To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, March 31st, 2023

Subject: URGENT - FIELD SAFETY NOTICE – Integra – Codman® Cranial Hand Drill – Reference: 826607 – 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 following products are available separately: CODMAN Cranial Hand Drill 82-6607, 5.8 mm Cranial Drill Bit, 82-6608 2.7 mm Cranial Drill Bit 82-6609. Each of the drill bits is packaged with a drill guide and a hex wrench. The CODMAN Cranial Hand Drill and the Cranial Drill Bits are intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Integra single-use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or resterilization, after a single patient use.

Primary clinical purpose of device:
The CODMAN® Cranial Hand Drill and Cranial Drill Bits are indicated when a craniotomy is required for placement of an intracranial pressure (ICP) monitoring device and/or cerebrospinal fluid drainage device.

Concerned reference and lot numbers:
826607 - Codman® Cranial Hand Drill
Lot 6563961
Lot 6568711
Lot 6568709
Lot 6568710

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for Codman® Cranial Hand Drill part number 826607: see details in Table 1 below.

Product Name Unique Device Identifier (UDI)	Catalog Number	Lot number	Manufacturing Dates	Expiry Dates	Distribution Dates
Codman® Cranial Hand Drill UDI: 10381780514961	826607	6563961	2022-12-06	2027-11-30	January to February 2023
		6568711	2022-12-03	2027-11-30	January 2023
		6568709	2022-12-02	2027-11-30	January to February 2023
		6568710	2022-12-02	2027-11-30	January to February 2023

Table 1: Product and Distribution Information

During an investigation, Integra LifeSciences identified that these lots of Codman® Cranial Hand Drills were released with potential rust on them.

This voluntary recall is limited to the product and specific lots outlined in Table 1. No other products or lots are impacted. All other Codman® Cranial Hand Drills may be used with confidence and without limitation.

Risks to Health

Per the Health Hazard Evaluation conducted for this issue, the worst-case risks for the use of Codman® Cranial Hand Drill are:

- Inflammation, local toxicity, systemic toxicity, sensitivity, and revision surgery, with a severity of "Serious,"
- Infection, with a severity of "Serious"

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

If the Codman® Cranial Hand Drills have already been used, there is no long-term risk to patient and no follow up required besides standard operative care. To date, no injuries have occurred due to this issue. However, one complaint has been received involving no patient.

Actions to be Taken by Customers

1. Please **review and understand** the information provided in this letter.
2. If **you do have** units of the affected product:
    a. Remove the units immediately from service.
    b. Check the box on the enclosed form “I do have affected units.”
    c. Record on the form the total quantity of the affected product that you have.
3. If **you do not have** units of the affected product, check the box, “I do not have affected product.”
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 product, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product. An alternative product may be requested, or a credit note could be issued. Please select your preferable option in the reply form.
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,

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

CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN-2023-HHE-003**
FSN Date	**31/03/2023**
Device name	**Codman® Cranial Hand Drill**
Product Code	**826607**
Batches	**6563961/ 6568711 / 6568709 / 6568710**

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 units and I have quarantined them.*	**Quantity:**
☐	I do not have any affected units	
☐	Other Action (Define):	
☐	I have a query please contact me	*Customer to enter contact details if different from above and brief description of query*
Preferable option: ☐ Credit note ☐ Alternative product		
Print Name*		*Customer print name here*
Signature*		*Customer sign here*
Date*		

4. Return acknowledgement to Sender	
Email	emea-fsca-neuro@integralife.com
Distributor 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*	30/04/2023

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.