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

Saint Priest, 23 September 2024

URGENT - FIELD SAFETY NOTICE – Codman® Surgical Patties & Surgical Strips - RECALL

Legal manufacturer:

INTEGRA LIFESCIENCES PRODUCTION CORPORATION - 11 Cabot Boulevard - 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 & 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 references:

PATTIES			STRIPS	
801396	801401	801407	801449	801454
801397	801402	801408	801450	901455
801398	801403	801409	801451	801456
801399	801404		801452	801457
801400	801406		801453	

Dear Valued Integra Distributor,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of Codman® Surgical Patties & Surgical Strips products listed in Table 1 below.

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).

Risk 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.

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.

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

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number	Expiration Date	Distribution Dates (DD/MM/YYYY)
801396	CODMAN MICR PATIE RND/200	10381780514923, 20886704036446	**All lot numbers distributed between 01-Aug-2019 to 31-July-2024**	**All unexpired lots**	**All lots distributed between 01/08/2019 to 31/07/2024**
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			

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number	Expiration Date	Distribution Dates (DD/MM/YYYY)
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			

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

Actions to be taken by Distributors:

1. Please **review and understand** the information provided in this letter.
2. If **you do have** affected products in your warehouse:
    a. Quarantine them immediately.
    b. Check the box “I do have affected unit(s)” in the enclosed reply form.
    c. Record on the table 2. at the bottom of the reply form the total quantity of affected product(s) and lot number(s) that you have.
3. If **you do not have** affected product(s) in your warehouse**,** check the box, “I do not have affected unit(s)”.
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.
6. Please return the completed Reply form by email to emea-fsca@integralife.com, or Fax to +33 (0)4.37.47. 59.30. By filling in 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 product(s), Customer Service will contact you and provide an RMA number and directions to return the product(s). A credit will be processed upon receipt of returned goods.
8. We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCT TO RETURN OR NOT – A COMPLETED ACKNOWLEDGEMENT IS REQUIRED

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

Yours Sincerely,

Post Marketing Surveillance Department

Appendix: Field Safety Notice Reply Form (2 pages)

DISTRIBUTOR/IMPORTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**2024-HHE-013**
FSN Date	**23 September 2024**
Device name	**Codman® Surgical Patties & Strips**
Product Code	**See list in table 2 below**
Lots	**All lot numbers distributed between 01/08/2019 to 31/07/2024**

2. Distributor/Importer Details	
SRN Number	
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 have checked my inventory and I <u>have</u> affected products - enter number of devices and lot number	*Fill in the table 2 below*
☐	I have checked my inventory and I <u>do not</u> have affected products	
☐	I have identified customers that received affected products 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 <u>have</u> affected products available for return	*Fill in the table 2 below*
☐	My customers have not received any affected products, or all the received products were already consumed	
Print Name*		*Distributor print name here*
Signature*		*Distributor sign Here*
Date *		

4. Return acknowledgement to Sender	
Email	emea-fsca@integralife.com
Distributor Helpline	+33 (0) 6 30 20 69 66
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/
Deadline for returning the distributor reply form*	20/10/2024

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.

Table 2. List of products

Manufacturer's Product Number (Catalog Number)	Product Name (Description)	Lot Number(s) as identified on the box or on the pouch	Quantity (box) Note: partial box counts as a full box
801396	CODMAN MICR PATIE RND/200		
801397	SURGPAT X-RAY1/4X11/2-200		
801398	SURG PAT XRAY 1/4X3 -200		
801399	SURG PATXRAY 1/4X1/4-200		
801400	SURG PATXRAY 1/2X1/2-200		
801401	SURG PATXRAY 3/4X3/4-200		
801402	SURG PAT XRAY 1/2X1 -200		
801403	SURG PAT XRAY 1X1 -200		
801404	SURG PAT XRAY 1/2X1 1/2		
801406	SURG PAT XRAY 1/2X2 -200		
801407	SURG PAT XRAY 1/2X3 -200		
801408	SURG PAT XRAY 1X3 -200		
801409	SURG PAT XRAY 3X3 -200		
801449	CODMAN SRG STRP1/8X6-200		
801450	CODMAN SURGSTRIP1/4X6-200		
801451	CODMAN SURG STRP1/2X6-200		
801452	CODMAN SURG STRP3/4X6-200		
801453	CODMAN SURG STRIP1X6-200		
801454	CODMAN SURGSTRP11/2X6-200		
801455	CODMAN SURG STRIP2X6-200		
801456	CODMAN SURG STRIP3X6-200		
801457	CODMAN SRG STRP31/2X6-200		

To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, 23 September 2024

URGENT - FIELD SAFETY NOTICE – Codman® Surgical Patties & Surgical Strips - RECALL

Legal manufacturer:

INTEGRA LIFESCIENCES PRODUCTION CORPORATION - 11 Cabot Boulevard - 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 & 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 references:

PATTIES			STRIPS	
801396	801401	801407	801449	801454
801397	801402	801408	801450	901455
801398	801403	801409	801451	801456
801399	801404		801452	801457
801400	801406		801453	

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of Codman® Surgical Patties & Surgical Strips products listed in Table 1 below.

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).

Risk 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.

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.

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

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number	Expiration Date	Distribution Dates (DD/MM/YYYY)
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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			
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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			

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number	Expiration Date	Distribution Dates (DD/MM/YYYY)
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			

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

Actions to be taken by Customers:

1. Please **review and understand** the information provided in this letter.
2. If you **do have** affected units:
    a. Quarantine the units immediately.
    b. Check the box on the enclosed form “I do have affected units.”
    c. Record on the table 2. at the bottom of the reply form the total quantity of affected units and lot number(s) that you have.
3. If you **do not have** affected units, check the box, “I do not have affected units.”
4. Please **return the completed reply form by email to** emea-fsca@integralife.com, or Fax to +33 (0)4.37.47. 59.30. By filling in 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 units, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product(s). A credit note will be processed upon receipt of returned goods (except for consignments).
6. We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCT TO RETURN OR NOT – A COMPLETED ACKNOWLEDGEMENT IS REQUIRED

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

Yours Sincerely,

Post Marketing Surveillance Department

Appendix: Field Safety Notice Reply Form (2 pages)

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**2024-HHE-013**
FSN Date	**23 September 2024**
Product/ Device name	**Codman® Surgical Patties & Strips**
Product Code(s)	**See list in table 2 below**
Lots	**All lot numbers distributed between 01/08/2019 to 31/07/2024**

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 affected units - enter number of products and lot number	*Fill in the table 2 below*
☐	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*		

4. Return acknowledgement to Sender	
Email	emea-fsca@integralife.com
Customer Helpline	+33 (0) 6 30 20 69 66
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/
Deadline for returning the customer reply form*	20/10/2024

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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.

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