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

Saint Priest, 11 April 2025

URGENT - FIELD SAFETY NOTICE – RECALL

CODMAN® Disposable Perforator 14mm (réf. 26-1221) and CODMAN® Craniotomy Kit containing Disposable Perforator 14mm, Cranio-blade, Wire Pass Drill (réf. 26-1230)

Legal manufacturer:

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

EC Representative :

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

Medical device:

The CODMAN® Disposable Perforator is a single-use device. It is a disposable perforator with a Hudson end and is available in three color-coded sizes: 14mm (blue)- catalog no. 26-1221 11mm (green)- catalog no. 26-1222 9mm (yellow)- catalog no. 26-1223.
Craniotomy kit catalog no. 26-1230 contains disposable perforator 26-1221, Cranio-blade, Wire Pass Drill.

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:

26-1221 (same as 261221) – lots manufactured between 27-07-2022 to 12-07-2024
26-1230 (same as 261230) - lots manufactured between 24-05-2023 to 28-05-2024

Dear Valued Integra Distributor,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of **CODMAN® Disposable Perforator 14mm** listed in Table 1.

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) during its use.

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number (DD-MM-YY)	Expiration Date (DD-MM-YY)
26-1221	CODMAN® Disposable Perforator 14mm	10381780513599	Lot numbers with manufacturing dates between 27-07-2022 to 12-07-2024	30-06-2027 to 30-06-2029
26-1230	CODMAN® Craniotomy Kit containing Disposable Perforator Cranio-blade Wire Pass Drill 14mm	10381780513629	Lot numbers with manufacturing dates between 24-05-2023 to 28-05-2024	30-04-2028 to 30-04-2029

Note: the impacted lots were distributed between July 5, 2023, through September 27, 2024. Only specific lots distributed within this date range are impacted. The full list of impacted lot numbers is available in the attached excel file (Appendix 3.).

Based on the investigation, it was concluded that only the devices noted in Table 1 are impacted. The manufacturing process was corrected to prevent inadequate welds and any new products distributed outside of the impacted lots underwent the corrected manufacturing process.

Risk 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.**

As of February 10, 2025, 14 serious incidents have been reported in Europe and 2 in Great Britain.

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. Determine if the product you have is subject to the recall:
    a. Identify the impacted reference (s) and lot number (s).
    b. See Appendix 2 below for a sample of product label for where to locate the reference and lot number. The lot numbers are 7 digits long (only numbers)
    c. Open the excel file, use the find function Ctrl+F or use the dropdown arrow on the top of the column and see if your lot number(s) is (are) on the list.
3. If **you do have** affected product(s) 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 form the total quantity of affected unit(s) and lot number(s) that you have.
4. If **you do not have** affected product(s) in your warehouse**,** check the box, “I do not have affected unit(s)”.
5. Please check **your customer traceability records** for shipments of affected products.
6. **If you have shipped impacted products to your customers, please complete below:**
    a. Create a customer reply form with your contact details.
    b. Forward a copy of the Field Safety Notice to any of your customers that have purchased the affected products and lot numbers.
    c. Collect completed response forms and affected product(s) from your customers and indicate the total quantities and lot(s) in the distributor reply form (Appendix 1).
7. Please return the completed Reply form by email to emea-fsca@integralife.com,

    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 person concerned in your organization.
8. At receipt of the reply form, and if it is noted that you or your customers have affected product(s) available for return, Customer Service will contact you and provide an RMA number and directions to return the product(s). The credit will be processed upon receipt and verification of returned goods. Note: credit will only be given for the impacted lot(s) that are returned.
9. We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCTS 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 1: Field Safety Notice Reply Form (2 pages)
Appendix 2: Product label sample for reference 26-1221. Use Red Circle below to Identify Lot Number
Appendix 3: List of impacted lot numbers (Excel file).

DISTRIBUTOR/IMPORTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**2024-HHE-022 B**
FSN Date	**11 April 2025**
Device name	**CODMAN® Disposable Perforator 14mm/ CODMAN® Craniotomy Kit**
Product Code	**26-1221/26-1230**
Lots	**Impacted lot numbers in Appendix 3. (excel file)**

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 have affected units available for return - enter number of devices and lot number	
☐	I have affected units, and I can destroy them(1) – enter number of products and lot number (s) (1) *If you choose this option – Integra will provide you with a certificate of destruction upon receipt of the reply form*	
☐	I have checked my inventory and I do not have affected products	
☐	I have identified customers that received affected products and informed them of this Field Safety Notice *	
☐	I have attached customer list	
☐	I have received confirmation of reply for all identified customers	

☐	My customers have affected products – enter number of devices and lot number	
☐	My customers have not received any affected products, or all the received products were already consumed	
Print Name*		
Signature*		
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://www.integralife.com/
Deadline for returning the distributor reply form*	02/05/2025

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.

Appendix 2: Product Label sample

Reference 26-1221. Use Red Circle below to Identify Lot Number