August 14, 2018

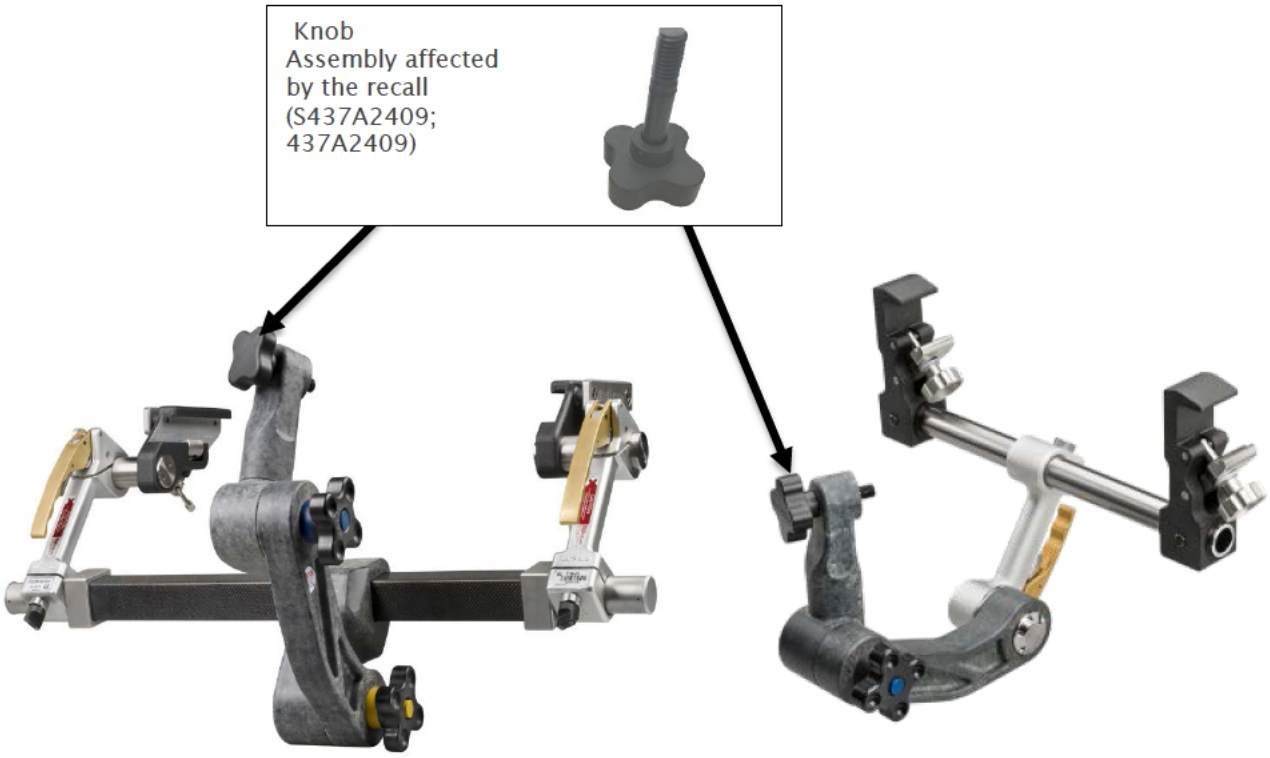
URGENT: VOLUNTARY MEDICAL DEVICE RECALL

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)

Dear Valued Distributor,

Cc: Chairman Medical Board and relevant Head of Departments.

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

A2600R

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

Use of the unit with the affected knob assembly may cause a delay in the surgical procedure. 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.

Integra • 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 • 800-654-2873 toll free • 609-750-4277 fax • integralife.com

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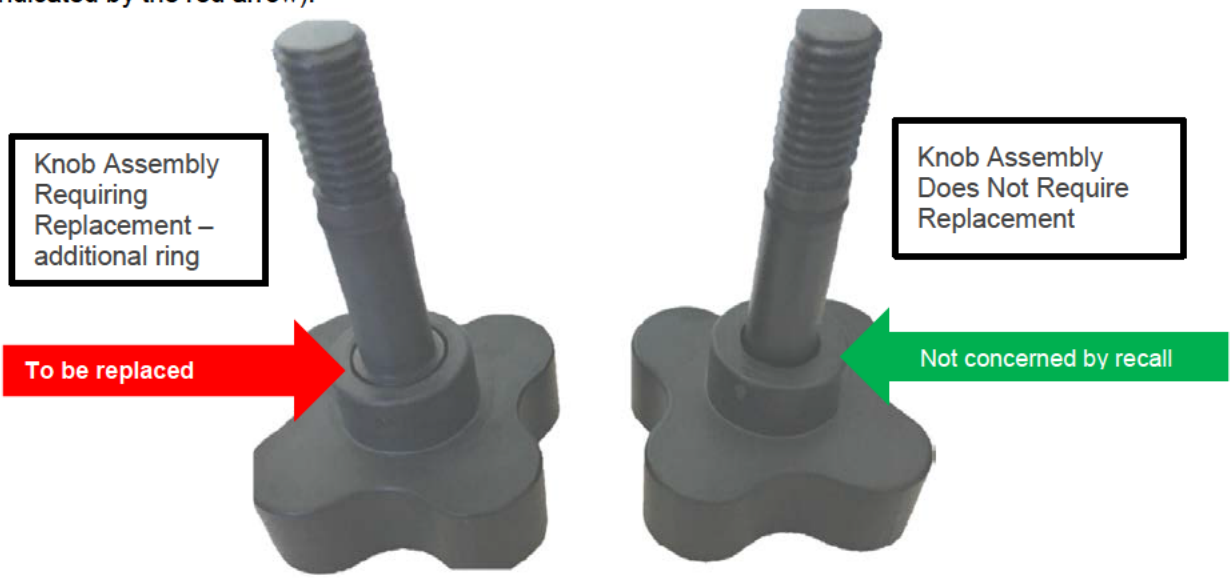
The affected knob assembly has an additional ring on the base as shown in the picture below (indicated by the red arrow).



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 internationalcs@integralife.com; FCA1@integralife.com or FAX to 1-609-750-4220 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

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 an affected product, contact: internationalcs@integralife.com; FCA1@integralife.com for replacement product.

Once the audit of your inventory and your final customers' inventory is completed, please sign and return the enclosed "Recall Acknowledgment and Return Form". The form confirms that you have received this Recall notification and that you intend to fully comply with it.

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With this form, you will ensure that all the devices affected will be quarantined including those already shipped to your customers until the receipt 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 acknowledgment 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 feel free to contact me for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

[redacted]

Tiffanie Chow
Director, Marketing
Integra LifeSciences

Enclosed: Recall Acknowledgment and Return Form (1 page)

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URGENT: VOLUNTARY MEDICAL DEVICE RECALL ACKNOWLEDGMENT FORM

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)

Please send the form back to:

By fax/telecopy: 1-609-750-4220
Or by e-mail: FCA1@integralife.com

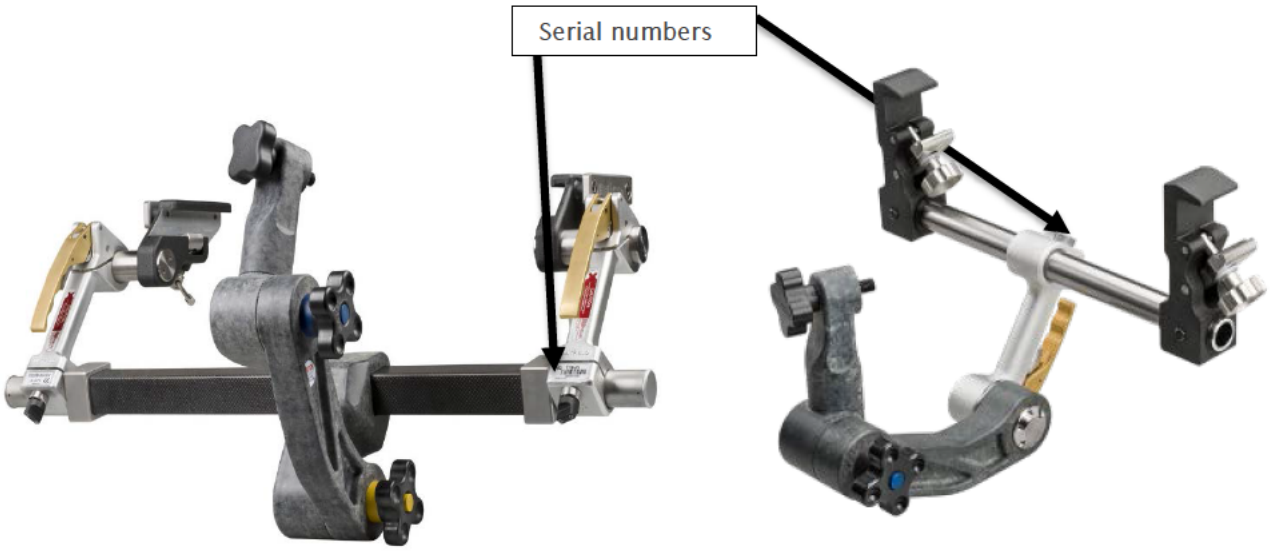
With this form, I confirm that:

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 forwarded this recall letter to the customers to which I have sold and/or consigned the concerned products. I will ensure that the form is duly returned to me signed by these customers.

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

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



A2079, A2079A, A2079E

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A2600R

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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 lot 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

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