

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

Saint Priest, 24/07/18

Subject: **URGENT - FIELD SAFETY NOTICE - RECALL NOTIFICATION LETTER**

Medical devices:

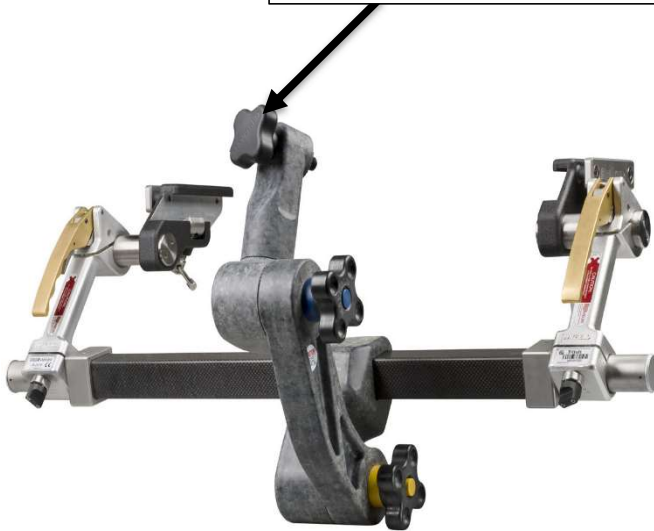
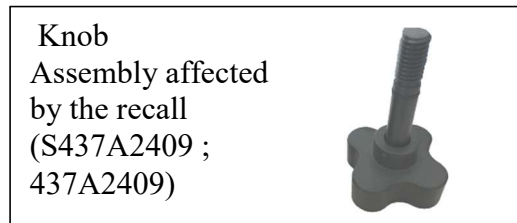
MAYFIELD® Infinity XR2 Radiolucent Base Unit (A2079), Standard; MAYFIELD® Infinity XR2 Low Profile Base Unit (A2079A); MAYFIELD® Infinity XR2 Radiolucent Base Unit, Extended (A2079E) and MAYFIELD® Spine Table Adaptor (A2600R)

Legal manufacturer:

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

Dear Valued Customer,

Integra LifeSciences has identified through complaints that the Knob Assembly of the MAYFIELD® Infinity XR2 Swivel Adapter, can fracture/break during use if over-tightened.



A2079, A2079A, A2079E

*A2079 and A2079E are identical. A2079A has different side brackets.

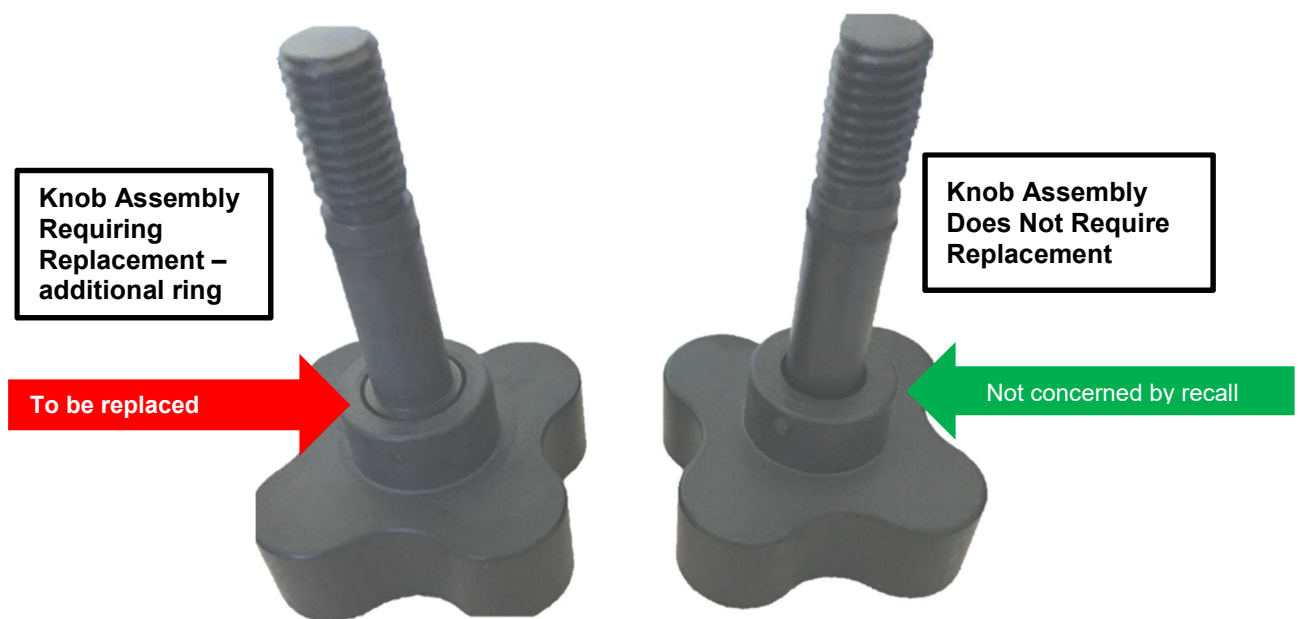


A2600R

Use of the unit with the affected knob assembly may cause a delay in the surgical procedure to reposition the patient's head since the Skull Clamp cannot be properly secured to the Base Unit or Spine Table Adaptor.

The potential for a low risk adverse patient health consequence exists, therefore Integra LifeSciences has made the decision to conduct a voluntary recall of the knob assembly.

The knob assembly concerned by this recall is the one on the left side here below that has an additional ring on its base (showed by the red arrow).



We are notifying you of this recall as our records indicate that you have been supplied with **devices listed below potentially with the Knob Assembly containing the additional ring**.

If you cannot determine if the Knob Assembly is wrong please quarantine them and contact emea-fsca-neuro@integralife.com to verify if your unit(s) is affected by the recall.

Description of products having the affected knob	Reference
MAYFIELD® Infinity XR2 Radiolucent Base Unit	A2079
MAYFIELD® Infinity XR2 Low Profile Base Unit	A2079A
MAYFIELD® Infinity XR2 Radiolucent Base Unit, Extended	A2079E
MAYFIELD® Spine Table Adaptor	A2600R

We kindly ask you to examine your inventory to determine if you have affected devices, please verify if the Knob Assembly contains the additional ring and quarantine them until the reception of the new Knob assembly.

New Knob assembly



Screw is yellow

We also kindly ask you to contact the final customers who may have the affected products and provide them with this letter. If they have affected product, they have to stop using them immediately and remove them from service.

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

With this form, you will ensure that all the devices affected will be quarantined including those already shipped to your customers until the reception of the new Knob assembly. You also confirm that this notification has been forwarded to every concerned customer.

Integra Customer Service will contact you upon receipt of this information to organize the replacement of the concerned products (Return Merchandise Authorization number assignment).

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.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Please feel free to contact me for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angélique Aubert
Compliance coordinator
Europe, Middle-East & Africa

Enclosed: Recall Acknowledgment and Return Form (2 pages)

RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices:

MAYFIELD® Infinity XR2 Radiolucent Base Unit (A2079), Standard; MAYFIELD® Infinity XR2 Low Profile Base Unit (A2079A); MAYFIELD® Infinity XR2 Radiolucent Base Unit, Extended (A2079E) and MAYFIELD® Spine Table Adaptor (A2600R)

Legal manufacturer:

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

July 2018

Please send the form back to:

By fax/telecopy: +33 (0)4 37 47 59 30

Or by e-mail: emca-fsca-neuro@integralife.com

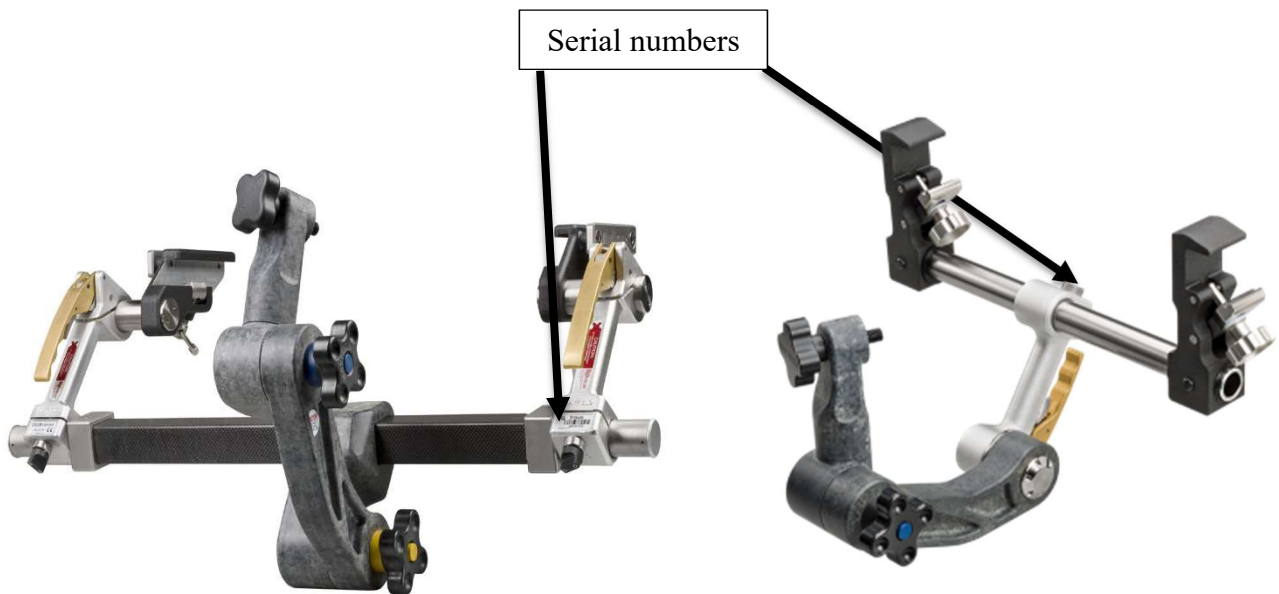
With this form, I confirm that:

I have received, read and understood the information provided in the Integra Recall notification regarding MAYFIELD® Infinity XR2 Radiolucent Base Unit (A2079), Standard; MAYFIELD® Infinity XR2 Low Profile Base Unit (A2079A); MAYFIELD® Infinity XR2 Radiolucent Base Unit, Extended (A2079E) and MAYFIELD® Spine Table Adaptor (A2600R).

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 ensure that all the affected products, including those I had already sent to my customers are being quarantined **until the reception of the new Knob assembly.**

I ensure that affected Knob assembly will be sent back to Integra.



A2079, A2079A, A2079E

*A2079 and A2079E are identical. A2079A has different side brackets.

A2600R

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 affected product(s) in my inventory or my final customers' inventory. These affected product(s) have been isolated and will be sent back.

Please indicate quantity and serial numbers in the table below.

Description of affected product	Reference	Serial number	Quantity
MAYFIELD® Infinity XR2 Radiolucent Base Unit	A2079		
MAYFIELD® Infinity XR2 Low Profile Base Unit	A2079A		
MAYFIELD® Infinity XR2 Radiolucent Base Unit, Extended	A2079E		
MAYFIELD® Spine Table Adaptor	A2600R		

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

.....
Distributor / Healthcare facility name

.....
Contact Name

.....
Street Address

.....
City, Country, Postal Code

.....
Telephone

.....
Email