To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, June 22, 2023

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – Codman® Cranial Access Kit, without drugs – Reference: 82-6617 – RECALL

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

EC Representative:
INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST, France – SRN : FR-AR-000002474

Medical device:
The Codman Cranial Access Kit is a disposable intracranial procedural kit which contains items used during each step of the cranial access procedure.

Primary clinical purpose of device:
The Codman Cranial Access Kit is indicated when a craniotomy is required for placement of an intracranial pressure (ICP) monitoring device and/or cerebrospinal fluid drainage procedures.

Concerned reference and lot numbers:
82-6617 - Codman® Cranial Access Kit, without drugs
Lots:
21HDC519
21JDC435
21KDB171
21KDC558
21LDB727
22CDA795
22FDB915
23ADB154

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of Codman® Cranial Access Kits part number 82-6617 distributed from February 2020 to date: see details in Table 1 below.

Product Name Unique Device Identifier (UDI)	Product Code	Lot number	Manufacturing Dates	Expiry Dates	Distribution Dates
Codman® Cranial Access Kit, without drugs UDI: 10381780520399	82-6617	21HDC519	13/11/2021	17/09/2023	December 2021 to January 2022
		21JDC435	22/12/2021	11/11/2023	February 2022 to June 2022
		21KDB171	07/02/2022	24/01/2023	April 2022 to August 2022
		21KDC558	14/03/2022	10/12/2023	April 2022 to October 2022
		21LDB727	16/12/2021	08/10/2023	December 2021 to January 2022
		22CDA795	18/04/2022	21/03/2024	August 2022 to February 2023
		22FDB915	16/08/2022	30/04/2024	February 2023 to March 2023
		23ADB154	20/02/2023	30/04/2024	March 2023

Table 1: Product and Distribution Information

During an investigation, Integra LifeSciences identified regulatory noncompliances related to the CE-marking of the Codman Cranial Access Kits 82-6617. In particular, this kit is considered as a system pack under article 12 of the Medical Device Directive (93/42/EC) and requires CE marking of each component. The ventricular needle not CE marked anymore shall not be provided with the kit.

This voluntary recall is limited to reference 82-6617 and specific lots outlined in Table 1. No other products are impacted. All other references of Codman® Cranial Access kits may be used with confidence and without limitation.

Risks to Health

As per the Health Hazard Evaluation conducted for this issue, no risk for the patient was identified as there is no associated product defect. This action is due to a regulatory compliance issue.

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

If the Codman® Cranial Access Kit has already been used, there is no risk to patient and no additional follow up is required besides standard operative care. No complaint was received due to this issue.

Actions to be Taken by Customers

1. Please **review and understand** the information provided in this letter.
2. If **you do have** affected kits:
    a. Quarantine the kits immediately.
    b. Check the box on the enclosed form “I do have affected kits.”
    c. Record on the form the total quantity of affected kits and lot number that you have.
3. If **you do not have** affected kits, check the box, “I do not have affected kit.”
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 kits, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product. If credit note is required, please check the box in the reply form. Alternatively, you can contact your sales representative to discuss substitute options.
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-006**
FSN Date	**14/06/2023**
Device name	**Codman® Cranial Access Kit without Drugs**
Product Code	**82-6617**
Lots	**21HDC519 / 21JDC435 / 21KDB171 / 21KDC558 / 21LDB727 / 22CDA795 / 22FDB915 / 23ADB154**

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 do have affected kits and I have quarantined them.*	**Quantity: Lot:** **Quantity: Lot:** **Quantity: Lot:**
☐	I do not 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*
☐	Credit note required	
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*	14/07/2023

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.