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

3rd November 2016

URGENT FIELD SAFETY NOTICE

Commercial Name of Affected Product:		ARROW ® OnControl® Bone Lesion Biopsy System Tray ARROW® OnControl® Aspiration System Tray ARROW® OnControl® Bone Lesion Biopsy System Tray ARROW® OnControl® Bone Lesion Biopsy System Trays ARROW® OnControl® Bone Marrow Biopsy System Comprehensive Tray ARROW® OnControl® Bone Marrow Biopsy System Tray ARROW® OnControl® Ported Aspiration System Tray ARROW® OnControl® System Sterile Procedure Tray OnControl® Biopsy System Ported Needle Tray			
Type of action:		**Recall**			
Teleflex Reference:		**EIF-000084**			
Product Code	**Lot/Batch**	**Product Code**	**Lot/Batch**	**Product Code**	**Lot/Batch**
9403-EU-006	**Refer to Appendix 2**	9461-VC-006	**Refer to Appendix 2**	9464-VC-006	**Refer to Appendix 2**
9403-VC-006		9462-EU-001		9465-VC-001	
9408-EU-006		9462-VC-001		9465-VC-006	
9408-VC-006		9462-VC-006		9466-EU-001	
9411-EU-006		9463-EU-001		9466-VC-001	
9411-VC-006		9463-VC-001		9466-VC-006	
9451-VC-006		9463-VC-006		9470-VC-006	
9458-VC-006		9464-EU-001		9471-VC-006	
9461-VC-001		9464-VC-001		9472-VC-006	

Dear Customer,

Details of affected devices
Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed products.

Description of the problem
Teleflex is recalling this product due to a potential incomplete seal on the outer sterile package. Because of the compromised packaging, the sterility of the inside drape, which is used in preparation for bone marrow aspiration with the OnControl system, cannot be guaranteed. If sterility of the drape is compromised, there is a potential for infection to occur.

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of affected product and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table, then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail address mentioned there.

3. If you have stock from the affected product, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned below, who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to the fax number below or provide a completed copy to your local Sales Representative.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. Immediately discontinue distribution and quarantine any products with the catalog and lot number listed above.
2. Using the provided customer letter and Recall Acknowledgement Form templates, communicate this recall to any of your customers who have received product included within the scope of the recall.
3. Have the customers return any affected product to you, together with a completed Recall Acknowledgement Form, for consolidation and return to Teleflex. In the event that an alternative approach is needed, contact Teleflex Customer Service for more information.
4. To return product, complete the enclosed Recall Acknowledgement Form and email or fax it to the contact listed on this notice. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) Number and will provide instructions for the return of product to Teleflex Medical.
5. If you and your customers have no affected stock, please complete the enclosed Recall Acknowledgment Form and email or fax it to the contact listed on this notice. This will allow us to document your receipt of this letter.
6. Once you have completed returning all of the recalled products from your own inventory, and collecting and consolidating all of the recalled products from your customers, please check the box on the enclosed Recall Acknowledgment Form that indicates that you have completed the recall and email or fax it to the contact listed on this notice. This will allow us to document completion of the recall.
7. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
8. 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 Teleflex.

Teleflex
Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

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. 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: Shane Kenny
Telephone: +353 (0)906460869
FAX: +353 (0)1 4370773
E-mail: Recalls.intl@teleflex.com

Teleflex 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 Teleflex,

Karen Boylan

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Karen Boylan - VP, Global RA/QA

Teleflex®

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref. EIF-000084

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +353 (0)1 4370773 **E-mail**: Recalls.intl@teleflex.com

Please check applicable box:

☐ We confirm receipt of this FSN and 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 completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action. The use and further distribution of the affected products has been stopped. All products are on hold and the quantity stated below will be returned. **Return Authorisation No _____**

Please CLEARLY print the below return information

Name of Affected Products	ARROW ® OnControl® Bone Lesion Biopsy System Tray ARROW® OnControl® Aspiration System Tray ARROW® OnControl® Bone Lesion Biopsy System Tray ARROW® OnControl® Bone Lesion Biopsy System Trays ARROW® OnControl® Bone Marrow Biopsy System Comprehensive Tray ARROW® OnControl® Bone Marrow Biopsy System Tray ARROW® OnControl® Ported Aspiration System Tray ARROW® OnControl® System Sterile Procedure Tray OnControl® Biopsy System Ported Needle Tray	
Product Number	**Lot Number**	**Quantity (Returning)**

Return Instructions:

- Please label product returns as “Field Action Returns”.
- Include a copy of this form (including RAN Number) with product returns.

Returns excluding ALL necessary documentation CANNOT be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	**Email Address:**
	Phone Number:
Form completed by:	
Print Name:	**Institution Stamp:**
Signature:	
Date:	