REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: CA1080S102S DATE: **December 14, 2001** PAGE: 1 of 8

SEALED SOURCE TYPE: Brachytherapy source

MODEL: VS2000

DISTRIBUTOR: Varian Medical Systems
911 Hansen Way
Palo Alto, CA 94304-1028

MANUFACTURER: Varian Medical Systems (UK), Ltd.
Gatwick Road
Crawley, West Sussex RH10 2RG, United Kingdom

ISOTOPE:	MAXIMUM ACTIVITY:
Ir-192	13 Ci (481 GBq)

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (V) General medical use

CUSTOM SOURCE: _____ YES __X__ NO

NMSS/2

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DESCRIPTION:

The sealed source is a 0.6 mm diameter Nitinol (nickel-titanium alloy) wire with two Ir-192 sources singly encapsulated at the distal end. Maximum Ir-192 activity is 13 Ci. A drawing of the source wire assembly is provided in Attachment 1. The cores are made from iridium that has been isotopically enriched to a minimum 80 atom percent Ir-191. Elemental purity is greater than 99.9%. After fabrication, the iridium core is delivered to a reactor facility for neutron activation. Radionuclidic purity, at one day after the end of an irradiation, is greater than 99.9% Ir-192 on an activity basis. Overall uncertainty in measured activity of Ir-192 is ±3% (1σ).

Construction of a wire begins with a 2724 mm source wire blank. Electrical discharge machining or conventional drilling is used to cut a cavity into the distal end of the wire. Each wire is inspected to verify a minimum wall thickness of 0.0040 inch for the cavities formed by electrical discharge machining and 0.0035 inch for those formed by conventional drilling. A full hemispherical weld is applied to the proximal end of the wire, and the wire is sized to 2585 mm. The distal end of the wire is then heat treated to improve fatigue performance. Afterwards, two activated Ir-192 sources, each 2.5 mm in length and 0.35 mm in diameter, are loaded end-to-end into the cavity. A Nitinol plug is then inserted into the cavity. The butt is welded by laser or gas tungsten arc welding (GTAW) to encapsulate the sources. The weld is a full hemispherical seal weld. A welding specification requires that no resulting wall section be thinner than native wall.

Varian Medical Systems reports that the materials, design, and construction of the subject Model VS2000 are similar to their Models SL-777 and SL-777V. There are, however, three important differences between the two models. The iridium cores of the Model VS2000 are isotopically enriched in Ir-191 and are one-half the length of the Model SL-777 and SL-777V cores. In addition, the distal end of the Model VS2000 wire is heat treated. As a result of these design changes, the cycle life of the source has been increased from 500 cycles for the SL-777 and SL-777V sources to 1000 cycles for the subject VS2000 source. For reference, Varian Medical Systems' Models SL-777 and SL-777V are registered under Sealed Source and Device Certificate CA1080S101S.

LABELING:

The source wire is too small to be labeled effectively by engraving. A tag, however, is shipped with each source wire. The tag identifies the isotope, activity, date of assay, and source model number. The tag also has the standard radiation symbol, the words "CAUTION RADIOACTIVE

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MATERIAL," company name, emergency phone number, and a statement that California Department of Health Services has approved distribution of the sources only to persons specifically licensed by the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State to possess them. A drawing of the tag is provided in Attachment 2.

The shipping container is also labeled. The label provides the source wire model number, wire length, serial number, company name, and emergency phone number. A drawing of the label is provided in Attachment 3.

DIAGRAMS:

There are three attachments.

Attachment 1:	Drawing of source wire assembly.
Attachment 2:	Drawing of source wire tag.
Attachment 3:	Drawing of shipping container label.

CONDITIONS OF NORMAL USE:

Model VS2000 is intended for specific and exclusive use in Varian Associates, Inc. Model VariSource HDR Remote Afterloader, but not the low-speed drive design of this model. These afterloaders are used in clinical settings by trained professional staff. The afterloaders are not subject to extreme conditions of corrosion, vibration, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, or thermal cycling. Varian Medical Systems has evaluated impact conditions and has specified a minimum bending radius of 1.7 cm.

Varian Medical Systems reports that the useful life of the source is 120 days or 1000 wire extensions, whichever occurs first. The user of the afterloader shall document each wire extension to ensure that the 1000 wire extension limit is not exceeded. Varian Medical Systems reports that source wires are exchanged approximately every 120 days, due to radioactive decay of the Ir-192 and the source wire extension limit. The source carries "special form" certification pursuant to 49 CFR 173 Subpart I - "Radioactive Materials" and International Atomic Energy Agency Safety Series No. 6, "Regulations for the Safe Transport of Radioactive Materials," as amended in 1990. The 13 Ci Ir-192 source may be transported in a DOT Type A container.

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PROTOTYPE TESTING:

The subject Model VS2000 wires were prototype tested pursuant to standards set forth in ISO 2919-1980. The wires that were tested were welded by GTAW. The wires achieved an ISO 2919-1980 classification of ISO/C53211, which is approximately equivalent to an ANSI N43.6-1997 classification of 97C53211. The two standards have slightly different impact test conditions. These classifications match the recommended performance conditions provided in the two standards.

A note in ISO 2919-1980, Annex C states that interstitial and intracavitary sources may be subject to severe deformation during use, and that manufacturers and users may wish to formulate additional or special test procedures. Varian Medical Systems has fatigue tested the Model VS2000 wire by cycling the wire through a 180 degree turn around an unconstrained 1.7 cm radius pathway. Cycling was continued until failure. The minimum bending radius authorized by Varian Medical Systems for the subject wire is also 1.7 cm. The fatigue testing model is based upon a worst-case scenario. Varian Medical Systems reports that a Weibull plot of the fatigue data, when extrapolated, indicates a 99.5% reliability at 1000 cycles, at the lower 95% confidence bound. **Varian Medical Systems may authorize clinical applicators having a minimum bend radius of less than 1.7 cm provided that it has been demonstrated that the wire meets the same fatigue limit of 99.5% reliability at 1000 cycles, at the lower 95% confidence bound.**

Fatigue data were obtained with wires that had been welded by GTAW. Varian Medical Systems demonstrated, through testing and an engineering analysis of their comparable Models SL-777 and SL-777V, that the laser weld provides containment equivalent to the GTAW weld in this application. Laser welds had no material section thinner than native wall. In addition, the reflowed weld zone had no voids.

EXTERNAL RADIATION LEVELS:

The exposure rate constant for Ir-192 (unfiltered) is 4.69 $Rcm^2/mCi\text{-}hr$. Varian Medical Systems calculates the exposure rates for a 10 Ci Ir-192 source as follows:

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Distance (in)	Distance (cm)	Exposure rate (R/hr)
2.0	5	1876
11.8	30	52.1
39.4	100	4.69

QUALITY ASSURANCE AND CONTROL:

British Standards Institute (BSI) has certified that Varian Oncology Systems (Palo Alto, CA) operates a quality management system that complies with the requirements of BS EN ISO 9001:1994 and EN 46001. The scopes of the registrations are radio and electronic capital goods, and design and manufacture of linear accelerators and accessories used in radiotherapy treatment of disease. BSI has also certified that Varian-TEM Limited (Crawley, West Sussex, United Kingdom) operates a quality management system that complies with the requirements of BS EN ISO 9001:1994 and EN 46001. The scopes of the registrations are medical and scientific instruments and control systems, and VariSource afterloader and other radiotherapy equipment and accessories. Manufacturing subcontractors are audited and approved by Varian Medical Systems (UK), Ltd. using a Quality Vendor Assessment Procedure. Varian Medical Systems' "Systems Policy Manual" and Varian Medical System (UK), Ltd.'s "Quality Manual" are on file with California Department of Health Services.

Varian Medical Systems has committed to fatigue testing one wire from each production batch, which is generally 15 wires. Wires that are tested will have gone through the same production process as the commercially distributed wires, except that the test wires will be loaded with iridium cores that are not radioactive. Test wires are cycled through the series of tests described in the section titled "Prototype Testing." The number of cycles needed to cause failure is monitored and is used in a fatigue model to ensure that those wires that are commercially distributed have a low probability of failure. Varian Medical Systems has committed to these tests as well as additional fatigue modeling and production line tests. Varian Medical Systems reports this testing will act as a continuous monitor of their Quality Management System.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The source shall be distributed only to persons specifically licensed by the NRC, an Agreement State, or a licensing state.

2. Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates, the sources shall be handled by experienced licensed personnel using adequate handling equipment and procedures.

3. The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.

4. A Leak Test Certificate and Certificate of Measurement shall be supplied with each source.

5. The source carries "special form" certification pursuant to 49 CFR 173 Subpart I - "Radioactive Materials" and International Atomic Energy Agency Safety Series No. 6, "Regulations for the Safe Transport of Radioactive Materials," as amended in 1990. After fabrication, each source shall be leak tested pursuant to guidance provided in ANSI N43.6-1997. Each source to be used clinically shall carry a traceable calibration.

6. The source shall not be subjected to conditions that exceed its ISO 2919-1980 classification of ISO/C53211.

7. The minimum bending radius authorized by Varian Medical Systems for the Model VS2000 wire is 1.7 cm. **Clinical applicators having a minimum bend radius of less than 1.7 cm may be authorized by Varian Medical Systems provided that it has been demonstrated that there is no detrimental effect on the wire pursuant to reliability criteria provided in Varian Medical Systems' "Applicator Specification" document.**

8. The sources shall not be stored or transported in Teflon-lined catheters. Hydrogen fluoride and hydrofluoric acid generated by radiolysis of Teflon may corrode the weld and wall material.

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9. The useful life of the source is 120 days or 1000 wire extensions, whichever occurs first. The user of the afterloader shall document each wire extension to ensure that the 1000 wire extension limit is not exceeded.

REVIEWER'S NOTES:

A. The inspector and license reviewer are referred to NUREG 1480, "Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center, Indiana, Pennsylvania, on November 16, 1992." This NUREG report describes a wire break, misadministration, and various licensing issues pertinent to HDR afterloaders.

B. Varian Medical Systems' Model VS2000 meets the recommended ISO 2919-1980 classification for interstitial and intracavitary appliances. There is, however, a low probability that a source wire will break during clinical usage. Users of the subject wires, therefore, shall be trained to identify and respond appropriately to a wire break. In addition, the licensee shall have an effective radiation safety program and a written procedure that covers a wire break.

C. On April 2, 1999, Varian Associates, Inc. (Palo Alto, CA) reorganized into three separate public companies: Varian Medical Systems, Varian, Inc., and Varian Semiconductor Equipment Associates, Inc. Varian Oncology Systems and Varian Medical Systems (UK), Ltd. (formally Varian TEM) are now divisions of Varian Medical Systems.

10. This registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

Varian Medical Systems' Model VS2000 is expected to maintain its integrity under normal use and likely accident conditions based upon prototype test results, engineering analysis on the integrity of the laser weld, and continuing fatigue modeling and testing of one wire in each production batch.

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Based upon our review of sealed source Model VS2000, its ISO 2919-1980 classification, and the information and test data cited below, we **continue to** conclude that the source is acceptable for licensing purposes.

Furthermore, we **continue to** conclude that this source would be expected to maintain its containment integrity, subject to the Reviewer's Notes A and B above, for normal conditions of use and accidental conditions that might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for sealed source Model VS2000 are hereby incorporated by reference and are made part of this registry document.

1. Varian Medical Systems' application dated September 29, 1999, with enclosures thereto.

2. Varian Medical Systems' facsimile dated March 7, 2000.

3. Varian Medical Systems' letters dated February 8, 2000, with enclosure thereto, March 7, 2000, with enclosure thereto, March 9, 2000, with enclosures thereto, March 10, 2000, with enclosures thereto, March 13, 2000, March 14, 2000, with enclosures thereto, March 15, 2000, with enclosures thereto, March 21, 2000, with enclosures thereto, April 3, 2000, with enclosures thereto, **and October 24, 2001, with enclosure thereto, and November 30, 2001, with enclosure thereto.**

ISSUING AGENCY: California Department of Health Services

Date: December 14, 2001 Reviewer: _____
Ronald Rogus, Ph.D.

Date: December 14, 2001 Concurrence: _____
Xiaosong Yin

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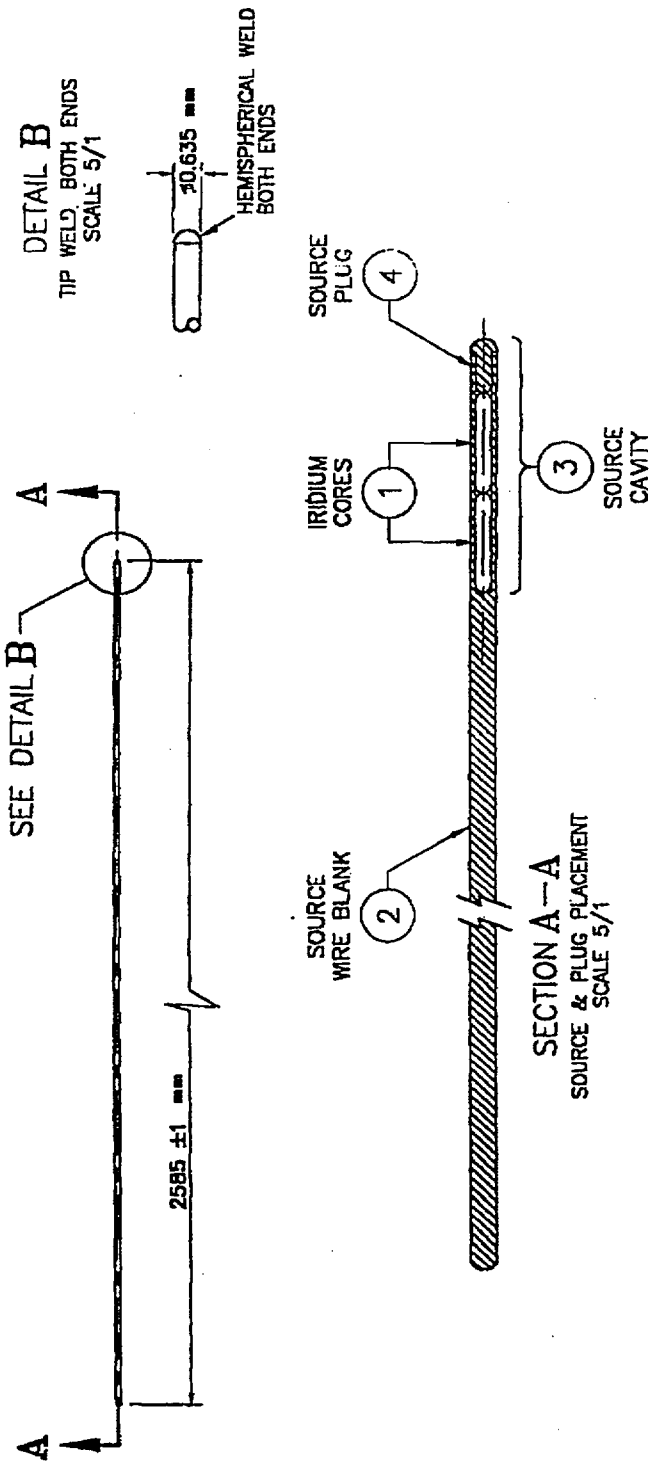
NO.: CA1080S102S DATE: **December 14, 2001** ATTACHMENT 1

Source wire assembly



SPECIFICATIONS

MAT'/ : PAPER – 13 PT

TAG SIZE : 150 X 75

CLIP UPPER CORNERS : 20 X 20

COLOUR : YELLOW TAG WITH RED CHARACTERS

FIBRE REINFORCED EYELET

300 LG STRING TIE (KNOTTED)

TEXT TYPE : HELVETICA MEDIUM

TEXT SIZE : AS DRAWN

PROOF PRINT REQUIRED FOR APPROVAL

BAG AND TAG AND IDENTIFY WITH DRG NO AND ISSUE NO

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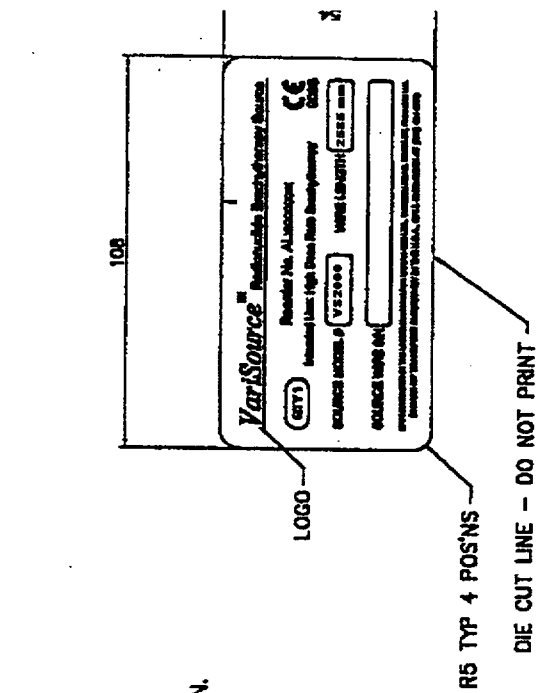
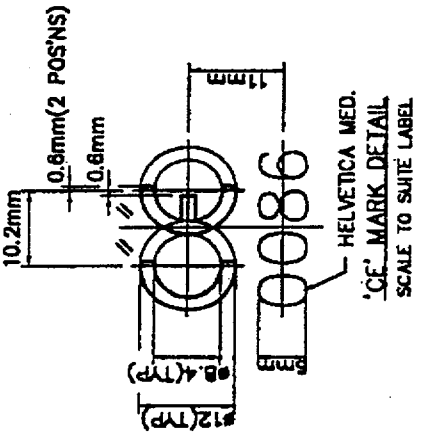
Shipping container label



NOTES:
1. MATERIAL: FASSON 60# C1S WHITE LITHO STOCK S-246 ADHESIVE
2. PRINT BLACK ON WHITE STOCK.
3. TYPEFACE: LOGO TO BE TIMES NEW ROMAN BOLD ITALIC. OTHER TEXT TO BE HELVETICA.
   POSITION, SIZE AND WEIGHT TO BE CLOSE TO THOSE SHOWN.
4. PRINTED CHARACTER SIZES MAY BE SCALED FROM A FULL SIZE A3 PRINT OF THIS DRAWING.
5. FINAL ARTWORK SUBJECT TO APPROVAL BY VARISOURCE ENGINEER.
6. BAG & TAG & IDENTIFY WITH DRAWING NUMBER AND APPROPRIATE ISSUE NUMBER.



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