**URGENT: FIELD SAFETY NOTICE**

**MSS-16-837A-FA / MSS-16-837B-FA**

Medical Device Safety Advisory Notice

Date: <<insert date here>>

BD Eclipse™ Injection Needle, BD Eclipse™ Injection Needle with BD Luer-Lok™ Syringe and BD Preset™ Eclipse™ Arterial Blood Collection Syringe

**Note: The BD Vacutainer® Eclipse™ Blood Collection Needle and BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle are NOT affected by this matter.**

**For the Attention of:**

* Customers using BD Eclipse™ Injection Needles, BD Eclipse™ Injection Needles with BD syringes and customers using BD Preset™ Eclipse™ Arterial Blood Collection Syringes
* Procurement, Medical Director, Risk Manager, Head of Pharmacy, Medical Device Safety Officer, Respiratory Care Manager, Emergency Care Manager, Phlebotomy Manager

**Description of the problem:**

BD has received reports of safety cover/shield disengagement, which has the potential to lead to a needlestick injury (NSI) when using the BD Eclipse™ Injection Needle and BD Preset™ Eclipse™ Arterial Blood Collection Syringes. Based on the customer reports, in some cases when the safety cover/shield 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/shield is locked (activated) followed by a second “click” sound when the safety cover/shield is locked over the needle. This may potentially increase the risk of NSI if the user assumes the safety cover/shield is locked after the initial “click”.

BD advises customers using **BD Eclipse™ Injection Needles, BD Eclipse™ Injection Needles with BD syringes** 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.”

BD advises customers using the **BD Preset™ Eclipse™ Arterial Blood Collection Syringes** to follow the pictorials in the IFU which indicate that the shield should fully cover the used needle. An extract has been provided below:



The following pictures provide examples of how you would confirm whether the cover/shield is locked/engaged:

|  |  |
| --- | --- |
| **Un-Locked BD Eclipse™ Needle** | **Locked BD Eclipse™ Needle** |
|  |  |

**Potential hazard and potential risk to patients**

There is no risk to patients or users if the instruction for use is followed, the product can continue to be used. BD is actively working on implementing corrective actions.

**Details of affected devices**

This product advisory affects the BD devices listed below:

|  |  |
| --- | --- |
| **Catalogue Number** | **Description** |
| 305757 | BD Eclipse™ Needle 30GX1/2 |
| 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 |
| 305793 | BD Eclipse™ Needle 22GX1-1/2 BNS |
| 305795 | BD Eclipse™ Needle 25GX1 BNS |
| 364389 | BD Preset™ Eclipse™ Arterial Blood Collection Syringe 1.6 ml draw / 0.7x32mm (22G) |
| 364390 | BD Preset™ Eclipse™ Arterial Blood Collection Syringe 1.6 ml draw / 0.7x25mm (22G) |
| 364391 | BD Preset™ Eclipse™ Arterial Blood Collection Syringe 1.6 ml draw / 0.64x25 mm (23G) |
| 364393 | BD Preset™ Eclipse™ Arterial Blood Collection Syringe 1.6 ml draw / 0.5x16mm (25G) |

**Actions:**

Please complete and return the enclosed Acknowledgement Form by e-mail or fax to **add contact details**

**Transmission of this Field Safety Notice**

Please distribute this communication to all users of the BD Eclipse™ Injection Needles, BD Eclipse™ Injection Needles with BD syringes and BD Preset™ Eclipse™ Arterial Blood Collection Syringes.

**Contact Reference Person**

If you have any questions, or would like to discuss this issue further, please feel free to contact your local BD Account Manager **add contact details**

We confirm that the appropriate regulatory agencies have been informed of these actions.

Yours sincerely,



ppa. Dr. Bernd Peschke Lorna Darrock

Regulatory Compliance Manager Regulatory Affairs Manager
BD Medical EEMA BD Preanalytical Systems EEMA

**(Name & Signature of Local Contact)**

**ACKNOWLEDGEMENT FORM**

Please read in conjunction with Field Safety Notice MSS-016-837A-FA / MSS-16-837B-FA and return the form to insert appropriate e-mail address or by fax to: insert fax number as soon as possible or no later than the xxx

**□** I have read and understood this Field Safety Notice and have distributed the

 information to all possibly impacted departments within my organization.

|  |  |
| --- | --- |
| Organisation / Hospital / Clinic : |  |
| Department (*if applicable*) : |  |
| Address : |  |
| Postcode : |  | City : |  |
| Contact Name : |  |
| Job Title : |  |
| Contact Telephone Number : |  |
| Contact E-mail Address : |  |
| Signature : | Date : |

*This form must be returned to BD before this action can be considered closed for your account*