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

7th 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: Herr Horst Erbe
Fax: +49 7151 / 406-566
Telephone: 07151 / 406 – 431
e-mail: horst.erbe@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,

[redacted]

Teleflex®

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref. EIF-000084

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +49 7151 /406-566 E-mail: horste.erbe@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:	

Appendix 2 - EIF-000084

Product Code	Lot/Batch
9403-EU-006	010742 011231 011942 013606
9403-VC-006	010848 011230 011587 012101 012348 012697 013245 013888 014127 014208 014407
9408-EU-006	010740 010948 011049 011377 011588 012117 012961 013054 013476 014124 014137 014167 014233 014424 014455 014701
9408-VC-006	010438 010439 010556 010557 010737 010738 010739 010946 010947 011037 011046 011047 011048 011215 011216 011217 011380 011381 011383 011384 011385 011675 011676 011945 011946 011947 012139 012140 012141 012142 012353 012354 012355 012356 012463 012464 012465 012570 012572 012573 012686 012687 012688 012895 012896 013074 013084 013085 013122 013185 013255 013256
9408-VC-006	013257 013258 013477 013478 013688 013894 013895 013896 013897 014111 014112 014113 014114 014115 014134 014135 014136 014199 014200 014201 014202 014306 014307 014308 014420 014422 014423 014569 014570 014571 014703 014805
9411-EU-006	010741 010950 011376 012116 012960 013051 013687 014311 014454
9411-VC-006	010440 010559 010949 011052 011218 011374 011386 011720 011948 012352 012459 012578 012689 012894
9411-VC-006	013060 013246 013468 013509 013689 013891 014121 014139 014168 014197 014203 014310 014425 014617
9451-VC-006	010183 010560 010780 010951 010972 011042 011050 011348 011382 011583 011709 011952 012343 012568
9451-VC-006	012690 013071 013247 013470 013692 013735 013898 014125 014138 014232 014312 014565
9458-VC-006	010561 010562 010723 010781 010782 010817 010872 010893 010952 010953 010964 010969 010977 011039 011040 011041 011060 011061 011223 011378 011379 011555 011556 011557 011710 011711 011712 011949 011950 011951 012143 012144 012145 012146 012344 012345 012346 012460 012461 012462 012575 012576 012577 012691 012692 012693 012897 012898 013072 013086 013248 013249 013250 013471 013472 013473 013694 013695 013696 013734 013904 013905 013906 013907 014116 014117 014118 014119 014129 014130 014131
9458-VC-006	014132 014193 014194 014195 014196 014313 014314 014315 014402 014404 014405 014406 014607 014608 014609
9461-VC-001	012579S 013469S
9461-VC-006	011227 011492 011938 012694 013065 013686 014615
9462-EU-001	010894S 011715S 012458 013244S 013685S 013690S 014166S 014205S 014623S 014627S
9462-VC-001	010743S 010778S 010954S 012580S 012891S
9462-VC-006	010743 010778 010954 011495 011545 011582 011714 012130 012581 013251 013860 013893 014128 014316
9463-EU-001	010895S 011449S 013050S 014165S 014206S 014318S 014426S 014626S
9463-VC-001	010331S 010955S 011716S 012133S 013066S
9463-VC-006	010331 010955 011513 011584 011717 011834 012131 012349 013070 013474 013890 013899 014230 014317 014616
9464-EU-001	010896S 011450S
9464-EU-001	012134S 013008S 013067S 013475S 013510S 013601S 013691S 014320S 014563S 014809S
9464-VC-001	010744S 010956S 011718S 012135S 012695S 013262S
9464-VC-006	010744 010956 011051 011491 011590 011719 011939 012136 012350 012696 012778 013252 013902 014025 014120 014231 014319 014453 014618
9465-VC-001	010957S 011940S 014321S
9465-VC-006	010957 011496 011941 012137 012351 013286 013901 014322
9466-EU-001	010897S 011451S 013049S 013846S 013892S 014164S 014207S 014430S 014624S
9466-VC-001	010844S 010958S 011722S 012685S
9466-VC-006	010844 010958 011512 011544 011589 011723 012129 012466 013887 014123 014209 014323
9470-VC-006	010859 011511
9471-VC-006	013107 013260 013889 014126 014324
9472-VC-006	013108 013261