To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, September 21st, 2023

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – Expanding Codman® CereLink® ICP Monitor Recall to include CereLink® ICP Extension Cable, Reference: 826845

This Field Safety Notice is an update of a precedent Field Safety Notice: FSN 2022-HHE-006 310822

Legal manufacturer:

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

EC Representative:

Integra LifeSciences Services (France) – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST, France – SRN : FR-AR-000002474

Medical device:

The CereLink® ICP Extension Cable is a 3m-long cable that is reusable and is supplied nonsterile.

Primary clinical purpose of device:

The CereLink® ICP Extension Cable is intended for use as a connecting cable between the ICP input channel of the CereLink® ICP Monitor and a CereLink® ICP Sensor.

Concerned reference and lot numbers:

CereLink® ICP Extension Cable, reference: 826845
All lot numbers distributed.

Dear Valued Integra Customer,

The purpose of this letter is to notify you that Integra LifeSciences is expanding the existing voluntary recall for the CereLink® ICP monitor due to out-of-range readings to include all CereLink® ICP Extension Cables (details listed in Table 1 below).

Table 1: Product and Distribution Information

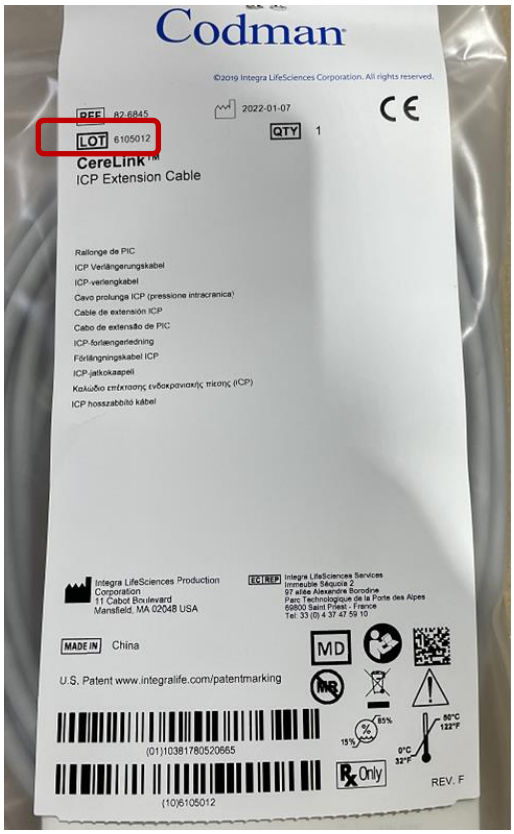
Product Name	Catalog Number	UDI-DI	Lot numbers
CereLink® ICP Extension Cable	826845	10381780520665	All lot numbers distributed

In the original investigation, based on the information known at that time, the CereLink® ICP Extension cable (when provided separately) was out of scope. As an output of the root cause and failure investigation, the design of the extension cable was modified to incorporate a solution to address the “out of range readings” issue.

Therefore, Integra is reaching out to you to return all CereLink® ICP Extension Cables that you may have in your stock. This includes all the CereLink® ICP Extension Cables included with the monitor AND all CereLink® ICP Extension Cables provided separately (See Table 1 for more details and Figure 1 for a picture of the cable.).

Figure 1: Reference # 826845- CereLink® ICP Extension Cable

Figure 2: Label on CereLink® ICP Extension Cable packaging, showing Integra lot number



Risk to Health

Since the CereLink® ICP Monitors were already recalled from the market (Recall letter FSN-2022-HHE-006 310822), there is no risk associated with the CereLink® ICP Extension Cable as the CereLink® ICP Extension Cable cannot be used without the CereLink® ICP Monitor.

Actions to be Taken by Customers:

1. Please review and understand the information provided in this letter.
2. Please check your inventory: If you still have the CereLink® ICP Extension Cable (Part# 826845) that came with the CereLink® ICP monitor (Reference #826820) and/or CereLink® ICP Extension Cable purchased separately (Reference # 826845), please quarantine the CereLink® ICP Extension Cable immediately.
3. Complete the attached "Reply Form" (even if you have no product on hand) and return the completed form by email to emea-fsca-neuro@integralife.com, or Fax to +33 (0)4.37.47. 59.30. **We expect a response within 3 weeks.** By filling out this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. You also confirm that this notification has been forwarded to every concerned person in your organization.
4. Upon receipt of this reply form, and if it is noted that you have any CereLink® ICP Extension Cables, Integra Customer Service will contact you to organize the return of the concerned products and provide a Return Merchandise Authorization number.
5. We recommend that you retain a copy of the form for your records.
6. For any questions related to the product's future availability, please contact your sales representative.

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

Yours Sincerely,

Angélique AUBERT
Materiovigilance Correspondent

Appendix: Field Safety Notice Customer Reply Form (2 pages)

CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-2022-HHE-006
FSN Date*	September 21st, 2023
Device names*	CereLink® ICP Extension cable
Product Code	826845
Lot Numbers	All lot numbers distributed

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 stock and quarantined inventory. *	
☐	I have identified CereLink® ICP Extension cable available for return	Qty: Lot: Qty: Lot: Qty: Lot: *Lot on the packaging, if available (see Figure 2)*
☐	No CereLink® ICP Extension cable are available for return, I do not have any affected devices.	
☐	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-neuro@integralife.com.
Customer Helpline	+33 (0) 6 38 15 85 03
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/
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	September 30th, 2023

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.