

Urgent Medical Device Recall 1st Notification

ARROW® Access, Arterial Catheterization, CVC, Hemodialysis, Large-Bore CVC, MAC, PI CVC, PICC, PSI & Vessel Catheterization Kits

Internal Reference: EIF-000206

December 22, 2017

To: Customer of Arrow International Products

Arrow International has issued a recall for the following product codes and lot numbers:

Product Code	Lot/Batch Numbers
See attached	See attached

Arrow International is recalling the product referenced above because the packaging may not be completely 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 that you have received products that are subject to this recall. We are now notifying our customers to take the following actions:

1. If you have affected stock, immediately discontinue use and quarantine any products with the product codes and lot numbers listed above, so that the affected products can be returned to Arrow.
2. To return product, complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) Number and will provide instructions for the return of products to Arrow International.
3. If you have no affected stock, please complete the enclosed Recall Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document your receipt of this letter.

The U.S. Food and Drug Administration has been notified of this action.

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 at 1-866-246-6990.

For and on behalf of Teleflex,

Karen Boylan

Karen Boylan
VP, Global RA/QA

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
AK-22702-P1A	13F17D0194	ASK-09907-LGH1	13F17A0052	ASK-45703-PRH	13F17E0402	
	13F17F0486		13F17C0390		13F16M0019	
AK-42703-P1A	13F17A0135	ASK-11242-PHP	13F17D0179	ASK-45703-PRJ	13F17B0343	
	13F17C0355	ASK-12703-PCA	13F17F0240		13F17D0113	
	13F17E0212	ASK-12703-PRJ	13F17B0279	ASK-45703-PRWJ1	13F17A0067	
	13F17E0789		13F17D0112		13F17C0140	
	13F17F0386	ASK-15703-PCA	13F17F0575	ASK-45703-PUCD	13F17D0055	
AK-42802-P1A	13F17D0323	ASK-15703-PHH	13F17B0239	ASK-47702-PPHP	13F17F0255	
	13F17E0310		13F17C0300		13F17C0492	
	13F17E0467		13F17D0297		13F17B0152	
AK-42854-P1A	13F17B0041		ASK-15703-PLV	13F17F0015	CA-42703-P1A	13F17C0057
	13F17E0764	13F17E0390		CA-42854-P1A	13F17F0226	
AK-45703-P1A	13F17A0028	ASK-15703-PRH	13F17C0279	CA-45703-P1A	13F17A0157	
	13F17E0044	ASK-15703-PRJ	13F17B0265		13F17B0117	
	13F17E0448	ASK-15703-PRWJ	13F17B0199		13F17C0250	
13F17B0118	13F17C0400		CA-45854-P1A	13F17F0071		
AK-45703-PB1A	13F17F0385	ASK-21142-RH	13F16L0254	CDA-21242-1A	13F17F0437	
	AK-45802-P1A		13F17B0085	13F17B0196	CDA-22122-U1A	13F17E0616
13F17E0150			13F17C0046	13F17F0256		
AK-45802-P1A	13F17F0345	ASK-21242-MMC1	13F17D0212	CDA-25122-U1A	13F16M0184	
	AK-45854-P1A		13F16M0169	13F17E0770	CDA-29803-1A	13F17E0617
			13F17B0262	13F17F0438		13F17C0267
AK-45854-P1A	13F17C0468	ASK-21242-UCD	13F17E0656	CDA-29803-1A	13F17E0385	
	AK-46702-P1A		13F17E0751		13F17F0188	13F17A0022
AK-47702-P1A			13F17E0211	13F17F0459	CDA-42703-P1A	13F17A0301
ASK-04001-MS	13F17E0546	ASK-24301-GM	13F17B0037	13F17C0266		
ASK-04018-CC	13F17D0198		13F17E0451	13F17D0039		
	ASK-04300-PHP	13F17F0215	ASK-29804-UHN2	13F17D0188	CDA-42802-P1A	13F17C0318
ASK-04301-WBH	13F17D0048	ASK-29903-UCD	13F17E0570	CDA-42854-P1A	13F16M0048	
ASK-04510-HUM	13F17E0659	ASK-42703-PBM	13F17E0660		13F17E0124	
	13F17E0029	ASK-42703-PBM	13F17B0134	13F17F0497		
13F17E0537	13F17C0472		CDA-45703-P1A	13F17A0167		
ASK-04550-NYP	13F17A0075	ASK-42703-PRJ		13F17A0296	13F17B0145	
	13F17C0503			13F17D0110	13F17C0466	
	13F17D0296		13F17F0319	13F17E0095		
	13F17E0541	ASK-42802-PBM	13F17E0543	13F17F0261		
	13F17F0220		13F17F0208	CDA-45854-P1A	13F17C0325	
13F17G0002	ASK-42854-PNMM	13F17A0172	13F17D0283			
ASK-04550-UHC		13F17B0226	13F17B0401	CDA-47702-P1A	13F17B0249	
		13F17D0017	13F17E0163	CDC-09803-1A	13F17A0123	
13F17D0280	13F17E0631	13F17E0014				
ASK-09803-WBH1	13F17C0208	13F17F0338	13F17E0455			
ASK-09803-WBH1	13F17F0162	ASK-42854-PRJ	13F17E0796	13F17F0289		
	ASK-09903-KH	13F17F0231	ASK-45541-RWJ4	13F16M0274		
ASK-09903-LC	13F17E0382	ASK-45552-RWJ4	13F17D0187	CDC-09903-1A	13F16M0274	
	13F17F0206		13F17D0222		13F17E0040	
ASK-09903-PHP	13F17D0049	ASK-45703-AH	13F17E0849		13F17E0227	
ASK-09907-LGH1	13F16M0116		13F16M0173	13F17E0824		
			13F17C0414	CDC-11242-1A	13F17B0232	

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
CDC-11242-1A	13F17C0357	CDC-21242-1A	13F17E0867	CDC-29903-1A	13F16L0179
	13F17D0312		13F17F0439		13F17E0042
	13F17E0289	CDC-22122-1A	13F16M0268		13F17E0231
	13F17F0154		13F17C0395		13F17E0411
	13F17F0327		13F17E0158	13F17E0836	
	13F17F0614		13F17E0536	CDC-42703-B1A	13F17F0049
CDC-12123-P1A	13F17F0081		13F16M0266		13F17B0224
CDC-12703-1A	13F16L0177	CDC-22123-1A	13F17C0484	CDC-42802-1A	13F17E0142
	13F17E0449		13F17E0798		13F17E0830
	13F17E0873	CDC-24301-1A	13F17B0345	CDC-42854-1A	13F17D0275
	13F17F0295		13F17E0644		13F17D0325
CDC-12802-1A	13F16M0272		13F17E0871	CDC-45703-1A	13F16L0220
	13F17E0648		13F17F0291	CDC-45703-A1A	13F17E0463
CDC-15703-1A	13F17E0677		13F17B0124		
	13F17F0477	CDC-24306-1A	13F17B0355	CDC-45703-B1A	13F17E0685
CDC-15703-B1A	13F17A0318		13F17E0727	CDC-45802-1A	13F17E0358
	13F17F0083	CDC-25122-1A	13F17A0254	CDC-45802-B1A	13F17B0031
CDC-15802-1A	13F17B0122		13F17A0017		
	13F17F0512		13F17A0314	CDC-45854-1A	13F17C0470
CDC-17702-1A	13F17A0320	CDC-25123-1A	13F17D0060		
	13F17F0528			13F17E0799	CDC-46702-1A
CDC-21242-1A	13F17B0139		13F17F0489		
	13F17B0140	CDC-25142-1A	13F16M0233	CDC-47702-1A	13F17B0135
	13F17B0141		13F17D0190		13F17D0191
	13F17B0142	CDC-26142-1A	13F17B0137	EU-05052-HPMSB	13F17B0123
	13F17D0131		13F17D0225	NA-04550-X1A	13F17A0122
	13F17D0141	13F17C0339	13F17C0342		
	13F17E0509	CDC-29803-1A	13F17E0230		13F17E0364
	13F17E0510		13F17E0718		13F17E0827