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."

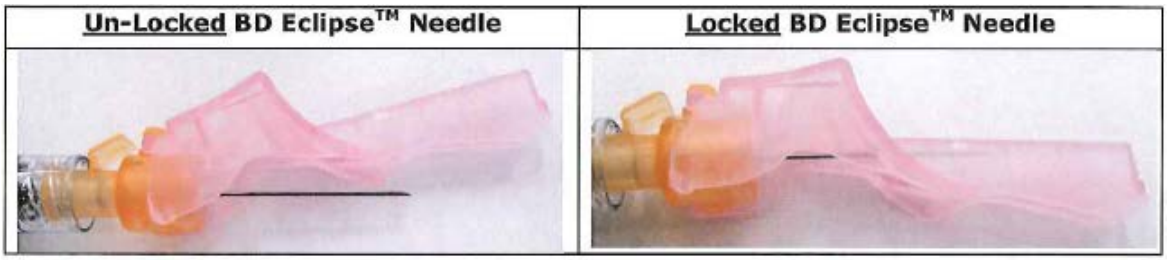


Figure 1: Examples of visual confirmation of un-locked and locked BD Eclipse™ Needle.

3. 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

Padraig Hegarty VP, QA

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

☐ 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

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	

Appendix 2 - EIF-000146

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
	23F16A0298		13F16L0037		13F16D0034		13F16H0254		13F16C0113
	23F16B0338		13F17B0386		13F16F0011		13F16L0007		13F16C0187
	23F16C0321		23F15K0020		13F16F0167		13F16M0013		13F16D0050
	23F16C0632		23F15L0028	ASK-09803-ST	13F15G0116		13F17A0296		13F16D0183
	23F16J0105		23F15M0248		13F15K0031	ASK-42802-PHF1	23F15H0023		13F16E0118
	23F16K0449		23F16A0380		13F16A0198	ASK-42802-PHF2	23F16C0614		13F16E0176
ASK-04001-DU4S	23F15K0375		23F16B0420		13F16C0022		23F16F0058		13F16F0195
ASK-04001-DU4S1	23F15K0983		23F16C1098		13F16E0041		23F16H0784		13F16G0047
	23F15M0640		23F16D0981		13F16G0107	ASK-42802-PST1	23F15L0211		13F16G0197
	23F16H0879		23F16F0706	ASK-12703-PRJ	13F15H0116		23F15M0109		13F16H0105
ASK-04001-DU5S	23F15J1102	ASK-04500-AH	23F16A0017		13F15H0232		23F16A0678		13F16M0047
	23F15K0441		23F16C0022		13F16A0239		23F16C0611		13F17B0152
ASK-04001-DU5S1	23F15L0631		23F16D0903		13F16G0127		23F16F0057		13F17C0057
	23F15M0638		23F16G0288		13F17B0279		23F16G0276	CA-42854-P1A	13F16A0037
	23F16L0206		23F16K0396	ASK-15703-PRJ	13F16C0102		23F16H0427		13F16K0302
ASK-04001-DU7	23F15K0345		23F16M0191		13F17B0265		23F16H0869	CA-45703-P1A	13F15H0195
ASK-04001-DU8	23F15K0346	ASK-04500-BGH	23F16B0560	ASK-15703-PST	23F15H0291	ASK-42854-PRJ	13F16B0187		13F15K0186
ASK-04001-DU9	23F15L0593		23F16D0123		23F15J0493		13F16H0153		13F15K0273
	23F16A0300		23F16F0676		23F15K0443		23F16J0194		13F15L0132
	23F16B0028		23F16H0477		23F15L0772	ASK-45552-SPH	23F16G0519		13F16A0181
	23F16B0523		23F17B0281		23F15M0668	ASK-45703-AH	13F16L0026		13F16C0008
	23F16J0151	ASK-04500-HFH2	23F16A0745		23F16C0430		13F16M0173		13F16D0048
	23F16K0363		23F16B0517		23F16E0052		23F15H0111		13F16E0119
	23F16K0431		23F16C0215		23F16F0931		23F15J0813		13F16H0093
	23F16K0820		23F16D0252	ASK-21142-HF2	23F15L0097		23F15K0247		13F17A0157
	23F16L0181		23F16E1135	ASK-21142-HF3	23F16A0805		23F15L0209		13F17B0117
ASK-04018-HCA	13F16K0085		23F16G0337		23F16C0559		23F15M0494		23F16B0383
	23F15L0172		23F16H0831		23F16F0593		23F15M0984		23F16C0505
	23F15M0324		23F16K0682		23F16J0827		23F16B0076	CA-45854-P1A	13F16C0116
	23F16A0393		23F17A0077		23F16K0685		23F16B0708	CA-47702-P1A	13F16C0116
	23F16E0381		13F16J0126	ASK-22122-MM	23F16B0882		23F16C0453		13F15H0181
	23F16G0598		13F16J0243		23F16E1096		23F16D0248	CDA-21242-1A	13F15H0275
ASK-04018-ST	23F15J0121		13F16K0174		23F16H0392		23F16E0015		13F15M0159
	23F15K0900		13F16M0091		23F16K0354		23F16E1075		13F16A0195
	23F15L0580		23F15H0722	ASK-22702-CA	13F16H0081		23F16F0656		13F16D0187
	23F16A0921		23F15J0075		13F16M0301		23F16G0270		13F16L0209
	23F16D0372	ASK-04500-HF-S	23F15K0096	ASK-29803-MM	23F15M0909	ASK-45703-PHHM1	23F15J1096	CDA-22122-U1A	13F16L0048
	23F16E0822		23F15L0559		23F16C0275		23F16H0293		23F15M0612
	23F16F1016		23F15M0173		23F16D0914	ASK-45703-PRJ	13F15H0190		23F16A0372
ASK-04020-MHT	13F17A0040		23F15M0828		23F16E1217		13F15J0025		23F16C0574
	23F15K0258		23F16B0732		23F16H0493		13F15K0028		23F16D0090
	23F15L0001		23F16B0773		23F16J0295		13F16B0113		23F16H0557
	23F15M0014		23F16D0206	ASK-42703-PRJ	13F15H0270		13F16D0026		13F16M0184
	23F16A0001		23F16F0866		13F15L0045		13F16F0052		23F16B0952
	23F16A0817	ASK-04510-MM3	23F16A0492		13F15L0110		13F16F0228		23F16C0756
	23F16C0532		23F16C0031		13F15L0163		13F16M0019	CDA-25123-1A	13F16A0219
	23F16D0305		23F16E0274		13F15M0118		13F17B0343	CDA-29803-1A	13F15H0203
	23F16E0982		23F16G0572		13F16A0100	ASK-45854-PST	23F16B0888		13F15J0254
	23F16F0788		23F16H0805		13F16A0235	ASK-46702-AH	23F16A0225		13F15L0155
	23F16G0772		23F17A0240		13F16B0075	CA-42703-P1A	13F15H0209		13F15M0100
	23F16H0752	ASK-09801-ST	13F15G0150		13F16D0006		13F15H0250		13F16A0035
	23F16J0136		13F15G0493		13F16D0125		13F15L0056		13F16A0145
	23F16K0287		13F15H0091		13F16E0075		13F16A0070		13F16B0029
	23F16K0765		13F15H0161		13F16F0004		13F16A0201		13F16B0127
	23F16M0088		13F15M0002		13F16F0158		13F16B0096		13F16C0042

Appendix 2 - EIF-000146

Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch
CDA-29803-1A	13F16D0148	CDA-45703-P1A	13F16K0306	CH-45854-H	71F16L0175	DE-24701S-AG1	71F16D0546	DE-25703S-AG1	71F16D1416
	13F16D0186		13F16L0091	CH-47702-H	71F16D0364		71F16E0505		71F16E1086
	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
CDA-42703-P1A	13F15K0214		13F16D0191	DE-04701-BGH	71F16B1962		71F17B0909		71F16J2167
	13F15K0244	CDA-47702-P1A	13F15M0133		71F16C1543		71F17B1779		71F16M0402
	13F16A0253		13F17B0249		71F16D1010	DE-24701S-AGK	71F16C0533		71F17A2345
	13F16B0143		23F15H0100		71F16F0248		71F16D0547	DE-25703S-AGK	71F16C1437
	13F16C0077		23F16H0389		71F16G0840		71F16E0127		71F16D0138
	13F16D0081	CDC-41541-JX1A	23F16B0062		71F16J0605		71F16E1081		71F16D1711
	13F16D0205		23F16J0195		71F16J1533		71F16F0260		71F16E1087
	13F16F0139	CDC-41552-JX1A	23F15K0377		71F16K0478		71F16F1797		71F16F0266
	13F16F0213		23F16H0074		71F16K1790		71F16G1021		71F16H0773
	13F16J0016	CDC-41563-JX1A	23F15J1064		71F16M1481		71F16J1780		71F16H0925
	13F16L0092	CDC-42041-JX1A	23F16G0546		71F17A1733		71F16J1927		71F16J0365
	13F17A0022		23F16K0605	DE-04701S-AGK	71F16E1739		71F16K1246		71F16J2165
	13F17A0301	CDC-42052-JX1A	23F16D0269		71F16H0059		71F17B0908		71F16K1581
CDA-42802-P1A	13F15H0144		23F16J0961		71F16J0600	DE-24703S-AGK	71F16L1514		71F16L1108
	13F15H0182	CDC-42063-JX1A	23F16A0883		71F16K1261		71F17A1919		71F16M0387
	13F16A0090		23F16B0057	DE-04730S-AGK	71F16D0604	DE-25000-KBR	71F16B0360		71F17B0562
	13F16D0087		23F16C1099		71F16E1735		71F16C0559	DE-25855S-AGK	71F17A2102
	13F16F0081		23F16F0374		71F16G0827		71F16C1441	DE-26702-DK	71F16M0165
	13F16K0239		23F16K0474		71F16J1819		71F16D1743		71F17B2022
	13F16L0285	CDC-42541-JX1A	23F16F0313		71F16L2084		71F16E1110	EU-04041-HPMSB	13F15L0004
CDA-42854-P1A	13F16A0074	CDC-42552-JX1A	23F15K0646		71F16M1440		71F16F1028		13F16K0297
	13F16A0236		23F16E1198		71F16H2161		71F16G0247	EU-04052-HPMSB	13F15H0325
	13F16L0071	CDC-42563-JX1A	23F16B0027		71F16K0048		71F16G1342		13F15K0142
	13F16M0048	CDC-43041-JX1A	23F16D0282		71F17A1916		71F16H1114	EU-05041-HPMSB	13F15M0107
CDA-44041-HPK1A	23F16H0311	CH-24701-H	71F16D0112	DE-14955S-AGK	71F16L1515		71F16H2137		13F16B0076
	23F16L0434		71F16E0899	DE-15703S-AGK	71F16D0091		71F16J0723		13F16H0352
	23F17B0138		71F16F0720		71F16D1189		71F16J1275		13F17B0098
CDA-44052-HPK1A	23F16H0967		71F16H0301		71F16E0124		71F16J1979		13F15H0234
	23F16L0317		71F16J2385		71F16E1080		71F16K0749		13F15J0052
	23F16L0735		71F16L0213		71F16F0848		71F16K2001		13F16B0077
CDA-45041-HPK1A	23F16H0443		71F17B1780		71F16G0225		71F16L0305		13F16C0156
	23F16L0435	CH-24701-KM	71F16D1338		71F16H1239		71F16M1117	EU-05052-HPMSB	13F16E0036
CDA-45052-HPK1A	23F16H0966		71F16J1783		71F16H1541		71F17A0658		13F16E0169
	23F16L0736	CH-25855-KM	71F16D1339		71F16J0546		71F17A2580		13F16J0124
CDA-45063-HPK1A	23F16M0332	CH-45703-H	71F16B0816		71F16J1025		71F17B0587		13F17B0123
CDA-45541-HPK1A	23F16L0737		71F16B1418		71F16J2275		71F17B1195		23S15D1420
CDA-45552-HPK1A	23F16M0042		71F16B2174		71F16K0787		71F17C0469	EU-05541-HPMSB	13F16B0045
CDA-45703-P1A	13F15H0256		71F16D0363		71F16L0059		71F17C1282	EU-24041-HPMSB	71F15K0499
	13F15K0005		71F16E0558		71F16M0883	DE-25000-KVI	71F16B0705		71F15K1002
	13F15L0131		71F16E0648		71F17A0702		71F16C0532		71F15K1644
	13F16A0087		71F16H0747		71F17A0816		71F16D0256		71F16B1497
CDA-45703-P1A	13F16A0176		71F16H1192		71F17B2249		71F16D1688		71F16C0604
	13F16A0255		71F16H2210		71F17C0503		71F16H0629		71F16C0861
	13F16B0144		71F16M0998	DE-17702-BGH	71F16B1813		71F16H2080		71F16D0378
	13F16C0009		71F17A0840		71F16C0530		71F16J0318		71F16E0247
	13F16C0193		71F17A1802		71F16H2118		71F16M0923		71F16E1185
	13F16D0189	CH-45854-H	71F16C0629		71F16L2072		71F17A0635		71F16E1853
	13F16G0238		71F16E0832		71F17C0891	DE-25703S-AG1	71F16C1436		71F16F1940
	13F16H0082		71F16F0387	DE-24701S-AG1	71F16C1773		71F16D0139		71F16G1341

Appendix 2 - EIF-000146

Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch	Product Code	Lot/Batch
EU-24041-HPMSB	71F16J0267	EU-25541-HPMSB	71F16E1176	IB-12853-GUC	71F16K1968	UK-00420-MID	71F15K0912	UK-05041-THT	71F16E1181
	71F16J0774		71F16H1316		71F16M1228		71F15K1645		71F16H1320
	71F16J1792		71F16J0788		71F17A1678		71F15L1262		71F16K1913
	71F16L1208		71F16J2222		71F17C1266		71F15M0090		71F17A1012
	71F16M1409		71F16K0184	IB-25855-HLP	71F16B1612		71F16A1175	UK-05052-MSB	71F16C0113
	71F17B0741		71F16K1907		71F16D0830		71F16B1474		71F16C1918
EU-24052-HPMSB	71F15K1666	EU-25552-HPMSB	71F16E1061		71F16F0809		71F16C1445		71F16D1165
	71F16C0115		71F16J1807		71F16F1114		71F16E1649		71F16E1103
	71F16C1916		71F16K0229		71F16G0141		71F16F0034		71F16M0466
	71F16D0960		71F16K0911		71F16J0174		71F16F1925		71F17A1490
	71F16E0180		71F16K1899		71F16K0992		71F16H0113	UK-05052-RDE1	71F16B1772
	71F16E1746		71F17A0769		71F16L1179		71F16J0789		71F16E1360
	71F16J1440	EU-25563-HPMSB	71F16D0987		71F16M0348		71F16J1791		71F16F1899
	71F16J1801		71F16F0976		71F17B0146		71F16M1457		71F16J1442
	71F16K0231		71F16K0485	IB-45703-HRH	71F16B0823		71F17A0308		71F16K0228
	71F16M1449	EU-45703-MSB	71F15L0096		71F16B1427		71F17A0765		71F17A1843
	71F17A0286		71F16A0648		71F16C2021		71F17B0751	UK-05063-MSB	71F16B2341
EU-24063-HPMSB	71F16B1161		71F16B0821		71F16E0483		71F17C0194		71F16E0906
	71F16D0988		71F16B1424		71F16E0659	UK-04041-RDE1	71F15L0264		71F16K0487
	71F16K0482		71F16B2176		71F16H0746		71F16B0712		71F16K1894
EU-25041-HPMSB	71F15K0924		71F16C2028		71F16M1006		71F16B1840		71F16M0384
	71F15K1643		71F16E0494		71F17A1804		71F16D0236	UK-22855-MSB	71F16D0168
	71F16B1500		71F16F0432		71F17C1259		71F16E1174		71F16E0204
	71F16C1116		71F16H0749	IB-45854-GUQ	71F16C0243		71F16J2347		71F16F0610
	71F16E0245		71F16H2205		71F16C1303		71F16L1737		71F16F1549
	71F16E1184		71F16J2251		71F16E0831		71F17A1491		71F16K1645
	71F16F1825		71F16M1003		71F16F0382	UK-04041-THT	71F15K1667		71F16M0996
	71F16G0712		71F17A0841		71F16F1553		71F16E1173		71F17A2333
	71F16H1314		71F17A1810		71F16G1296		71F16L1740	UK-25000-MSB	71F16B1948
	71F16J0782		71F17B0923		71F16J1428		71F17A1011		71F16D1703
	71F16J1793	EU-45854-MSB	71F16C0241		71F16L0177	UK-04052-RDE1	71F16D0952		71F16G1037
	71F16J2214		71F16C1305		71F16L0513		71F16E0909		71F16G1343
	71F16J2215		71F16E0830		71F17B0428		71F16J1805		71F16J0336
	71F16M0197		71F16F0390		71F17B0429		71F16L2081		71F16K1287
	71F17B0891		71F16L0174	IB-47702-HRH	71F16C2180	UK-05041-MSB	71F15K0928		71F16L0139
EU-25052-HPMSB	71F15K0927	EU-47702-MSB	71F15L1715		71F16F0821		71F15K1646		71F16L1083
	71F15K1655		71F16A1118		71F16G1297		71F16B1959		71F16L2107
	71F16B1775		71F16C2177		71F16K0071		71F16C1944		71F16M1465
	71F16C0110		71F16F0825		71F17A1498		71F16E1187		71F17A0854
	71F16C1913		71F16K1979		71F17A1499		71F16G1034		71F17B0823
	71F16D0950		71F16L1673	IE-42854-MRC	71F16L1848		71F16J0265		71F17C0050
	71F16E0179		71F17A1503	NL-25000-SLZ	71F16C1544		71F16J0771	UK-25004-ANHS	71F16C1748
	71F16E1398		71F17A1813		71F16D0603		71F16M0195		71F16E1175
	71F16F1828	GR-22122-FMSB	71F16D0868		71F16E1059		71F17B0893		71F16F0721
	71F16J1437		71F16F0979		71F16F1904	UK-05041-RDE1	71F16C0982		71F16G0428
	71F16J1803		71F16L2179		71F16J1482		71F16E0248	UK-25005-ANHS	71F16C1862
	71F16K0916		71F16D0419		71F16K1269		71F16E1180		71F16D0984
	71F16K1898		71F16H0188		71F16L1407		71F16F0709		71F16F0719
	71F16L1198		71F16L0797		71F16M0433		71F16J0779		71F16F2061
	71F16M1428	GR-25122-UFMSB	71F16J1478		71F16M1480		71F16J2348	UK-25006-ANHS	71F16C1749
	71F17A0305	GR-45703-MSB	71F16M1005		71F17A2038		71F16K1866		71F16F0717
	71F17A1833	GR-47702-MSB	71F16K1438		71F17B1192		71F16L0325	UK-25855-MSB	71F16M0349
EU-25063-HPMSB	71F16D0871	IB-12853-GUC	71F16E0018		71F17C0471		71F16L1202		71F16B1882
	71F16E0176		71F16E1688	TI-42854-MSB	71F17A2348		71F16M0383		71F16D1012
	71F16K0483		71F16F1423	UK-00320-MID	71F16B0415		71F17A0073		71F16E1655
EU-25541-HPMSB	71F15K1669		71F16G0387		71F17A0560		71F17A1495		71F16F0487
	71F16B1507		71F16H0934		71F17A1445		71F17C0293		71F16G1298
	71F16C1534		71F16J2232		71F17C0039	UK-05041-THT	71F15K1648		71F16G1441
									71F16K1890
									71F16K2076
									71F16L1064
									71F16L2166
									71F17B1274

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

URGENT PRODUCT ADVISORY NOTICE

December 29, 2016

Dear Customer:

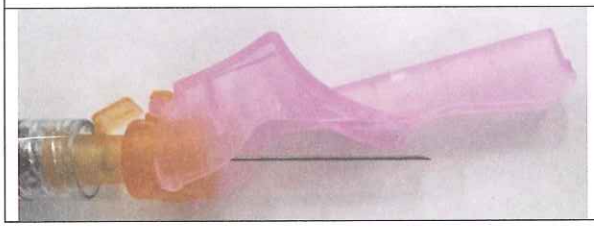
BD has received reports of safety cover disengagement and needlestick injury (NSI) for the **BD Eclipse™ Needle**. Based on the customer reports, in some cases when the safety cover is pushed over the needle it disengages, resulting in an exposed needle which can increase the risk of NSI.

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".

BD advises customers to be aware of this matter and follow the instructions for use (IFU) to:

> "Center 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. **Visually confirm** that the needle is covered when pushing the safety cover over the needle."

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

Un-Locked BD Eclipse™ Needle	Locked BD Eclipse™ Needle
	

BD is actively working on implementing corrective actions. This product advisory affects the BD Eclipse™ Needle included in the Catalog Numbers (Ref) listed on Attachment A: List of Potentially Affected Catalog Numbers. Please note that the product can continue to be used.

The BD Vacutainer® Eclipse™ Blood Collection Needle and BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle are not affected by this matter.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Distribute this communication to all users of the BD Eclipse™ Needle within your facility.
2. Complete the Business Response Card form and fax it back to BD at **1-877-650-5404** or email the completed form to **bd7609@stericycle.com**. Return of this form will acknowledge your receipt and understanding of this notification.

If you have any questions please contact **1- 877-650-7691** between 8AM and 5 PM ET Monday through Friday.

The safety and well-being of patients and healthcare workers is the primary objective for BD and we aim to ensure that only the highest quality product is used by our customers. We apologize for any inconvenience you may have experienced and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

Sincerely,

Bruce Culleton, MD
VP WW Med Affairs Med & Procedural Sol
BD Medical

Sergio Gadaleta, Ph.D.
Sr Vice President Regulatory Affairs
Medical Segment, BD Medical

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

Urgent Product Advisory Notice
BD Eclipse™ Needle

Attachment A: List of Potentially Affected BD Eclipse™ Catalog Numbers

Catalog (Ref) #	Product Description
305757	BD Eclipse™ Needle 30GX1/2
305758	BD Eclipse™ Needle 27GX1/2
305759	BD Eclipse™ Needle 25GX5/8
305761	BD Eclipse™ Needle 25GX1
305762	BD Eclipse™ Needle 23GX1
305763	BD Eclipse™ Needle 22GX1-1/2
305764	BD Eclipse™ Needle 21GX1 TW
305765	BD Eclipse™ Needle 21GX1-1/2 TW
305766	BD Eclipse™ Needle 18GX1-1/2
305767	BD Eclipse™ Needle 25GX1-1/2
305768	BD Eclipse™ Needle 22GX1
305769	BD Eclipse™ Needle 23GX1-1/4
305775	BD Eclipse™ 1ml S/T syringe with needle 30GX1/2
305776	BD Eclipse™ 1ml S/T syringe with needle 30GX1/2
305778	BD Eclipse™ 1ml LL syringe with needle 30Gx1/2
305779	BD Eclipse™ 3ml LL syringe with needle 21GX1 TW
305780	BD Eclipse™ 1ml LL syringe with needle 25GX5/8
305781	BD Eclipse™ 3ml LL syringe with needle 25GX5/8
305782	BD Eclipse™ 3ml LL syringe with needle 23GX1
305783	BD Eclipse™ 3ml LL syringe with needle22GX1-1/2
305784	BD Eclipse™ 3ml LL syringe with needle 21X1-1/2 TW
305785	BD Eclipse™ 5ml LL syringe with needle 22Gx1-1/2
305786	BD Eclipse™ 10ml LL syringe with needle 22GX1-1/2
305787	BD Eclipse™ 3ml LL syringe with needle 25GX1
305788	BD Eclipse™ 3ml LL syringe with needle 22GX1
305789	BD Eclipse™ 1ml LL syringe with needle 27X1/2
305790	BD Eclipse™ Needle 18GX1-1/2 BNS
305792	BD Eclipse™ Needle 21X1-1/2 TW BNS
305793	BD Eclipse™ Needle 22GX1-1/2 BNS
305794	BD Eclipse™ Needle 23X1 BNS
305795	BD Eclipse™ Needle 25GX1 BNS
305796	BD Eclipse™ Needle 25X1-1/2 BNS
305797	BD Eclipse™ Needle 22GX1 BNS
364389	BD Preset™ Eclipse™ syringe with needle 3ml (1.6) 22X1.25" CE
364390	BD Preset™ Eclipse™ syringe with needle 3ml (1.6) LL 22X1" CE
364391	BD Preset™ Eclipse™ syringe with needle 3ml (1.6) LL 23X1" CE
364393	BD Preset™ Eclipse™ syringe with needle 3ml (1.6) 25x5/8" CE

Event 7609 ID 55005023
ARROW INTERNATIONAL INC
B55005023-6561

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

Business Response Card
Urgent Product Advisory Notice
BD Eclipse™ Needle

PLEASE RETURN THIS FORM SO THAT WE MAY AKNOWLEDGE YOUR RECEIPT AND UNDERSTANDING OF THIS NOTIFICATION

Fax the completed form to BD at **1-877-650-5404** or email the completed form to **bd7609@stericycle.com**.

☐ **I have read and understood the attached notice.**
Name:
Title:
Signature/Date:

Company Name: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone No. _____