Arrow International
c/o Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

28-January-2019

URGENT - FIELD SAFETY ADVISORY NOTICE

Commercial Name of Affected Product:	**Arrow® Two-Lumen Central Venous Catheterization Kit with Blue FlexTip® Catheter** **Arrow® Two-Lumen Central Venous Catheterization Set with Blue FlexTip® Catheter**
Type of action:	**Advisory Notice**
Arrow Reference:	**EIF-000320**
Product code	**Lot/Batch**
AH-11802 CD-10802	Refer to Appendix 1 for a list of lots impacted

Dear Customer,

Details of affected devices
Arrow International has voluntarily issued an advisory notice for the above product code and lot numbers.

Description of the problem
The product lidstock contains a labelling error. The lidstock states the incorrect priming volume. The priming volumes printed on the extension lines are correct.

Incorrect Label Details	**Correct Label and Printed Extension Line Details**
Priming Volume (ml)	Priming Volume (ml)
- Distal: 0.49	- Distal: 0.55
- Proximal: 0.55	- Proximal: 0.49

Due to the very small difference between the correct priming volume versus what is listed on the lidstock, and because the priming volumes printed on the extension lines are correct, there would not be a clinically significant effect from a health hazard standpoint.

Utilization of the incorrect priming volume is expected to result in a trivial difference in dosing/administration of medications.

No patient injury has been reported pertaining to this issue. Product code and lot combinations not referenced in Appendix 1 are not impacted by this notification.

Our records indicate you have received products that are subject to this notification.

Product is not being recalled, you may continue to use the products in scope of this advisory notice.

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

Our records indicate your facility has received product in scope of this advisory notice. Please provide this Advisory Notice to all those who need to be aware of it within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

If you are a distributor, provide this field safety notice to all your customers who have received product in scope of this Field Action. There is no further action required.

If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Arrow International.

Arrow International

Arrow informs all customers, employees of Arrow and distributors on this Field Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.
Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service
Contact: Sales Assistants **Telephone:** +31 (0) 880021500
FAX: 0880021510 **Email:**productcomplaints.netherlands@teleflex.com

Arrow International 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.

For and on behalf of Arrow International,

Appendix 1 - Scope

Product Code	Batch			
AH-11802 Arrow® Two-Lumen Central Venous Catheterization Kit with Blue FlexTip® Catheter	71F14E0696	71F14K0658	71F15E0493	71F15L0621
	71F14E1541	71F14K1683	71F15F0090	71F15M0787
	71F14F1154	71F14L0719	71F15H0574	71F16A0278
	71F14H0474	71F14M1375	71F15H1503	71F16B0054
	71F14H1215	71F15A0025	71F15J0570	71F16B1306
	71F14J0852	71F15A1592	71F15J2098	
	71F14J1889	71F15D1460	71F15L0153	
CD-10802 Arrow® Two-Lumen Central Venous Catheterization Set with Blue FlexTip® Catheter	71F14H0908	71F15K0223	71F16M1878	71F18A0343
	71F14J0958	71F15L0155	71F17A0524	71F18A1856
	71F14J1954	71F15L1514	71F17A1118	71F18B0295
	71F14J1955	71F15M0771	71F17A1119	71F18B3053
	71F14K1117	71F16A0286	71F17A2452	71F18C0752
	71F14L0040	71F16A1142	71F17C0184	71F18C1686
	71F14L0813	71F16B0097	71F17C0408	71F18C2250
	71F14M0892	71F16B1126	71F17C2294	71F18C3030
	71F14M1389	71F16B2212	71F17C2749	71F18C3042
	71F15A0039	71F16C1127	71F17D0329	71F18D2222
	71F15D1461	71F16D1063	71F17E1237	71F18E1357
	71F15E1320	71F16E0976	71F17E2316	71F18E1753
	71F15F1005	71F16F0403	71F17F0829	71F18F2625
	71F15F1955	71F16F1512	71F17G1171	71F18G0263
	71F15G0461	71F16G0246	71F17G1628	71F18G2183
	71F15G1764	71F16H0027	71F17H2043	71F18H0650
	71F15H0569	71F16H0595	71F17J0668	71F18H1673
	71F15H1347	71F16L0623	71F17L1848	71F18J0116
	71F15J0063	71F16L1734	71F17M1416	
	71F15J1055	71F16M0795	71F17M1978	