Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

15.03.2011

URGENT
FIELD SAFETY NOTICE

Commercial Name of Affected Product:	Super Arrow-Flex(R) Percutaneous Sheath Introducer Set with Integral Hemostasis Valve/ Si Port
Type of action:	Market Withdrawal
Part No:CL-07635 **Lot No**: CF0061539	

Dear Customer,

1. Details of affected devices

Teleflex Medical, through its subsidiary Arrow International, Inc. ("Arrow") has issued a voluntary Field Action for products in the attachment.

2. Description of the problem

We have received complaints that one side of the pouch seal was not properly sealed. Therefore, the packaging may have been compromised, and sterility of the product cannot be guaranteed. If non-sterile product is used, there is a potential for infection to occur.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

Advice on action to be taken by Medical Staff

1. We request that you check stock for product within the scope of this field action. Users should cease use and distribution of stock from the affected lot number and quarantine all products from the affected lot number immediately.

2. If you have no stock from the affected lot number, please indicate so on the 'field safety corrective action acknowledgement and stock status form' and fax to your local Teleflex Medical Customer Service/Sales Rep as indicated on the 'field safety corrective action acknowledgement and stock status form' (Appendix 1)

3. If you do have stock from the affected lot number, please contact your local Teleflex Medical Customer Service/Sales Rep (or Distributor) as indicated on the attached 'field safety corrective action acknowledgement and stock status form' for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the enclosed 'field safety corrective action acknowledgement and stock status form'

4. Complete the enclosed 'field safety corrective action acknowledgement and stock status form' providing detail on stock from the affected lot number under your control within the scope of this Field Safety Action and immediately email the completed form to **orders.uk@teleflexmedical.com** This will allow us to document your receipt of this letter and the amount of product you have on hand for return.

5. Your local Teleflex Medical Customer Service/Sales Rep (or Distributor) will coordinate the product return with you.

6. Teleflex Medical Customer Service can credit your account when the product is returned.

Instruction for Distributors of affected product

If you are a distributor, Teleflex Medical requires that you communicate this field safety corrective action notice to your customers who received product within the scope of this field safety corrective action by providing:

- A copy of this Field Safety Notice to them.
- A copy of the 'field safety corrective action acknowledgement and stock status form' (Appendix 1)

The 'field safety corrective action acknowledgement and stock status form' is required to be completed in its entirety, signed and returned to you (the Distributor).

As a Distributor, it is your responsibility to provide Teleflex Medical with confirmation that all of your consignees have been contacted under this field safety corrective action. Please forward the completed Acknowledgement Form to **orders.uk@teleflexmedical.com or by fax on 01494 524 650**

Please be advised that all affected European Economic Area/Switzerland (EEA/CH) Member State Competent Authorities will be notified by Teleflex Medical where we have distributed product directly. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH area please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex Medical.

4. Teleflex Medical

Teleflex Medical is notifying any potentially affected Customers, Teleflex Medical employees and Distributors of this Field Safety Notice.

5. Transmission of this Field Safety Notice

This notice should be passed on all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

6. Contact reference person

Should you require any further information or support concerning this issue, please contact:

For Customer Service
Hélène Sauvage
Email: orders.uk@teleflexmedical.com
Fax: 01494 524 650
Phone: 01494 532 761

For Product Specific Queries:
Joanna Bryant on 07423 452378

This field safety corrective action is voluntary and all affected competent authorities have been advised of this Field Safety Corrective Action.

Teleflex Medical 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 at **orders.uk@teleflexmedical.com**

Signed by:

[redacted]
VP Quality Assurance & Regulatory Affairs, EMEA
Attachments as follows: Appendix 1 :'field safety corrective action acknowledgement and stock status form'

Appendix 1

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT AND STOCK STATUS FORM

Medical Device Field Safety Corrective Action Concerning Teleflex Medical, through its subsidiary Arrow International, Inc. ("Arrow") Products

Immediate Attention Required

RETURN COMPLETED FORM IMMEDIATELY TO: orders.uk@teleflexmedical.com or by fax on 01494 524 650

☐ We have no inventory of stock from the affected lot number within the scope of this Field Action.	☐ We have the following affected stock from the affected lot number at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities. ☐ Please credit our account once you have received the returns

Please print product numbers clearly.

Product	**Super Arrow-Flex(R) Percutaneous Sheath Introducer Set with Integral Hemostasis Valve/ Side Port (no seal)**	
Product Number	**Lot Number**	**Quantity (unit)**
CL-07635	**CF0061539**	

Print Name/Title _____ Date _____

Signature _____ Telephone Number _____

Institution Name _____

Address _____

City, State, Zip Code _____

Return Authorisation No _____

Customer No _____