

Arrow International Inc. ("Arrow")
c/o Teleflex,
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

21st January 2016

URGENT FIELD SAFETY NOTICE

Commercial Name of Affected Product:		ARROW® Super Arrow-Flex® Percutaneous Sheath Introducer Set	
Type of action:		Recall	
Arrow Reference:		EIF1507-34	
Product Codes			
CL-07035	CL-07635	CL-07735	CL-07835
Lot Numbers			
Refer to Appendix 2			

Dear Customer,

Details of affected devices

Arrow International, Inc. ("Arrow") has initiated a voluntary Field Safety Corrective Action for the above listed products.

Description of the problem

Arrow has issued a recall for these products due to potential packaging damage. Therefore, the sterility of the product cannot be guaranteed. If a non-sterile product is used, there is potential for infection to occur. No patient injuries have been reported related to this issue.

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 affected product and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned there.
3. If you have stock from the affected product, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned in section 6 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 the fax number below or provide a completed copy to your local Sales Representative.

5. Arrow (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 that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to the fax number below.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Arrow distribute directly will be notified by Arrow.
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.

Arrow International Inc. ("Arrow")

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 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: Shane Kenny
FAX: +353 (0)1 4370773

Telephone: +353 (0)906460869
E-mail: Recalls.intl@teleflex.com

Arrow 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, Inc.



Padraig Hegarty – Sr. Director QA

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref. EIF1507-34 JUV

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +353 (0)1 4370773

E-mail: Recalls.intl@teleflex.com

Please check applicable box:

☐ 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. The use and further distribution of the affected products has been stopped. All products are on hold and the quantity stated below will be returned.
Return Authorisation No _____	

Please CLEARLY print the below return information:

Name of Affected Products:	ARROW® Super Arrow-Flex® Percutaneous Sheath Introducer Set EIF1507-34 JUV	
Product Number	Lot Number	Quantity (Returning)

Return Instructions:

- Please label product returns as "Field Action Returns".
 - Include a copy of this form (including RAN Number) with product returns.
- Returns excluding ALL necessary documentation CANNOT be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
	Phone Number:
Form completed by:	
Print Name :	
Signature :	
Date:	

Material Number	Batch/Lot	Material Number	Batch/Lot	Material Number	Batch/Lot	Material Number	Batch/Lot	Material Number	Batch/Lot	Material Number	Batch/Lot
CL-07035	CF0045142	CL-07635	CF0043747	CL-07635	CF1084050	CL-07635	CF3018102	CL-07635	14F14K0382	CL-07735	CF0087127
CL-07035	CF0087118	CL-07635	CF0044445	CL-07635	CF1094408	CL-07635	CF3028486	CL-07635	14F14L0352	CL-07735	CF0088323
CL-07035	CF0090127	CL-07635	CF0045312	CL-07635	CF1095121	CL-07635	CF3028692	CL-07635	14F14M0121	CL-07735	CF0090136
CL-07035	CF0128575	CL-07635	CF0046072	CL-07635	CF1095422	CL-07635	CF3029687	CL-07635	14F15A0234	CL-07735	CF0102551
CL-07035	CF1022799	CL-07635	CF0057307	CL-07635	CF1106140	CL-07635	CF3030417	CL-07635	14F15A0341	CL-07735	CF0104733
CL-07035	CF1034863	CL-07635	CF0058371	CL-07635	CF1106463	CL-07635	CF3031073	CL-07635	14F15B0076	CL-07735	CF0115515
CL-07035	CF1046302	CL-07635	CF0058639	CL-07635	CF1106567	CL-07635	CF3041971	CL-07635	14F15B0156	CL-07735	CF0117962
CL-07035	CF1060275	CL-07635	CF0059715	CL-07635	CF1106866	CL-07635	CF3064771	CL-07635	14F15B0372	CL-07735	CF0128881
CL-07035	CF1083652	CL-07635	CF0060443	CL-07635	CF1117776	CL-07635	CF3065130	CL-07635	14F15C0066	CL-07735	CF1010273
CL-07035	CF2019968	CL-07635	CF0061539	CL-07635	CF1118184	CL-07635	14F13G0058	CL-07635	14F15D0009	CL-07735	CF1022804
CL-07035	CF2021329	CL-07635	CF0062000	CL-07635	CF2010024	CL-07635	14F13G0104	CL-07635	14F15D0089	CL-07735	CF1023188
CL-07035	CF2045237	CL-07635	CF0062968	CL-07635	CF2010554	CL-07635	14F13G0229	CL-07635	14F15D0183	CL-07735	CF1034955
CL-07035	CF2056298	CL-07635	CF0074416	CL-07635	CF2011013	CL-07635	14F13H0292	CL-07635	14F15D0395	CL-07735	CF1035534
CL-07035	CF2092322	CL-07635	CF0074954	CL-07635	CF2021345	CL-07635	14F13H0421	CL-07635	14F15E0180	CL-07735	CF1046237
CL-07035	CF2125658	CL-07635	CF0086388	CL-07635	CF2021568	CL-07635	14F13J0267	CL-07635	14F15E0393	CL-07735	CF1057122
CL-07035	CF3031070	CL-07635	CF0088268	CL-07635	CF2022380	CL-07635	14F13K0066	CL-07635	14F15F0177	CL-07735	CF1057847
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CL-07035	14F13K0334	CL-07635	CF0090990	CL-07635	CF2044557	CL-07635	14F13M0040	CL-07635	14F15H0237	CL-07735	CF1071533
CL-07035	14F14A0435	CL-07635	CF0104732	CL-07635	CF2044918	CL-07635	14F14A0310	CL-07635	14F15H0400	CL-07735	CF1084052
CL-07035	14F14B0295	CL-07635	CF0115512	CL-07635	CF2055632	CL-07635	14F14A0420	CL-07635	14F15H0442	CL-07735	CF1094634
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CL-07035	14F14F0184	CL-07635	CF0117991	CL-07635	CF2067193	CL-07635	14F14B0309	CL-07635	14F15J0128	CL-07735	CF1106857
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CL-07035	14F14L0126	CL-07635	CF1022803	CL-07635	CF2078723	CL-07635	14F14D0013	CL-07735	CF0016456	CL-07735	CF2010449
CL-07035	14F15A0097	CL-07635	CF1022900	CL-07635	CF2079280	CL-07635	14F14D0155	CL-07735	CF0026767	CL-07735	CF2011017
CL-07035	14F15A0473	CL-07635	CF1023194	CL-07635	CF2079792	CL-07635	14F14D0351	CL-07735	CF0027385	CL-07735	CF2032701
CL-07035	14F15C0455	CL-07635	CF1035539	CL-07635	CF2079893	CL-07635	14F14D0373	CL-07735	CF0028486	CL-07735	CF2033764
CL-07035	14F15E0083	CL-07635	CF1046005	CL-07635	CF2080185	CL-07635	14F14F0230	CL-07735	CF0031869	CL-07735	CF2044055
CL-07035	14F15E0392	CL-07635	CF1046603	CL-07635	CF2080838	CL-07635	14F14F0284	CL-07735	CF0043766	CL-07735	CF2044562
CL-07035	14F15G0350	CL-07635	CF1057461	CL-07635	CF2081222	CL-07635	14F14G0425	CL-07735	CF0045145	CL-07735	CF2055623
CL-07035	14F15L0009	CL-07635	CF1058601	CL-07635	CF2114750	CL-07635	14F14H0028	CL-07735	CF0046070	CL-07735	CF2055885
CL-07635	CF0014629	CL-07635	CF1069026	CL-07635	CF2115091	CL-07635	14F14H0309	CL-07735	CF0057960	CL-07735	CF2067195
CL-07635	CF0016145	CL-07635	CF1069417	CL-07635	CF2125371	CL-07635	14F14J0021	CL-07735	CF0059633	CL-07735	CF2068127
CL-07635	CF0026765	CL-07635	CF1071115	CL-07635	CF2125810	CL-07635	14F14J0098	CL-07735	CF0060473	CL-07735	CF2078858
CL-07635	CF0027875	CL-07635	CF1071530	CL-07635	CF3016842	CL-07635	14F14J0336	CL-07735	CF0062110	CL-07735	CF2079277
CL-07635	CF0029004	CL-07635	CF1082816	CL-07635	CF3017268	CL-07635	14F14K0036	CL-07735	CF0063321	CL-07735	CF2079801
CL-07635	CF0031879	CL-07635	CF1083655	CL-07635	CF3017895	CL-07635	14F14K0099	CL-07735	CF0074956	CL-07735	CF2079894

Material Number	Batch/Lot	Material Number	Batch/Lot	Material Number	Batch/Lot	Material Number	Batch/Lot
CL-07735	CF2080840	CL-07735	14F15H0347	CL-07835	CF2056307	CL-07835	14F15B0230
CL-07735	CF2125806	CL-07735	14F15J0269	CL-07835	CF2056890	CL-07835	14F15B0367
CL-07735	CF3017886	CL-07735	14F15K0186	CL-07835	CF2067792	CL-07835	14F15C0185
CL-07735	CF3018109	CL-07735	14F15K0481	CL-07835	CF2068581	CL-07835	14F15F0282
CL-07735	CF3028509	CL-07835	CF0014633	CL-07835	CF2079137	CL-07835	14F15G0159
CL-07735	CF3028705	CL-07835	CF0026778	CL-07835	CF2079794	CL-07835	14F15G0470
CL-07735	CF3039881	CL-07835	CF0028429	CL-07835	CF2079908	CL-07835	14F15H0402
CL-07735	CF3030420	CL-07835	CF0029002	CL-07835	CF2080524	CL-07835	14F15K0482
CL-07735	CF3031076	CL-07835	CF0043169	CL-07835	CF3016368		
CL-07735	CF3041472	CL-07835	CF0046789	CL-07835	CF3016852		
CL-07735	CF3052851	CL-07835	CF0058376	CL-07835	CF3018112		
CL-07735	CF3065365	CL-07835	CF0061314	CL-07835	CF3028508		
CL-07735	14F13G0062	CL-07835	CF0062035	CL-07835	CF3029318		
CL-07735	14F13H0125	CL-07835	CF0063323	CL-07835	CF3039885		
CL-07735	14F13H0221	CL-07835	CF0086389	CL-07835	CF3031078		
CL-07735	14F13H0412	CL-07835	CF0098907	CL-07835	CF3041826		
CL-07735	14F13J0045	CL-07835	CF0090978	CL-07835	CF3042524		
CL-07735	14F13J0151	CL-07835	CF0104735	CL-07835	CF3053165		
CL-07735	14F14A0132	CL-07835	CF0128583	CL-07835	CF3065135		
CL-07735	14F14A0423	CL-07835	CF1022800	CL-07835	14F13G0155		
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