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

May-2023

URGENT – FIELD SAFETY NOTICE

Type of Action	**Recall**				
Teleflex Reference	EIF-000535				
Product Name	HORIZON® Microclip™ Titanium Ligating Clips w/tape				
Product Code	**Lot Numbers**				
005200	73A2200857	73A2300018	73A2300176	73A2300326	73A2300520
	73A2300778	73D2200216	73D2200559	73E2200634	73E2200874
	73E2201099	73F2200193	73F2200200	73F2200482	73F2200711
	73G2200168	73G2200345	73G2200560	73G2200754	73H2200115
	73H2200294	73H2200433	73H2200453	73J2200747	73J2200763
	73K2200014	73K2200095	73K2200101	73K2200299	73K2200566
	73K2200713	73L2200064	73L2200066	73L2200323	73L2200448
	73L2200717	73L2200902	73M2200129	73M2200367	

Note: Reference **Appendix 2 for Unique Device Identifier (UDI) information**

Dear Customer,

Details of affected devices
Teleflex Medical Europe Limited has initiated a voluntary Field Safety Corrective Action ("FSCA") for the above listed products; refer to Appendix 2 for Unique Device Identifier ("UDI").

Description of the problem & immediate actions required
Teleflex Medical Europe Limited is initiating this voluntary FSCA for the above-listed products because the clip cartridges for the affected product is missing a key feature that restricts the application of the clip to the applier. With this step feature missing on the cartridge, the clip is mounted in a more variable position, allowing the clips to load farther back in the clip applier jaw grooves. This may potentially result in inappropriate or inadequate clip application to vascular structures. Additionally, this introduces a further risk to the patient whereby the tips of the applier may project further past the tissue to be ligated, potentially risking injury to other distal anatomical structures.

As of 05-April-2023, 2 complaints reporting difficulty loading clips have been received for products in scope of this field correction. 1 complaint has been received for the identified missing feature on the clip cartridge.

No patient injuries have been reported at this time.

Our records indicate you have received products that are subject to this FSCA.

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	**1**
Distributors	**2**

Action list number 1 – Medical facilities

1. We request that you immediately check your inventory for product within the scope of this FSCA. Users should cease use and distribution of affected product and immediately quarantine the affected product.
2. If you have impacted product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and contact Teleflex Customer Service by calling the phone number provided below. Teleflex Customer Service will issue a Return Goods Authorisation (RGA) number to you. Write the (RGA) number into the respective field in the Acknowledgement Form and promptly return this form to the e-mail address below.
3. If you do not have impacted product, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and return the form to Teleflex at the contact details provided.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received impacted product. Each of your customers is then required to complete the Acknowledgement Form and return it to you.
2. We request that you immediately check your inventory for impacted product. Cease use and distribution of impacted product and immediately quarantine the affected product. You may then return all product in scope.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined in actions 1 and 2 of this Action List Number 2. Upon completion of your actions, please forward the completed Acknowledgement Form to the e-mail address below. **Important** - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.
4. Please be aware that all European Economic Area/Switzerland, United Kingdom (EEA/CH/UK) and Turkey (TR) Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
5. If you have further distributed product outside of your country, please notify Teleflex Customer Service by return e-mail to the e-mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/UK/TR area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Customer Service at the contact information below.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation 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. Please 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)86 3479154
Email: Recalls.Intl@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We regret any inconvenience this action may cause your operations. If you have any other questions, please contact your local Teleflex sales representative or Teleflex Customer Service.

The undersign confirms this notice has been notified to the appropriate Regulatory Authority.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, Global QA (Manufacturing)

Teleflex

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000535

RETURN COMPLETED FORM IMMEDIATELY TO:

E-mail: Recalls.Intl@teleflex.com

☐ We confirm receipt of this FSN and completion of the required actions contained therein. We further confirm that our inventory does **NOT** include products impacted by this Field Action.	☐ We confirm receipt of this FSN and completion of the required actions contained therein. We further confirm our inventory **DOES** include products impacted 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 Goods Authorisation No** _____

Complete this Acknowledgement Form and return the completed form immediately using the contact information above.

Product code	Lot/batch number	Quantity returning
Important - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.		

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

Note: Non-FSCA product returns should be processed per standard product return processes.

INSTITUTION NAME (E.G., NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**PHONE/FAX/E-MAIL**
FORM COMPLETED BY	**STAMP**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

Appendix 2: EIF-000535 - Product code / Lot Number / Unique Device Identifier (UDI)

Product Code	Lot Number	Unique Device Identifier (UDI)
005200	73A2200857	(01)24026704696394(17)270131(11)220201(10)73A2200857
	73A2300018	(01)24026704696394(17)280102(11)230103(10)73A2300018
	73A2300176	(01)24026704696394(17)280103(11)230104(10)73A2300176
	73A2300326	(01)24026704696394(17)280108(11)230111(10)73A2300326
	73A2300520	(01)24026704696394(17)280116(11)230117(10)73A2300520
	73A2300778	(01)24026704696394(17)280123(11)230124(10)73A2300778
	73D2200216	(01)24026704696394(17)270407(11)220408(10)73D2200216
	73D2200559	(01)24026704696394(17)270418(11)220419(10)73D2200559
	73E2200634	(01)24026704696394(17)270516(11)220517(10)73E2200634
	73E2200874	(01)24026704696394(17)270523(11)220524(10)73E2200874
	73E2201099	(01)24026704696394(17)270530(11)220531(10)73E2201099
	73F2200193	(01)24026704696394(17)270605(11)220606(10)73F2200193
	73F2200200	(01)24026704696394(17)270606(11)220607(10)73F2200200
	73F2200482	(01)24026704696394(17)270613(11)220614(10)73F2200482
	73F2200711	(01)24026704696394(17)270620(11)220621(10)73F2200711
	73G2200168	(01)24026704696394(17)270704(11)220705(10)73G2200168
	73G2200345	(01)24026704696394(17)270710(11)220711(10)73G2200345
	73G2200560	(01)24026704696394(17)270717(11)220718(10)73G2200560
	73G2200754	(01)24026704696394(17)270724(11)220725(10)73G2200754
	73H2200115	(01)24026704696394(17)270801(11)220802(10)73H2200115
	73H2200294	(01)24026704696394(17)270808(11)220809(10)73H2200294
	73H2200433	(01)24026704696394(17)270815(11)220816(10)73H2200433
	73H2200453	(01)24026704696394(17)270815(11)220816(10)73H2200453
	73J2200747	(01)24026704696394(17)270926(11)220927(10)73J2200747
	73J2200763	(01)24026704696394(17)270926(11)220927(10)73J2200763
	73K2200014	(01)24026704696394(17)271002(11)221003(10)73K2200014
	73K2200095	(01)24026704696394(17)271003(11)221004(10)73K2200095
	73K2200101	(01)24026704696394(17)271003(11)221004(10)73K2200101
	73K2200299	(01)24026704696394(17)271009(11)221010(10)73K2200299
	73K2200566	(01)24026704696394(17)271017(11)221018(10)73K2200566
	73K2200713	(01)24026704696394(17)271023(11)221024(10)73K2200713
	73L2200064	(01)24026704696394(17)271031(11)221101(10)73L2200064
	73L2200066	(01)24026704696394(17)271031(11)221101(10)73L2200066
	73L2200323	(01)24026704696394(17)271107(11)221108(10)73L2200323
	73L2200448	(01)24026704696394(17)271113(11)221122(10)73L2200448
	73L2200717	(01)24026704696394(17)271121(11)221128(10)73L2200717
	73L2200902	(01)24026704696394(17)271127(11)221205(10)73L2200902
	73M2200129	(01)24026704696394(17)271204(11)221215(10)73M2200129
	73M2200367	(01)24026704696394(17)271212(11)221213(10)73M2200367

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