State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Arrow International Recalls Intra-Aortic Balloon Series For Failure Of Balloon To Inflate

Recall Date	Product Description	Recalling Firm	Recall Reason
6/12/2024	**Arrow Fiberoptix Intra-Aortic Balloon Catheter Kit** A) REF IAB-05830-LWS b) REF IAB-05840-LWS c) REF IAB-05850-LWS	**ARROW INTERNATIONAL INC.** Morrisville, North Carolina	Teleflex received reports indicating an infrequent condition that, when not identified and corrected promptly, could result in serious health consequences. The issue may manifest as: -failure of the intra-aortic balloon to completely inflate over its full length - damaged or broken central lumen in the segment contained within the balloon - helium loss or blood in the helium pathway.
6/12/2024	**Arrow Ultraflex Intra-Aortic Balloon Catheter Kit** A) REF IAB-06830-U b) REF IAB-06840-U c) REF IAB-06850-U	**ARROW INTERNATIONAL INC.** Morrisville, North Carolina	Failure of the intra-aortic balloon to completely inflate over its full length
6/12/2024	**Arrow Ultra 8 lab Intra-Aortic Balloon Catheter Kit** A) REF IAB-05830-U b) REF IAB-05840-U	**ARROW INTERNATIONAL Inc.** Morrisville, North Carolina	Failure of the intra-aortic balloon to completely inflate over its full length

Recall Class	Product Identification	Distribution	Affected Dates

I	**Arrow Fiberoptix**
	a) REF IAB-05830-LWS, UDI: (01)10801902161892(17)241231(10)18F23A0038 - (01)10801902172843(17)461121(10)18F24C0185;
	b) REF IAB-05840-LWS, UDI: (01)10801902167733(17)240531(10)18F22F0072 - (01)10801902172867(17)260228(10)18F24C0105;
	c) REF IAB-05850-LWS, UDI: (01)10801902167726(17)240831(10)18F22J0037(13)220927 - (01)10801902172881(17)260228(10)18F24C0034(13)240315
		7939 Units Nationwide including California	Must include first affected date

I	**Arrow Ultraflex** A) REF IAB-06830-U, UDI: (01)10801902161939(17)240731(10)18F22H0008 - (01)10801902172898(17)260331(10)18F24D0086; b) REF IAB-06840-U, UDI: (01)10801902161946(17)240430(10)18F22E0023 - (01)10801902172904(17)260228(10)18F24C0141; c) REF IAB-06850-U, UDI: (01)10801902144192(17)240831(10)18F22J0020(13)220916 - (01)10801902172911(17)260131(10)18F24B0010(13)240207	44807 Units Nationwide including California	Must include first affected date
I	**Arrow Ultra 8** a) REF IAB-05830-U, UDI: (01)10801902172850(17)240531(10)18F22F0023 - (01)10801902182019(17)260331(10)18F24C0131; b) REF IAB-05840-U, UDI: (01)10801902161922(17)240630(10)18F22G0051 - (01)10801902172874(17)251130(10)18F23K0008	3138 Units Nationwide including California	Must include first affected date

For additional information, please visit the FDA website for Fiberoptix, Ultraflex, and Ultra8

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov