

URGENT FIELD SAFETY NOTICE

Subject: Wedge May Be Incorrectly Labeled
Commercial Name of Affected Product: Clinac®
FSCA Identifier: CP-03070
Date of Notification: 2011-04-06
Type of Action: Notification and field correction

Details on Affected Devices: Type 3 hard wedge assemblies (Clinac Accessory) – see attached list of possibly affected units

Varian has identified an anomaly for Type 3 hard wedges whereby the labeling on the wedge tray may not correctly match the wedge body. For example, a 45° wedge body mounted on a tray labeled " 60° " or a 15° wedge body mounted on a tray labeled " 30° ". In all cases the wedge body is labeled with the correct wedge angle. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian is taking to address the issues.

Description of Problem:

The wedge angle labeling on the wedge tray may not correctly match the wedge body. In all cases the wedge body is labeled with the correct wedge angle.

Definitions:

Definition of Re-plan:

When a patient is switched from one treatment linear accelerator to another, the process of re-creating the treatment plan for the new linear accelerator.

Details:

Varian has identified a manufacturing anomaly for Type 3 hard wedges whereby the labeling on the wedge tray may not correctly match the wedge body. In all cases the wedge body is labeled with the correct wedge angle. For example:

- A 45° wedge body mounted on a tray labeled " 60° ".
- A 15° wedge body mounted on a tray labeled " 30° ".

Other combinations are possible. It is expected that a large discrepancy would be more apparent to both Varian manufacturing and the customer, and is therefore less likely.

During typical acceptance, commissioning, and QA of wedges it is expected that the incorrect wedge labeling would be detected. Alternately it is also possible that the wedge would be fully commissioned with data that is consistent with the wedge body, and that all treatments with that wedge would be correctly planned and delivered.

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However the following scenarios may result in treatment with a wedge that does not match the treatment plan:

- Commissioning of the treatment planning system with the pre-defined Eclipse Beam Data (aka "gold beam data"), plus failure to spot-check that commissioning data against measured wedge data.
- Replacement of a correctly labeled wedge with an incorrectly labeled wedge, plus failure to spot-check measured wedge data for the new wedge against existing wedge data.
- Transfer of patient between two Clinacs without re-planning, where the linear accelerators have wedges that are labeled and commissioned as identical, but are physically different.

Recommended User Action:

- IMMEDIATELY inspect all wedges.

Immediately inspect all wedges to verify that the wedge angle label on the wedge body matches the wedge angle label on the wedge tray. As shown in Figure 1, wedge tray labels are printed directly on the tray, wedge body labels are stamped in the edge of the wedge body.

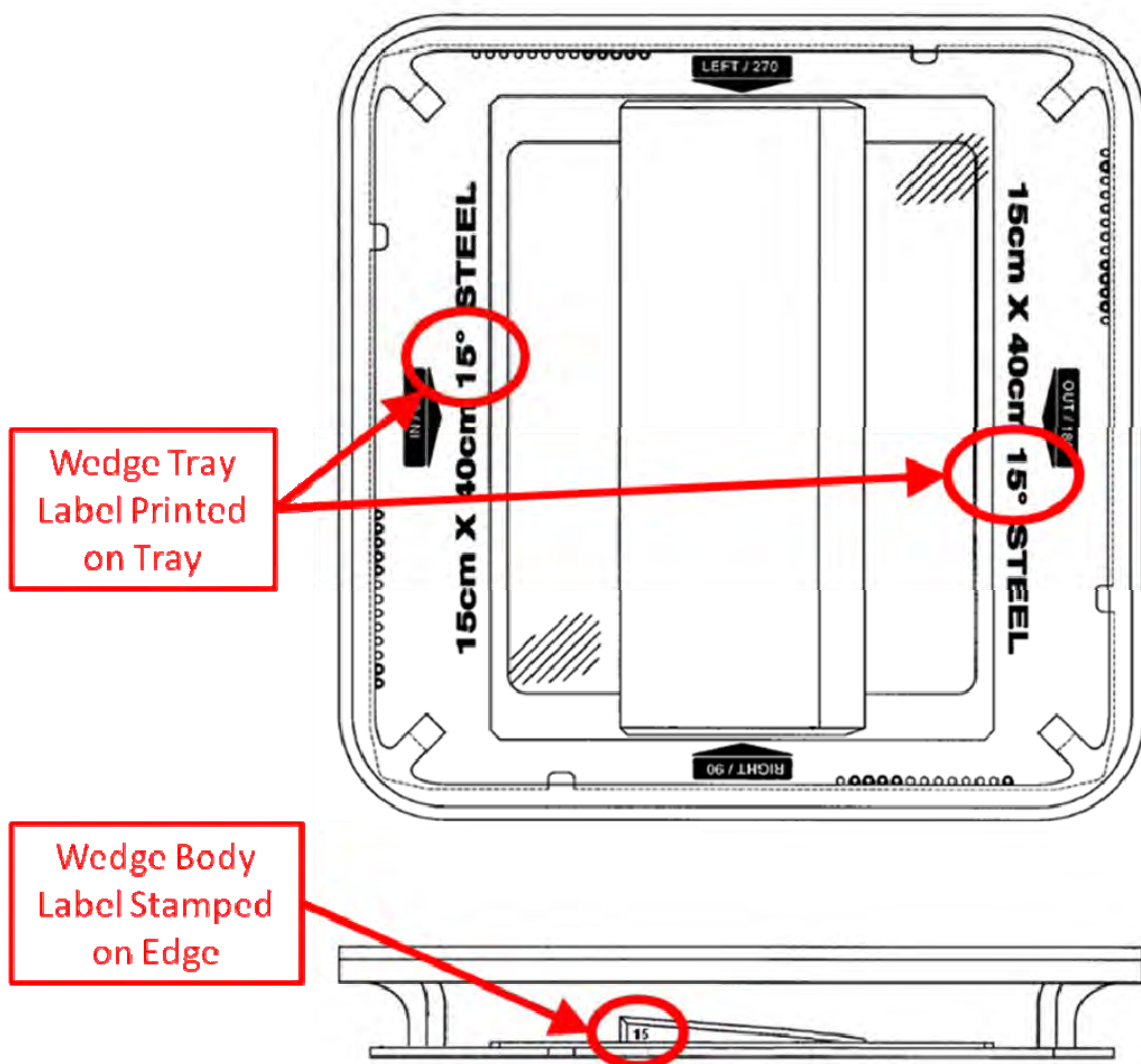


Figure 1 - location of wedge tray and wedge body labels

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If any wedge is identified with mismatched labeling:

- Immediately remove that wedge from clinical use, and take steps to segregate it and clearly identify it as not for clinical use.
- Immediately notify Varian Service of the anomalous wedge.
- Evaluate the clinical impact on past treatments by measuring the wedge data (profiles, transmission factor, etc.) and comparing it to the commissioned data for that wedge.
- If your clinical procedure allows for switching of patients between linear accelerators without re-planning, evaluate the clinical impact on past treatments by comparing measured data of the mislabeled wedge with measured data of the comparable wedge on the other linear accelerator(s).

- Always measure wedge data at installation of new or replacement wedges.

Always measure wedge data (e.g. transmission, profiles, etc.) when installing a brand new wedge or when replacing a wedge, and use the measured data to commission the treatment planning system or to verify existing planning data. It is the responsibility of the customer to make the clinical decision of performing full commissioning measurements or limited spot checks of critical parameters only.

- Verify all treatment accessories of "matched" linear accelerators.

When treating two (or more) linear accelerators as "matched", and switching patients between them without re-planning, Varian recommends verification that the treatment accessories for those linear accelerators are correctly matched.

Varian Corrective Action:

- Notification of customers is by way of this Urgent Device Correction letter.
- Since detecting this issue, Varian has enhanced our manufacturing quality control process to further ensure correct labeling of wedges.
- At the request of the customer Varian will replace any wedge that is identified as mislabeled.

Please advise the 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 District or Regional Manager.

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



Michael Pignataro, Manager, Reporting and Corrections

2011-04-06

Date

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Varian Medical Systems - www.varian.com

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APPENDIX

LIST OF AFFECTED DEVICE SERIAL NUMBERS

H140001	H140051	H140099	H140147	H140240	H140747	H140794	H140841	H140891	H180058	H180168
H140002	H140052	H140100	H140148	H140700	H140748	H140795	H140842	H140892	H180059	H180170
H140003	H140053	H140101	H140149	H140701	H140749	H140796	H140843	H140893	H180062	H180171
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Wedge May Be Incorrectly Labeled

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