**To the attention of Medical Device Vigilance responsible / Central Pharmacy**

Saint Priest, April 10th, 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:**
**7312131**
**7291974**
**7291975**
**7289690**
**7312137**
**7312139**

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 Date | Expiry Date | Distribution Dates |
|---|---|---|---|---|---|
| Cranial Access Kit, without drugs, bit and guard<br><br>UDI: 10381780263906 | INS5HND | 7312131 | 12/12/2023 | 03/09/2025 | From 28/12/2023 to 28/03/2024 |
| | | 7291974 | | | |
| | | 7291975 | | | |
| | | 7289690 | 03/01/2024 | | |
| | | 7312137 | 08/01/2024 | | |
| | | 7312139 | | | |

**Table 1: Product, lots and Distribution Information**

The decision to conduct a voluntary removal of the product was based on the following: through an internal investigation, it was identified that there is a defect (potential holes and tears) in the sterile packaging (header bag) of the Cranial Access Kit which creates a potential sterility concern. The header bag represents the sterile barrier for the Cranial Access Kit, which is sold as a single use, sterile kit. The root cause has been confirmed to be incorrect material handling practice at our manufacturing site.

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 in EMEA 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 note will be processed, upon receipt of returned goods.
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-2024-HHE-004 A** |
| FSN Date | **April 10, 2024** |
| Device name | **Integra® Cranial Access Kit without Drugs** |
| Product Code | **INS5HND** |
| Lots | **7312131 – 7291974 – 7291975 – 7289690-7312137 – 7312139** |

| **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:**<br>**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* |
| 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<br>Integra Immeuble Séquoia 2,<br>97 allée Alexandre Borodine<br>Parc technologique de la Porte des Alpes<br>69800 Saint Priest, France |
| Web Portal | https://integralife.eu/ |
| Fax | +33 (0)4 37 47 59 30 |
| Deadline for returning the customer reply form* | 03/05/2024 |

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.