

**Notice Information: - Warning
20 April 2009**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:
- Chief Executive Officer
 - Director of Radiology
 - Radiographers
 - Radiologists
 - Risk Managers
 - Clinical Engineering
 - Supplies / Purchasing Manager

Part 3. Problem/Issue

a) Problem/Issue:

The potential for patients and healthcare professionals to be injured by catching their fingers at various pinch-points on the Exact couch top. A number of incidents occurred since the distribution of a field safety notice (FSN) highlighting the issue. <o:p></o:p>

Part 4. Background Information

a) Background Information:

This safety notice relates to all machines fitted with the Exact couch top, whether equipped with an Exact Couch or the ETR couch with Exact Couch top upgrade. This will include both low and high energy C-Series Clinacs, Acuity and Ximatron product lines.

Varian Medical Systems advised the Irish Medicines Board (IMB) of an issue they discovered with the Exact couch top. They identified several locations on the couch that can cause severe injuries to staff and patients when in use. There have been a number of injuries reported to date, as a result of which Varian Medical Systems initiated a field safety corrective action.

There are several locations on the underside of the Exact couch top that could present a pinch hazard. Three main points that a user should be aware of:

Port film clip/lateral carriage intersection

Couch magnet mechanism / lateral carriage intersection

Couch top box section / lateral carriage intersection

Reference Appendix 1 for the FSN (reference CP-00019) supplied by Varian Medical Systems for further information.

Varian Medical Systems distributed a FSN in August 2008 to all hospitals / clinics they had identified as being affected by this issue. An updated FSN was distributed in March 2009 that included additional devices that had not been included in the original FSN. This updated FSN was only distributed to the hospitals / clinics where the additional devices were located.

Since the distribution of the original FSN in August 2008, there have been further incidents in hospitals/clinics that had received the FSN.

To date there have been no incidents reported in Ireland. The modific

modifications for all affected devices in Ireland are scheduled for completion by the end of July 2009.

Part 5. Action to be taken

a) Action to be taken:

Ensure that FSN (reference CP-00019) supplied by Varian Medical Systems is circulated to all users of the Exact couch top.

Report any incidents to the IMB.

Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

<st1:City w:st="on"><st1:place w:st="on"> Dublin
</st1:place></st1:City> 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Varian Medical Systems UK Limited

<st1:Street w:st="on"><st1:address w:st="on"> Gatwick Road

</st1:address></st1:Street><st1:place w:st="on"> Crawley
</st1:place> RH10 9RG

U <st1:country-region w:st="on"><st1:place w:st="on"> nited Kingdom

</st1:place></st1:country-region> Telephone: +44-1293-531244

E-mail: onc.helpdesk@varian.com

IMB Safety Notice SN2009(01): Exact Couch Top

Appendix 1 of IMB Safety

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Part 7. Keywords

a) Keywords:

Exact Couch Top, SN2009(01)