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

INTEGRA
LIMIT UNCERTAINTY

Saint Priest, May 29, 2015

*Subject:* **URGENT – FIELD SAFETY NOTICE – RECALL**
*Medical devices:* **Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting**
*Reference:* 110-4L
*Legal Manufacturer:* Integra NeuroSciences - 5955 Pacific Center Blvd - San Diego CA, 92121, USA
*Affected lot numbers: Please refer to table below*

Dear Customer,

Through an internal review, Integra LifeSciences Corporation (Integra) has identified certain lot numbers of the 110-4L Camino® Intracranial Pressure Monitoring Catheters that may have been incorrectly assembled. Specifically, the o-ring in the bolt adapter may be in the wrong location and as a result, there is a potential CSF/blood could leak from the bolt adapter.

There has not been any report of a patient injury or adverse health consequences as a result of such leakage, most likely as the bolt adapter is inserted and connected to the Licox® Introducer bolt which contains a hermetic seal that serves as the primary barrier to such leakage.

Out of an abundance of caution, Integra is voluntary recalling the lot numbers of the 110-4L Camino® Catheter that may contain an incorrectly assembled bolt adapter.

| Description of affected product | Reference | Affected Lot Numbers |
|---|---|---|
| **Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting** | 110-4L | **305000291459; 305000299228; 305000300396; 305000301413; 305000312261; 305000315716; 30500X294240; 30500X304371; 30500X309674; 30500X318076; 3050RX285879; 3050RY297365; 305E00318970; 305E0X320986** |

**Our records indicate that you received one or more Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting affected.**

**Integra kindly asks you to examine your inventory to determine if you have these devices.**

Once the audit of your inventory is achieved, please separate them from your inventory, stop using them immediately and remove them from service and quarantine them.

Then, please complete the attached Recall Acknowledgement and Return Form and return it promptly as per the instructions on the form.

**Once your Recall Acknowledgement and Return Form is received and if you have identified affected product(s), our Customer Service will contact you and provide an RMA number and instructions for returning the product(s).**

With this form, you will ensure that all the affected devices will be sent back to Integra. You also confirm that this notification has been forwarded to every concerned user.

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



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

We also recommend that you keep a copy of this notification and a signed copy of the acknowledgement form for your records.

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.

Please note that your National Competent Authority 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 Recall Acknowledgement and Return Form.

For any questions or concerns, please contact the following e-mail address:
emea-fsca-neuro@integralife.com.

Sincerely,

**Angélique AUBERT**
Compliance coordinator
Europe, Middle-East & Africa



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# RECALL ACKNOWLEDGMENT AND RETURN FORM

*Medical devices:* **Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting**
*Reference:* 110-4L
*Legal Manufacturer:* Integra NeuroSciences - 5955 Pacific Center Blvd - San Diego CA, 92121, USA
*Affected lot numbers: Please refer to table below*

**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

I have received, read and understood the information provided in the Integra Field Safety Notice regarding **Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting.**

My inventory has been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ **Yes**, I do have affected product(s) in my inventory. *Please indicate quantity in the table below:*

| Description of affected product | Reference | Affected Lot Numbers | Quantity |
|---|---|---|---|
| **Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting** | 110-4L | **305000291459; 305000299228; 305000300396; 305000301413; 305000312261; 305000315716; 30500X294240; 30500X304371; 30500X309674; 30500X318076; 3050RX285879; 3050RY297365; 305E00318970; 305E0X320986** | |

☐ **No**, I do not have the affected product in my inventory.

With this form,
- I confirm that I have received this Field Safety Notice and that I intend to fully comply with it;
- I confirm that this Field Safety Notice has been circulated to appropriate people within my healthcare facility;
- I ensure that all the affected products are being quarantined and will be returned to Integra.

**Please complete contact point details below.**

Customer/Site Name _____ Customer Contact Name _____

Street Address _____

City, Country, Postal Code _____ Telephone _____

Email _____

Fax _____ Signature _____



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