

URGENT: FIELD SAFETY NOTICE
MSS-16-837A-FA / MSS-16-837B-FA

Medical Device Safety Advisory Notice

Date: Friday 13th January

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, BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle and BD Eclipse™ with SmartSlip™ technology 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:

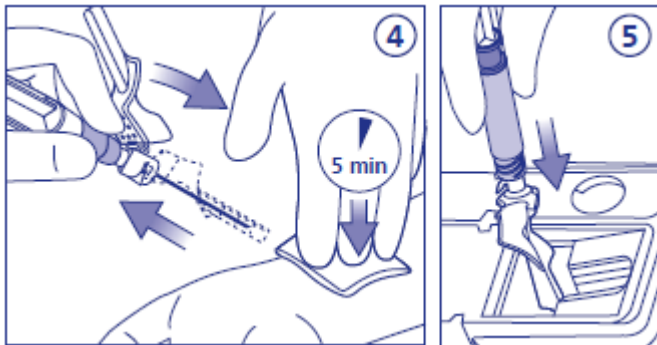
BD has received reports of safety cover/shield disengagement, which has the potential to lead to a needlestick injury (NSI) when using the BD Eclipse™ Injection Needle and BD Preset™ Eclipse™ Arterial Blood Collection Syringes. Based on the customer reports, in some cases when the safety cover/shield 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”.

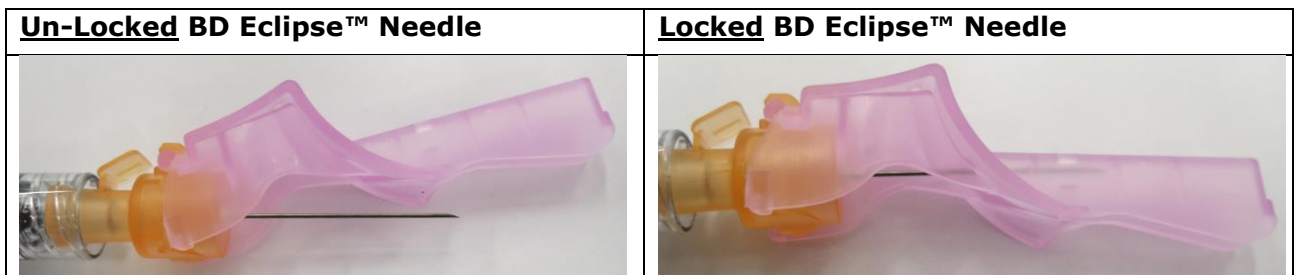
BD advises customers using **BD Eclipse™ Injection Needles, BD Eclipse™ Injection Needles with BD syringes** to be aware of this matter and follow the instructions for use (IFU) to:

“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:



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 needle 22GX1-1/2
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 jonathan.green@bd.com or 01865 781528.

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 or Jonathan Green at jonathan.green@bd.com

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

Yours sincerely,



ppa. Dr. Bernd Peschke
Regulatory Compliance Manager
BD Medical EEMA



Lorna Darrock
Regulatory Affairs Manager
BD Preanalytical Systems EEMA



Robert Navesey
Marketing Manager
BD Preanalytical Systems UK&I

ACKNOWLEDGEMENT FORM

Please read in conjunction with Field Safety Notice MSS-016-837A-FA / MSS-16-837B-FA and return the form to jonathan.green@bd.com or by fax to: 01865 781528 as soon as possible or no later than the **27th January 2017.**

- 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 (<i>if applicable</i>) :	
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