To the attention of Quality Assurance Dpt and/or Regulatory Affairs Dpt or Management

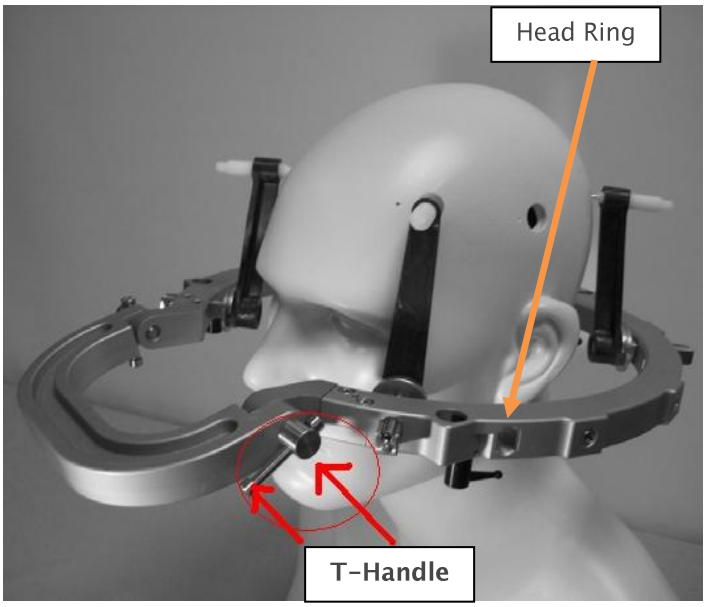
Customer: Distributor name

Saint Priest, October 22, 2012

Subject: **URGENT – RECALL NOTIFICATION LETTER**
Medical device: **Integra CT-compatible Intubation Head Ring Assembly**
References: HRAIM
Legal Manufacturer:
Integra Burlington MA, Inc - 22 Terry Ave, Burlington, MA 01803 - USA
Devices affected: all units manufactured since February 7, 2006.

Dear Customer,

Integra LifeSciences Corporation (Integra) has determined that when the T-handle on the **Integra CT-compatible Intubation Head Ring Assembly** (**HRAIM**) intubation hoop is tightened on some units, it may stop in a vertical position that prevents the *CRWPRECISE* (also known as the CRW Precision Stereotactic Frame) and *CRWASL* (CRW Arc System) from being properly seated on the head ring (please see picture below). This issue is due to the screw head present in the T-handle.



Following complaints received and in order to prevent any occurrence of this issue, Integra has modified the screw head on the HRAIM. Moreover, Integra is taking a very conservative approach to resolve this inconvenience for its customers by initiating a voluntary Field Safety Corrective Action to provide you with the information needed to have the current screw head replaced with the new one.

We are notifying you of this Field Safety Notice as our records indicate that you have purchased an **Integra CT-compatible Intubation Head Ring Assembly** or an **Integra CRW™ Stereotactic Arc** *(which contains an **Integra CT-compatible Intubation Head Ring Assembly***) within the last six years.

Description of affected product	Reference
Integra CT-compatible Intubation Head Ring Assembly	HRAIM

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

To ensure Integra is able to expediently replace the current screws with the new screws for your HRAIM unit(s), we kindly ask you to examine your inventory to determine if you have an Integra CT-compatible Intubation Head Ring Assembly or an Integra CRW™ Stereotactic Arc (which contains an Integra CT-compatible Intubation Head Ring Assembly) that you have received since February 7, 2006.

We also kindly ask you to contact the final customers who may have the affected products and provide them with this letter.

Once the audit of your inventory and your final customers' inventory achieved, please complete the attached Recall Acknowledgement and Return Form and please return it promptly as per the instructions on the form.

Integra will provide you with needed quantity of new screws along with a rework instructions allowing you to easily replace the current screws by the new ones.

If you or your final customers are in possession of the products listed as above (affected reference and batch), please quarantine them until you receive the modified screws.

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

Thank you for your cooperation with this Recall and for returning the attached Recall Acknowledgement and Return Form. We would like to apologize for any inconvenience this situation may have caused you.

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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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical device: **Integra CT-compatible Intubation Head Ring Assembly**
References: HRAIM
Legal Manufacturer:
Integra Burlington MA, Inc - 22 Terry Ave, Burlington, MA 01803 - USA
Devices affected: all units manufactured since February 7, 2006.

Please Complete and Return Promptly

Please fill out this form and return by email or fax:
By fax/telecopy: **+33 (0)4 37 47 57 32**
Or by e-mail: emea-fsca-neuro@integralife.com

Customer: Distributor name

I have received and read the voluntary recall notification regarding **Integra CT-compatible Intubation Head Ring Assembly (HRAIM)**

My inventory and my final customers' inventory have been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ Yes, I do have the affected product in my inventory or my final customers' inventory.
Please indicate quantity in the following table:

Description of affected products	References	Affected units	Quantity
Integra CT-compatible Intubation Head Ring Assembly	HRAIM	All units manufactured since February 7, 2006.	

With this form,
- I confirm that I have received this recall notification and that I intend to fully comply with it
- I confirm that this recall notification has been circulated to all affected users / customers. They have been asked to check their inventory and quarantine the affected products.
- I ensure that all the affected products, including those I had already sent to my customers, will be replaced as per the rework instructions that Integra will send to me along with the modified screws.

☐ No, I do not have affected products in my inventory or my final customers' inventory.

_____ _____
Customer/Site Name Customer Contact Name

_____
Street Address

_____ _____
City, Country, Postal Code Signature

_____ _____
Email Telephone

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