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

December-2022

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall - Removal				
Teleflex Reference	HRA00089				
Product Codes	Commercial Name	Batch/Lot Numbers			
6600-010	Expro Elite Snare, 10mm, Intl	665959	678036	680324	708751
6600-015	Expro Elite Snare, 15mm, Intl	668106	677694	677815	707326
		708847	714040		
6600-025	Expro Elite Snare, 25mm, Intl	669252	678536	705472	708628
		714416			
6600-035	Expro Elite Snare, 35mm, Intl	668691	679810	700934	706480
		712276	714158	714945	

Dear Customer,

Details of affected devices

Vascular Solutions LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary Field Safety Corrective Action ("FSCA") for the above listed products.

Description of the problem & immediate actions required

This voluntary FSCA is for the above-listed products as it has been determined that the product may contain corrosion (iron oxide) on the inner coil of the device. In the event the affected product is used, there is a potential risk for the particulate matter to become liberated and introduced into body, resulting in embolization of the particulate.

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 by e-mail to Teleflex Customer Service.
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 Teleflex Customer Service. **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: Cliodhna Coffey **Telephone:** +353 906460940
Email: queries.ie@teleflex.com

Teleflex and its subsidiary Vascular Solutions LLC are 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.

For and on behalf of Teleflex and Vascular Solutions LLC,

Padraig Hegarty

Padraig Hegarty VP, Global QA (Manufacturing)

Appendix 1

Customer No _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. HRA00089

RETURN COMPLETED FORM IMMEDIATELY TO:

Email: queries.ie@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	