URGENT - FIELD SAFETY NOTICE – RECALL

CODMAN MICROSENSOR® Basic kit and (ref.62-6631)
CERELINK® ICP sensor Basic kit (ref.82-6850)

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 devices:

Ref 62-6631

The CODMAN MICROSENSOR® Basic Kit consists of the CODMAN MICROSENSOR® ICP Transducer and a 14-gauge Tuohy Needle with stylet. The CODMAN MICROSENSOR® ICP Transducer is a catheter with a microminiature strain gauge pressure sensor mounted at one end and an electrical connector at the other end. It is designed for use with the ICP EXPRESS® Monitor, catalog no. 82-6634 (117 volts of alternating current) and 82-6635 (230 volts of alternating current) or any other suitable Codman pressure monitoring interface or device. The CODMAN MICROSENSOR® Basic Kit is designed for use with the CODMAN® Cranial Hand Drill, catalog no. 82-6607. The drill facilitates access to the intraparenchymal area.

Ref 82-6850

The CERELINK® ICP Sensor Basic Kit consists of the CERELINK® ICP Sensor (ICP Sensor) and a 14-gauge Tuohy Needle with stylet. The ICP Sensor is a nylon tube with a microminiature strain gauge pressure transducer (sensing element) mounted at one end and an electrical connector at the other end. It is designed for use with a Codman intracranial pressure monitoring device.

Primary clinical purpose of device:

CODMAN MICROSENSOR® Basic Kit and CERELINK® ICP Sensor Basic Kit are indicated when direct ICP monitoring is required. The kits are indicated for use in both subdural and intraparenchymal pressure monitoring applications only.

Concerned references:

62-6631 (same as 626631)
82-6850 (same as 826850)

Saint Priest, 12 December 2025

To the attention of Medical Device Vigilance responsible / Central Pharmacy

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of **CODMAN MICROSENSOR® Basic kit and CERELINK® ICP sensor Basic kit** listed in Table 1. During an investigation, Integra LifeSciences identified lots that were released with potential corrosion stains on the surface of the 14-gauge Tuohy needle that is included within the sensor kits (ref 62-6631 and 82-6850).

To date, no adverse events or complaints related to this issue have been reported in Europe.

Integra LifeSciences will initiate a voluntary recall of the impacted lots. This recall applies only to products within the specific lot numbers listed in Appendix 3 of this communication. Table 1 summarizes the impacted products.

Table 1: Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number
62-6631	**CODMAN MICROSENSOR® Basic kit**	10381780514466	See Appendix 3. for impacted lot numbers and expiration dates
82-6850	**CERELINK® ICP sensor Basic kit**	10381780520672	

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

No other product or lots are impacted; all other CODMAN MICROSENSOR® Basic Kit and CERELINK® ICP Sensor Basic Kit may be used with confidence.

Risk to health

Per the Health Hazard Evaluation conducted for this issue, the potential harms associated with the use of products affected by potential corrosion on the 14-gauge Tuohy needle (included in the kit) include inflammation, infection, toxic response, and the need for medical intervention beyond the standard of care. If the product has already been used, there is no long-term risk to the patient, and no follow-up is required beyond standard postoperative care.

There are no concerns regarding needle integrity, and only negligible concern regarding particulate generation from the stylet. The stained portion observed within the needle results from processing residue that is firmly adhered to the interior wall and would not be affected by passage of the ICP transducer catheter. Minor corrosion may appear on the exterior of the stylet and is only slightly more likely to result in particulate generation. This is expected to occur only after years of storage and would not have affected prior clinical use. The stylet is removed before insertion of the transducer catheter;

therefore, any corrosion-related particulate is unlikely to be transferred into the lumen of the needle or introduced to the patient

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 (appendix 3), 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):
    a. Quarantine the kits 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. **Please be advised that if the products were obtained through a purchasing group or a distributor, you should contact them directly. Kindly avoid using this return address.**
6. 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.

At receipt of your form, and if it is noted that you have affected kits 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 option may be available based on available inventory. Otherwise, please reach your sales representative to discuss an alternative option. The replacement order will be processed upon receipt and verification of returned goods and/or certificate of destruction.

If you do have expired products, discard/destruct following your normal protocol. No return of expired products will be processed.

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 products. Use Red Circle below to Identify Lot Number
Appendix 3: List of impacted lot numbers and expiration dates (Excel file)

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**2025-HHE-013**
FSN Date	**12 December 2025**
Product/ Device name	**CODMAN MICROSENSOR® Basic kit** **CERELINK® ICP sensor Basic kit**
Product Code(s)	**62-6631** **82-6850**
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 do not 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 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 customer reply form*	05/01/2026

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 Lot Number

Figure 1: Product Label for CODMAN MICROSENSOR® Basic Kit (Ref 62-6631).	Figure 2: Product Label for CERELINK® ICP Sensor Basic Kit (Ref 82-6850).