To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, 24 September 2025

URGENT - FIELD SAFETY NOTICE – RECALL
CODMAN® Disposable Perforator 11mm (26-1222)
CODMAN® Disposable Perforator 9mm (26-1223)

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

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:

26-1222 (same as 261222)
26-1223 (same as 261223)

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of **CODMAN® Disposable Perforator 11mm and CODMAN® Disposable Perforator 9mm** listed in Table 1.

Reason for Recall:

- On April 11, 2025, Integra issued a voluntary recall for the 14mm Codman® Disposable Perforator due to an inadequate weld (proud weld) on specific lots of 14mm perforator that can potentially cause the product to disassemble (break/separate).
- To date, there have been no complaints or adverse events reported in relation to the 9mm and 11mm Codman® Disposable Perforators disassembly. Out of an abundance of caution, as the 9 and 11mm perforators are manufactured using the same equipment and operating parameters that affected the 14mm Perforator, Integra has made the decision to expand the scope of the field action to include the 9mm and 11mm perforators as noted in Table 1.

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot number	Expiration Dates (DD-MM-YY)
26-1222	CODMAN® Disposable Perforator 11mm	10381780513605	See Appendix 3. for impacted lot numbers	30/04/2028 to 31/07/2029
26-1223	CODMAN® Disposable Perforator 9mm	10381780513612		31/03/2027 to 31/07/2029

Note: the full list of impacted lot numbers is available in the attached excel file (Appendix 3.).

Risks to health:

Perforator disassembly may occur before, during, or after the craniotomy in devices which have inadequate welds. Per the Health Hazard Evaluation conducted for this issue, this may cause inconvenience and prolong the procedure time in order to address the disassembly. If during use, 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. However, should the perforator disassemble following a failure to disengage, there is a potential for additional injury, such as dural tear with hemorrhage.

As of September 11th, 2025, there have been no complaints or adverse events related to disassembly for the 9 mm and 11 mm Codman® Disposable Perforators listed in Table 1.

Our records indicate that you may have received product from the affected lots in the attached excel file (Appendix 3.).

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.**

Actions to be taken by Customers:

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 and lot number.
    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 **have** affected product(s):
    a. Quarantine the units immediately.
    b. Check the box "I do have affected units." on the acknowledgement form.
    c. Record on the form the total quantity of affected products and lot number(s) that you have.
4. If you **do not have** affected product(s), check the box, "I do not have affected units."
5. 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 21 calendar days from the receipt of this notification.** You also confirm that this notification has been forwarded to every person concerned in your organization.
6. At receipt of your form, and if it is noted that you have affected units available for return, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product(s). If you can dispose of the products, Integra will provide a certificate of destruction for completion. A replacement order will be processed upon receipt and verification of returned goods and/or certificate of destruction.
7. If you do have expired products, discard/destruct following your normal protocol.
8. 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: Sample of a product label. Use Red Circle below to Identify Lot Number (1 page)
Appendix 3: List of impacted lot numbers (Excel file)

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**2025-HHE-012**
FSN Date	**24 September 2025**
Product/ Device name	**CODMAN® Disposable Perforator 11mm** **CODMAN® Disposable Perforator 9mm**
Product Code(s)	**26-1222 / 26-1223**
Lots	**Impacted lot numbers in Appendix 3. (excel file)**

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 <u>have</u> affected units, and I can discard 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*	Ref	Lot number	Quantity
☐	I have checked my inventory and I <u>have</u> affected units available for return	Ref	Lot number	Quantity
☐	I <u>do not</u> have any affected units.			
☐	I have a query please contact me			

Print Name*	
Signature*	
Date*	

4. Return acknowledgement to Sender	
Email	emea-fsca@integralife.com
Customer Helpline	+33 6 85 30 03 19
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 customer reply form*	20/10/2025

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 action.

Appendix 2: Product Label sample

Use Red Circle below to Identify reference and lot number

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

Saint Priest, 24 September 2025

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CODMAN® Disposable Perforator 9mm (26-1223)

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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

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:

26-1222 (same as 261222)
26-1223 (same as 261223)

Dear Valued Integra Distributor,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of **CODMAN® Disposable Perforator 11mm and CODMAN® Disposable Perforator 9mm** listed in Table 1.

Reason for Recall:

- On April 11, 2025, Integra issued a voluntary recall for the 14mm Codman® Disposable Perforator due to an inadequate weld (proud weld) on specific lots of 14mm perforator that can potentially cause the product to disassemble (break/separate).
- To date, there have been no complaints or adverse events reported in relation to the 9mm and 11mm Codman® Disposable Perforators disassembly. Out of an abundance of caution, as the 9 and 11mm perforators are manufactured using the same equipment and operating parameters that affected the 14mm Perforator, Integra has made the decision to expand the scope of the field action to include the 9mm and 11mm perforators as noted in Table 1.

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot number	Expiration Dates (DD-MM-YY)
26-1222	CODMAN® Disposable Perforator 11mm	10381780513605	See Appendix 3. for impacted lot numbers	30/04/2028 to 31/07/2029
26-1223	CODMAN® Disposable Perforator 9mm	10381780513612		31/03/2027 to 31/07/2029

Note: the full list of impacted lot numbers is available in the attached excel file (Appendix 3.).

Risks to health:

Perforator disassembly may occur before, during, or after the craniotomy in devices which have inadequate welds. Per the Health Hazard Evaluation conducted for this issue, this may cause inconvenience and prolong the procedure time in order to address the disassembly. If during use, 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. However, should the perforator disassemble following a failure to disengage, there is a potential for additional injury, such as dural tear with hemorrhage.

As of September 11th, 2025, there have been no complaints or adverse events related to disassembly for the 9 mm and 11 mm Codman® Disposable Perforators listed in Table 1.

Our records indicate that you may have received product from the affected lots in the attached excel file (Appendix 3.).

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.**

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 and lot number.
    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 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.
7. Please return the completed and appropriate reply form by email to emea-fsca@integralife.com,
8. 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 21 calendar days from the receipt of this notification.** You also confirm that this notification has been forwarded to every person concerned in your organization.
9. At receipt of your form, and if it is noted that you have affected units available for return, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product(s). If the products can be discarded, Integra will provide a certificate of destruction for completion. A replacement order will be processed upon receipt and verification of returned goods and/or certificate of destruction.
10. 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 1: Field Safety Notice Reply Form (2 pages)
Appendix 2: Sample of a product label. Use Red Circle below to Identify Lot Number (1 page)
Appendix 3: List of impacted lot numbers (Excel file).

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**2025-HHE-012**
FSN Date	**24 September 2025**
Device name	**CODMAN® Disposable Perforator 11mm** **CODMAN® Disposable Perforator 9mm**
Product Code	**26-1222 / 26-1223**
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 <u>have</u> affected units, and I can discard 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*	Ref	Lot number	Quantity
☐	I have checked my inventory and I <u>have</u> affected units available for return	Ref	Lot number	Quantity
☐	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	Ref	Lot number	Quantity
☐	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 6 85 30 03 19
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*	20/10/2025

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

Use Red Circle below to Identify reference and lot number