To the attention of Medical Device Vigilance responsible / Central Pharmacy / BioMedical Engineer

Saint Priest, July 4, 2014

Subject: **URGENT – FIELD SAFETY NOTICE**
Medical device: **Camino® Intracranial Pressure Monitoring Kits**
References: 110-4B, 110-4G, 110-4H, 110-4L
Legal Manufacturer:
Integra LifeSciences Corporation dba Integra NeuroSciences, 5955 Pacific Center Boulevard, San Diego, California, 92121, USA
Devices affected: all units.

Dear Customer,

The purpose of this Field Safety Notice is to inform you that Integra LifeSciences Corporation (Integra) has recently revised the labelling of certain Camino® Intracranial Pressure Monitoring Kits to indicate they are UNSAFE in a Magnetic Resonance (MR) environment.

Only the following Camino® Intracranial Pressure Monitoring Kits are affected:

Description of affected product	References
OLM Intracranial Pressure Monitoring Kit	110-4B
Post Craniotomy Subdural Pressure Monitoring Kit	110-4G
Ventricular Bolt Pressure Monitoring Kit	110-4H
Intracranial Pressure Monitoring Catheter Kit with Licox® IMC Bolt Fitting	110-4L

These Camino® Intracranial Pressure Monitoring Kits are used by qualified neurosurgeon when direct measurement of intracranial pressure in the parenchyma or the subarachnoid space (110-4B/110-4L); or in the subdural space, post craniotomy (110-4G); or when direct pressure measurement and cerebrospinal fluid drainage (110-4H), is clinically important.

There have been no reports of patient injury or adverse health consequences associated with the current labelling on Camino Catheters. However, until you receive products with the revised labelling that includes MR Unsafe symbols on the package labels and to the distal end of the catheters, we are providing the attached MR Safety Bulletin.

For your convenience the bulletin has also been posted on the Integra Web site for the affected kits and can be viewed by following the steps below:

http://www.integralife.com

- Select “For The Neurosurgeon”;
- Select “ICP Monitoring”;
- Select the Camino catheter of interest
- Select "Contraindications”.

We are notifying you of this Field Safety Notice as our records indicate that you have purchased the products describing hereinbefore.

Please ensure that this Field Safety Notice and the attached MR Safety Bulletin are distributed to the appropriate surgery team(s) within your institution.

Integra LifeSciences Services (France)
Siège Social : Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine ▪ Parc Technologique de la Porte des Alpes ▪ 69800 Saint Priest ▪ France
33 (0)4 37 47 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

Please fill in, sign and return the attached Field Safety Notice Acknowledgement and Return Form.

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

Integra recommends you also maintaining a copy of this notification and signed copy of the acknowledgement form for your records.

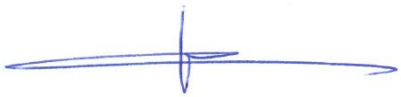
Regulatory agencies may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

Please note that your National Competent Authority has been alerted of this field safety notice.

Thank you for your cooperation with this Field Safety Notice.

For any questions or concerns, please contact Jean-Charles Moncenis at the following e-mail address: jean-charles.moncenis@integralife.com.

Sincerely,



Jean-Charles MONCENIS
Senior Regulatory Affairs Product Manager
Neurosurgery Products Division
Europe, Middle-East & Africa

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FIELD SAFETY NOTICE ACKNOWLEDGMENT AND RETURN FORM

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Please Complete and Return Promptly

Please fill out this form and return by email or fax:
By fax/telecopy: **+33 (0)4 37 47 59 30**
Or by e-mail: emea-fsca-neuro@integralife.com

With this form,
- I confirm that I have received, read and understood the information provided in the Integra Field Safety Notice.
- I confirm that this Field Safety Notice has been circulated to the appropriate surgery team(s) within my institution along with the additional Instructions for Use (IFU) Warning.

_____ Customer/Site Name	_____ Customer Contact Name
_____ Street Address	
_____ City, Country, Postal Code	_____ Signature
_____ Email	_____ Telephone

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