

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

10th April 2017

URGENT - FIELD SAFETY NOTICE

Commercial Name of Affected Product:	ARROW® Kits with BD Eclipse™ Needles
Type of action:	Advisory Notice
Arrow Reference:	EIF-000146
Product code/Lott number	Refer to Appendix 2

Dear Customer,

Details of affected devices

Arrow International has received an Urgent Product Advisory Notice from Becton-Dickinson (BD) for their Eclipse™ Needles. Arrow International purchased these Eclipse™ Needles from BD and packaged them with certain Arrow products. Refer to Appendix 2 for list of affected product codes and lot numbers.

Description of the problem

According to the BD letter, a copy of which is attached, Becton-Dickinson (BD) has received reports of safety cover disengagement and needlestick injury (NSI) for the BD Eclipse™ Needle. Based on customer reports, in some cases when the safety cover is pushed over the needle it disengages, resulting in an exposed needle which can increase the risk of NSI. Some customer reports indicate an audible “click” sound before the safety cover is locked (activated) followed by a second “click” sound when the safety cover is locked over the needle. This may potentially increase the risk of NSI if the user assumes the safety cover is locked after the initial “click.”

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

Our records indicate your facility has received product in scope of this field safety notice. Note this is an advisory notice only. You may continue to use the finished goods containing this needle that you have in stock and will continue to receive.

Arrow International are notifying customers to take the following actions:

1. Please provide this field safety notice to all users of the Arrow products listed in the attachment, containing the BD Eclipse™ Needle, within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice.
2. When using the BD Eclipse™ Needle, follow the instructions for use (IFU) to “Centre your thumb or forefinger on the textured finger pad and push the safety cover forward over the needle until you hear or feel it lock. Per Figure 1, visually confirm the needle is covered when pushing the safety cover over the needle.”

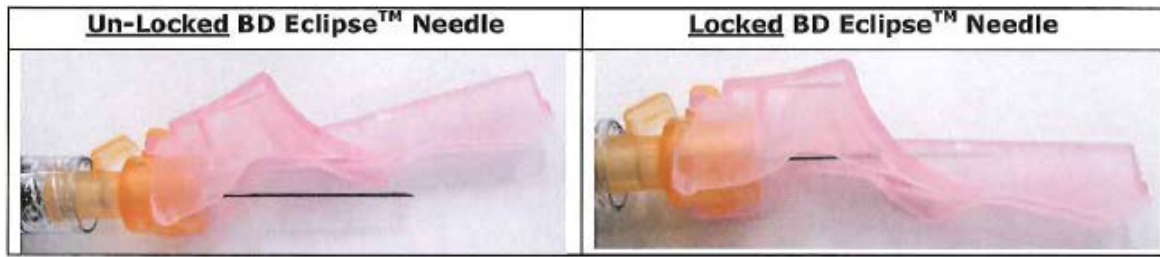


Figure 1: Examples of visual confirmation of un-locked and locked BD Eclipse™ Needle.

- Complete the enclosed Acknowledgement Form and fax or email it to the below Customer Service contact details. This will allow us to document your receipt of this letter. You need **not** follow the instructions in the attached BD letter regarding completion of BD's Business Response Card. Instead, complete and return the Arrow Acknowledgement Form and as instructed here.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

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. There is no further action required.

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.

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.

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: nicole.morawiec@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*

Appendix 1

Customer No.

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000146 - ARROW® Kits with BD Eclipse™ Needles

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93

E-mail : nicole.morawiec@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and acknowledge that we have read and understood the Urgent Medical Device Notification for ARROW® Kits with BD Eclipse™ Needles.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	ARROW® Kits with BD Eclipse™ Needles
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Complete this Acknowledgement form and return immediately by using the fax number or e-mail address above.

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

Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch
ASK-04001-DU10	23F15L0662	ASK-04020-MUSC	13F16J0041	ASK-09801-ST	13F16B0103	ASK-42703-PRJ	13F16H0029	CA-42703-P1A	13F16B0140
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	23F16B0338		13F17B0386		13F16F0011		13F16L0007		13F16C0187
	23F16C0321		23F15K0020		13F16F0167		13F16M0013		13F16D0050
	23F16C0632		23F15L0028	13F15G0116	13F17A0296	13F16D0183			
	23F16J0105		23F15M0248	13F15K0031	23F15H0023	13F16E0118			
	23F16K0449		23F16A0380	13F16A0198	23F16C0614	13F16E0176			
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ASK-04001-DU4S1	23F15K0983	23F16C1098	ASK-12703-PRJ	13F16E0041	ASK-42802-PST1	23F16H0784	13F16G0047		
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	23F16H0879	23F16F0706		13F15H0116		23F15M0109	13F16H0105		
ASK-04001-DU5S	23F15J1102	23F16A0017	ASK-15703-PRJ	13F15H0232	ASK-45552-SPH	23F16A0678	13F16M0047		
	23F15K0441	23F16C0022		13F16A0239		23F16C0611	13F17B0152		
ASK-04001-DU5S1	23F15L0631	23F16D0903	ASK-15703-PST	13F16G0127	ASK-45703-AH	23F16F0057	13F17C0057		
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ASK-04001-DU7	23F15K0345	23F16M0191	ASK-15703-PRJ	13F17B0265		23F16H0869	13F15H0195		
ASK-04001-DU8	23F15K0346	23F16B0560	ASK-21142-HF2	23F15H0291	ASK-42854-PRJ	13F16B0187	13F15K0186		
ASK-04001-DU9	23F15L0593	23F16D0123		23F15J0493		13F16H0153	13F15K0273		
	23F16A0300	23F16F0676		23F15K0443		23F16J0194	13F15L0132		
	23F16B0028	23F16H0477	23F15L0772	23F16G0519	13F16A0181				
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	23F16K0363	23F16B0517	23F16E0052	23F15H0111	13F16E0119				
	23F16K0431	23F16C0215	23F16F0931	23F15J0813	13F16H0093				
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23F16L0181	23F16E1135	23F16A0805	23F15L0209	13F17B0117					
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	13F16E0086		13F17A0167		71F16F0822		71F16E1743		71F16F1498
	13F16F0023		13F17B0145		71F16H0300		71F16F1224		71F16F1883
	13F16F0234		23F15J0140		71F16H1146		71F16G1022		71F16H0772
	13F16G0079		23F15J0671		71F16K0075		71F16H0677		71F16H0924
	13F16M0122		23F16J0314		71F16L0979		71F16J1779		71F16H0937
CDA-29903-1A	23F15H0777	CDA-45854-P1A	13F16A0171		71F17A1500		71F16K1245	71F16J0565	
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	13F16C0077	23F16H0389	71F16G0840		71F16E0127		71F16D0138		
	13F16D0081	23F16B0062	71F16J0605		71F16E1081		71F16D1711		
	13F16D0205	23F16J0195	71F16J1533		71F16F0260		71F16E1087		
	13F16F0139	23F15K0377	71F16K0478		71F16F1797		71F16F0266		
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	13F16L0092	23F16G0546	71F17A1733		71F16J1927		71F16J0365		
	13F17A0022	23F16K0605	71F16E1739		71F16K1246		71F16J2165		
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	23F17B0138		71F16F0720		71F16D1189		71F16J1275		13F17B0098
CDA-44052-HPK1A	23F16H0967	CH-24701-H	71F16H0301		71F16E0124	DE-25000-KVI	71F16J1979	EU-05052-HPMSB	13F15H0234
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	23F16L0435		71F16D1338		71F16H1239		71F16M1117		13F16E0036
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CDA-45703-P1A	13F15H0256	CH-45703-H	71F16D0363		71F16L0059	DE-25000-KVI	71F17C1282	EU-24041-HPMSB	71F15K0499
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Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch					
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	71F16J0782	71F17B0923	71F16J1428	71F17A1011	71F16D1703									
	EU-25052-HPMSB	71F16J1793	EU-45854-MSB	71F16C0241	NL-25000-SLZ	71F16L0177	UK-04052-RDE1	71F16D0952	UK-25000-MSB	71F16G1037				
		71F16J2214		71F16C1305		71F16L0513		71F16E0909		71F16G1343				
		71F16J2215		71F16E0830		71F17B0428		71F16J1805		71F16J0336				
		71F16M0197		71F16F0390		71F17B0429		71F16L2081		71F16K1287				
		71F17B0891		71F16L0174		71F16C2180		71F15K0928		71F16L0139				
71F15K0927		EU-47702-MSB		71F15L1715		IB-47702-HRH		71F16F0821		UK-05041-MSB	71F15K1646	UK-25004-ANHS	71F16L1083	
71F15K1655			71F16A1118	71F16G1297	71F16B1959		71F16L2107							
71F16B1775			71F16C2177	71F16K0071	71F16C1944		71F16M1465							
71F16C0110			71F16F0825	71F17A1498	71F16E1187		71F17A0854							
71F16C1913			71F16K1979	71F17A1499	71F16G1034		71F17B0823							
EU-25052-HPMSB	71F16D0950	GR-22122-FMSB	71F16L1673	NL-25000-SLZ	71F16L1848	UK-05041-RDE1	71F16J0265	UK-25005-ANHS	71F17C0050					
	71F16E0179		71F17A1503		71F16C1544		71F16J0771		71F16C1748					
	71F16E1398		71F17A1813		71F16D0603		71F16M0195		71F16E1175					
	71F16F1828		71F16D0868		71F16E1059		71F17B0893		71F16F0721					
	71F16J1437		71F16F0979		71F16F1904		71F16C0982		71F16G0428					
	71F16J1803		71F16L2179		71F16J1482		71F16E0248		71F16C1862					
	71F16K0916		71F16D0419		71F16K1269		71F16E1180		71F16D0984					
	71F16K1898		71F16H0188		71F16L1407		71F16F0709		71F16F0719					
	EU-25063-HPMSB	71F16L1198	GR-25122-UFMSB	71F16L0797	NL-25000-SLZ	71F16M0433	UK-05041-RDE1	71F16J0779	UK-25006-ANHS	71F16F2061				
		71F16M1428		71F16J1478		71F16M1480		71F16J2348		71F16C1749				
		71F17A0305		GR-45703-MSB		71F17A2038		71F16K1866		71F16F0717				
		71F17A1833		GR-47702-MSB		71F17B1192		71F16L0325		71F16M0349				
		71F16D0871		IB-12853-GUC		71F16E0018		TI-42854-MSB		71F17C0471	UK-05041-THT	71F16L1202	UK-25855-MSB	71F16B1882
		71F16E0176				71F16E1688				71F17A2348		71F16M0383		71F16D1012
71F16K0483	71F16F1423	71F16B0415	71F17A0073		71F16E1655									
EU-25541-HPMSB	71F15K1669	71F16G0387	71F17A0560		71F17A1495	71F16F0487								
	71F16B1507	71F16H0934	71F17A1445		71F17C0293	71F16G1298								
	71F16C1534	71F16J2232	71F17C0039		71F15K1648	71F16G1441								
									71F16K1890					
									71F16K2076					
									71F16L1064					
									71F16L2166					
									71F17B1274					