

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

12<sup>th</sup> April 2018

**URGENT - FIELD SAFETY NOTICE**

<b>Commercial Name of Affected Product:</b>	<b>Various Arrow Products Refer to Appendix 2 for full product details</b>
<b>Type of action:</b>	<b>Recall</b>
<b>Arrow Reference:</b>	<b>EIF-000256</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 is recalling the product referenced in Appendix 2 because the packaging may not be sealed. If the packaging is compromised in this manner, 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.

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:** Nicole Morawiec

**FAX:** +41 (0) 31 818 40 93

**Telephone:** +41 (0) 31 818 40 90

**E-mail:** nicolemorawiec@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,*

*Padraig Hegarty*

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**Padraig Hegarty VP, QA**

Appendix 1

**FIELD SAFETY CORRECTIVE ACTION  
ACKNOWLEDGEMENT FORM**

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

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

Ref. EIF-000256

**RETURN COMPLETED FORM IMMEDIATELY TO:**

FAX: +41 (0) 31 818 40 93

E-mail: nicolemorawiec@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.  <b>Return Authorisation No</b> _____
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**PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.**

COMMERCIAL NAME OF AFFECTED PRODUCTS:	EIF-000256 – Various Arrow Products	
PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package.
- Please label returns as **“Field Action Returns”**

**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>	

## EIF-000256 - Appendix 2

Commercial Names	
ARROWg+ard Blue PLUS® Pressure Injectable CVC Kit	Epidural Needle
Micron Flat Epidural Filter	Extension Line Slide Clamps
Luer-Slip Loss of Resistance Syringe	Large Volume Abdominal Paracentesis Kit
Catheter Clamp with Fastener	MAC Two-Lumen CVC
Radiopaque Polyurethane Sheath/Dilator,	Maximal Barrier Drape
ARROW JACC	Multi-Lumen CVC Kit
Arrow PICC®	Peel Away Sheath over Dilator
Arrow-Clarke Pleura-Seal Thoracentesis Kit	Percutaneous Sheath Introducer Kits
Arrow-Flex Percutaneous Sheath Introducer Kit	PICC Catheter Trimmer
ARROWg+ard Blue PLUS CVC Kit,	Prep Tray with Maximal Barrier Precautions
ARROWg+ard Blue MAC	Pressure Injectable ARROWg+ard Blue PLUS(R) CVC Kits
ARROWg+ard Blue® PSI Kit	PSI Kits
Arrow-Johans™ ECG Adapter	Radial Arterial Kits
Arterial Catheterization Kits	Sheath Adapter with Cath-Gard®
Catheter Hemostasis Valve	SnapLock™ Catheter/Syringe Adapter
Clear Fenestrated Drape with Adhesive	Spring Wire Guide Introducer Needles
Continuous Nerve Block Needle	TheraCath Epidural Catheter
Echogenic Introducer Needle	VPS Rhythm ECG Accessory Packs
	VPS TipTracker Stylet Accessory

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
AB-00090	13F17G0253	AN-04418	13F17F0738	ASK-00002-1A	13F17L0462
AB-00150	13F17A0200		13F17J0445	ASK-00376-SU	13F17B0089
	13F17F0505	13F17A0211	13F17L0152		
	13F17G0256	13F17B0082	ASK-01000-UPMS	13F17A0280	
	13F17J0455	13F17C0378		13F17H0434	
AB-17040-N	13F17C0193	13F17D0082	ASK-04000-HMC	13F17L0480	
	13F17K0105	13F17E0023		13F17A0216	
AB-17080-N	13F17C0198	13F17E0329	ASK-04001-BID2	13F17D0073	
	13F17J0280	13F17E0838		13F17F0163	
AB-17110-N	13F17A0063	13F17F0432	ASK-04018-OH1	13F17G0522	
AB-17140-N	13F17A0061	13F17F0813		13F17H0487	
	13F17B0252	13F17G0333		13F17L0121	
	13F17F0190	13F17H0059		13F17L0651	
	13F17L0701	13F17J0002	13F17A0195		
AB-18080-N	13F17A0064	13F17L0598	ASK-04020-AH	13F17D0213	
	13F17C0225	13F17A0213		13F17F0428	
	13F17D0342	13F17C0109		13F17K0314	
	13F17J0229	13F17C0479	13F17L0113		
	13F17K0592	13F17E0208	ASK-04020-DH	13F17E0562	
	13F17M0002	13F17F0254		13F17G0537	
AB-18110-N	13F17A0201	13F17F0727		13F17K0188	
	13F17D0246	13F17G0357	13F17L0167		
AI-07000	13F17C0232	13F17J0161	ASK-04020-MIHS	13F17B0102	
	13F17G0194	13F17J0274		13F17C0283	
	13F17H0047	13F17L0441		13F17F0221	
	13F17J0083	13F17A0065		13F17G0480	
AN-04318	13F17A0231	13F17B0190	ASK-04020-RIHM	13F17J0045	
	13F17B0321	13F17D0264		13F17L0127	
	13F17C0241	13F17F0246		13F17B0307	
	13F17D0233	13F17F0653	ASK-04020-HF	13F17D0070	
	13F17E0301	13F17J0082		13F17E0417	
	13F17E0725	13F17K0412		13F17G0012	
	13F17F0603	13F17E0104	ASK-04020-HF1	13F17G0508	
	13F17G0193	13F17F0318		13F17H0421	
	13F17J0089	13F17G0569		13F17L0155	
	13F17K0232	13F17J0423	ASK-04120-HF	13F17L0478	
	13F17L0230	13F17L0130		13F17A0174	
	13F17L0231	13F17A0212	ASK-04120-HF	13F17F0139	
13F17L0232	13F17D0025	13F17C0179			
13F17L0233	13F17D0154	ASK-04120-HF1	13F17E0655		
AN-04320	13F17A0131		13F17E0193	13F17G0301	
	13F17B0101		13F17F0352	13F17H0284	
	13F17B0320	13F17G0102	13F17K0566		
	13F17D0234	13F17G0102	13F17M0019		
	13F17F0242	13F17G0347	13F17C0281		
	13F17H0488	13F17H0347	13F17G0398		
	13F17J0454	13F17K0324	13F17C0360		
	13F17M0003	13F17K0377	13F17D0034		

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Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
ASK-04120-HF1	13F17E0093	ASK-09803-CCH1	13F17J0149	ASK-15703-PVH	13F17J0096
	13F17F0468		13F17K0582		13F17K0195
	13F17G0269	ASK-09803-SRH	13F17G0220		13F17L0138
	13F17J0101	ASK-09803-ST	13F17F0180		13F17L0679
	13F17K0311		13F17F0364	13F17E0597	
	13F17L0489		13F17K0083	13F17F0395	
ASK-04301-TJ	13F17E0674		ASK-09817-MM	13F17L0479	ASK-21142-WHC2
	13F17G0265	13F17E0675		13F17L0532	
	13F17J0087	13F17G0548	ASK-21242-NYP	13F17A0076	
	13F17K0099	13F17K0431		13F17B0076	
	13F17L0250	13F17A0259		13F17B0225	
ASK-04510-EHP1	13F17C0128	ASK-09903-TJ		13F17B0200	13F17E0773
	13F17E0615			13F17F0676	13F17H0129
	13F17F0694		13F17J0417	13F17J0020	
	13F17H0262		13F17L0510	13F17J0395	
	13F17L0342	13F17A0258	13F17L0012		
ASK-04510-HFH	13F17A0277	ASK-09903-UM	13F17D0075	ASK-21242-PR	13F17B0260
	13F17B0385		13F17G0275		13F17F0591
	13F17E0360		13F17L0615		13F17L0010
	13F17G0221	13F17E0762	13F17L0273		
	13F17H0339	ASK-09903-UPA	13F17F0599	ASK-24306-VC	13F17M0136
	13F17K0080		13F17H0058		13F17D0267
	13F17K0580		13F17J0241		13F17F0310
	13F17M0020		13F17L0114		13F17H0326
13F17D0003	13F17L0485		13F17K0315		
ASK-04510-HFH2	13F17D0072	ASK-09907-SB	13F17D0180	ASK-24306-WHC1	13F17B0024
	13F17F0130		13F17H0192	ASK-24306-WHC2	13F17E0019
	13F17F0774		13F17K0223		13F17E0673
	13F17H0352		13F17K0555		13F17J0236
	13F17K0304	ASK-15402-HOP	13F17C0183	ASK-29803-SJH	13F17L0497
	13F17L0180		13F17F0775		13F17A0276
	13F17L0641		13F17B0389		13F17D0104
ASK-04510-TR2	13F17B0248	ASK-15703-LDP1	13F17E0430		13F17F0165
	13F17C0011		13F17F0580		13F17G0452
ASK-09601-UM1	13F17B0007		13F17H0545		13F17H0251
	13F17A0183		13F17K0403		13F17K0284
	13F17J0184		13F17L0285	13F17L0363	
	13F17K0101	ASK-15703-PHMC	13F17A0285	13F17C0105	
13F17K0286	13F17C0381		13F17E0803		
ASK-09801-ST	13F17F0301		13F17D0214	13F17G0422	
	13F17H0020		13F17E0356	13F17H0161	
	13F17J0003		13F17F0736	13F17H0204	
	13F17K0299	13F17H0483	13F17K0193		
ASK-09803-CCH1	13F17B0054	ASK-15703-PNYP	13F17H0123	ASK-29903-UW1	13F17M0197
	13F17C0382	ASK-15703-PVH	13F17D0024		13F16L0231
	13F17E0074		13F17E0454	13F17F0691	
	13F17F0265		13F17G0083	ASK-42703-AEH	13F17A0266
	13F17G0168		13F17H0048		13F17F0360

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Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
ASK-42703-AEH	13F17G0155	ASK-42703-VC	13F17M0194	ASK-45703-PTJH	13F17K0220
	13F17H0435	ASK-42802-DMC	13F17C0063		13F17L0560
	13F17K0074		13F17F0665	ASK-45703-PWHC1	13F17E0022
	13F17L0365		13F17H0388	ASK-45703-SCH	13F17B0193
	13F17M0304	13F17D0321	13F17E0461		
ASK-42703-MHW	13F16M0282	ASK-42802-PWHC1	13F17H0137	ASK-45703-UAB	13F17G0450
	13F17D0183		13F17L0063		13F17C0210
	13F17H0260		13F17L0555	ASK-45703-VAH	13F16M0294
	13F17M0344	13F17B0388	13F17E0398		
ASK-42703-OLL1	13F17C0293	ASK-42802-VC	13F17E0134	ASK-45703-VC	13F17H0074
	13F17E0414		13F17H0132		13F17A0219
	13F17J0243		13F17K0152		13F17C0013
ASK-42703-PAM1	13F17K0077	ASK-42854-PRR	13F17B0034		13F17C0431
	13F17L0494		13F17B0278		13F17D0166
ASK-42703-PHCH	13F17B0408		13F17E0800	13F17F0070	
	13F17E0421		13F17H0142	13F17F0714	
	13F17L0288		13F17K0160	13F17G0590	
ASK-42703-PSHR1	13F17C0361	ASK-45703-AEH	13F17E0712	13F17J0392	
	13F17F0207		13F17H0264	13F17L0070	
	13F17H0518		13F17K0086	13F17E0141	
	13F17M0278		13F17K0547	13F17E0300	
ASK-42703-PTJH	13F17A0168		ASK-45703-LDP1	13F17L0647	13F17H0147
	13F17C0074	13F17G0033		13F17J0336	
	13F17D0339	ASK-45703-PBHS	13F16M0260	13F17C0072	
	13F17G0029		13F17C0150	13F17E0166	
	13F17G0453		13F17E0406	13F17H0261	
13F17L0509	13F17G0421		13F17J0339		
ASK-42703-RV1	13F17B0020	ASK-45703-PDMC1	13F17H0420	13F17L0020	
	13F17B0269		13F17L0522	13F17L0401	
	13F17C0303		13F16M0164	13F17E0669	
	13F17F0317	ASK-47702-VC	13F17A0008	13F17H0311	
	13F17H0062		13F17D0204	13F17L0076	
	13F17J0386		13F17F0582	13F17A0199	
	13F17K0583		13F17G0317	13F17C0048	
ASK-42703-SBM	13F17L0455	ASK-45703-PNY	13F17H0537	13F17D0270	
	13F17C0308		13F17K0441	13F17F0258	
ASK-42703-SJH	13F17F0761		13F17M0159	CC-00004	13F17G0529
	13F17E0547		13F17A0047		13F17A0198
	13F17F0680		13F17B0011		13F17C0056
	13F17G0214	13F17H0012	13F17D0135		
	13F17J0347	13F17L0421	13F17D0236		
ASK-42703-VC	13F17L0150	ASK-45703-PNY	13F17H0124	13F17F0075	
	13F17D0165		13F17H0451	13F17F0600	
	13F17F0312	ASK-45703-PTJH	13F17B0016	13F17G0179	
	13F17G0302		13F17C0089	13F17H0107	
	13F17H0070		13F17D0105	13F17H0367	
	13F17J0350		13F17F0062	13F17J0198	
13F17L0064	13F17H0250	13F17K0212			

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Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
CC-00007	13F17B0257	CDC-42854-P1A	13F17G0287	EC-05000	13F17F0498
	13F17D0260		13F17H0118		13F17F0609
	13F17E0342		13F17K0156		13F17F0789
	13F17F0076		13F17L0017		13F17G0250
	13F17F0795		13F17M0158		13F17J0076
	13F17J0271		13F17J0061		13F17K0413
CC-00008	13F17B0050	CDC-45703-P1A	13F17J0084	EF-05500	13F17K0414
	13F17D0271		13F17J0451		13F17K0415
	13F17F0078		13F17K0249		13F17K0416
	13F17J0276		13F17K0250		13F17D0240
CD-00001	13F17G0258		13F17K0383		13F17G0371
	13F17J0281		13F17K0575		13F17K0408
CDC-15703-P1A	13F17A0025	CDC-45703-PB1A	13F17L0576	EG-04900	13F17C0326
	13F17E0279		13F17M0154		13F17E0123
	13F17E0457		13F17B0350		13F17F0584
	13F17F0160		13F17E0048		13F17G0519
	13F17F0769		13F17E0719	13F17H0292	
	13F17G0349		13F17H0308	JR-42063-HPHNM	13F17C0327
	13F17J0133		13F17L0099	JR-42563-HPHNM	13F17F0099
	13F17J0134		13F17C0396	LR-05501	13F17C0328
	13F17L0103		13F17C0439		13F17F0296
	13F17M0200		13F17D0062		13F17G0202
CDC-42703-P1A	13F16M0232	13F17D0284	13F17H0104		
	13F17J0065	13F17E0618	13F17J0207		
	13F17J0450	13F17F0126	13F17C0408		
	13F17K0069	13F17G0293	13F17E0419		
	13F17K0136	13F17H0263	13F17F0683		
	13F17K0288	13F17J0055	13F17H0283		
	13F17K0419	13F17K0168	13F17K0545		
	13F17K0567	13F17L0021	13F17E0607		
	13F17L0223	13F17L0353	13F17G0356		
	13F17L0573	13F17L0590	MSO-29903-AHS	13F17K0327	
CDC-42802-P1A	13F17B0333	CN-04018	13F17B0039	MSO-45703-AHS	13F17L0350
	13F17C0338		13F17C0181		13F17C0230
	13F17D0322		13F17D0226		13F17D0161
	13F17E0539		13F17E0065		13F17F0068
	13F17E0870		13F17E0724		13F17G0364
	13F17F0116		13F17F0651		13F17H0351
	13F17H0136		13F17G0531		13F17J0387
	13F17J0024		13F17H0377		13F17K0579
	13F17K0268		13F17J0273		13F17L0487
	13F17L0062		13F17L0216		13F17B0315
	13F17L0207		13F17L0218	13F17C0033	
	13F17L0397		13F17B0147	13F17C0462	
	CDC-42854-P1A		13F17C0137	EC-05000	13F17C0176
13F17E0177		13F17C0419	13F17F0550		
13F17E0598		13F17E0464	13F17G0229		
13F17F0644		13F17F0039	13F17H0049		



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Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
NA-04550-1A	13F17H0328	PR-35541-HPHNM	13F17B0046	PR-45563-HPHNL	13F17C0354
PC-00001-T	13F17C0349		13F17B0161		13F17D0341
	13F17F0300		13F17C0353		13F17J0402
PL-05041	13F17G0050	PR-35552-HPHNL	13F17F0652	PR-45563-HPHNM	13F17L0688
	13F17J0360		13F17B0322	RHY-100-ECGJ	13F17A0120
	13F17K0376		13F17J0008		13F17A0287
PL-05052	13F17C0435	PR-35552-HPHNM	13F17B0109	RHY-100-ECGJ	13F17C0018
	13F17E0720		13F17B0318		13F17D0136
	13F17G0077		13F17F0245		13F17E0122
	13F17G0514	PR-35563-HPHNL	13F17F0445	RHY-100-ECGO	13F17A0288
PN-00215-E	13F17J0072	PR-35563-HPHNM	13F17K0495	RHY-177-TTSAP	13F17A0119
	13F17K0211	PR-44041-BAS	13F17F0101		13F17D0019
	13F17L0700	PR-44052-BAS	13F17F0103		13F17D0130
13F17C0329	13F17K0128		13F17D0186		
PN-00217-E	13F17E0118	PR-44063-BAS	13F17F0104		13F17D0278
	13F17F0503		13F17K0129		13F17E0113
	13F17G0093	PR-45041-BAS	13F17F0105		13F17F0193
	13F17G0534		13F17K0241		13F17F0480
	13F17H0383	PR-45052-BAS	13F17F0106		13F17G0074
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PR-35041-HPHNM	13F17B0290	PR-45541-BAS	13F17F0107	SA-09847	13F17J0208
	13F17C0231	PR-45541-HPHNL	13F17A0165		13F17K0438
	13F17D0238		13F17D0327		13F17B0051
	13F17F0276		13F17G0008		13F17E0713
	13F17F0577		13F17H0416		13F17F0767
	13F17H0365		13F17H0572	13F17J0010	
	13F17J0409	PR-45541-HPHNM	13F17K0238	SC-14703	13F17A0109
	13F17K0490		13F17L0049		13F17D0071
	13F17L0394		13F17B0174		13F17E0795
	13F17L0395		13F17C0188		13F17F0743
13F17B0092	13F17E0738		13F17H0099		
PR-35052-HPHNM	13F17B0256	PR-45552-BAS	13F17G0006	SF-29803-1	13F17K0227
	13F17C0043		13F17F0108		13F17C0004
	13F17D0094	PR-45552-HPHNL	13F17K0237	SS-09903-S	13F17G0030
	13F17D0239		13F17C0467		13F17H0405
	13F17E0224		13F17E0017		
	13F17F0586		13F17E0758		
	13F17H0354		13F17F0523		
	13F17J0196	PR-45552-HPHNM	13F17B0178		
	13F17K0549		13F17C0469		
	13F17L0474		13F17E0120		
	13F17L0697		13F17G0412		
	13F17M0121		13F17H0393		
	PR-35541-HPHNL		13F17F0219	PR-45563-BAS	13F17J0172
13F17H0523		13F17L0335			
PR-35541-HPHNM	13F17A0110		13F17F0109		