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

May-2022

URGENT – FIELD SAFETY NOTICE

Type of Action	**Advisory Notice**					
Teleflex Reference	EIF-000506					
Commercial Name	Arrow 3-Lumen Central Venous Catheters (CVC) Set					
Product Code	**Lot Number**					
CV-12123-F	71F20A0430	71F20A2583	71F20B0793	71F20B2188	71F20C1356	71F20D1047
	71F20E2225	71F20G2376	71F20K0771	71F20K2265	71F20L0567	71F20M1262
	71F21B0849	71F21B0850	71F21B2430	71F21C0637	71F21C0964	71F21D0025
	71F21E0586	71F21E1030	71F21E2583	71F21F1156	71F21J0698	
DE-12123-MA	71F20C2009	71F20E0273	71F20F1283	71F20G2609	71F20H1801	71F20M0919
	71F21B2793	71F21D0564	71F21G0165	71F21G1000	71F21H0584	71F21K1715
	71F21L0255					
MO-12123-F	71F18F2178					
NL-12123F-AZN	71F17L0032	71F19J0827	71F20A1907	71F20E0001	71F20J0296	71F20K2157
	71F20M1513	71F21D1026	71F21F2094	71F21G0163	71F21G1041	
UD-12123	71F18F2175	71F18J1900	71F18L0304	71F19E1598		

* Refer to **Appendix 2** for Unique Device Identifier (UDI) information.

Dear Customer,

Details of affected devices

Arrow International LLC, a subsidiary of Teleflex, has initiated an advisory notice for the Arrow CVC product referenced above.

Description of the problem & immediate actions required

Arrow International LLC, a subsidiary of Teleflex, is initiating a voluntary Field Safety Corrective Action (FSCA) because the gravity flow rates on the affected product lidstock are incorrect. Refer to the image below for the correct gravity flow rates.

Lumen	Priming Volume* (mL)	Gravity Flow Rate† (mL/hr)
Distal (16 Ga.)	0.4	2855
Medial (12 Ga.)	1.4	10765
Proximal (12 Ga.)	1.3	11686

The gauge of the lumen is appropriately labelled on the hubs and the expected flow rate ordinarily associated with those gauges is commonly understood in clinical practice.

No patient injury has been reported pertaining to this issue at this time. This advisory notice impacts only the product code and lot combinations listed above.

Our records indicate you have received products that are in scope of this action.

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

Depending on your location please adhere to the following Action list:

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	**1**
Distributors	**2**

Action list number 1 – Medical facilities

1. Check your inventory for product in scope of this FSCA.
2. If you do not have affected product, mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form using the contact listed below.
3. If you do have affected product, mark the according checkbox on the Acknowledgement Form (Appendix 1), return the form using the contact listed below, and place a copy of this FSCA with all affected product.

Action list number 2 – Distributors

1. Update the contact details on pages three and four from Teleflex customer service contact details to your contact details.
2. Provide this field safety notice to all customers who have received product in scope of this FSCA. Request that your customer complete the Acknowledgement Form (Appendix 1) and return to you.
3. Check your inventory for product in scope of this FSCA, refer to Appendix 2 for the list of affected codes and lots. Place a copy of this FSCA with all affected product.
4. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward your completed Acknowledgement Form to Customer Service.
5. Please be aware that all European Economic Area/Switzerland/United Kingdom (EEA/CH/UK) and Turkey Member State Competent Authorities in which Teleflex distributes directly will be notified by Teleflex.
6. If you have further distributed affected product outside of your country, please notify Teleflex by return email to the email address listed below.
7. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR/UK region, please notify your local competent authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs impacted customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice
This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected product has 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) 88 00 215 00
FAX: +31 (0) 88 00 215 10
Email: productcomplaints.netherlands@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We sincerely regret 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 Teleflex,
xxx

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000506

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +31 (0) 88 00 215 10 **Email:** productcomplaints.netherlands@teleflex.com

☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action.

Complete this Acknowledgement form and return immediately by using the contact information above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**Phone/FAX**
FORM COMPLETED BY	**Stamp**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

Appendix 2 – Product code / Lot number / Unique Device Identifier (UDI)

Product Code	Lot Number	UDI
CV-12123-F	71F20A0430	(01)20801902122838(17)211214(10)71F20A0430
	71F20A2583	(01)20801902122838(17)250103(10)71F20A2583
	71F20B0793	(01)20801902122838(17)250115(10)71F20B0793
	71F20B2188	(01)20801902122838(17)250204(10)71F20B2188
	71F20C1356	(01)10801902136944(17)220630(10)71F20C1356
	71F20D1047	(01)20801902122838(17)250402(10)71F20D1047
	71F20E2225	(01)20801902122838(17)250531(10)71F20E2225
	71F20G2376	(01)20801902122838(17)250701(10)71F20G2376
	71F20K0771	(01)20801902122838(17)241130(10)71F20K0771
	71F20K2265	(01)20801902122838(17)250228(10)71F20K2265
	71F20L0567	(01)20801902122838(17)250228(10)71F20L0567
	71F20M1262	(01)20801902122838(17)250331(10)71F20M1262
	71F21B0849	(01)10801902179514(17)250430(10)71F21B0849
	71F21B0850	(01)20801902122838(17)250430(10)71F21B0850
	71F21B2430	(01)20801902122838(17)250430(10)71F21B2430
	71F21C0637	(01)20801902122838(17)250331(10)71F21C0637
	71F21C0964	(01)10801902170856(17)260214(10)71F21C0964
	71F21D0025	(01)20801902122838(17)250430(10)71F21D0025
	71F21E0586	(01)20801902122838(17)250430(10)71F21E0586
	71F21E1030	(01)20801902122838(17)250430(10)71F21E1030
	71F21E2583	(01)20801902122838(17)250430(10)71F21E2583
	71F21F1156	(01)20801902122838(17)250430(10)71F21F1156
	71F21J0698	(01)20801902122838(17)250430(10)71F21J0698
DE-12123-MA	71F20C2009	(01)00801902089533(17)220331(10)71F20C2009
	71F20E0273	(01)00801902089533(17)220511(10)71F20E0273
	71F20F1283	(01)00801902089533(17)220617(10)71F20F1283
	71F20G2609	(01)00801902089533(17)220730(10)71F20G2609
	71F20H1801	(01)00801902089533(17)220823(10)71F20H1801
	71F20M0919	(01)10801902179385(17)221213(10)71F20M0919
	71F21B2793	(01)10801902179385(17)230302(10)71F21B2793
	71F21D0564	(01)10801902179385(17)230421(10)71F21D0564
	71F21G0165	(01)10801902185539(17)230630(10)71F21G0165
	71F21G1000	(01)10801902185539(17)230731(10)71F21G1000
	71F21H0584	(01)10801902185539(17)230731(10)71F21H0584
	71F21K1715	(01)10801902185539(17)230930(10)71F21K1715
	71F21L0255	(01)10801902185539(17)231031(10)71F21L0255
MO-12123-F	71F18F2178	(01)00801902029805(17)220630(10)71F18F2178
NL-12123F-AZN	71F17L0032	(01)10801902136944(17)220630(10)71F17L0032
	71F19J0827	(01)10801902136944(17)240131(10)71F19J0827
	71F20A1907	(01)10801902136944(17)240831(10)71F20A1907
	71F20E0001	(01)10801902136944(17)241130(10)71F20E0001
	71F20J0296	(01)10801902136944(17)250601(10)71F20J0296
	71F20K2157	(01)10801902136944(17)250630(10)71F20K2157
	71F20M1513	(01)10801902136944(17)250831(10)71F20M1513
	71F21D1026	(01)10801902136944(17)251130(10)71F21D1026
	71F21F2094	(01)10801902190021(17)251231(10)71F21F2094
	71F21G0163	(01)10801902190021(17)251231(10)71F21G0163
	71F21G1041	(01)10801902190021(17)251231(10)71F21G1041
UD-12123	71F18F2175	(01)00801902038166(17)220531(10)71F18F2175
	71F18J1900	(01)00801902038166(17)221031(10)71F18J1900
	71F18L0304	(01)00801902038166(17)220930(10)71F18L0304
	71F19E1598	(01)00801902038166(17)230301(10)71F19E1598