To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, December 1, 2023

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – CODMAN® VPV® SYSTEM – Reference: 823192R – Incorrect Instructions for use (IFU) - FIELD SAFETY ACTION

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

Swiss Representative :
INTEGRA LIFESCIENCES SERVICES (Switzerland) LTD – Fidulem SA, Avenue Mon-Repos 24 – 1005 – Lausanne – Suisse – CHRN-AR : 20001538

Medical device:
The CODMAN® VPV® SYSTEM comprises the program unit, the transmitter, a 3m long power cord, and ultrasound gel in a carrying case.

Primary clinical purpose of device:
The CODMAN® VPV® SYSTEM is designed for use only with CODMAN® HAKIM® Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to noninvasively adjust the CODMAN HAKIM Programmable Valve to the selected setting and provides confirmation of the valve adjustment, without the need for radiographic imaging when an “Adjustment Complete” message is displayed.

Concerned reference:
823192R

Serial Numbers:
V11598

Dear Valued Integra Customer,

Integra LifeSciences is issuing this Field Safety Notice regarding the CODMAN® VPV® SYSTEM you received from March to September 2023: see details in Table 1 below.

Product Name	Product Code	Serial numbers	Distribution Dates
CODMAN® VPV® SYSTEM UDI# 10381780519348	823192R	V11598	From March 2023 to September 2023

Table 1: Product and Distribution Information

An incorrect Instructions for Use (IFU) was supplied with the CODMAN® VPV® SYSTEM. A US IFU was included in the packaging instead of the European version.

US IFU (ref # 208525001)
EU IFU (ref # 208526001)

This error is limited to the specific serial numbers outlined in Table 1. No other products are impacted.

Risks to Health

Based on the health hazard evaluation conducted for this issue, no risk for the patient was identified as there is no associated product defect. This safety action is due to a regulatory compliance issue due to the incorrect IFU provided.

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

Actions to be Taken by Customers

1. Please **review and understand** the information provided in this letter.
2. If **you do have** affected units:
    a. Check the box on the enclosed form “I do have affected units.”
    b. Record on the form the total quantity of affected units.
    c. Discard the incorrect IFU ((ref # 208525001)
3. If **you do not have** affected units, check the box, “I do not have affected unit.”
4. Please return the completed reply 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.

5. At receipt of your form, and if it is noted that you have affected units, Integra will send you the correct IFU.
6. We recommend that you retain a copy of the form for your records.

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-2023-HHE-007**
FSN Date	**01/12/2023**
Device name	**CODMAN® VPV® SYSTEM**
Product Code	**823192R**

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 inventory*	
☐	I <u>do have</u> affected units and I confirm that I discarded the US IFU	**Quantity:** **Serial number:**
☐	I <u>do not</u> have any affected units	
☐	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 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://integralife.eu/
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	26/12/2023

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 action.