

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

9<sup>th</sup> May 2018

## **URGENT - FIELD SAFETY NOTICE**

<b>Commercial Name of Affected Product:</b>	<b>ARROW® Multiple-Lumen Central Venous Catheter</b>
<b>Type of action:</b>	<b>Recall</b>
<b>Arrow Reference:</b>	<b>EIF-000258</b>
<b>Product Codes/Lot Numbers</b>	<b>Refer to Appendix 2</b>

Dear Customer,

### **Details of affected devices**

Arrow International is issuing a recall for the above listed product.

### **Description of the problem**

Arrow International has received complaints related to increased resistance encountered when introducing the CVC over the Spring Wire Guidewire. Arrow International is recalling the product referenced above because this may lead to procedural delay, and there may be a need of medical intervention by changing the catheter for another CVC catheter.

Our records indicate your facility has received product in scope of this field safety notice.

### **FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS**

#### **ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF**

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in Appendix 2, then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.
3. If you have stock from the affected product as referred to in Appendix 2, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned below who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

**INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT**

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
2. As a Distributor you are required to confirm to Arrow International that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Arrow International.
4. 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.

Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Arrow International distribute directly will be notified by Arrow.

**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:** Customer Service  
**Telephone:** 07151 / 406-0  
**FAX:** 07151 / 406-566  
**E-Mail:** [Recalls.de@teleflex.com](mailto:Recalls.de@teleflex.com)

**Product Management**

**Contact:** Sabine Schewior  
**Telephone:** 0172 / 776 3565  
**Fax:** 07151 / 406 530  
**E-Mail:** [sabine.schewior@teleflex.com](mailto:sabine.schewior@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

**FIELD SAFETY CORRECTIVE ACTION  
ACKNOWLEDGEMENT FORM**

Customer No. \_\_\_\_\_

**PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED**

Ref. EIF-000258

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: 07151 / 406-566

Email: recalls.de@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does <b>NOT</b> include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory <b>DOES</b> include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned.  Return Authorisation No _____
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**PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.**

<b>COMMERCIAL NAME OF AFFECTED PRODUCTS:</b>	EIF-000258 - ARROW® Multiple-Lumen Central Venous Catheter	
<b>PRODUCT NUMBER</b>	<b>LOT NUMBER</b>	<b>QUANTITY (Returning)</b>
<ul style="list-style-type: none"> <li>Include a copy of the <b>completed Acknowledgement Form</b> in the returns package with the returned units</li> <li>Ensure the <b>RAN number is clearly visible</b> on the returns package.</li> <li>Please label returns as <b>"Field Action Returns"</b></li> </ul>		

Complete this Acknowledgement form and return immediately by using the fax number or e-mail address above.

<b>INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)</b>	
<b>INSTITUTION ADDRESS</b>	<b>Phone / Fax</b>
<b>FORM COMPLETED BY:</b>	<b>Stamp</b>
PRINT NAME: _____	
SIGNATURE: _____	
<b>DATE</b>	

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Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
BB-12853	71F17H2018	CS-12853-E	71F17J0340	CV-12853	71F18A3198	
	71F17L1680		71F17L1685		71F18B0628	
	71F17M0865		71F18A0292		71F18B0631	
	71F18A2769		71F18B2069	CZ-10853-KCH	71F17K1071	
	71F18B0232		71F17H2131		71F17L1010	
BB-22853	71F17K1535	CS-15853	71F17H2137	DE-12853-S	71F17H2023	
	71F17L2454		71F17J0706		71F17J0801	
	71F17M0774		71F17J0945		71F17M1601	
	71F18A2917		71F17K0791		71F18A2987	
	71F18B0817		71F17L1956		71F18B0471	
BR-12853	71F17H2024		CS-15853-E	71F17L1966	DE-14853-KN	71F18B1392
	71F17J0939			71F17L2040	DE-14853-KN1	71F17K2102
	71F17J1043			71F18A1370		71F17L0962
	71F17L1678			71F18A1477		71F17L1743
	71F17L1993			71F18A1601		71F17L2911
	71F17M0968	71F17H2132		71F17M0932		
	71F18A0296	71F17J1917		71F18A0980		
BR-14853-EK	71F17K2101	CS-15853-E	71F17L1955	DE-15853-GKB		71F18A1555
	71F17L0646		71F18A0682			71F18A3180
	71F17M1926		71F18A1372			71F18B1390
	71F18A0603		71F18A1380			71F18B1896
	71F18A1600		71F17K0290		71F18B2681	
	71F18B1937		71F17K0773		71F17H1145	
BR-15853	71F17H2136	CS-22853-E	71F17L0525	DE-15853-KWEN	71F17J0366	
	71F17J0954		71F17L0964	71F18A1103		
	71F17K0748		71F17M1413	71F17J0364		
	71F17L1947		71F18A3316	71F17L2550		
	71F17L1958		71F18B1157	71F17L2885		
	71F18A0701	CS-25853	71F17K1684	DE-15853-S	71F17H2135	
	71F18A1374		71F17K2342		71F17L1949	
	71F18A1882		71F17L2401		71F17L1954	
BR-15853-E	71F18A1378	CS-25853-E	71F18B1160	DE-15853-UKSH	71F18A1381	
	71F18B1934		71F17K1603		71F17H2134	
BR-22853	71F17L0555	CS-25853-E	71F17K1610	DE-15853-UKSH	71F17J0800	
	71F18A2998		71F17L1301		71F17K0561	
	71F18A2999		71F17L1306		71F17L1965	
	71F18B0465		71F17M0955		71F18A0535	
CS-10853	71F17J1298	CS-25853-E	71F17M0957	DE-22853-BB	71F18A1376	
	71F17K1048		71F18B1161		71F18B1603	
	71F17L3121		71F17H2016		71F17K0573	
	71F17M1446		71F17H2019		71F17K2273	
CS-12853	71F18A0370	CV-12853	71F17J0330	DE-22853-ELOG	71F17M0189	
	71F17H2012		71F17L1152		71F17M0246	
	71F17H2020		71F17L1594		71F17K0551	
	71F17J0707		71F17L1799	71F17K1058		
	71F17J1501		71F17M0845	71F17L0601		
	71F17L1138		71F17M0846	71F17M0778		
	71F17M0852		71F17M1386	71F18B2617		
	71F18A0294		71F17M1412	71F17L0638		
	71F18B1204		71F17M1462	DE-22853-KOB	71F18A2915	

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Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
DE-22853-LMU1	71F17K0574	EU-15853-N	71F17H2129	NL-12853-MUMC	71F17H0690
	71F17M0192		71F17H2133		71F17J0736
	71F18A2913		71F17L1957		71F17L1140
DE-25853-BB	71F17M0869		71F17L1959		71F17M0821
	71F18B0199		71F18A0574		71F18B1734
DE-25853-CP	71F17K1601		EU-25853-CVT		71F18A1379
	71F17K1604	71F17K1602		71F17L0922	
	71F17L1025	71F17K1612		71F17L1149	
	71F17M0872	71F17K2324		71F17M0951	
	71F18B0245	71F17L1023		71F18A2770	
DE-25853-ELOG	71F17K1611	EU-25853-CVT	71F17L2403	SA-12853	71F18B1699
	71F17K2341		71F17M0861		71F17H2014
	71F17L1022		71F18B0198		71F17J1547
	71F17L2474		71F18B0205		71F17L1038
	71F17M0874	71F18B0433	71F17M1381		
	71F18B0186	71F17L2399	71F17M1382		
DE-25853-GKB	71F18B0455	EU-25853-N	71F17L2400	SA-15853	71F17M1383
	71F18C0025		71F18B0179		71F17M1384
DE-25853-MHER	71F17L1019	FR-12853-DP	71F18B0203		71F17M1385
	71F18B0197		71F17M0859		71F18A2763
DE-25853-MSG	71F17K2323		71F18A2767		71F17M1384
	71F17M0870	FR-12853-IP	71F17H1998		71F17H2128
	71F18B0242		71F17L1033		71F17J1916
DE-25853-S	71F17K2327		71F17M1453		71F17L1952
	71F17L0558		71F18A2768		71F18A0691
	71F17L2402	71F18B1629	71F18A1389		
DE-25853-SKFR	71F18B0435	FR-15853-DP	71F18A0687	71F18A1956	
	71F18B1769	FR-15853-IP	71F18A0685	71F18B1590	
DE-S12853-LU	71F18A0428	HF-15853-EK	71F17J0960	UH-15853	71F17H2138
	71F18A0967		71F17L1960		71F17L0051
	71F18B0670		71F17L2260		71F17L1962
DE-S22853-KOB	71F17K0575	IB-12853-GUC	71F18A1641		71F18A0688
	71F17L0642		71F17H1067	71F17L0926	
	71F18B0672		71F17K1032	71F18A1251	
DE-S25853-AHH	71F17L2378		71F17L1733		
	71F18B0190		71F18A1963		
DM-12853	71F17H0688	ICU-15853	71F18A1142		
	71F17L1683	LS-15853	71F17H2237		
	71F17M1379		71F17J1081		
	71F18A0225		71F18A0693		
	71F18A2765		71F18A0694		
71F18B0725	71F18A0695				
EU-12853-N	71F17J0350	NL-10853-AZN	71F18A1388		
	71F17L1144		71F18A1388		
	71F18B1382		71F17J1295		
EU-15853-CVET	71F17K0582		71F17K0767		
	71F17L1964		71F17L0536		
	71F18A2120		71F17L1737		
	71F18B1672	71F17L2657			
			71F17M0510		
			71F18A2404		