To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, January 12th, 2024

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – Integra® Cranial Access Kit, without drugs – Reference: INS5HND – RECALL

Legal manufacturer: INTEGRA PAIN MANAGEMENT - 3498 WEST 2400 SOUTH #1050 WEST VALLEY CITY, UT 84119 – US-MF-000018493

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

Medical device:
The Cranial Access Kit consists of various accessories used during a ventriculostomy procedure. The kit includes a hand drill with chuck, and a drill bit with depth guard. The depth guard allows accurate, secure, and easy to use adjustment of hand drill depth. Hand drill depth is selected by setting the depth guard to the required distance. The kit contains various instruments, including scalpels, needles, syringes, skin marker and ruler, fenestrated drape, towels, sponges and gauze.
The Cranial Access Kit is single use and disposable.

Primary clinical purpose of device:
The Cranial Access Kit allows for access to the subarachnoid space or the lateral ventricles of the brain. The kit is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF, and to monitor ICP.

Concerned reference and lot numbers:
INS5HND - Integra® Cranial Access Kit, without drugs
Lots:
7248999
7249001
7253133
7253135
7253136

Dear Valued Integra Customer,

Integra LifeSciences is voluntarily issuing this Field Safety Notice for the recall of Integra® Cranial Access Kit part number INS5HND presented in the table below:

Product Name Unique Device Identifier (UDI)	Product Code	Lot numbers	Manufacturing Dates	Expiry Dates	Distribution Dates
Cranial Access Kit, without drugs, bit and guard UDI: 10381780263906	INS5HND	7248999	08-aug-23	17-july-25	From Sept. 22, 2023 To Oct. 20, 2023
		7249001	06-sept-23	29-june-25	
		7253133	07-sept-23	29-june-25	
		7253135	13-sept-23	16-july-25	
		7253136	18-sept-23	16-july-25	

Table 1: Product, lots and Distribution Information

Through an internal investigation, it was identified that there is a defect in the sterile packaging (header bag) of the Cranial Access Kit, causing the packaging to fail the required packaging integrity testing criteria. Therefore, there is a potential sterility concern for any lots produced with this header bag. This packaging represents the sterile barrier for the Cranial Access Kit, which is sold as single use, sterile kit.

This voluntary recall is limited to reference INS5HND, and specific lots outlined in Table 1.

Risks to Health

Based on the health hazard evaluation conducted for this issue, the potential harms are infection, fever, allergic reaction, and/or toxic reaction if a kit with compromised sterility is used. In addition, there are no long-range health consequences expected due to this issue. Furthermore, if the kits were used and standard post-operative care is followed, no further patient follow-up is required.

Integra has not received any complaint that could have been linked to this defect.

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 in 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. A credit or replacement order can be processed based on the availability for the quantity noted on the 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,

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-012**
FSN Date	**January 12th, 2024**
Device name	**Integra® Cranial Access Kit without Drugs**
Product Code	**INS5HND**
Lots	**7248999 – 7249001 – 7253133 – 7253135 - 7253136**

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 kits and I have quarantined them.*	**Quantity: Lot:** **Quantity: Lot:**
☐	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
Distributor 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*	09/02/2024

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.