To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, August 31st, 2022

Subject: URGENT - FIELD SAFETY NOTICE – Integra – Codman® CereLink® ICP Monitor, Model: 826820: ICP Monitor Reading Default – RECALL

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

CH Representative :
ILS Services Switzerland Ltd – Fidulem SA, Avenue Mon-Repos 24 – 1005 – Lausanne – Switzerland – CHRN-AR: 20001538

Medical device(s):
The Codman® CereLink® ICP Monitor (ICP Monitor) is a standalone portable device that continuously monitors intracranial pressure (ICP). When connected to a Codman® CereLink® ICP Sensor (ICP Sensor), ICP Monitor provides a numeric display of the mean ICP, ICP waveform and mean ICP trend. For detailed waveform analysis, the ICP Monitor generates real time digital data and an output signal that can be interfaced directly to the pressure channel input on most patient bedside monitors.
The entire CereLink® System is comprised of the ICP Monitor, ICP Sensor, and cables.

Primary clinical purpose of device(s):
The ICP Monitor is intended for use as an interface between compatible strain-gauge type pressure transducers and standard physiological pressure monitoring systems. The ICP Monitor is also intended for use as an independent pressure monitor for displaying the mean, systolic and diastolic values of a physiologic pressure waveform in the absence of an external patient monitor.

Concerned reference and serial numbers:
826820 - Codman® CereLink® ICP Monitor
All serial numbers ranging from CLK2111003 to CLK2215542

Dear Valued Integra Customer,

The purpose of this letter is to notify you that Integra LifeSciences is voluntarily recalling (removing) the CereLink® ICP monitor (details listed in Table 1 below) due to out-of-range readings.

Please note that this letter replaces the notification sent on July 6, 2022, for the out-of-range readings issue. The impacted products remain the same as those previously reported in the June 22, 2022, letter and are listed in the table below.

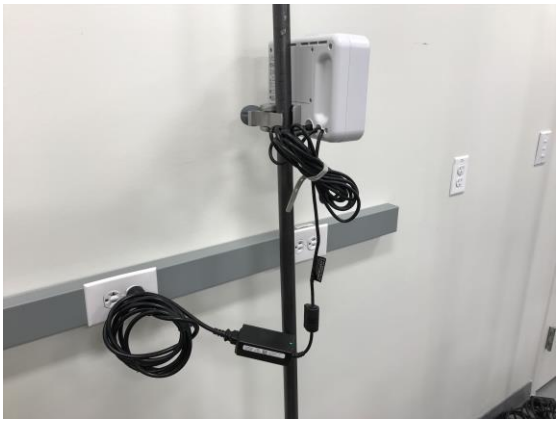
Product Name	Catalog Number	UDI-DI	Serial Numbers	Distribution Dates
Codman® CereLink® ICP Monitor	826820	10381780533788	All serial numbers ranging from CLK2111003 to CLK2215542	From June 2021 to May 31, 2022

Table 1: Product and Distribution Information

The decision to conduct a voluntary removal of the product is based on the ongoing root cause investigation. This investigation has revealed two contributing causes for the out-of-range readings, including electrical interference from the external environment (i.e., cable management) and interference from a component on the circuit board of the monitor.

Should you have a patient with a CereLink® ICP monitor in use, continued use of the monitor already in place should only be determined by an individualized risk-benefit analysis by the responsible attending clinician. If you continue to use a CereLink® ICP monitor, carefully monitor the patient, ensure deliberate cable management (as seen below in Figure 1) and discontinue use of the monitor once patient care is complete as soon as clinically possible.

Figure 1: An Example of Deliberate Cable Management



Excess AC Cord and DC Cord are coiled and secured near the CereLink® Monitor to avoid crossing each other or other cables.

AC and DC Cords are tangled together.

As a reminder, when an out-of-range reading occurs, the following system message appears on the CereLink® ICP monitor: “Sensor or extension cable failure!” “Disconnect and replace cable or sensor." As of July 31, 2022, 83 reportable complaints involving the monitor, cable, and sensor, have occurred globally for the out-of-range issue.

Of these complaints, 24 CereLink® System complaints have included a report of an additional procedure to place a new ICP sensor, which is considered a serious harm. The remaining system complaints were categorized as negligible or moderate.
The associated harms are described in the table below.

Risk to Health:

Based on the complaint analysis completed since the June 22, 2022, letter was sent, the risk profile for the risks to health identified below remains the same.

Harm	Risk Severity
Monitor displayed error message that was able to be resolved with basic troubleshooting such as unplugging or swapping out cables, power cycling, etc., or occurred in a Demo or prior to surgery (temporary discomfort/inconvenience to user)	Negligible
Monitor displayed error message that required patient to be sent for additional imaging and/or the sensor to be removed (incorrect treatment, causing minor, transient, or self-limiting injury).	Moderate
Monitor displayed error message that resulted in the patient undergoing an additional procedure to place another ICP sensor (incorrect treatment, causing injury requiring treatment beyond standard of care: additional procedure to place another CereLink ICP sensor).	Serious
Monitor displayed error message that resulted in incorrect treatment, causing herniation and/or brain death.	Critical*

**Zero (0) complaints have resulted in critical harm associated with the CereLink ICP monitor.*

Table 2: Identified harms and severity

The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

Actions to be Taken by Customers:

1. If you have a CereLink® ICP monitor, Part #826820, discontinue using the product as soon as clinically possible, remove the product from service, quarantine the monitor.
2. Please review and understand the information provided in this letter.
3. If you have a CereLink® ICP monitor, Part #826820, that is not currently being used on a patient, please remove the product from service, quarantine the monitor.
4. If you have a CereLink® ICP monitor, Part #826820, that is being used on a patient, continued use should only be determined by an individualized risk-benefit analysis by the responsible attending clinician.
    a) If you continue to use the CereLink ICP monitor on the patient, carefully monitor the patient and ensure deliberate cable management (as seen above in Figure 1).
    b) If you observe a progressive decline in the ICP readings, use another monitoring system for continued patient care, as soon as clinically possible.
    c) Once patient care is complete, discontinue use of the monitor, remove the product from service.
5. 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. By filling 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 concerned person in your organization.
6. Integra Customer Service will contact you upon receipt of this Reply Form to organize the return the concerned products and provide Return Merchandise Authorization number. Please return the power supply Part #826826 along with the monitor Part #826820.
7. We recommend that you retain a copy of the form for your records.
8. For any questions related to replacement options or products 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
EMEA Compliance Coordinator

Enclosed: 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*	31/08/2022
Product/ Device name*	Codman® CereLink® ICP Monitor
Product Code(s)	826820
Batch/Serial Number (s)	All serial numbers from CLK2111003 to CLK2215542

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. *	*Customer to complete or enter N/A*
☐	I performed all actions requested by the FSN. *	*Customer to complete or enter N/A*
☐	The information and required actions have been brought to the attention of all relevant users and executed. *	*Customer to complete or enter N/A*
☐	I have checked my stock and quarantined inventory. *	
☐	I have identified affected devices available for return	*Indicate quantity, Serial Number(s) or provide list* *Qty: SN:* *Qty: SN:* *Qty: SN:* *Qty: SN:* *Qty: SN:* *Qty: SN:*
☐	No affected devices are available for return I do not have any affected devices.	*Customer to complete or enter N/A*
☐	Other Action (Define):	
☐	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*	30/09/2022

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.