URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	**Exact Arm Elbow Motor Shaft**
***Commercial Name of Affected Product*:**	**On-Board Imager®**
***Affected Version(s) / Lot(s)*:**	**Type 01 Elbow Motors**
Reference / FSCA Identifier:	**CP-14167**
Date of Notification:	***2014-03-20***
***Type of Action*:**	**Notification and Correction**

Description of Problem:
Varian has received three reports that the shaft of the Type 01 elbow motor for Exact arms used in the On-Board Imager® [OBI] device have failed due to belt over-tensioning. This over tensioning would have taken place during servicing. This failure would allow the Exact arm to swing freely with gravity. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian Medical Systems is taking to address the issue.

No injuries have been reported to-date. Only Type 01 elbow motors are subject to these potential failures. Later, Type 02 elbow motors are not affected. TrueBeam is not affected. You are receiving this letter because your accelerator was shipped with OBI Type 01 Elbow motors.

Details:
In the three known failures, belt over-tensioning caused the motor shaft to fail over time. This failure permitted the Exact arm elbow joint to swing freely with gravity. A message such as "kV detector elbow axis not calibrated" or "kV source elbow axis not calibrated" may appear, or the user may hear a grinding or shearing sound at or before the time of failure.

Potential injury from the kV source striking a patient is dependent upon the anatomic site being treated and the height of the couch. The risk is greatest when the OBI x-ray source is extended or retracted while it is above the patient. A geometric analysis determined that when the couch is positioned for a pelvis treatment [e.g., prostate treatments], the head of the patient could be positioned within the arc travelled by the kV source. If the kV source were to strike the patient's head or chin, a fracture injury is possible. Pelvic treatments with couch vertical positions less than 10 centimeters below isocenter have the highest potential for injury.

For the kV detector arm and the MV detector arm, the force generated is significantly lower due to the lower mass of the arm, and the normal clinical imaging distance. The force generated could potentially result in an injury such as bruising, but is unlikely to result in facial injuries.

Recommended User Action
Until Varian inspects the OBI Exact arms, users should not extend or retract the kV Source arm when it is above a patient. Users should ensure that the gantry is positioned so that the kV Source is lateral to, or underneath, the patient-couch prior to extending or retracting the arm.

Varian mandates specific tooling for tensioning the Exact arm motor belts in its instructions. Sites doing their own servicing or using a third party service provider, must ensure that they are

following Varian service instructions. For questions, please contact your local Varian Medical Systems Customer Support District or Regional Manager.

Varian Medical Systems Actions:
Varian is notifying all affected users with this document.

A Varian Medical Systems Customer Support Service representative will arrange a site visit to check the belt tension of the Type 01 elbow motors of all OBI and MV Exact arms. If over-tensioned belts are detected, the elbow motor will be replaced with a Type 02 elbow motor.

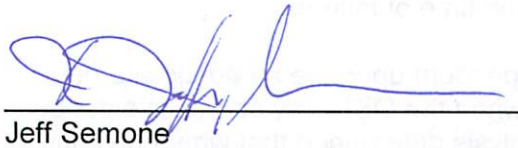
This document contains important information for the continued safe and proper use of your equipment.

- Please retain a copy of this document along with your most current product labeling.
- Advise the appropriate personnel working in your radiotherapy department of the content of this letter.
- For future reference, this document will be posted to the Varian Medical Systems customer support website: http://www.MyVarian.com.

In order to satisfy regulatory requirements, we request that you complete the attached Recall Return Response form and email it to Varian Medical Systems at returnresponse@varian.com.

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Varian Medical Systems Customer Support District or Regional Manager.

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.



Jeff Semone
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2014-03-26
Date (YYYY-MM-DD)

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