MDE
MARYLAND DEPARTMENT OF THE ENVIRONMENT
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OCT 3 2013

Traci Kime, Sealed Source Device Assistant
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Mail Stop E 24
Rockville, Maryland 20852

RE: SEALED SOURCE & DEVICE REGISTRY

Dear Ms. Kime:

Please find Maryland Department of the Environment's (MDE) Radiological Health Program (RHP) sealed source and device sheets for Elekta Inc., dba Nucletron Corporation. The seven sheets, were transferred to the State of Georgia and are currently listed in the SSD registry as active with GA designations. The sheets issued in the Maryland and being deactivated are:

MD-0497-D-104-S now MD-0497-D-809-S
MD-0497-S-107-S now MD-0497-S-810-S
MD-0497-D-108-S now MD-0497-D-811-S
MD-0497-D-110-S now MD-0497-D-812-S
MD-0497-S-113-S now MD-0497- S-813-S
MD-0497-D-114-S now MD-0497-D-814-S
MD-0497-D-115-S now MD-0497-D-815-S

At this time, Maryland no longer holds any SSD sheets for Elekta/dba Nucletron. If you have any questions, please feel free to contact Mrs. Barbara Park, Mr. Ray Manley or me at (410) 537-3301.

Sincerely,

Roland G. Fletcher, Program Manager IV
Radiological Health Program
Air and Radiation Management Administration

RGF/REM/BJP/cc

Enclosure(s): Seven SSD registrations

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO: **MD-0497-D-809-S** DATE: **July 22, 2013** PAGE: 1 OF 14
(now GA-0497 –D-104-S)

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

MODEL: MicroSelectron-HDR Classic (device formerly registered as MicroSelectron-HDR)

DISTRIBUTOR: Elekta, Inc, d/b/a Nucletron
c/o CSC-Lawyers Incorporating Service Company
7 St. Paul Street, Suite 1660
Baltimore, Maryland 21202

MANUFACTURER: Nucletron Engineering B.V.
Waardgelder 1
3905 TH Veenendaal
The Netherlands

SEALED SOURCE MODEL DESIGNATIONS:

Model 096.001 (formerly registered as DRN 07735, CIL BV and MS-HDR)

Manufactured by: Mallinckrodt Medical BV Petten, Holland
or
AEA Technology/QSA Global, Inc.
Burlington, Massachusetts

Model CSNOO10-192

Manufactured by: Alpha-Omega Services, Inc., 1282 Big Woods and Stark Road, Edgerly, Louisiana 70668

ISOTOPE: Iridium-192 MAXIMUM ACTIVITY:
10 curies (370 GBq) in Afterloader. 12 curie (444 GBq) replacement source stored for decay to 10 curies (370 GBq) at facility.

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (AC) Photon-emitting remote afterloaders
CUSTOM DEVICE: _YES x NO

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DESCRIPTION:

The microSelectron-HDR Classic is a remote controlled afterloading system used for the treatment of cancer by interstitial, intracavitary, intraluminal, endovascular (PARIS IDE) and surface applicator treatments. The unit eliminates radiation exposure normally received by hospital staff during interstitial treatments.

The patient implant is carried out in the normal way using either flexible or rigid applicators. The doctor's clinical technique is not changed; radiation exposure formerly caused by source handling and transfer is eliminated. If treatment must be interrupted, the source is withdrawn and stored in the safe in less than 8 seconds. Both at the end of the treatment and in case of power failure the source is automatically returned to the safe in the Treatment Unit. In the event of complete system failure there is a hand control that can manually return the source to the safe.

The microSelectron-HDR Classic has two timers. The primary countdown timer is contained in the Treatment Unit microprocessor and counts the dwell time per position of the source. The primary timer value is sent to the Control Unit for checking and display. The secondary (up counter) is located in the Control Unit microprocessor and counts the time the source is out of the safe. The Control Unit also displays this value.

The operator manual supplied with the microSelectron-HDR Classic, in addition to routine operating instructions, explains how to program the microprocessor for standard treatments, proper emergency response, and the non-routine operations of source replacement.

The microSelectron-HDR Classic consists of:
a. Treatment Unit
b. Control Unit
c. Patient applicator
d. Junction Box, Door Interlock Switch, Emergency Stop Switches

Treatment Unit: The Treatment Unit contains the main safe for the Iridium-192 source (up to 10 curies [370 GBq]), dual drive mechanisms for source and check cables, an indexing system to permit 18 channels of treatment, the main power supply, emergency backup

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DESCRIPTION (cont.):

battery system, and telescoping treatment head to adjust the height of the Treatment Unit for different body sites. Although the Treatment Unit is mounted on wheels so that it can be placed in a convenient location for treatment of patients, it is not to be considered a portable device to be moved anywhere. It must be used only in a properly shielded room with permanent electrical interconnections and the Control Unit must be located outside that shielded room. A facility may have two or more such shielded rooms with permanent electrical wiring and move the unit from one room to the other based on treatment needs. The computer in the Treatment Unit is the master computer that controls all treatment parameters. The emergency stop switches and the door interlock switches directly control the motor drives in the Treatment Unit. In the event of a loss of power, the emergency backup batteries power the electronics to retract the source to the shielded position within the safe and alert the operator of the condition. Once power is restored, the system is ready to resume treatment at the point it was interrupted. The Control Unit contains the primary timer that continuously monitors the treatment dwell time of each position.

Drive Mechanism: The microSelectron-HDR Classic uses a mechanical drive with an anti-kink storage mechanism and a stepping motor that only steps in a forward direction thus eliminating all backlash. To ensure that the source can always go through the applicator, and make the correct steps, a check cable run always precedes the treatment run. This checks the conditions of the entire applicator and that the steps can take place.

Control Unit: The Control Unit contains a second microprocessor that is used for the input of routine and treatment-specific data. The Control Unit monitors the progress of the treatment and displays treatment parameters including dwell position, dwell time, and any error codes that may be generated by the system. The Control Unit has the capacity to store 99 standard treatments, and the dwell times are automatically corrected for the decay of the Iridium-192 source. The Control Unit also contains the printer that automatically records all treatment parameters and produces a hardcopy of any error messages. The Control Unit also contains a secondary timer that counts the time period the source is out of the safe. It generates an alarm in the event the secondary timer deviates from the sum of the programmed dwell times.

The Control Unit enables 48 possible source treatment positions (or steps) of 0.25 centimeters (cm), 0.5 cm, or 1.0 cm and giving treatment lengths of 12 cm, 24 cm, or 48 cm. Variable dwell times for each source position can be programmed and displayed. The control unit can store and display up to 18 independent treatment channels with source positions and treatment times and is used with the 18 channel indexing system.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DESCRIPTION (cont.):

The system can store multiple standard source configurations and times, which are automatically corrected for the decay of the iridium-192 source. In the case of main power failure, the system contains a battery backup that will maintain treatment data and return the source to the fully shielded position. A printer records all patient treatment data, source configurations and times.

Treatment Control Station (TCS): The Treatment Control Station is being offer by the manufacturer to customers as an alternative to the Control Unit. The TCS allows the user to program a treatment and monitor a treatment in progress. The TCS console consists of a PC based graphics terminal that, uses a MS Windows based software management program. All device-programming functions are carried out at the TCS, including default set-up parameters for the Treatment Unit and the data entry of radioactive source specifications. The TCS also controls secondary timing and provides independent "Start", "Interrupt" and source location indicators. Treatment data is entered manually, based on a standard plan or imported from the Nucletron Treatment Planning System (PLATO).

Patient Applicator: Each machine may be supplied with applicators for the treatment of the bronchus and esophagus, which have a special adapter that fits into the front of the indexing unit. All connecting tubes are individually inserted and locked. The machine cannot send out a source unless an applicator is properly connected. Every treatment by a live source is preceded by a check cable run to detect any blockage or constrictions in order to ascertain that the live source can move freely both out and back. If the check cable run does not move freely out and back, the treatment run is not started and the source remains within the safe until all obstructions are removed.

Junction Box: The Junction Box is an interconnection box that allows termination of electrical cables between the Control Unit and the Treatment Unit as well as the door interlock switches and emergency stop switches. The electrical wiring between the

Control Unit and the Treatment Unit are permanently installed in each shielded room. Both the door interlock switch and the emergency stop switches directly control source retraction at the Treatment Unit within the shielded room.

Endovascular Radiotherapy (PARIS Clinical Trial-Investigational Device Evaluation):

Nucletron Corporation indicates that the PARIS clinical trial is intended to demonstrate

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DESCRIPTION (cont.):

the clinical utility of endovascular brachytherapy to prevent restenosis following balloon angioplasty. The trial is a double blind randomized study to be conducted at approximately fifteen (15) clinical sites and involving 300 subjects with half of those subjects treated with radiation and the other half being sham treated with the check cable only. An initial feasibility study of 40 subjects, at five institutions, was approved by the Food and Drug Administration (FDA) under IDE Number G970061/S2 on October 7, 1997. FDA approval for the randomized portion of the study was received in May 1998, under IDE number G970061/S15, and is expected to last two to three years. The study involves the sham or radiation treatment of femoral/popliteal artery lesions between the lengths of 5 to 15 centimeters following balloon angioplasty. The balloon position is checked radiographically and the catheter is immobilized. A 6Fr adapter is used to attach the closed end radiation sheath in the centering catheter system to the afterloader. Nucletron Corporation states that no physical modifications to the microSelectron-HDR Classic, as described and evaluated in this sealed source and device sheet, are necessary to conduct this study. The inflatable balloon centering catheter system is manufactured by Guidant Corporation and includes a radiopaque marker to identify the tip of the catheter. Guidant Corporation manufactures these catheters with balloon diameters (when inflated to 4 atmospheres) of 4, 5, 6,7 and 8 millimeters, and lengths of 10 and 20 centimeters. The prescription dose and location of dose delivery established by the manufacturer for this protocol are 1400 centigray delivered to a point 2 millimeters into the arterial wall. The treatment plans are set up for conventional use with Model microSelectron-HDR assuming 10 curies (370 GBq) as the source activity. Nucletron Corporation states that those protocols specific to the Paris study are stored in different memory locations than those used for normal clinical use and sufficiently preclude their accidental use during a normal clinical use. The manufacturer indicates that explicit training will be provided to participating personnel at PARIS sites by qualified Nucletron employees (clinical research monitors).

LABELING:

A self adhesive "Caution-Radioactive Material" label with the radiation trefoil symbol is attached to the Treatment Unit. Self adhesive labels specifying the microSelectron trade name and manufacturer's name is also attached both to the Treatment Unit and to the back of the Control Unit (SEE ATTACHMENT IV).

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

DIAGRAMS:
For treatment unit – see Attachment I
For Control unit – see Attachment 2
For Source – see Attachment 3
For Identification label - see Attachment 4

SOURCE CAPSULE:
The source capsule is in its third configuration as described in Attachment II. Because higher purity iridium is available allowing higher activation per unit mass, one large iridium source replaces the 8 individual pellets used formerly. Thus the source capsule is shortened, permitting a tighter radius of curvature. This change to the shorter source required an adjustment in the cable length for proper source positioning. See attachment II indicating the distance from the tip of the source to the center of radioactivity. The microSelectron-HDR Classic iridium-192 source capsule, whose activity ranges from 1 to 10 curies (37 to 370 GBq), is laser welded to a 1.1-mm diameter drive cable. The drive mechanism is a constant 1.1-mm diameter ensuring accurate placement of the source. Source capsule dimensions are approximately 5 mm in length and 1.1 mm in diameter. The total length of the cable, cable tail and source is 2000 mm ± 0.5 mm (SEE ATTACHMENT III).

CONDITIONS OF NORMAL USE:

The unit is intended for interstitial, intracavitary, intraluminal endovascular (PARIS IDE) and surface applicator treatments. The patient may be treated as a hospital in-patient, a hospital or clinic outpatient or in a private medical office. In all cases both the patient and the Treatment Unit must be in a properly shielded room adequate to protect the general public and auxiliary personnel from unnecessary radiation exposure. Except for the PARIS study, the treatment procedure is identical to that of normal brachytherapy implants but with shorter treatment times.

The system must be permanently installed in a shielded room where the temperature does not exceed 40° C or fall below 0° C and will be operated under the direction of a radiotherapist. The recommended useful life of the sources is 3-4 months in terms of useful dose rate efficiency.

The anticipated catastrophic condition that might occur is fire. Normally hospitals, clinics, and private offices would be constructed to meet local and national fire regulations; however, the tungsten shielding in the Treatment Unit is deemed adequate for any predicted catastrophe. Additionally, the system is designed so that the patient can be quickly disconnected and the source stored in the shield in a matter of seconds

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

PROTOTYPE TESTING:

The microSelectron-HDR Classic is a predicate device similar to the Selectron LDR, Selectron HDR, and the microSelectron-LDR in terms of treatment delivery. It is subjected to the same quality control checks as the above units. Most of the data applicable to the other remote afterloading systems is also applicable to the microSelectron-HDR Classic. Additionally the life of cable drive system has been tested and estimated to be greater than ten (10) years. Prototype testing for the Nucletron Source model 096.001 was done in The Netherlands using ISO 2919 specifications and met the standards of BAM (Bundesanstalt für Materialforschung und-prüfung), the Federal Institute for Materials Testing – Germany. Sources are manufactured under ISO Classifications 1677/DIN 25246 BS 5288 and C53211.

EXTERNAL RADIATION LEVELS:
The tungsten safe of the Treatment Unit is designed to contain the radiation of the 10 Curie (370 GBq) Iridium-192 source and limit the radiation exposure at 10 cm from the surface of the Treatment Unit to less than 1.0 mR/hr (10μSv/hr). Devices with serial numbers 9160 and higher have been designed to meet this standard. Devices with serial numbers 9001-9159 contain a main safe and supplementary shielding that were designed to limit the radiation exposure to 0.25 mR/hr (2.5μSv/hr) at 1 meter.

QUALITY ASSURANCE AND CONTROL:
Complete information on the manufacturer's quality assurance program on the microSelectron-HDR after loading brachytherapy unit has been submitted and deemed acceptable by Maryland.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. This device shall be distributed only to persons specifically licensed by the NRC or an Agreement State.

2. The source shall be leak tested at intervals not to exceed six (6) months using techniques capable of detecting 0.005 microcuries (0.185 kBq) of removable contamination.

3. Handling, storage, use, transfer, and disposal is to be determined by the licensing authority. Because the sealed sources have high exposure rates, they must be installed and transferred only by experienced, trained and licensed personnel using adequate handling of equipment and procedures.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: Continued

4. The device shall be installed and initially tested for proper operations of the source exposure mechanism, safety warning component labels, external radiation levels (both source exposed and source shielded) and leak tested by trained service personnel specifically licensed to do so by the NRC or Agreement States. Further, the reviewer should request documentation of training/experience of the service representative who will install and service the device.

5. The device shall be installed in a shielded room that has adequate interlocks and labeling to meet the requirements of COMAR 26.12.01.01, Part D, Section D.201, Section D.601 or comparable NRC or Agreement State Regulations.

6. For the Paris trial, the medical physicist should not be blinded because the device has not been modified. The radiation alarm will sound when the treatment is with IR-192 and will not sound when a sham treatment is done.

7. For the Paris trial, in order to assist in preventing the source from being captured in the radiation sheath of the catheter system, the catheter should be sutured in place at the insertion site and the patient's lower limbs immobilized.

8. For the Paris trial, the user should have a provision in their license to conduct human studies and only after FDA IDE approval has been granted.

9. The Nucletron model designation 096.001 sealed source and the Alpha Omega Services, Inc CSNOO10-192 source are approved by the Maryland Department of the Environment (MDE) Radiological Health Program (RHP) for use in the Model MicroSelectron-HDR Classic. The Nucletron Corporation source is not registered in a separate certificate.

10. The Nucletron Corporation model 096.001 sealed source is manufactured identically by Mallinckrodt Medical BV, Petten, Holland, and AEA Technologies, Inc., Burlington, MA.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: Continued

11. The source wire shall not be cut or altered by the licensee.

12. This registration sheet and the information contained with the references shall not be changed without the written consent of the Maryland Department of the Environment.

13. **The ownership of this registration was transferred to the State of Georgia on July 22, 2013, and is registered as GA-0497-D-104-S.**

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and data submitted, we continue to conclude that the microSelectron-HDR Classic device and model 096.001 source are acceptable for licensing purposes. We conclude that this device and source will be expected to maintain the containment integrity for both normal and accidental conditions that might occur during routine use.

REFERENCES:
The following supporting documents for the microSelectron-HDR are hereby made part of this registry document which was re-issued by the State of Georgia when Nucletron moved to the State of Georgia:

1. The Nucletron Corporation application for evaluation dated October 27, 1986 and letters with attachments dated January 30, 1990, April 26, 1991, and November 21, 1991.
2. Nucletron Corporation letter and attachments dated June 20, 1996.
3. Nucletron Corporation letter and attachments dated November 26, 1997 and June 5, 1998.
4. Nucletron Corporation letter and attachments dated September 14, 1998, January 7, 1999 and January 22, 1999.
5. Nucletron Corporation letter and attachments dated February 12, 1999, March 25, 1999, February 23, 2000, March 30, 2000, August 18, 2000, August 25, 2000 and January 17, 2001.
6. Nucletron Corporation letters and attachments dated October 28, 2001 and December 27, 2001.
7. Letters and attachments from the State of Louisiana specific to the Alpha-Omega Services, Inc, sealed source Model CSNOO10-192 dated October 2, 2001, November 16, 2001 and November 29, 2001.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

REFERENCES, CONTINUED

8. Nucletron Corporation letter and attachments dated February 5, 2002 defining the device manufacturer's concerns with the use of third party service and third party sources.
9. Nucletron Corporation letter dated April 22, 2003 changing the distribution address, letter and attachments dated July 14, 2003, adding a source manufacturer, letter with attachment dated August 4, 2003, and letter dated November 11, 2003.
10. Nucletron Corporation letter dated September 22, 2010, changing the distribution address.
11. Elekta, Inc. letter dated January 25, 2012.
12. Letter dated January 30, 2012, from Nucletron, an Elekta Company.
13. Elekta, Inc. d/b/a Nucletron letter dated June 6, 2012
14. **Elekta letter date July 22, 2013, requesting deactivation of this Maryland SSD registration due to the registration transferred to the State of Georgia.**

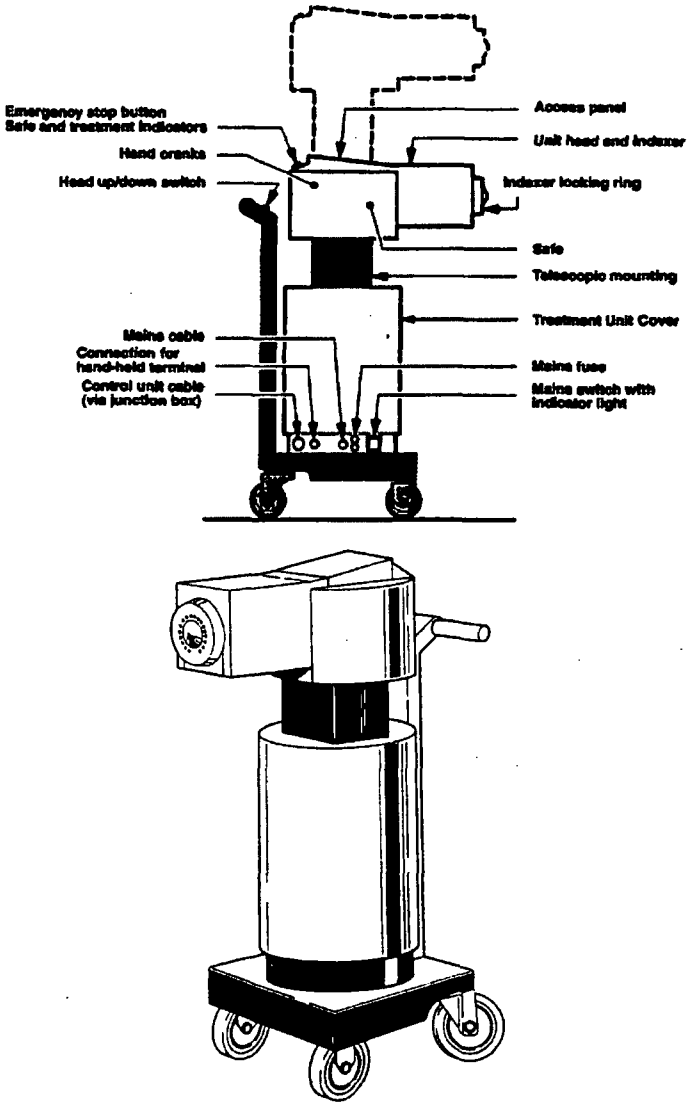
DATE: 7/22/13 REVIEWED BY: Barbara J. Park
Barbara J. Park

DATE: 7/22/13 CONCURRENCE:
Raymond E. Manley

ISSUING AGENCY:
Maryland Department of the Environment
Radiological Health Program
1800 Washington Boulevard, Suite 750
Baltimore, Maryland 21230

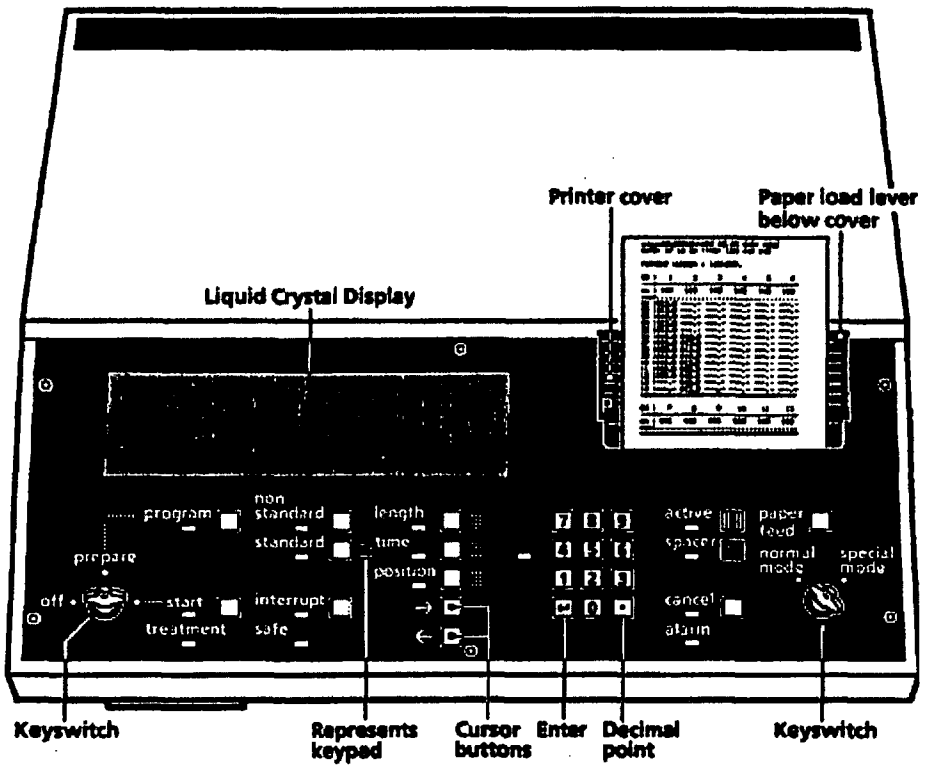
DEVICE TYPE: Remote Afterloading Brachytherapy Unit

ATTACHMENT 1 -TREATMENT UNIT



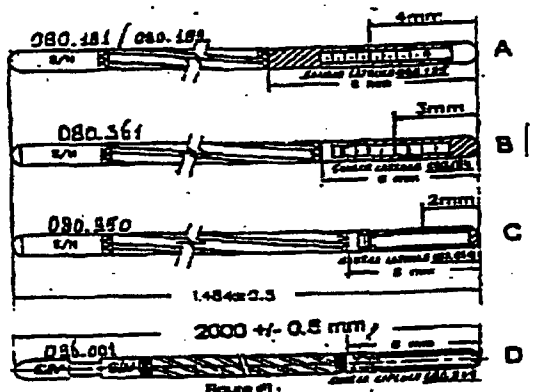
DEVICE TYPE: Remote Afterloading Brachytherapy Unit

ATTACHMENT 2 -CONTROL UNIT

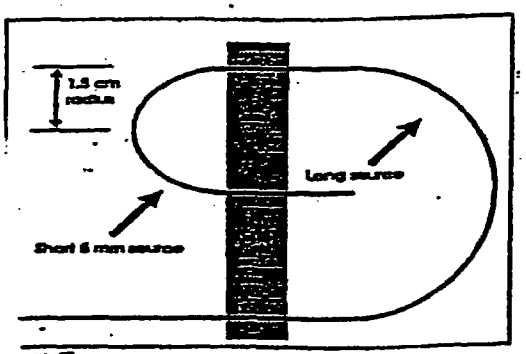


DEVICE TYPE: Remote Afterloading Brachytherapy Unit

ATTACHMENT 3 – Source Capsule and Cable



A May 1987 to June 1989
B July 1989 to May 1991
C June 1991 to May 1993
D January 1993 to present



June 92 schematic illustration

NEW DESIGN OF ^{192}Ir SOURCE

Effective with the June 1991 dispatch of ^{192}Ir sources a new style of sealed source assembly is used.

This new capsule is only 5 mm long, 1.0 mm shorter than the previous version and is manufactured with a single pellet of iridium.

Major advantages of this new design include:

1. The iridium pellet is 3.5 mm long X 0.6 mm diameter resulting in a more isotrophic source.

2. The shorter capsule increases the ability to pass tighter curves, giving a greater flexibility where applicator curvature is a consideration. (See Figure 2)

3. Improved manufacturing quality control.

NOTE 1: Source (See Figure 1)
A) May 1987 to June 1989
B) July 1989 to May 1991
C) June 1991 to present
Capsule dimensions = 5.0 mm x 1.1 mm
Iridium dimensions = 3.5 mm x 0.6 mm
D) January 1993 to present

NOTE 2: The user must confirm the position of the center of activity of the source in relation to the position of the Radiographic markes (brenchial, GYN) and make an appropriate adjustment in the length to position 1.

DEVICE TYPE: Remote Afterloading Brachytherapy Unit

ATTACHMENT 4 -DEVICE LABEL