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

April 15, 2025

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – RECALL Codman® Disposable Perforator 14mm, Part# 261221 and CODMAN Craniotomy Kit containing Disposable Perforator 14mm, Cranio-blade, Wire Pass Drill, Part# 261230

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

Medical devices and Primary clinical purpose of device:
The CODMAN® Disposable Perforator is for use in perforating the cranium. When properly used, it is designed to automatically disengage once perforation is accomplished and when pressure is removed from the drill point.

Concerned references and lot numbers:
References are available in Table 1.
The full list of impacted lot numbers is available in this link:
https://products.integralife.com/file/general/14mm_codman_disposable_perforator_disassembly_recall_list_of_impacted_lots.pdf

Dear Valued Integra Customer,

Integra LifeSciences is issuing this Voluntary Medical Device Recall Notice for the Codman® Disposable Perforator 14mm products listed in Table 1.

Reason for Recall

During an investigation of complaints, Integra LifeSciences identified that there is an inadequate weld (proud weld) on specific lots of 14mm Codman® Disposable Perforators that can potentially cause the product to disassemble (break/separate). As of February 10, 2025, a total of 83 complaints have been received worldwide regarding product disassembly, out of which 81 have been reported as product malfunctions and 2 were considered not reportable. In addition, out of the 83 complaints, 9 have been reported as serious injuries.

Risks to Health

Perforator disassembly may occur before, during, or after the craniotomy in devices which have inadequate welds. If disassembly occurs

- Before the procedure - It may cause inconvenience to the user and prolong the procedure time.
- During use - If downward pressure is removed or in instances when the outer drill sticks into the cranial bone, the disassembled perforator may need to be removed either manually or using additional surgical instruments.
- During use - Should downward pressure not be removed and a failure to disengage occurs, serious patient injury such as dural tear with hemorrhage (inclusive of sagittal sinus tears with hemorrhage) may occur.
- After use - Upon removal of the perforator from the craniotomy, it may cause inconvenience to the user and prolong the procedure time if additional craniotomies are required.

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 affected lots.

Actions to be Taken by Distributor:

1. Determine if the product you have is subject to the recall
    a. Identify the impacted part number and lot number,
    b. See Appendix 3 and 4 below for a sample Product Label for where to locate the part number and lot number.
    c. The lot number will be 7 digits long (no letters/only numbers).
    d. Open the following link to a pdf file with a list of all recalled lot codes: https://products.integralife.com/file/general/14mm_codman_disposable_perforator_disassembly_recall_list_of_impacted_lots.pdf
    e. In the pdf file, use the find function from the Edit drop down menu or Ctrl+F to see if your Lot number(s) is (are) on the list.

2. If you do have affected product listed in Table 1, **remove the product from further distribution.**
3. Complete the attached Acknowledgment Form (Appendix 1).
4. If you **do** have affected product, check the box "I do have affected product." Record the lot number and total quantity of affected product you have.
5. If you **do not** have affected product, check the box, "I do not have affected product."
6. Complete the entirety of the Acknowledgement Form and send via email to FCA3@integralife.com or FAX to 1-609-750-4220.
7. Keep a copy of the form for your records.
8. Please check your customer traceability records for shipments of above catalog and lot numbers.
9. If you have shipped impacted product to your customers, please complete below:
    a. Please create an acknowledgement form from you to your customers. You can use the customer reply form in Appendix 2 as an example- please make sure you update the contact information.
    b. Forward a copy of this Field Safety Notice to any of your customers that have purchased the above catalog and lot numbers.
    c. Please collect completed response forms and affected product from your customers and indicate the total quantities and lot(s) in the Distributor reply form (Appendix 1).
    d. When the form from you have been received and it is noted that you have the affected product, Customer Service will contact you and provide an RMA number and directions to return the product. Distributors can request a credit for the quantities which they return. Note: Credit will only be given for the impacted lot(s) that are returned.

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. We recommend you also maintain a copy of this notification and signed copy of acknowledgement form for your records.

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 FCA3@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Mary O'Neill

Mary O'Neill, Corporate Global Quality Assurance, Post-Market Surveillance

Enclosed:
Appendix 1: Distributor Reply Form
Appendix 2: Customer Reply Form
Appendix 3: Product Label for Part# 261221
Appendix 4: Product Label for Part# 261230.

APPENDIX 1: DISTRIBUTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN 2024-HHE-022B**
Devices names	**Codman® Disposable Perforator**
Products Codes	**See list in Table 1 below**
Lots: Link to full list of impacted lot numbers: https://products.integralife.com/file/general/14mm_codman_disposable_perforator_disassembly_recall_list_of_impacted_lots.pdf	

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)	Lot Number(s)	Quantity
261221	CODMAN Disposable Perforator 14mm		
261230	CODMAN Craniotomy Kit containing Disposable Perforator 14mm, Cranio-blade, Wire Pass Drill		

4. Return acknowledgement to Sender	
Email	FCA3@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-022B**
Devices names	**Codman® Disposable Perforator**
Products Codes	**See list in Table 1 below**
Lots: Link to full list of impacted lot numbers: https://products.integralife.com/file/general/14mm_codman_disposable_perforator_disassembly_recall_list_of_impacted_lots.pdf	

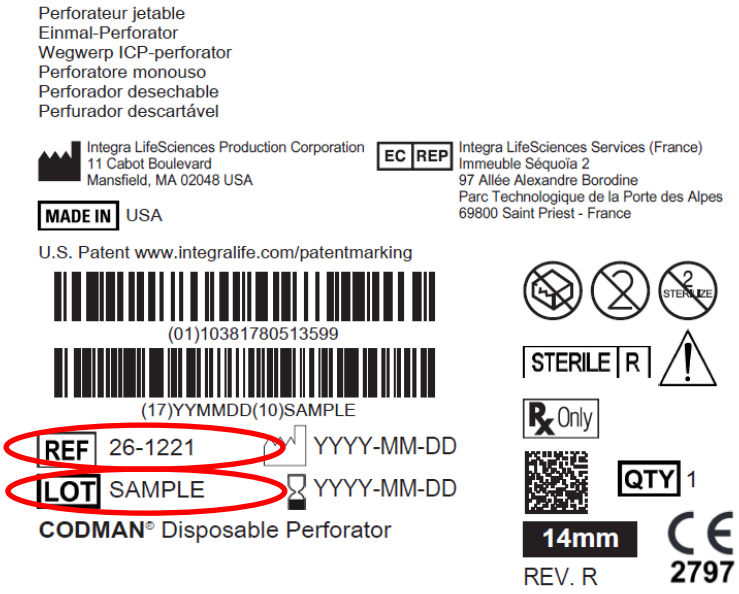
2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

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)	Lot Number(s)	Quantity
261221	CODMAN Disposable Perforator 14mm		
261230	CODMAN Craniotomy Kit containing Disposable Perforator 14mm, Cranio-blade, Wire Pass Drill		

Appendix 3: Product Label for Part# 261221. Use Red Circle below to Identify Lot Number



Appendix 4: Product Label for Part# 261230. Use Red Circle below to Identify Lot Number