

Urgent Field Safety Notice

September 26, 2018

CyberKnife® M6™ Treatment Delivery System Robot Wrist Inspection

Issue Summary

Accuray Incorporated (Accuray) has been informed of two issues related to components of the robot contained within the CyberKnife® M6™ System. The issues involve the wrist assembly which is the final linkage between the robot arm and the linear accelerator. One issue relates to the fastening process for the wrist assembly which may not have been implemented properly for specific units. The second involves incorrect material being used in a small number of wrist castings. These issues may lead to premature wrist failure, resulting in a linear accelerator fall.

Please ensure that all necessary personnel in your facility are made aware of this notification and know that Accuray will inspect all CyberKnife M6 Systems to identify whether an issue exists.

Cause

In a limited number of robot wrist assemblies, the fastening process for mounting the wrist assembly may not have been implemented properly. Additionally, in a small number of wrist castings, incorrect material was used.

Affected Product

Only Accuray CyberKnife M6 Systems may potentially be affected by these issues.

Safety Instructions

Customers do not need to take any additional action. The fastening process issue manifests with oil leaks, noise during motion, or positioning errors. Consistent with normal practice, please contact Accuray Customer Support if you experience any of these issues.

Product Correction

Accuray will inspect all CyberKnife M6 Systems to identify whether each system contains the fastening process variation or the affected wrist components. If Accuray detects either issue, then we will arrange for the remediation of the specific system. No correction is necessary for systems that are inspected and found not to contain the fastening process variation or the wrist casting with incorrect material.

Accuray is committed to providing our customers and their patients with products that deliver safe and effective radiation treatments. If an issue is identified, Accuray will work with the customer to address the situation with minimal impact to their patients' treatment schedules.

For questions about this Field Safety Notice, please contact Accuray Customer Support using the Service Request form available at www accuray.com/service-requests or by phoning one of our regional support lines (North America +877.668.8667, other regional phone numbers are listed at www accuray.com/service-requests).

Sincerely,



Darl Moreland
Senior Vice President, Regulatory, Quality, and Compliance
Accuray Incorporated

Acknowledgement Form

Urgent Field Safety Notice

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

Urgent Field Safety Notice concerning the CyberKnife® M6™ Treatment Delivery System Robot Wrist Inspection

I confirm that I understand the content of this Urgent Field Safety Notice dated September 26, 2018 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 with your User Manual and forward a copy to:

Accuray International
REGULATORY AFFAIRS & QUALITY ASSURANCE EIMEA:
E-mail: EIMEA-RAQA@accuray.com