

Saint Priest, 14/12/18

Subject: **URGENT - FIELD SAFETY NOTICE - SAFETY INFORMATION**

Medical devices: **Integra MAYFIELD® SKULL Clamp A1059, A1108, A1114, A1117, A2000, A2114, A3059**

Legal manufacturer: *Integra LifeSciences Corporation - 4900 Charlemar Dr. Building A - Cincinnati OH, 45227, USA*

EC Rep: **INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoia 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST**

Concerned batches:
All lots sold between 2004 - 2015

Dear Valued Customer,

Integra LifeSciences Group is voluntarily reinforcing the MAYFIELD® Skull Clamps, A1059, A1108, A1114, A1117, A2000, A2114, A3059 Instructions for Use and intending to emphasize the current MAINTENANCE and recommended FREQUENCY associated with the safe use of the MAYFIELD® Skull Clamps, listed below:



MAYFIELD® Modified Skull Clamp (A1059)



MAYFIELD® Triad Skull Clamp (A1108)



MAYFIELD® Infinity Skull Clamp System (A1114)



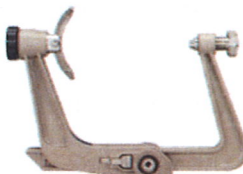
MAYFIELD® MR/X-ray Skull Clamp (A1117)



MAYFIELD® 2000 Skull Clamp (A2000)



MAYFIELD® Infinity XR2 Skull Clamp (A2114)



MAYFIELD® 2 Skull Clamp (A3059)

To ensure proper function and to extend the life and performance of the equipment, Integra LifeSciences recommends the following

Recommended Action	Recommended Frequency
Return the device to the Integra LifeSciences Repairs department for detailed inspection and servicing.	Once/year
Request that Integra NeuroSpecialists perform routine inspection of the device	Twice/year

In the absence of proper care and servicing of the device, negative effects may be seen after repeated processing over time which may lead to reduced performance.

Please refer to the Integra LifeSciences website at the following links for the complete Instructions for Use for the MAYFIELD® Skull Clamps, A1059, A1108, A1114, A1117, A2000, A2114, A3059, including Inspection and Service Notes for routine checks to be performed on the device.

A1059 <https://www.integralife.com/file/general/1507668433.pdf>
A1108 <https://www.integralife.com/file/general/1542033759.pdf>
A1114 <https://www.integralife.com/file/general/1541425560.pdf>
A1117 <https://www.integralife.com/file/general/1541425953.pdf>
A2000 <https://www.integralife.com/file/general/1511821613.pdf>
A2114 <https://www.integralife.com/file/general/1542033855.pdf>
A3059 <https://www.integralife.com/file/general/1541426050.pdf>

We are notifying you of this Field Safety Notice as our records indicate that you have been supplied with **devices listed below.**

Description of affected product	Reference
MAYFIELD® Skull Clamp	A1059
MAYFIELD® Triad Skull Clamp	A1108
MAYFIELD® Infinity Skull Clamp	A1114
MAYFIELD® MR/X-ray Skull Clamp with Excite 3.0T Adaptor	A1117
MAYFIELD® 2000 Skull Clamp	A2000
MAYFIELD® Infinity XR2Skull Clamp	A2114
MAYFIELD® Composite SeriesSkull Clamp	A3059

We kindly ask you to examine your inventory to determine if you have concerned devices.

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

Once identified we recommend you contact service & repair for preventive maintenance if necessary.

Once the audit of your inventory and your final customers' inventory achieved, please sign and return the "Acknowledgment Form" enclosed, by which you confirm that you have received this notification and you intend to fully comply with this Safety notification.

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 Acknowledgement and Return Form.

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

Sincerely,



Angélique AUBERT
Compliance Coordinator
Europe, Middle-East & Africa

Enclosed: Recall Acknowledgement and Return Form (1 page)

ACKNOWLEDGMENT FORM

Medical devices:

MAYFIELD® Skull Clamp (A1059), MAYFIELD® Triad Skull Clamp (A1108); MAYFIELD® Infinity Skull Clamp (A1114), MAYFIELD® MR/X-ray Skull Clamp with Excite 3.0T Adaptor (A1117), MAYFIELD® 2000 Skull Clamp (A2000), MAYFIELD® Infinity XR2Skull Clamp (A2114), and MAYFIELD® Composite Series Skull Clamp (A3059).

Legal manufacturer:

Integra LifeSciences Corporation - 4900 Charlemar Dr. Building A - Cincinnati OH, 45227, USA

Concerned batches:

All lots sold between 2004 - 2015

November 2018

Please send the form back to:

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 regarding MAYFIELD® Skull Clamp (A1059), MAYFIELD® Triad Skull Clamp (A1108); MAYFIELD® Infinity Skull Clamp (A1114), MAYFIELD® MR/X-ray Skull Clamp with Excite 3.0T Adaptor (A1117), MAYFIELD® 2000 Skull Clamp (A2000), MAYFIELD® Infinity XR2Skull Clamp (A2114), and MAYFIELD® Composite Series Skull Clamp (A3059). I have / will comply with the Field Safety Notice.

I have transferred this recall letter to the persons to whom I have sold and/or place on consignment the concerned products. I ensure that the form is duly returned to me signed by these persons.

I have transferred this Field Safety Notice to final customers.

Customer Name

Date

Street Address

City/State/Zip Code

Telephone Number

Signature