To the attention of Quality Assurance Dpt or Regulatory Affairs Dpt or Management

September 25, 2024

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – RECALL Codman® Surgical Patties and Strips

Legal manufacturer:
INTEGRA LIFESCIENCES PRODUCTION CORPORATION, 11 CABOT BOULEVARD, MANSFIELD, MA 02048

Medical devices and Primary clinical purpose of 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. 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 references and lot numbers:
References are available in Table 1.
All non-expired lot numbers are concerned.

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for Codman® Surgical Patties and Surgical Strips products listed in Table 1, for all lot numbers distributed from 08/01/2019 to 07/31/2024.

Reason for Recall

During an internal investigation, Integra LifeSciences identified higher-than-expected levels of endotoxin within the raw material used to produce Codman Surgical Patties and Strips that may have resulted in out-of-specification levels of endotoxin in those finished goods. Consequently, while the endotoxin levels identified were higher than expected, the possibility of adverse health consequences actually occurring remains remote (see Risk to Health below).

Risks to Health

Per the Health Hazard Evaluation conducted for this issue, adverse health consequences resulting from higher-than-expected levels of endotoxins may include mild febrile response, and/or mild local transitory inflammation, hypotension, or nausea.

Please note that there have been zero (0) complaints received relating to the potential harms identified in this "Risk to Health" section.

If you have already used the products affected by this recall and standard operative care was followed, **there is no additional patient follow-up required.**

Our records indicate that you may have received product from these lots.

Actions to be Taken by Distributor:

1. Please review and understand the information provided in this letter.
2. f **you do have** affected units of the affected products in your warehouse:
    a. Remove the units from further distribution
    b. Check the box "I do have affected units" in the enclosed "Distributor reply form" in Appendix 1.
    c. Record on the form the total quantity and lot numbers of affected units you have.

3. If **you do not have** affected product**,** check the box, “I do not have affected units”.
4. Please check **your customer traceability records** for shipments of affected products.
5. **Forward a copy of the enclosed Field Safety Notice** to any of your customers that have purchased the affected products. Forward a copy of the enclosed Field Safety Notice to any of your customers that have purchased the affected product. You can use Appendix 2: Customer Reply Form, as applicable for your customers.
6. Please return the completed Reply form by email to FCA1@integralife.com or FAX to 1-609-750-4220. 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.
7. At receipt of the reply form, and if it is noted that you or your customers have affected products, customer service will contact you and provide an RMA number and directions to return the products.
8. 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.

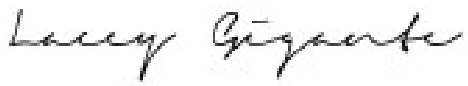
National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

Finally, if required by the national medical device regulation of your distribution area, please ensure this Field Safety Corrective Action is notified to the national competent authorities.

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 our Quality at fca1@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,



Lacey Gigante, Corporate Global Quality Assurance, Post-Market Surveillance

Enclosed:
Appendix 1: Distributor Reply Form
Appendix 2: Customer Reply Form

APPENDIX 1: DISTRIBUTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN 2024-HHE-013**
Devices names	**Codman® Surgical Patties and Strips**
Products Codes	**See list in Table 1 below**
Lots	**All unexpired lots**

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	
☐	I do have affected units and I have quarantined them.*	*If yes, please indicate quantity and lot numbers in Table 1*
☐	I have checked my inventory and I do not have affected unit*	
☐	I have identified customers that received affected units and informed them of this Field Safety Notice *	**Date of communication:**
☐	I have attached customer list	
☐	I have received confirmation of reply for all identified customers	
☐	My customers have affected devices available for return	
☐	My customers have not received any affected units, or all the received units were already consumed	
Print Name* *Distributor print name in the right column*		
Signature* *Distributor sign name in the right column*		
Date *		

Mandatory fields are marked with *

Appendix 1- Table 1: List of product references concerned by the recall

Manufacturer's Product Number (Catalog Number)	Product Name (Description)	UDI Number	Lot Number(s) (as identified on the pouch or box)	Quantity(box) *Note: partial box counts as a full box*
801396	CODMAN MICR PATIE RND/200	10381780514923, 20886704036446		
801397	SURGPAT X-RAY1/4X11/2-200	10381780514930, 20886704036453		
801398	SURG PAT XRAY 1/4X3 -200	10381780514947, 20886704036460		
801399	SURG PATXRAY 1/4X1/4-200	10381780514954, 20886704036477		
801400	SURG PATXRAY 1/2X1/2-200	10381780514961, 20886704036484		
801401	SURG PATXRAY 3/4X3/4-200	10381780514978, 20886704036491		
801402	SURG PAT XRAY 1/2X1 -200	10381780514985, 20886704036507		
801403	SURG PAT XRAY 1X1 -200	10381780514992, 20886704036514		
801404	SURG PAT XRAY 1/2X1 1/2	10381780515005, 20886704036521		
801406	SURG PAT XRAY 1/2X2 -200	10381780515012, 20886704036538		
801407	SURG PAT XRAY 1/2X3 -200	10381780515029, 20886704036545		
801408	SURG PAT XRAY 1X3 -200	10381780515036, 20886704036552		
801409	SURG PAT XRAY 3X3 -200	10381780515043, 20886704036569		
801449	CODMAN SRG STRP1/8X6-200	10381780515050, 20886704036576		
801450	CODMAN SURGSTRIP1/4X6-200	10381780515067, 20886704036583		
801451	CODMAN SURG STRP1/2X6-200	10381780515074, 20886704036590		
801452	CODMAN SURG STRP3/4X6-200	10381780515081, 20886704036606		
801453	CODMAN SURG STRIP1X6-200	10381780515098, 20886704036613		
801454	CODMAN SURGSTRP11/2X6-200	10381780515104, 20886704036620		
801455	CODMAN SURG STRIP2X6-200	10381780515111, 20886704036637		
801456	CODMAN SURG STRIP3X6-200	10381780515128, 20886704036644		
801457	CODMAN SRG STRP31/2X6-200	10381780515135, 20886704036651		

4. Return acknowledgement to Sender	
Email	fca1@integralife.com
Fax	**1-609-750-4220**

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.

APPENDIX 2: CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN 2024-HHE-013**
Devices names	**Codman® Surgical Patties and Strips**
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*		

Appendix 2- Table 1: List of product references concerned by the recall

Manufacturer's Product Number (Catalog Number)	Product Name (Description)	UDI Number	Lot Number(s) (as identified on the pouch or box)	Quantity(box) *Note: partial box counts as a full box*
801396	CODMAN MICR PATIE RND/200	10381780514923, 20886704036446		
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801408	SURG PAT XRAY 1X3 -200	10381780515036, 20886704036552		
801409	SURG PAT XRAY 3X3 -200	10381780515043, 20886704036569		
801449	CODMAN SRG STRP1/8X6-200	10381780515050, 20886704036576		
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