

February 26, 2021

Urgent Field Safety Notice

CyberKnife® System Standard Treatment Couch Roll and Patient Fall

Issue Summary

Accuray® Incorporated (Accuray) has discovered an issue related to the Standard Treatment Couch (STC). Following treatment, a patient was sitting on the STC with a clinical staff member at their side. When the patient stood up, the couch tilted and moved freely in the roll direction. The patient fell to the floor however, there was no injury to the individual and no further medical attention was necessary. The couch was able to move due to a loose linkage arm that connects to the roll motor in the STC.

Please ensure that all necessary personnel in your facility are made aware of this issue.

Reason for Urgent Field Safety Notice

While unlikely, the set screws that connect the linkage arm to the roll motor can loosen over time. The motion of a patient standing up can unseat the linkage arm. The immediate resolution at the clinical site was to reassemble the linkage and tighten the set screws.

Affected Product

This issue affects all CyberKnife System sites that use the STC.

Safety Instructions

Customers may continue to use the STC and CyberKnife System. However, those who assist patients should provide extra care when individuals are getting on or off the STC.

Product Correction

Accuray is committed to providing our customers and their patients with products that deliver safe and effective radiation treatments. Accuray has a service work instruction that includes inspection of the set screws referenced above. A Field Action will be initiated for Field Service Engineers to perform the

work instruction and verify the integrity of the overall couch system, including the linkage arm and its connection to the roll motor. Furthermore, this work instruction will be performed on an annual basis.

Contact Information

For questions about this Field Safety Notice, please contact Accuray Customer Support by phone or email, using the Service Request form available at <http://www accuray.com/service-requests>.

This notice has been sent to the appropriate Regulatory Agencies.

Sincerely,



Daniel Biank
Vice President, Regulatory Affairs
Accuray Incorporated
1209 Deming Way
Madison, WI 53717

Acknowledgement Form

Urgent Field Safety Notice

I acknowledge that I have received the following document from Accuray:

Urgent Field Safety Notice concerning the CyberKnife® System Standard Treatment Couch Roll and Patient Fall.

I confirm that I understand the content of this Field Safety Notice dated February 26, 2021 and have distributed the information to all applicable members of my staff.

Hospital Name: _____

System Serial Number(s): _____

Signature: _____

Name (print): _____

Date: _____

Please keep this Field Safety Notice document with your User Manual and forward a copy to:

Email to:

FANotification@Accuray.com

Or send hard copy to:

FA Notification (Product Surveillance)
Accuray Incorporated
1209 Deming Way
Madison, WI 53717