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

Saint Priest, December 24, 2014

Subject: **URGENT – FIELD SAFETY NOTICE – RECALL**
Medical devices: **Mayfield® Ultra 360 Base Unit**
Reference: A2009
Legal Manufacturer: Integra LifeSciences - 4900 Charlemar Dr. Building A - Cincinnati, OH 45227, USA
Affected lot numbers: All lot numbers are involved.

Dear Customer,

Integra LifeSciences Corporation (Integra) has identified that there is a possibility for the locking handle mechanism of the Mayfield® Ultra 360 Base Unit to fail during use.

The Mayfield® Ultra 360 Base Unit provides the ability to position and hold a patient head while the patient is in the prone, supine, lateral or park-bench and sitting positions. They are intended to be used during diagnostic examinations or surgical procedures where a rigid support between the surgical table and a headrest or skull clamp is necessary and positional freedom is required.

Figure 1: Mayfield® Ultra Base Unit

There has not been any report of a patient injury or adverse health consequences as a result of such a failure. Out of an abundance of caution, Integra is voluntary recalling all Mayfield® Ultra 360 Base Units to inspect and where necessary, repair them.

Description of affected product	Reference	Affected Lot Numbers
Mayfield® Ultra 360 Base Unit	A2009	**All lot numbers**

Our records indicate that you received one or more Mayfield® Ultra 360 Base Unit(s).

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

Integra kindly asks you to examine your inventory and your final customers' inventory to determine if you have these devices.

Once the audit of your inventory and your final customers' inventory achieved, Integra recommends to your final customers to discontinue use of the device and remove them from service until they are repaired by an authorized Integra Repair Center.

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).

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

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,

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

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

RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices: **Mayfield® Ultra 360 Base Unit**
Reference: A2009
Legal Manufacturer: Integra LifeSciences - 4900 Charlemar Dr. Building A - Cincinnati, OH 45227, USA
Affected lot numbers: All lot numbers are involved.

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 **Mayfield® Ultra 360 Base Unit.**

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 and/or my final customers' inventories.
Please fill out in the table below:

Description of affected product	Reference	Affected Lot Number & Quantity
Mayfield® Ultra 360 Base Unit	A2009	

☐ **No**, I do not have the affected product in my inventory and/or my final customers' inventories

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 all affected users / customers. They have been asked to check their inventory and to discontinue the use of the affected products and to remove them from service;
- I ensure that all the affected products, including those I had already sent to my customers, 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 _____

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