To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, October 2nd, 2023

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA / STRYKER – RECALL - TissueMend® - RA2023-3324751

Legal manufacturer:
TEI Biosciences Inc. – 7 Elkins Street, Boston, MA, 02127, USA. SRN: US-MF-000012766

EC Representative:
INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST, France – SRN : FR-AR-000002474

Distributor :
Stryker endoscopy – 5900 Optical Court – San Jose – CA – 95138 - USA

Medical devices and Primary clinical purpose of device:
TissueMend® matrix is intended for reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

Concerned references and lot numbers:
References are available in the Reply form in Appendix 1.
All non-expired lot numbers are concerned.

Dear Valued Customer,

Stryker received an Urgent Medical Device letter on the 23rd of May 2023 from the Legal Manufacturer Integra LifeSciences.

Integra LifeSciences voluntarily issued a Field Safety Notice for TissueMend® products listed in Appendix 1, distributed from March 1, 2018, to date.

Reason for Recall:

Based on an internal investigation, Integra LifeSciences has identified issues with in-process and finished goods endotoxin testing that may result in out of specification endotoxin results. Accordingly, we are recalling those products per the instructions below. Our records indicate you have received at least one of those products, including products in consignment.

No complaint has been received (worldwide) for which endotoxin could not completely be eliminated as a possible contributor to patient signs and symptoms (see Risk to Health section below for the harms).

Risks to Health

Per the Health Hazard Evaluation conducted for this issue, the potential harms due to high levels of endotoxins may include low-grade fever, inflammation, and/or inflammatory response leading to fever (pyrexia), and/or surgical intervention/revision surgery. Per the conclusion of this evaluation, there is a remote possibility of these adverse health consequences occurring.

If you have already implanted or used the products affected by this recall, we recommend you monitor the patient for a fever in the immediate postoperative period according to the standard hospital or clinician protocol. If these harms do occur, they would most likely begin to present themselves after the first few days to within a few weeks post-operative care.

The risks have been assessed based on the International Standards for Medical Devices (ISO 14971) and other applicable regulations.

Actions to be Taken by Customer

1. Please **review and understand** the information provided in this letter.
2. Immediately check your internal inventory for affected devices.
3. If **you do have** units of the affected products:
    a. Segregate the affected units in a secure location for return to Stryker.
    b. Remove the units immediately from service.
    c. Check the box on the enclosed form “I do have affected units.”
    d. Record on the form the total quantity and lot numbers of the affected product that you have.
4. Circulate this Recall-Removal notice internally to all interested/affected parties.
5. Maintain awareness of this communication internally until all required actions have been completed within your facility.
6. Inform Stryker if any of the subject devices have been distributed to other organizations. If yes, provide contact details so that Stryker can inform the recipients appropriately.
7. Please inform Stryker of any adverse events concerning the use of the subject devices.
8. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
9. Email the completed form to your local Stryker contact.
10. At receipt of your form, and if it is noted that you have affected products, our logistic partner will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected products.
11. We recommend that you retain a copy of the form for your records.

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1 and EU 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

The receipt of this form ensures that Stryker has achieved a level of effectiveness in communicating this information.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Reply Form.

Should you have any questions regarding these instructions, please contact your Stryker contact for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angélique Aubert Integra LifeSciences Sr Specialist Post Marketing Surveillance EMEA	Stryker Materiovigilance correspondent

Appendix 1: Field Safety Notice Customer Reply Form (2 pages)

APPENDIX 1: CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN 2023-HHE-005T / RA2023-3324751**
FSN Date	**02/10/23**
Devices names	**See list in Table 1 below**
Products Codes	**See list in Table 1 below**
Lots	**All unexpired lots**

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. *	
☐	I performed all actions requested by the FSN *	
☐	The information and required actions have been brought to the attention of all relevant users and executed.*	
☐	I have checked my inventory*	
☐	I do have affected units and I have quarantined them.*	*If yes, please indicate quantity and lot numbers in Table 1*
☐	I do not have any affected units	
☐	I have a query please contact me	*Customer to enter contact details if different from above and brief description of query*
Print Name*		*Customer print name here*
Signature*		*Customer sign here*
Date*		

Note: Your signature indicates that you have received and understand the enclosed notification.

If you have loaned or sold any of the units listed, please, forward a copy of this notice to the new users and advise Stryker of their new location.

Table 1: List of product references concerned by the recall

Unique Device Identification	Product reference	Product designation	Quantity + lot number(s)
10381780113621	6495-9-001	TissueMend® 5x6cm	
10381780113638	6495-9-004	TissueMend® 6x10cm	
10381780113645	6495-9-006	TissueMend® 3x3cm	

4. Return acknowledgement to Sender	
Email	Quality-gsa@stryker.com
Customer Helpline	+49 2065 837-122
Postal Address	Burgunderstrasse 13, 4562 Biberist
Web Portal	www.stryker.com
Fax	+41 32 641 69 55
Deadline for returning the customer reply form*	6th of November 2023

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective action.