

## **URGENT - FIELD SAFETY NOTICE**

**Subject: Forceful insertion or extensive use of SRS Conical Collimator Mount may lead to damage of the Conical Collimator Mount and Clinac Interface Mount.**

**Commercial Name of Affected Product:** Optical Guidance Platform  
**FSCA Identifier:** CP-00356  
**Date of Notification:** 2010-08-18  
**Type of Action:** Notification and Correction

### **Details on Affected Devices:**

This notice concerns the Optical Guidance Platform used for Clinac® or Novalis® TX machines. See Appendix for complete list

### **Description of Issue:**

We are writing to warn you of the possible damage to the SRS Conical Collimator Mount if excessive force is asserted while inserting the Conical Collimator Mount into the Clinac interface mount on the gantry head, or extensive use under normal conditions.

This advisory notice provides a description of the conditions that may lead to damage, how to detect the condition and provides instructions for cone insertion without damage.

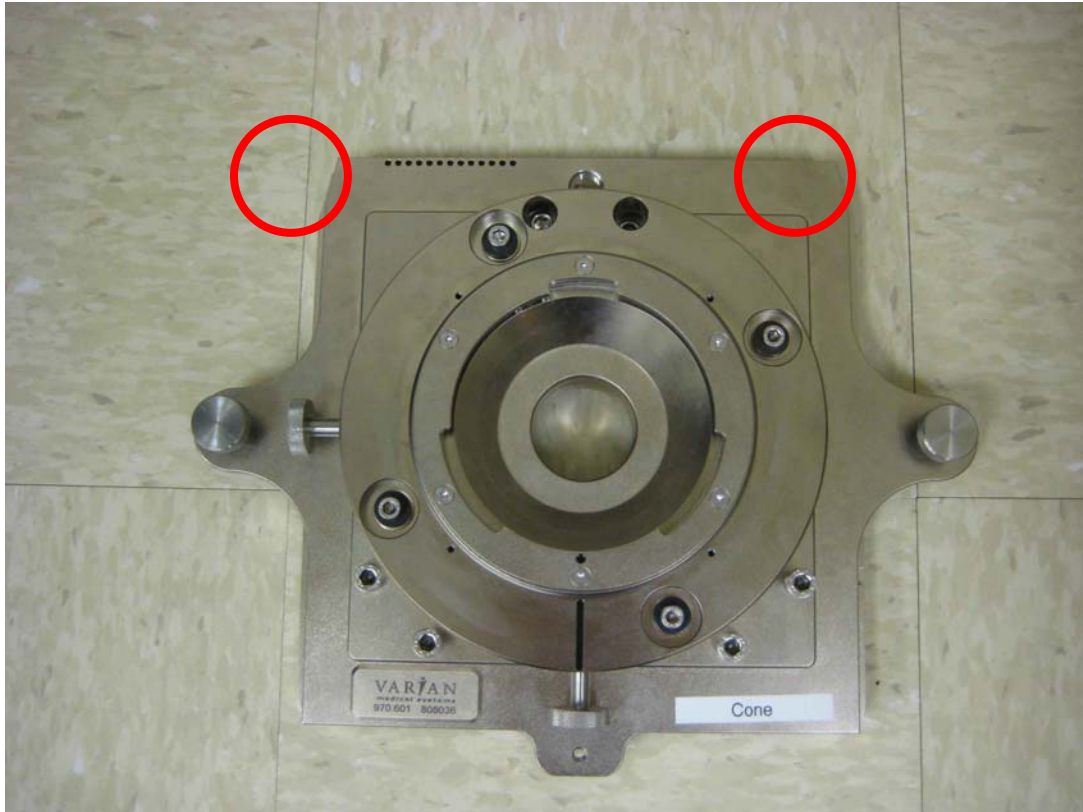
If the SRS Conical Collimator Mount is inserted with excessive force, then the corners of the SRS Conical Collimator Mount and the interface mount may be damaged. The damage may cause the SRS Conical Collimator Mount to be displaced from its calibrated position. Additionally, the optical reader may be damaged.

### **Details:**

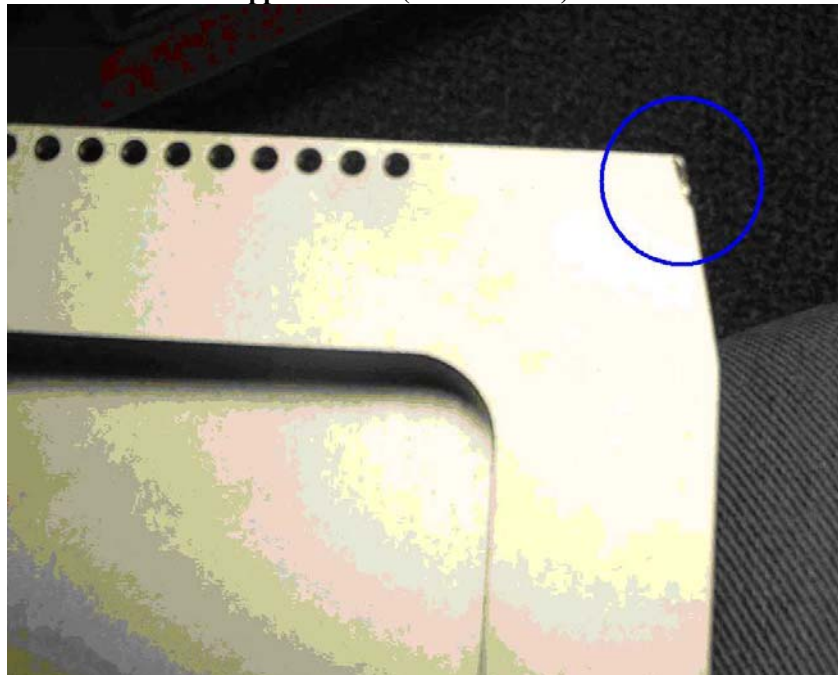
If the SRS Conical Collimator Mount is inserted forcefully, the Clinac Interface Mount on the linac or the Conical Collimator Mount itself may be dented, causing the position of the SRS Conical Collimator Mount to be different from the calibrated position. It has been observed that damage may occur when the Conical Collimator Mount is pushed with force over the distance from the initial insertion point at the Clinac interface mount until the installed position. This damage may be very slight, but accumulates over multiple insertions. As a consequence the cone will be misaligned from its calibrated position. The problem may be detected using the Winston-Lutz QA test. The degree of misalignment can be measured from the Winston-Lutz films. If the misalignment is unacceptable, the Conical Collimator Mount may be re-aligned by Varian Service.

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**Figure 1 Conical Collimator Mount. Upper corners (circled in red) come in contact with the Interface Mount**



**Figure 2 Damaged Corner (circled in blue)**

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### **Recommended User Action:**

- The gantry should be set to zero degrees (IEC). The Conical Collimator Mount should be inserted into the slot of the interface mount. Gentle force should be applied to slide the Conical Collimator Mount until it reaches the edge of the interface mount. At this point, the user should firmly push the Conical Collimator Mount to seat the Conical Collimator Mount to the interface mount.
- The Winston Lutz test must be performed every time the SRS Conical Collimator Mount is inserted. This is imperative in order to verify that proper alignment is obtained. This is an addition to older Instructions for Use for the device.
- Varian has made other changes to the Optical Guidance Platform Instructions for Use – we strongly recommend you download the most recent version at [www.MyVarian.com](http://www.MyVarian.com)

### **Varian Actions:**

- Varian is notifying all affected customers with this document.
- Varian is developing a modified Conical Collimator Mount which will be more robust. Once this development is complete, your Conical Collimator Mount will be replaced with the new design product.

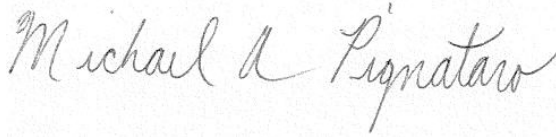
**Please advise the appropriate personnel working in your radiotherapy department of the content of this letter.**

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 Manager.

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



\_\_\_\_ on behalf of Dave Hall\_\_\_\_  
Dave Hall, Manager, Reporting and Corrections

\_\_\_\_**2010-08-18**\_\_\_\_  
Date

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### APPENDIX

#### LIST OF AFFECTED DEVICE SERIAL NUMBERS

Listed are the affected system Serial Numbers. The last four digits represent the serial number of the device.

HZ10046	HZ10434	HZ10730	HZ12039	HZ12085	HZ13059
HZ10054	HZ10438	HZ10731	HZ12040	HZ12086	HZ13062
HZ10061	HZ10460	HZ10733	HZ12041	HZ12087	HZ13064
HZ10070	HZ10495	HZ10737	HZ12042	HZ12088	HZ15070
HZ10083	HZ10507	HZ10740	HZ12043	HZ12089	HZ15118
HZ10108	HZ10508	HZ10743	HZ12046	HZ12090	HZ15480
HZ10126	HZ10509	HZ10762	HZ12047	HZ12091	HZ17002
HZ10138	HZ10513	HZ11001	HZ12048	HZ12094	HZ17003
HZ10144	HZ10537	HZ11002	HZ12049	HZ12095	HZ17005
HZ10154	HZ10540	HZ11004	HZ12052	HZ12096	HZ17007
HZ10170	HZ10544	HZ11006	HZ12054	HZ12098	HZ17010
HZ10172	HZ10547	HZ11007	HZ12056	HZ12101	HZ17011
HZ10185	HZ10557	HZ11019	HZ12057	HZ12103	HZ17027
HZ10196	HZ10584	HZ11021	HZ12058	HZ12107	HZ17040
HZ10209	HZ10594	HZ12001	HZ12059	HZ12108	HZ17062
HZ10245	HZ10601	HZ12002	HZ12060	HZ12125	HZ17069
HZ10258	HZ10612	HZ12004	HZ12061	HZ12126	HZ18006
HZ10273	HZ10617	HZ12005	HZ12062	HZ12188	HZ18020
HZ10274	HZ10620	HZ12006	HZ12064	HZ13020	HZ18062
HZ10283	HZ10629	HZ12007	HZ12067	HZ13021	HZ18066
HZ10293	HZ10640	HZ12008	HZ12068	HZ13022	HZ18077
HZ10294	HZ10646	HZ12009	HZ12069	HZ13026	HZ18193
HZ10299	HZ10649	HZ12012	HZ12070	HZ13030	HZ19020
HZ10330	HZ10652	HZ12013	HZ12071	HZ13031	HZ19023
HZ10337	HZ10656	HZ12016	HZ12072	HZ13039	HZ19035
HZ10347	HZ10670	HZ12023	HZ12073	HZ13041	HZ19113
HZ10352	HZ10674	HZ12026	HZ12074	HZ13042	HZ19175
HZ10368	HZ10675	HZ12027	HZ12075	HZ13044	HZ19227
HZ10398	HZ10681	HZ12029	HZ12077	HZ13046	HZ19228
HZ10401	HZ10684	HZ12030	HZ12080	HZ13047	HZ19229
HZ10403	HZ10693	HZ12033	HZ12081	HZ13049	HZ19235
HZ10404	HZ10698	HZ12036	HZ12082	HZ13050	HZ19236
HZ10412	HZ10703	HZ12037	HZ12083	HZ13053	HZ19997
HZ10426	HZ10724	HZ12038	HZ12084	HZ13055	HZ19998