

URGENT PRODUCT ADVISORY NOTICE

December 29, 2016

Dear Customer:



BD has received reports of safety cover disengagement and needlestick injury (NSI) for the **BO 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- 76 91** 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.



Sincerely,

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**Urgent Product Advisory Notice
BD Eclipse™ Needle**

Attachment A: List of Potentially Affected BD Eclipse™ Catalog Number s

Catalog (Refl#)	Product Description
305757	BO Eclipse™ Needle 30GX1/2
305758	BO Eclipse™ Needle 27GX1/2
305759	BO Eclipse™ Needle 25GX5/8
305761	BO Eclipse™ Needle 25GX1
305762	BO Eclipse™ Needle 23GX1
305763	BO Eclipse™ Needle 22GX1-1/2
305764	BO Eclipse™ Needle 21GX1 TW
305765	BO Eclipse™ Needle 21GX1-1/2 TW
305766	BO Eclipse™ Needle 18GX1-1/2
305767	BO Eclipse™ Needle 25GX1-1/2
305768	BO Eclipse™ Needle 22GX1
305769	BO Eclipse™ Needle 23GX1-1/4
305775	BO Eclipse™ 1ml SIT syringe with needle 30GX1/2
305776	BO Eclipse™ 1ml SIT syringe with needle 30GX1/2
305778	BO Eclipse™ 1ml LL syringe with needle 30GX1/2
305779	BO Eclipse™ 3ml LL syringe with needle 21GX1 TW
305780	BO Eclipse™ 1ml LL syringe with needle 25GX5/8
305781	BO 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	BO 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	BO Preset™ Eclipse™ syringe with needle 3ml (1.6) 22X1.25" CE
364390	BO Preset™ Eclipse™ syringe with needle 3ml (1.6) LL 22X1" CE
364391	BO 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 rNC

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1st Ion 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 .

D <u>I have read and understood the attached notice.</u>
Name:
Title:
Signature/ Date:

Company Name: - - - - -
Address: - - - - -
City: - - - - - State: ____ - Zip Code: - - - - -
Phone No. _ _ - - - - -