Urgent Medical Device Corrective Notice

Do Not Allow Alcohol-based Solutions to contact Introducer Needles when utilizing Arrow Kits

Arrow® Kits and Sets with Introducer Needles
EIF-000468-01

February 2022

To: Customer of Arrow Kits and Sets with Introducer Needles

IMPORTANT – Please send a copy of this notification to the following personnel in your organization at a minimum: Anesthesiology Department, Intensive Care Departments (Adult, Pediatric, Neonatal), Critical Care Department, Emergency Department, Coronary Care Unit, Vascular Access Service, Operating Room/Service, Surgical Department, Resident Training Department.

Device: Arrow® Kits and Sets with Introducer Needles

Scope: Teleflex and its subsidiary Arrow International are issuing this advisory notice for kits and sets with introducer needles.

Issue: Cracked Introducer Needle

Summary of Issue: Teleflex has received complaints reporting that the introducer needle hub in some Arrow® kits crack under stress during the catheterization procedure. Teleflex has identified the following practices that may increase the risk of cracking, including

1) Needle hub contact with wet cutaneous antisepsis alcohol–based solution (i.e.: CBA in combination with octenidine)
2) pouring of alcohol–based solution (i.e.: CBA/octenidine solution) over the gloves of the clinician performing the device insertion
3) using alcohol-based antiseptic solutions (i.e.: CBA/octenidine solution) in place of ultrasound gel
4) application of CBA in combination with octenidine through a spray bottle resulting in direct contact of the antiseptic and needle hub

These clinical practices, combined with a lack of adequate drying time, may overexpose the needle hub to alcohol-based antiseptic solutions such as CBA/octenidine solution. If the needle hub is saturated with an antiseptic solution, it may weaken. A weakened needle combined with the standard insertion method which requires pressure to be placed on the needle may result in a cracked needle hub.

If a cracked needle hub is not detected prior to use, the clinician may experience false signs of a possible insertion related pneumothorax. In addition, the clinician may not be able to aspirate a flashback of blood during needle introduction.

Teleflex does not recommend use of an alcohol-based antiseptic solution in place of an approved ultrasound gel for invasive procedures. Additionally, Teleflex advises following good clinical practice for skin antisepsis, which includes sufficient **dry** time (i.e., three minutes or more) for the skin antisepsis **prior** to needle insertion.

Customer Action:

Our records indicate you have received product that is subject to this advisory.

1. Send a copy of this notice to the following personnel within your organization at a minimum: Anesthesiology Department, Intensive Care Departments (Adult, Pediatric, Neonatal), Critical Care Department, Emergency Department, Coronary Care Unit, Vascular Access Service, Operating Room/Service, Surgical Department, Resident Training Department.
2. Place a copy of this notice with all Arrow® Kits and Sets with Introducer Needles to ensure all clinicians are aware of the identified risk.
3. Please direct clinical education and product support questions to clinical.affairs.emea@teleflex.com
4. Acknowledge receipt of this Urgent Medical Device Notice complete the enclosed Acknowledgement Form (Appendix 1) and fax it to 0711 / 49 05 08 71, Attn: Customer Service or email to recalls.de@teleflex.com.

Note: This Urgent Medical Device Corrective notice revises. a Field Safety Corrective Action notice circulated in a letter in Q2 2021. Additional clinical information has guided the revision to that letter. Regardless of previous response issued, please complete the acknowledgement form to ensure this action has been implemented at your facility.

Relevant countries: Based on the origin of the reported complaints and the clinical practices identified, this Urgent Medical Device Corrective notice is being sent to customers in Germany and Austria only.

Containment: Corrective actions are being implemented at the manufacturing facility to reduce the risk of cracking when the needle is exposed to alcohol-based solutions.

Teleflex and Arrow International are committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause you.

For and on behalf of Teleflex and Arrow International,

[redacted]

Appendix 1

Customer No

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000468-01

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: 0711 / 49 05 06 08 **E-mail:** recalls.de@teleflex.com

☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action.

Complete this Acknowledgement Form and return immediately by using 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	