

May 27, 2015

URGENT - VOLUNTARY MEDICAL DEVICE RECALL
Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting
Catalogue No. 110-4L

Dear Valued Customer:

Through an internal review, Integra LifeSciences 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. To-date, there have been no complaints or injuries reported for 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.

Regardless of the lack of complaints or injuries, Integra is voluntarily recalling the lot numbers of the 110-4L Camino Catheter that may contain an incorrectly assembled bolt adapter. Our records indicate that you received one or more of these lot numbers.

Integra is asking that you do the following:

1. Review your inventory and determine if you have affected 110-4L Camino Catheters from the lot numbers listed on the next page. **If you do not, they are not affected and you can continue to use them.**
2. If you do have product with lot numbers listed on the next page, **stop using them immediately and remove them from service.**
3. Complete the attached form. If you do not have product with the lot numbers listed, check the box, **I do not have any product with a lot number on the list below.**
4. If you do have product with the lot numbers listed, check the box, **I do have product(s) with a lot number below.** Circle the lot numbers and record the total quantity of all lot numbers you have.
5. Complete the other information and return it by email or fax as indicated on the form. Additionally, notify your national regulatory agency if it is required by your national medical device regulations.

When your form is received, Customer Service will contact you and provide an RMA number and directions to use when returning the products. The completed form ensures that you and Integra have achieved effectiveness in communicating this information that is required by regulatory authorities.

Should you have any questions regarding these instructions, please contact Customer Service at 609-936-5400 or email at LAPAC_CS@INTEGRALIFE.COM

We apologize for any inconvenience this may cause and thank you for your cooperation in this effort.

Sincerely,

Hanuman Jampani
Senior Director, Marketing
Integra Life Sciences

RECALL ACKNOWLEDGMENT AND RETURN FORM

Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting

Catalogue No. 110-4L

Please complete this form and return promptly to:

FCA3@integralife.com or FAX to 1-609-275-9445

I have received, read, and understand the information provided in the Integra Voluntary Medical Device Recall Notification.

I do not have any product with a lot number on the list below.

I do have product(s) with a lot number below.

Please circle any lot numbers that you have that ARE AFFECTED and the TOTAL QUANTITY.

Reference	Product Description	Affected Lot Numbers	Total Quantity
110-4L	Camino® Intracranial Pressure Monitoring Catheter with Licox® IMC Bolt Fitting	305000291459, 305000299228, 305000300396, 305000301413, 305000312261, 305000315716, 30500X294240, 30500X304371, <u>30500X309674</u> , 30500X318076, 3050RX285879, 3050RY297365, 305E00318970, 305E0X320986	11

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Customer/Site Name

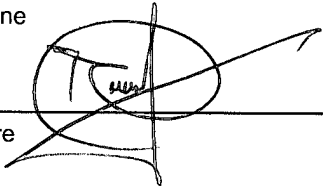
RUA PEIXOTO GOMIDE, 515

Street Address

+55 (11) 3371-1586

Telephone

Signature



ROBSON PEREIRA

Customer Contact Name

SÃO PAULO - CEP 01409-001

City, Postal Code

ROBSON@DABASONS.COM.BR

Email

05/28/15