To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, November 28th, 2022

Subject: URGENT - FIELD SAFETY NOTICE – Integra – Codman® Surgical Patties X-RAY 1/2X1/2-200 – Reference: 801400 – RECALL

Legal manufacturer: INTEGRA LIFESCIENCES PRODUCTION CORPORATION, 11 Cabot Boulevard, 02048 Mansfield, MA, 02048 USA – SRN: US-MF-000009189

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

Medical device:
Codman® Surgical Patties and Codman® Surgical Strips are manufactured of Cottonoid® Material with X-ray detectable markers. All patties have a suture string attached for ease in performing postsurgical count verification.

Primary clinical purpose of device:
The surgical patties and surgical strips are indicated for the use in protection of tissue, including brain and other tissues of the central nervous system, during surgery.

Concerned reference and lot number:
801400 - Codman® Surgical Patties XRAY 1/2X1/2-200 Lot 6396457

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for Codman® Surgical Patties part number 801400, lot 6396457: see details in Table 1 below.
During an investigation, Integra LifeSciences identified that this lot of Codman® Surgical Patties was released with out-of-specification endotoxin results. Three units of this lot were tested: the results were respectively 2.60 EU per device, 3.77 EU per device and 3.01 EU per device. However, the required specification for endotoxin is < 2.15 endotoxin units (EU) per device.

Product Name Unique Device Identifier (UDI)	Catalog Number	Lot number	Manufacturing Date	Expiration Date	Distribution Dates
Codman® Surgical Patties XRAY 1/2X1/2-200 UDI: 10381780514961	801400	6396457	05 July 2022	30 June 2027	August to September 2022

Table 1: Product and Distribution Information

This voluntary recall is limited to the product and specific lot outlined in Table 1, above. No other products or lots are impacted. All other Codman® Surgical Patties may be used with confidence and without limitation.

Risk to Health

Per the Health Hazard Evaluation conducted for this issue, the worst-case risk for the use of Surgical Patties with endotoxin value greater than 2.15 EU per device but not exceeding 10 EU per device is potentially a minor transient fever.
If the Codman® Surgical Patties have already been used, there is no long-term risk to patient and no follow up required besides standard post operative care.
To date, no complaints have been received and no serious injuries have occurred due to this issue.

The risks have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

Actions to be Taken by Customers

1. Please **review and understand** the information provided in this letter.
2. If **you do have** units of the affected product:
    a. Remove the units immediately from service.
    b. Check the box on the enclosed form "I do have affected units."
    c. Record on the form the total quantity of the affected product that you have. The units that have been already opened and partially consumed are also concerned by this recall.
3. If **you do not have** units of the affected product, check the box, "I do not have affected product."
4. Please return the completed reply form by email to emea-fsca-neuro@integralife.com, or Fax to +33 (0)4.37.47. 59.30. By filling this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. **We expect a response within 3 weeks.** You also confirm that this notification has been forwarded to every concerned person in your organization.
5. At receipt of your form, and if it is noted that you have affected product, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product. A replacement order will also be placed for the quantity noted on the form.
6. We recommend that you retain a copy of the form for your records.

The receipt of this form ensures that Integra 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.

Please feel free to contact our Post Market Surveillance Department at emea-fsca-neuro@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angélique AUBERT
EMEA Compliance Coordinator

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

CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN-2022-HHE-010**
FSN Date	**28/11/2022**
Device name	**Codman® Surgical Patties XRAY 1/2X1/2-200**
Product Code	**801400**
Batch	**6396457**

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.*	**Quantity of boxes**: or **Quantity of pouches:**
☐	I do not have any affected units	
☐	Other Action (Define):	
☐	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*		

4. Return acknowledgement to sender	
Email	emea-fsca-neuro@integralife.com
Customer Helpline	+33 (0) 6 38 15 85 03
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allée Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	https://integralife.eu/
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	30/12/2022

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 actions.