

URGENT MEDICAL DEVICE CORRECTION

Subject: The gantry drive chain may break, allowing the gantry to rotate without motor control.

Reference: High Energy Clinac linear accelerators

Date of Notification: 08/31/2006

Contact Information: Varian Oncology Helpdesk – 888-VARIAN5 (888- 827-4265)
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This letter is to advise you that an anomaly has been identified in certain Varian High Energy Clinacs equipped with a Gantry Direct Drive that contains a “Half-link” part in its Gantry Drive Chain.

You are receiving this letter because your Clinac(s) have the Gantry Direct Drive mechanism. Please note that not all Varian customers will receive this notice as the number of Clinacs that may be affected is approximately 5% of Varian’s worldwide installed base.

This notice provides a description of the anomaly, corrective actions you should implement to minimize the effects of the anomaly, and steps Varian is taking to address the issue.

Anomaly:

Definitions

- Gantry Drive Chain: the chain connecting the gantry drive motor to the gantry assembly.
- Half-link: a shortened link in the drive chain designed to accommodate small adjustments to the chain length.
- Gantry Direct Drive: a gantry rotation drive assembly that does not use a slip clutch.

Description

Under certain circumstances, the Gantry Drive Chain may break during gantry motion, allowing the gantry to “coast” or rotate without motor control. It is possible that the gantry may then collide with a person or with an object that does not move (or is not moved) out of its path before contact or which does not physically stop the motion beforehand. This could possibly cause serious physical injury.

Details:

All Varian Clinacs use a Gantry Drive Chain. The Gantry Drive Chain controls all motions of the gantry, including both starting and stopping of the gantry. Some Clinacs use a Gantry Direct Drive system that improves positional accuracy and some of those Gantry Direct Drive systems contain a Gantry Drive Chain that includes a Half-link. Only machines with the serial numbers included on the Affected Serial Number list (attached) may be affected.

During normal operation, conditions of high stress on the Gantry Drive Chain may occur and the Half-link may break, disengaging the chain from the gantry. In some cases the breaking of the Half-link will be

associated with a loud “popping” sound, however in other cases it may only be apparent to the user as a loss of motion control.

All Varian gantries are balanced in order to reduce gantry movement in the event the machine loses power or another situation occurs in which the gantry is no longer controlled by the Gantry Drive Chain. Gantry momentum prior to the Half-link break or possible gantry imbalance can cause the free rotation, or “coasting”, of the gantry for some period after the break. Although bearing friction will always impede the gantry motion causing it to stop, the amount of movement will depend on the level of bearing friction in the particular machine and gantry location at the moment of break. The typical gantry coast angle appears to be less than five degrees; however it is theoretically possible that this coast angle could be significantly greater.

Affected Serial Numbers:

See attached Appendix A

User Corrective Action:

1. Users should ensure that no persons or objects are in the path of the gantry when rotating the gantry, unless the required treatment position requires gantry movement in the couch path. This applies both to motions under pendant control and remote motions.
2. In situations where the required treatment position requires gantry movement in the path of the patient or the couch:
 - a. the user should go into the treatment room for each field to rotate the gantry to each new treatment position and carefully observe the gantry movement; and
 - b. upon observation of any unexpected gantry movement, the user should
 - immediately release the couch brake (lateral, longitudinal, or both) from the side panel and move the couch top/patient away from the moving gantry;
AND
 - NEVER press the emergency off on the Clinac, as it will terminate power to the system and require the battery pendant to move the couch longitudinally. This could cause delays in the user being able to move the couch top/patient out of the gantry path resulting in a collision with the patient or couch top.

Varian Corrective Action:

Notification of customers is by way of this Product Notification Letter.

Varian Service representatives will correct the problem on all affected Varian Clinacs.

A Varian Service representative will contact you shortly to schedule a visit to perform the modification required to address this problem.

Please advise all appropriate personnel working in your radiotherapy department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Varian Customer Support Representative.