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

12th Feb 2016

URGENT - FIELD SAFETY NOTICE

Type of Action	Recall	
Teleflex Reference:	EIF-000012	
WECK® AutoEndo5® Hem-o-lok® 5mm Automatic Endoscopic Hem-o-lok Applier		
Commercial Name	**Material**	**Batch**
Hem-o-lok Auto Endo5 Medium Large Ligating Clip Applier	543965 WK543965	73J1500065 73J1500066 73J1500280 73J1500440 73J1500565 73J1500566 73K1500193

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 Medical is recalling this product due to the possibility that a clip in the applier may be missing a boss. A boss is the part of the clip that is used to hold the clip within the applier jaws prior to application. If a clip is missing a boss, it may not hold securely within the applier jaws, and the surgeon will be unable to close the clip. Instead, the surgeon will need to advance to the next clip in order to accomplish ligation. The product Instructions For Use (IFU) cautions the user as follows: "After clip loading, always confirm that the clip remains in the applier jaws."

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: Hélène Sauvage **Telephone:** +44 (0)1494 532761
FAX: +44 (0)1494 524650 **E-mail**: orders.uk@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 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]

_____

Padraig Hegarty
VP, QA

Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000012

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +44 (0)1494 524650 **E-mail**: orders.uk@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® AutoEndo5® Hem-o-lok® 5mm Automatic Endoscopic Hem-o-lok Applier	
PRODUCT NUMBER	**LOT NUMBER**	**QUANTITY**

- 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	