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."

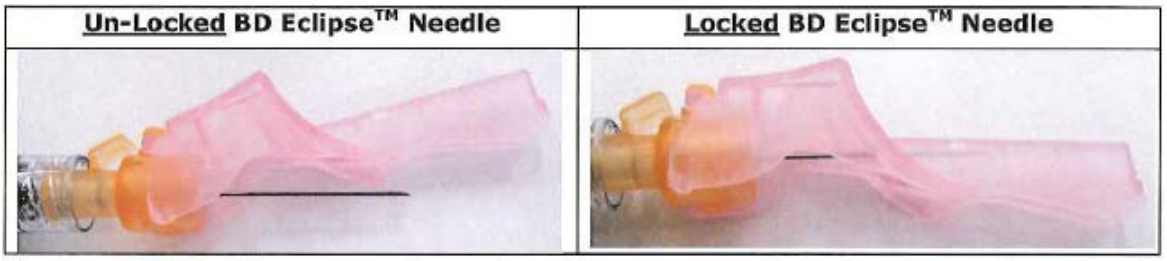

Figure 1: Examples of visual confirmation of un-locked and locked BD Eclipse™ Needle.

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: Debbie Kooiman/Gernel De Boer
Telephone: 088 00 215 00
FAX: 088 00 215 00
E-mail: orders.nl@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.

For and on behalf of Arrow 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 : 088 00 215 10 **E-mail :** order.nl@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	