



**BRACHYTHERAPY**

**Customer  
Technical Bulletin**

<b>Title</b>	<b>Damage to the Flexible Implant tube, blind end, part # GM11003730 (included set GM11004680)</b>	
<b>Date</b>		Initial Release: 09/20/2005

<b>Est. labor hours</b>	N/A	<b>CTB</b>	<b>CTB-GM-435A</b>
		<b>DWG. No.</b>	<b>N/A</b>

<b>Purpose</b>	To inform customers of a defect with the flexible implant tube with blind end, part number GM11003730, LOT 05/28/1, production date 07/2005 It has been reported that one (#1) tube has been easily damaged by a marker wire usually inserted for x-ray. The buttons (stops) are still in place, but marker wire has been pushed through the closed end of the tube.
<b>Effectivity</b>	All GammaMed customers who have been supplied with LOT <b>05/28/1</b>
<b>Prerequisites</b>	

REV	DATE	STB	INT	DESCRIPTION OF CHANGE	FILE NAME
A		N/A	CAZ	Initial Release	CTB-GM-435A

<b>Tools &amp; Equip</b>	N/A
<b>Reference Documents</b>	None.

<b>Modification Overview</b>	N/A
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Kit Part Number	Description
GM11003730	Flexible implant tube, blind end 350mm (set of 3 sterile)
GM11004680	Flexible Interstitial Implant Tube Set

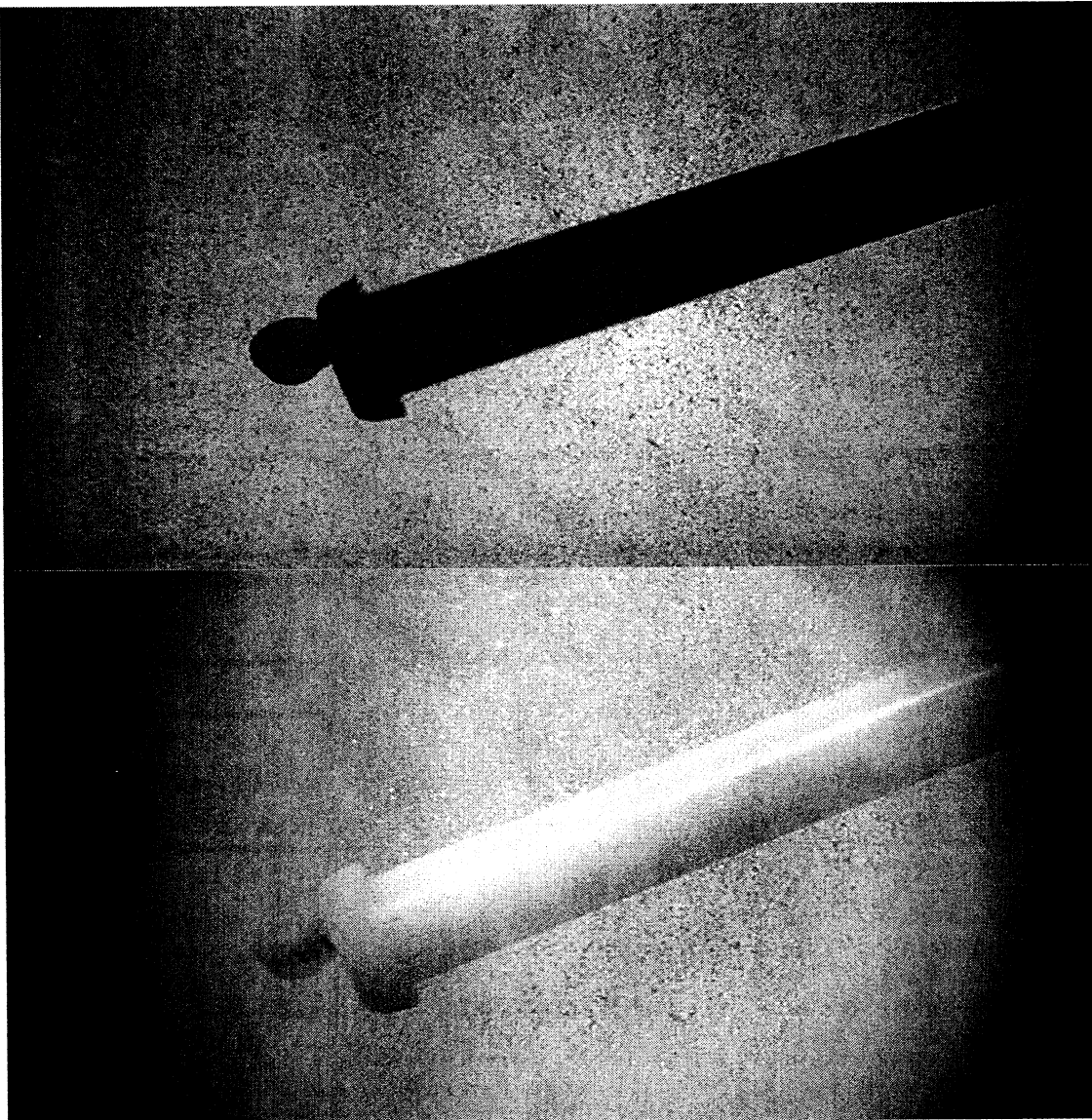
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Created By Claudia Andres-Zindler 09/20/2005	DATE	MARKETING DATE	REGULATORY DATE	R&D DATE	Operations DATE	Tech Support DATE	SHEET <b>1 OF 7</b>
Checked By Andy Partridge 09/21/2005	DATE	Tim Clark / Ted Jackson / Dave Hall	Mark Kattmann / Paul Verdon / Juergen Handke	Ted Jackson / Chris Heath / Gottfried Navratil	Mark Kattmann / Ken Mills / Wolfgang Zindler	John Morrison	CTB # REV A  CTB- VS-000

## 1. DISCREPENCY

It has been reported that one (#1) tube has been easily damaged by a marker wire usually inserted for x-ray. The blind end (stops) are still in place, but the marker wire has been pushed through the closed end of the tube.

In detail it was reported that a little round piece of plastic (the lid of the tube) had opened but was still attached to the tube.

Picture 1 is the distal end of a tube that shows the problem. During the examination this piece (lid) of plastic was removed using pliers.



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**Picture 1**

**2. EFFECTS**

- A separated lid could become ingested or in exceptional circumstances inhaled. If a lid were inhaled there may be a need to perform a bronchoscopy.
- If the distal end of the tube is open there is a small risk that the dummy wire could extend into the inside of the mouth. In this instance there is a very remote chance of an injury to the inside of the mouth.
- Liquid could enter the tube and be pulled back into the afterloader device, causing damage to the afterloader.

**3. CORRECTIVE ACTION**

After application the length cutting gauges and/or marker wires should be carefully inserted. With this LOT 05/28/1, production date 07/2005, treatments should be performed only at channel 20-24 of the GammaMed device, if planned number of channels allows so.

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Varian BrachyTherapy  
 700 Harris Street  
 Suite 109  
 Charlottesville, VA 22903

**RECIEPT VERIFICATION CARD**

**Customer receipt verification:**

Fill out the Receipt Verification Card and FAX or e-mail immediately To Varian  
 BrachyTherapy:  
 866-385-1322, or (949) 221-7631

**CTB Number: CTB-GM-~~XXXX~~A**

**Product Code: Flexible Implant tube, blind end, part # GM11003730  
 (included set GM11004680)**

**Name of Institution:**

**Date of Receipt:**

**Customer Name:**

**Comments:**

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## Varian BrachyTherapy Technical Support Contacts

### Toll Free Telephone Support

Country	Access number	Country	Access number	Country	Access number
Australia	1 800 144 130	Hungary	06 80013 318	Norway	800 16 327
Belgium	0800 74 248	Indonesia	001 803 0441 1109	Portugal	800 880 183
Canada	1 888 226 8633	Ireland	1 800 551 716	Singapore	800 44 11 100
Denmark	80 88 07 45	Israel	1 800 944 11 80	South Africa	0800 992 872
Finland	0800 11 68 92	Italy	800 790 535	Sweden	0200 21 45 08
France	0800 905 397	Japan	00531 78 22 21	Switzerland	0800 83 75 77
Germany	0800 182 6937	Luxembourg	0800 25 67	Taiwan	0080 04 40 99
Holland	0800 022 5072	Malaysia	1 800 808 605	UK	0800 068 06 88
Hong Kong	0800 96 21 42	New Zealand	0800 445 938	USA	1 800 360 7909

In addition, toll free access using the AT&T International direct dialing network is available in over 150 countries. To access this number, dial first the AT&T access number in your area (for the access code in your area, see internet address: [http://www.att.com/business\\_traveler/guides\\_and\\_access/international\\_dialing.html](http://www.att.com/business_traveler/guides_and_access/international_dialing.html)). Then after hearing the AT&T signature noise, and, "Please enter the number you are calling", dial: **800-360-7909**

For countries not listed above or not in the AT&T International dialing network, Telephone Support may be obtained via the following numbers:

UK: +44 1293-601-327

USA: +1-434-979-1540

Our Applications Specialists can immediately return any calls received on these numbers.

### Fax Support

Please fax your questions to BrachyTherapy Technical Support on:

UK: +44 1293-542-626

USA: +1-866-385-1322

+1-949-221-7631

### e-Mail

To submit a support request or general inquiry, please compose an email with a blank subject line, to: [brachyhelp@varian.com](mailto:brachyhelp@varian.com). Please indicate the name of your institution, your name and phone number, the product you are commenting on, and your system number (if known), as well as the description of the problem or question.

**www**

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**Varian Medical Systems – BrachyTherapy Offices**

**USA**

109-700 Harris Street  
Charlottesville, VA 22903  
Tel: 434-977-8495

**United Kingdom**

Gatwick Road  
Crawley, Sussex, RH10-9RG  
Tel: 44-1293-601219

**Germany**

Bergische Strasse 16  
42781, Haan  
Tel: 49-2129551-0

**Varian Medical Systems – Oncology Systems Field Service Offices**

*United States Centers*

*International Centers*

**Headquarters**

596 Alder Drive  
Milpitas, CA 95035  
Tel: 408-321-9400

**Australia**

Unit 6, 81 Frenchs Forest Road (East)  
Frenchs Forest  
New South Wales 2086  
Tel: 61-2/9975-8830

**Hong Kong**

Room 1018-20, Tower A  
Mandarin Plaza  
14 Science Museum Road  
Tsimshatsui East, Kowloon  
Tel: 852/2724-2836

**Northeast**

100 Walnut Avenue  
Suite 201  
Clark, NJ 07066  
Tel: 732-381-5300

**Brazil**

Rua São Carlos do Pinhal, 696  
9th andar CEP 01333-000  
Sao Paulo  
Tel: (55 11) 3457 2655

**Netherlands**

Nederland B.V  
Kokermolen 2  
3994 DH Houten  
Netherlands

**Southeast**

2250 Newmarket Parkway  
Suite 120  
Marietta, GA 30067  
Tel: 770-955-1775

**Denmark**

Lyskaer 9  
DK-2730 Herlev  
Tel: 45-44/500-100

**P.R China**

76 Zhichun Road  
Haidian District  
Beijing PRC 100086  
Tel: 86-10/6512-3667

**Midwest**

200 East Howard Street  
Suite 202  
Des Plaines, IL 60018  
Tel: 847-296-0660

**France**

283, rue de la Miniere  
78535 BUC Cedex  
France  
Tel: 0800 025 025

**Spain**

Via dos Castillas, 33  
Compl. Atica, Edif. 7 Bajo  
28224 Pozuelo de Alarcon  
Madrid, Spain  
34 91 799-4530

**Southwest**

403 International Pkwy  
Suite 503  
Richardson, TX 75081  
Tel: 972-238-7017

**Germany**

Alsfelder Strasse 6  
D-64289 Darmstadt  
Tel: 49-6151/7313-0

**Switzerland**

Chollerstrasse 38  
Postfach 3363  
CH-6303 Zug  
Tel: 41-41/749-8844

**West**

650 East Parkridge Avenue  
Suite 109  
Corona, CA 92879-1092  
Tel: 1-909-280-4406

**India**

Ground Floor, Municipal MKT  
behind Dinanath Mangeshkar Hall  
Tejpal Road, Vile Parle (E)

**United Kingdom**

Gatwick Road  
Crawley, Sussex  
RH10 2RG-U.K.  
Tel: 44-1293/53 12 44

**Italy**

Via Brescia 28D1  
20063 Cernusco S/N (MI)  
Italy  
Tel: 39-02-921-351

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