

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject:	X-Jaw Carrier Replacement
Commercial Name of Affected Product:	Clinac, Trilogy, Novalis Tx, Unique
Affected Version(s) / Lot(s):	Not applicable.
Reference / FSCA Identifier:	CP-08881
Date of Notification:	2012-08-14
Type of Action:	Notification and Correction
Details on Affected Devices:	Refer to appendix page.

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the Clinac, Trilogy, Novalis Tx and Unique jaw carriers. The jaw carriers function to couple the X-jaws to their respective drive screw mechanisms used for controlling field size (refer to Figure 1). Some jaw carriers were manufactured with the incorrect metal alloy, which can potentially cause the jaw carrier to crack.

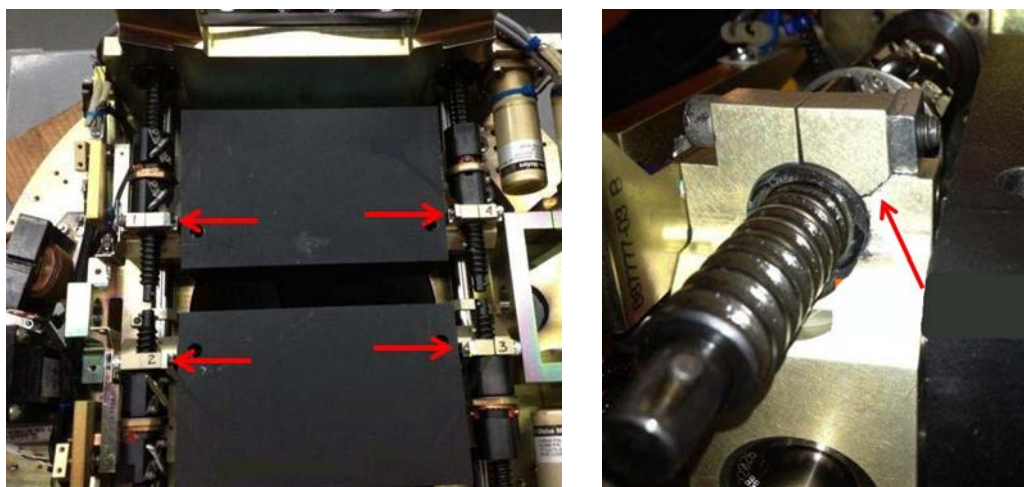


Figure 1. On the left picture, the X-jaws with the jaw carriers noted with the red arrows. On the right picture, the red arrow shows the point of failure on the jaw carrier.

If both jaw carriers on the same X-jaw were to crack, the jaw would be able to move freely in the closed direction. In this case, the deviation of the jaw position will not be detected by the position readout interlock circuitry. Treatment after such a failure occurs may lead to an under-dose of the intended target volume. This condition was found on some machines. No patient mistreatments were reported to Varian Medical Systems.

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.

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Recommended User Action

You are advised to:

- Immediately contact your Varian local service organization when abnormal noises are observed in the collimator head while rotating the Gantry or Collimator.
- Verify the jaw position prior to the treatment of every field. This is typically done using portal imaging or field light projection.

Varian Medical Systems Actions:

- Varian Medical Systems is notifying all possibly affected customers with this document.
- A Varian Medical Systems Customer Support Service representative will schedule a visit to inspect and replace the jaw carriers on your system as necessary.

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>.

Special Instructions for customers outside the USA and Canada: In order to satisfy regulatory requirements, we request that you complete the attached Proof of Notification Form once you have read this document and return it to Varian Medical Systems.

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.



Pete Coronado
Director, Regulatory Affairs

2012-08-14

Date (YYYY-MM-DD)

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Varian Medical Systems public site - www.varian.com

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APPENDIX LIST OF SERIAL NUMBERS

H140863	H294608	H294669	H294732
H140865	H294610	H294670	H294733
H140866	H294611	H294671	H294734
H140867	H294612	H294672	H294735
H140868	H294613	H294673	H294736
H140869	H294614	H294674	H294737
H140870	H294615	H294675	H294738
H140871	H294616	H294676	H294739
H140872	H294617	H294677	H294740
H140873	H294618	H294678	H294741
H140874	H294619	H294679	H294742
H140875	H294620	H294680	H294743
H140876	H294621	H294681	H294744
H140877	H294622	H294682	H294745
H140878	H294623	H294683	H294746
H140879	H294624	H294684	H294747
H140880	H294625	H294685	H294748
H140881	H294626	H294686	H294749
H140882	H294627	H294687	H294750
H140883	H294628	H294688	H294751
H140884	H294629	H294689	H294752
H140885	H294630	H294690	H294753
H140886	H294631	H294691	H294754
H140887	H294632	H294692	H294755
H140888	H294633	H294693	H294756
H140889	H294634	H294694	H294757
H140890	H294635	H294695	H294758
H140891	H294636	H294696	H294759
H140892	H294637	H294697	H294760
H140893	H294638	H294698	H294761
H140895	H294639	H294699	H294762
H140896	H294640	H294700	H294763
H140897	H294641	H294701	H294764
H140898	H294642	H294702	H294765
H140899	H294643	H294704	H294766
H140900	H294644	H294705	H294767
H181175	H294645	H294706	H294768
H181176	H294646	H294707	H294769
H181177	H294647	H294708	H294770
H181178	H294648	H294709	H294771
H181179	H294649	H294710	H294772
H181180	H294650	H294711	
H181181	H294651	H294712	
H181182	H294652	H294713	
H181183	H294653	H294714	
H181184	H294654	H294715	
H181185	H294655	H294716	
H181186	H294656	H294717	
H181187	H294657	H294718	
H181188	H294658	H294719	
H181189	H294659	H294720	
H181190	H294660	H294722	
H181191	H294661	H294723	
H181192	H294662	H294724	
H182000	H294663	H294726	
H182001	H294664	H294727	
H182002	H294665	H294728	
H182003	H294666	H294729	
H182005	H294667	H294730	
H294607	H294668	H294731	