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,

[redacted]

[redacted]

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. _____

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."

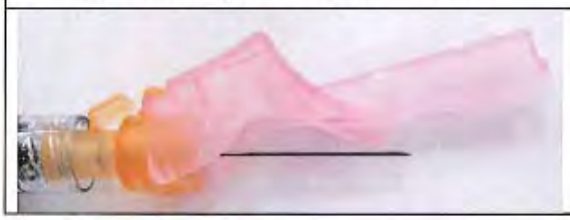
Un-Locked BD Eclipse™ Needle	Locked BD Eclipse™ Needle
	

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: Herr Horst Erbe
Telephone: 07151/406-431
FAX: +49 7151/406-566
E-mail: horst.erbe@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.

[redacted]
International,

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 : +49 7151/406-566 **E-mail :** horst.erbe@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	