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

12th October 2017

URGENT - FIELD SAFETY NOTICE

Commercial Name	WECK® Auto Endo5® Automatic Hem-o-lok® Clip Appliers
Teleflex Reference:	EIF-000189
Type of Action	Recall
Product code	Lot/Batch
AE05ML	Refer to Appendix 2

Dear Customer,

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

Description of the problem
The products referenced above are surgical clip appliers that are preloaded for use in minimally invasive surgical procedures. Teleflex is recalling these devices because they have a nonconformity that may cause clips to misload, jam, or fall out of the applier. There could be a delay in procedure if an applier becomes jammed or if a clip falls out of an applier.

Our records indicate that you have received product that is subject to this recall. We are now notifying our customers to take the following actions:

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 the affected product batch 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 below.

3. If you have stock from the affected product as referred to in above table, 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 Customer Service.

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. 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. Your customer is then required to complete the acknowledgement form and return this to you.

2. As a Distributor, you are required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.

3. 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.

4. 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 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: Shane Kenny
FAX:+353 (0) 1 4370773
Telephone: +353 (0)90 6460869
Email: Recalls.Intl@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause you or your patients. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex,

Padraig Hegarty VP, QA

Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000189

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 (0) 1 4370773 **Email:** Recalls.Intl@teleflex.com

☐ 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 is stopped. All products are put on hold and the amount below will be returned. **Return Authorisation No _____**

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	**WECK® Auto Endo5® Automatic Hem-o-lok® Clip Appliers**	
PRODUCT NUMBER	**LOT NUMBER**	**QUANTITY (Returning)**

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package.
- Please label returns as "**Field Action Returns"**

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	

EIF-000189

Appendix 2 – WECK® Auto Endo5® Automatic Hem-o-lok® Clip Appliers Recall

Product Code	Lot Number	Product Code	Lot Number
AE05ML	73A1700701	AE05ML	73H1600582
	73B1700183		73H1600583
	73B1700567		73H1600663
	73C1600069		73H1600664
	73C1600070		73H1600665
	73C1600071		73H1600666
	73C1700288		73H1600667
	73C1700289		73H1600668
	73C1700290		73J1600135
	73C1700292		73J1600136
	73C1700300		73J1600137
	73F1600036		73J1600138
	73F1600037		73J1600139
	73F1600038		73J1600414
	73F1600039		73J1600415
	73F1600040		73J1600416
	73F1600689		73K1600118
	73F1600690		73K1600457
	73F1600691		73K1600458
	73F1600692		73K1600497
	73F1600693		73K1600514
	73F1600694		73K1600614
	73G1600151		73L1600528
	73G1600431		73L1600529
	73G1600432		73L1600530
	73G1600716		73L1600531
	73G1600717		73L1600532
	73H1500014		73L1600563
	73H1500015		73M1600200
	73H1500016		73M1600201
	73H1600173		73M1600202
	73H1600174		73M1600279