-S730C	18F15F0037
IAB-S730C	18F15G0003
IAB-S730C	18F15G0011
IAB-S730C	18F15G0032
IAB-S730C	18F15H0046
IAB-S730C	18F15M0009
IAK-06845	18F14A0037
IAK-06845	18F14B0040
IAK-06845	18F14E0027
IAK-06845	18F14F0027
IAK-06845	18F14F0028
IAK-S7IT	18F14A0028
IAK-S7IT	18F14B0008
IAK-S7IT	18F14D0003

### About Teleflex Incorporated

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit [teleflex.com](http://teleflex.com).

Teleflex is the home of Arrow<sup>®</sup>, Deknatel<sup>®</sup>, Hudson RCI<sup>®</sup>, LMA<sup>®</sup>, Pilling<sup>®</sup>, Rusch<sup>®</sup> and Weck<sup>®</sup> – trusted brands united by a common sense of purpose.

### Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

View source version on businesswire.com: <http://www.businesswire.com/news/home/20160311005081/en/>

Source: Teleflex Incorporated

Teleflex Incorporated  
Jake Elguicze  
Treasurer and Vice President, Investor Relations  
610-948-2836