Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 195 **dated** 23/10/22 **Regarding NCMDR Recall of Codman CereLink ICP Monitor from (mfr: Integra LifeSciences Production Corporation).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 195 / 2022

27 -03-1444 H

23 -10-2022

Recall of Codman CereLink ICP Monitor from Integra LifeSciences Production Corporation.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17279
Product	Codman CereLink ICP Monitor.
Description	Medical electronics / Electromedical devices – electrodiagnostics.
Manufacturer	Integra LifeSciences Production Corporation
The affected products	Model: 826820 - Codman® CereLink® ICP Monitor All serial numbers ranging from CLK2111003 to CLK2215542.
Reason	Out-of-range readings.
Action	1. Refer to "Actions to be Taken by Customers" in the attached FSN. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
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INTEGRA
LIMIT UNCERTAINTY

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

Saint Priest, August 24th, 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

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

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

INTEGRA
LIMIT UNCERTAINTY

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.

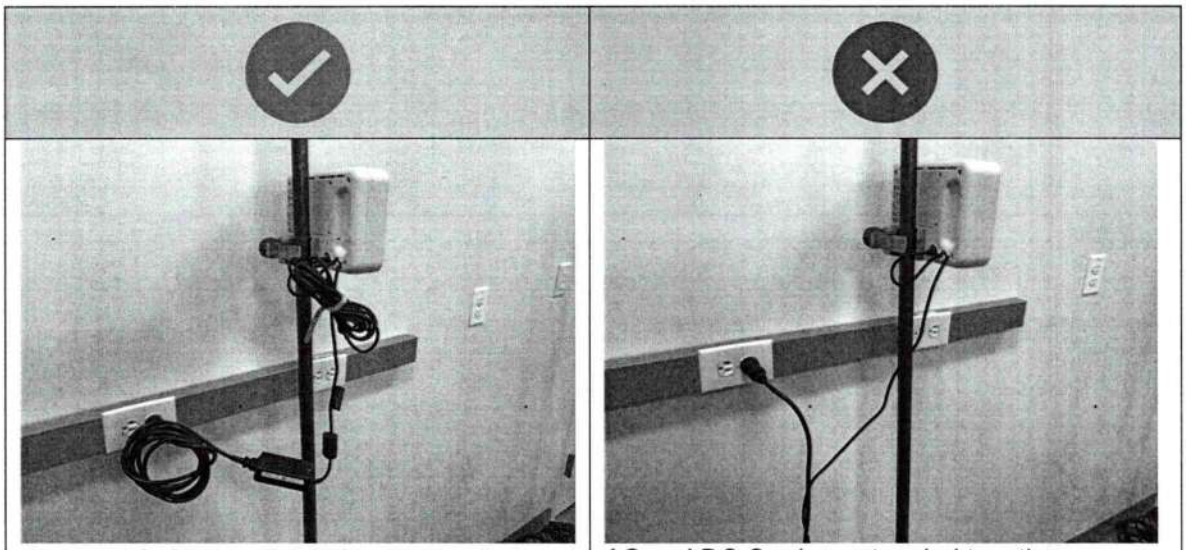
Please note that this letter replaces the notification sent on June 22, 2022, for the out-of-range readings issue. The impacted products remain the same as those previously reported in the June 22, 2022 letter and are listed in the table below.

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.

INTEGRA
LIMIT UNCERTAINTY

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, and follow steps 5-8.
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, and follow steps 5-8.
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, and follow steps 5-8.
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.
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.