



URGENT PRODUCT ADVISORY NOTICE

09 January 2017

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

<u>Un-Locked</u> BD Eclipse™ Needle	<u>Locked</u> 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.

Advancing the world of health



YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Please fill in the attached form whether or not you have any inventory remaining so that we may acknowledge your receipt of this notification. Simply complete the attached form, sign and fax the completed form to your local BD contact.
2. We also request that you forward this notice to any other person or groups within your organization for whom this information may be relevant.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

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.

Sincerely,



Rose Kwong
Senior Regulatory Affairs & Compliance Executive



Urgent Product Advisory Notice
BD Eclipse™ Needle

bd.com

Attachment A: List of Potentially Affected BD Eclipse™ Catalog Numbers
Please note that the product can continue to be used.

Catalog (Ref) #	Product Description
302811	NEEDLE 30X1/2 LL ECLIPSE
302812	NEEDLE 27X1/2 LL ECLIPSE
302813	NEEDLE 25X1 LL ECLIPSE BR
302814	NEEDLE 23X1 LL ECLIPSE BR
302815	NEEDLE 21X1 LL ECLIPSE
302816	NEEDLE 18X1-1/2 LL ECLIPSE
302817	NEEDLE 21X1 LL ECLIPSE
302818	NEEDLE 22X1 LL ECLIPSE BR
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 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
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

Advancing the world of health



Catalog (Ref) #	Product Description
305790	BD Eclipse™ Needle 18GX1-1/2 BNS
305791	BD Eclipse™ Needle 21GX1 TW 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
365059	BD Preset™ Eclipse™ syringe with needle 3ml (1.6) LL 23X1" BZ
365061	BD Preset™ Eclipse™ syringe with needle 3ml (1.6) LL 22X1" BZ
30281864	NEEDLE 22X1 LL ECLIPSE NS
30281364	NEEDLE 25X1 LL ECLIPSE
30281464	NEEDLE 23X1 LL ECLIPSE
30281564	NEEDLE 21X1 LL ECLIPSE
30281664	NEEDLE 18X1-1/2 LL ECLIPSE
30281764	NEEDLE 21X1-1/2 LL ECLIPSE
30281864	NEEDLE 22X1 LL ECLIPSE



**Urgent Product Advisory Notice
(CUSTOMER ACKNOWLEDGEMENT)**

BD Eclipse™ Needle

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact.

I confirmed that I have read and understood the Urgent Product Advisory Notice dated 09 January 2017, regarding the above BD product.

Other comments:

Completed by:

Name: _____ **Signature/Date:** _____

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

Telephone No.: _____ **Fax No.:** _____

Company stamp: