To the attention of Medical Device Vigilance Manager / Central Pharmacy

Saint Priest, 29 September 2021

Subject: **URGENT - FIELD SAFETY NOTICE** – Integra AccuDrain®, Hermetic™, LimiTorr™, MoniTorr™ - Alert about Potential User Error of CSF Access port – Information to users

Legal manufacturer:
INTEGRA LIFESCIENCES CORPORATION – 1100 CAMPUS ROAD, PRINCETON, NEW JERSEY, USA 08540

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

Medical devices:
AccuDrain®, Hermetic™, LimiTorr™, MoniTorr™: These systems are used to drain cerebrospinal fluid (CSF) from the ventricles of the brain or the lumbar subarachnoid space to an external drainage bag.

Primary clinical purpose of device(s):

Accudrain®: Draining and monitoring of cerebrospinal fluid (CSF) flow from the ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to: Reduce intracranial pressure (ICP), Monitor ICP, Monitor CSF, provide temporary CSF drainage.

Hermetic™: Draining and monitoring of CSF flow from the lateral ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to: Reduce ICP, Monitor ICP, Monitor CSF, provide temporary CSF drainage for patients with infected hydrocephalic shunts.

LimiTorr™ / MoniTorr™: The system allows for the drainage and monitoring of CSF from lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce ICP, to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP.

Concerned reference(s) and batches/serial numbers UDI described in the table below:
AccuDrain® : INS-8400, INS-8401,
Hermetic™ : INS-8301, INS-8302, INS-8600, INS-8601
LimiTorr™ : INS-9020, INS-9030
MoniTorr™: INS-1100

Dear Valued Customer,

The purpose of this letter is to notify you that the legal manufacturer Integra LifeSciences Corporation, is voluntarily issuing a Field Safety Notice for the part numbers listed in the table below.

Product Family	Description of Concerned Product	Reference	UDI
AccuDrain®	Accudrain Without the Anti-Reflux Valve	INS-8400	10381780023876
	Accudrain With Anti-Reflux Valve	INS-8401	10381780023883
Hermetic™	Hermetic Plus EVD System w/Reflux Valve	INS-8301	10381780023869
	Hermetic Plus EVD System w/o Reflux Valve	INS-8302	10381780071006
	CSF Drainage System w/Blue Stripe Tubing & 1-way Valve	INS-8600	10381780071099
	CSF Drainage System w/Green Stripe Tubing & Transd	INS-8601	10381780072164
LimiTorr™	LimiTorr Volume Limiting EVD 20 ML	INS-9020	10381780071105
	LimiTorr Volume Limiting EVD 30 ML	INS-9030	10381780071129
MoniTorr™	CSF Drainage System used with Pole Mount System	INS-1100	10381780071037

All lot numbers available on the market are concerned by this Field Safety Notice.
These references may not be available in all markets.

This Field Safety Notice is to notify healthcare professionals about adverse events that have occurred due to use error relating to the cerebrospinal fluid (CSF) needleless access ports on the Integra AccuDrain™ device. A total of seven (7) complaints have been received in the U.S. over the past three (3) years, and no complaint out of the U.S., regarding the use of the AccuDrain needleless access port for the injection of fluids, a use not intended per the device's Instructions for Use (IFU). One (1) of the seven (7) complaints, received in July 2021, resulted in a death. According to the complaint, intravenous (IV) contrast dye was inadvertently injected into the CSF patient access port on the AccuDrain device, potentially contributing to the death of the patient. Based on the complaint description, the CSF access port of the AccuDrain device was not used as intended per the IFU; the CSF access port is intended for draining and monitoring of CSF only.

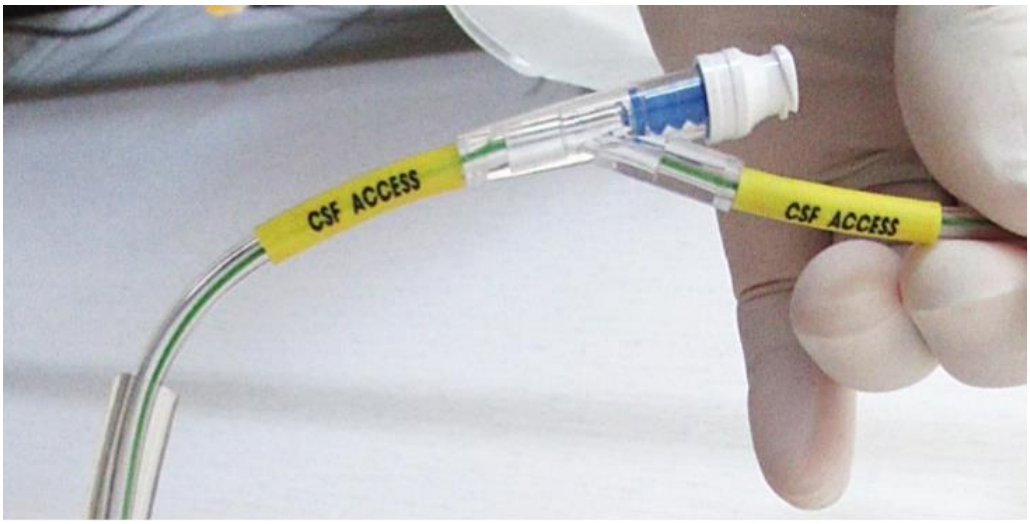
One of the factors believed to be contributing to these complaints may be the potential use of other devices with a needleless access port similar to the ports on some of Integra's external drainage devices, including AccuDrain, but intended to different indications, such as CareFusion Alaris Infusion sets, distributed by Becton, Dickinson, and Company (BD) (See Figure 1), intended to intravenous drug delivery.

Figure 1: Similar needleless port manufactured by BD

Integra CSF drainage devices in addition to AccuDrain are included in the scope of this Field Safety Notice because they use the same needleless access port.

There are no defects on the Integra CSF drainage devices, nevertheless Integra LifeSciences Corporation is issuing a Field Safety Notice out of an abundance of caution to remind you to verify the needleless access ports are being used for the proper indication. Integra CSF drainage devices have visual indicators noting that the needleless access ports on the device are intended to be used for CSF access only. The CSF drainage devices have markings to differentiate them from other, non-Integra devices, that contain needleless access ports, including a green or blue stripe on the tubing and yellow labels on one or both sides of the access port to alert the user that the port is for “CSF ACCESS” (see Figure 2).

Figure 2: Integra AccuDrain® needleless access port



The assessment completed by the legal manufacturer Integra LifeSciences Corporation, concluded that the hazard resulting in a wrong use on the access port could result in a critical harm of the patient: permanent impairment of a body function, permanent damage of a body structure, life-threating situation or even death of the patient. The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

To mitigate the risk, we kindly ask you to take aknowlegment of this Field Safety Notice and to use the Integra devices per the indications provided within the labeling. See above for indications of the devices within the scope of this Field Safety Notice.

We are notifying you of the Field Safety Notice as our records indicate that you have been supplied with one or more of the devices listed in the Table.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially concerned devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer reply is required. A form is attached to this Field Safety Notice. The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. Please complete the attached form to acknowledge your receipt of this letter and return it by email or fax as indicated on the form. Please retain a copy of the form for your records. Please feel free to contact your Integra Sales Rep or the customer service team with any questions you may have regarding this Field Safety Notice. **We expect a response within 3 weeks.**

The National Competent Authority of your country has been alerted of this Field Safety Notice.

Please feel free to contact me 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
EMEA Compliance Coordinator

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

Customer Reply Form

1. **Field Safety Notice (FSN) information**	
FSN Reference number*	FSN-2021-HHE-008-29092021
FSN Date*	29/09/2021
Product/ Device name*	AccuDrain® Hermetic™ LimiTorr™ MoniTorr™
Product Code(s)	AccuDrain® : INS-8400, INS-8401, Hermetic™ : INS-8301, INS-8302, INS-8600, INS-8601 LimiTorr™ : INS-9020, INS-9030 MoniTorr™ : INS-1100,
Batch/Serial Number (s)	All lots available

2. **Customer Details**	
Account Number	
Healthcare Organization Name*	
Organization 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 Organization**		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	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 38 15 85 03
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allées Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	www.integralife.eu
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	01 NOV 2021

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.