

Biocompatibles

August 3, 2009

Mr. Stephen Hammann
Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Br 2

2009 AUG -4 AM 10:46

RECEIVED
REGION 1

Amendment of License 06-30764-02^{MD} (Current Amendment No. 8) Docket No. 03036179
may

Re: Advanced Care Medical NARM License Amendment

Dear Mr. Hammann

Advanced Care Medical is requesting that in accordance with the termination of "final phase waivers" and the implementation in Connecticut of NRC Regulatory Authority for accelerator produced radioactive material, that the referenced distribution license be changed to reflect :

- A. Inclusion of accelerator produced isotopes on our license
- B. Our new owner Biocompatibles Inc. (attached NRC Document Docket 03036099, Control 142655 , 7/30/08)
- C. A dba designation (Advanced Care Medical/BrachySciences) to be used as follows on product labeling

Advanced Care Medical – brachytherapy orders received from sealed source companies
BrachySciences - brachytherapy orders received directly from hospitals

The specific license changes are as follows:

Item 1 : Licensee to be Biocompatibles Inc.
(dba Advanced Care Medical/BrachySciences)

Item 10: Add

<u>Isotope</u>	<u>Source/Model #</u>	<u>Max Activity per Source</u>
Pd-103	IsoAid IAPd-103A	15 mci internal activity
Pd-103	(NASI) MED3633	25 mci internal activity
Pd-103	Theragenics Model 200	10 mci internal activity

115 HURLEY ROAD OXFORD, CT 06478
TEL: 203.262 4194 FAX: 203.262.4193

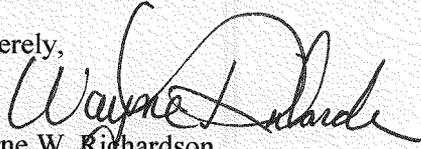
143992

NMSS/RGN1 MATERIALS-002

We have been providing Pd-103 sealed source isotopes for the treatment of prostate cancer since 2003 and have been registered for this Isotope with the State of Connecticut Department of Environmental Protection. There will be no changes to our Radiation Safety Program, which already includes the use of this isotope.

Please contact me if you have any questions about this amendment request.

Sincerely,



Wayne W. Richardson
Radiation Safety Officer
Biocompatibles Inc. (Advanced Care Medical)
115 Hurley Road, Bldg. 3A
Oxford, CT 06478

115 HURLEY ROAD OXFORD, CT 06478
TEL: 203.262.4194 FAX: 203.262.4193

ADDENDUM

- a. Provide a complete description of the transaction (transfer of stocks or assets, or merger).

**Ownership change previously acknowledged by NRC
Docket 03036099 Control 142655 7/30/08**

- b. Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who NRC may contact if more information is needed.

**New license name to be Biocompatibles Inc.
(dba Advanced Care Medical/BrachySciences)**

- c. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for any new personnel.

**No change in personnel or duties
No new personnel**

- d. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

**No changes to organization, location, facilities , equipment or
procedures that relate to the licensed program**

- e. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

Surveillance program is ongoing. There have been no changes

- f. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

**All records have been transferred
Ownership change previously acknowledged
by NRC
Docket 03036099 Control 142655 7/30/08**



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 30, 2008

Docket No. 03036099
Control No. 142655

License No. 06-30764-01

Gary Lamoureux
CEO
Advanced Care Medical
115 Hurley Road, Building 3A
Oxford, CT 06478

SUBJECT: ADVANCED CARE MEDICAL, CONSENT TO TRANSFER LICENSE,
CONTROL NO. 142655

Dear Mr. Lamoureux:

This refers to your letter dated July 28, 2008 describing the proposed transfer of your licensed activities to Biocompatibles International. From your letter, we understand that this transfer will not result in any change to the licensed name, location of use, materials, persons using licensed material, or persons responsible for radiation safety at the licensed facility.

Based on the above understandings, we have no objection to this transfer. Future changes in the licensed name, use, location, persons responsible for licensed material require submission of a request to amend the license. NRC approval must be received prior to implementation of the proposed change.

Thank you for your cooperation in this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Stephen Hammann".

Stephen Hammann
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Wayne Richardson, Radiation Safety Officer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION

NO: FL-1146-S-102-S

DATE: September 7, 2007
Revision 1 (Amended in its entirety)

PAGE 1 of 6

SEALED SOURCE TYPE:

Brachytherapy Seed

MODEL:

IAPd-103A (Advantage™ Pd-103)

MANUFACTURER:
& DISTRIBUTOR:

IsoAid, L.L.C.
7824 Clark Moody Boulevard
Port Richey, FL 34668

ISOTOPE:

Palladium 103

MAXIMUM ACTIVITY:

15 millicuries (185 MBq)

LEAK TEST FREQUENCY:

6 months

PRINCIPAL USE:

(AA) Manual Brachytherapy

CUSTOM DEVICE:

____ YES

X NO

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION****NO:** FL-1146-S-102-S**DATE:** September 7, 2007
Revision 1 (Amended in its entirety)**PAGE 2 of 6****SEALED SOURCE TYPE:**

Brachytherapy Seed

DESCRIPTION:

The IsoAid L.L.C. Model IAPd-103A source is an interstitial brachytherapy seed containing a silver x-ray marker. The Model IAPd-103 seed contains palladium 103 absorbed onto polystyrene spheres 0.5 millimeters in diameter contained within a 6.35mm length and 0.8 millimeter diameter titanium tube, which also contains a centrally located silver rod 0.5 millimeters in diameter and 1.25 millimeters in length. The tube is laser welded shut at both ends, hermetically sealing the radioactive silver rod inside. See the diagram in attachment 1.

The Model IAPd-103A seeds are checked for welding integrity microscopically ultrasonically cleaned and leak tested in accordance with International Standard ISO-9978. Seeds that pass the leak test are assayed for determination of Air Kerma and Apparent Activity. The seeds are sorted by activity and stored for distribution.

LABELING:

The small size of the individual seeds prevents labeling of each seed. Seeds are sorted and grouped by apparent activity range, assigned a unique lot number and placed in a vial which contain one inch thick stainless steel walls and stored in lead lined vault for eventual distribution. Affixed to the individual vials is a label stating "Caution: Radioactive Materials", isotope, Apparent activity or Total Apparent Activity, reference date, manufacturer's logo and the trefoil radiation symbol. An additional label is affixed to the lead shielded storage container in which a vial is placed stating "Caution: Radioactive Material", product description, Apparent or Total Apparent activity, number of sources, reference date, manufacturer's logo and a warning against distribution to unauthorized persons. The label complies with the provisions of 64E-5, Florida Administrative Code Subsection 64E-5.210(12).

DIAGRAM:

See attachment 1

CONDITIONS OF NORMAL USE:

The Model IAPd-103A source is designed for use in the interstitial treatment of cancerous tissue. These sources are not sterile when shipped which is stated on the label affixed to the vial. Testing of the source indicated they could withstand a maximum temperature of 400°C (752°F) and a maximum pressure of 290.1 psi.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION**

NO: FL-1146-S-102-S**DATE:** September 7, 2007
Revision 1 (Amended in its entirety)**PAGE** 3 of 6**SEALED SOURCE TYPE:**

Brachytherapy Seed

PROTOTYPE TESTING:

These sources were tested in accordance with ISO-2919 and leak tested following each test in accordance with ISO-9978. The ISO-2919 procedure involves testing of source for impact, temperature and pressure. Nine sources were selected for testing, with 3 sources used to conduct each test. No source after testing indicated leakage activity above 5 nanocuries. The results of the prototype testing indicate the IsoAid Model IAPd-103A (Advantage™ Pd-103) brachytherapy seed has a classification designation of ISO/01/C43211.

EXTERNAL RADIATION LEVELS:

External radiation levels from the Model IAPD-103A brachytherapy seed were determined by using an ionization chamber and the inverse square law with the following results:

Exposure Rate from a 3 μ Ci (111 kBq) Seed

<u>Distance From Source (cm)</u>	<u>Exposure Rate (mR/hr) – (μGy/hr)</u>		<u>Calculated Dose Rate (mrem/hr) – (mSv/hr)</u>	
20	2.12	21.2		
41	0.52	5.2	0.53	0.0053
61	0.21	2.1	0.23	0.0023

QUALITY ASSURANCE AND CONTROL:

IsoAid, L.L.C. conducts the following quality control tests and inspection of the Model IAPd-103A brachytherapy seed prior to distribution: visual inspection of the weld, ultrasonic cleaning, initial leak test and assay for activity. The IsoAid, L.L.C. quality control procedures are compatible with ISO 9001 standard and U.S. Nuclear Regulatory Commission Regulatory Guide 6.9.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION**

NO: FL-1146-S-102-S**DATE:** September 7, 2007
Revision 1 (Amended in its entirety)**PAGE 4 of 6****SEALED SOURCE TYPE:**

Brachytherapy Seed

LIMITATIONS OR OTHER CONSIDERATIONS OF USE:

- ⇒ These sources shall be distributed to persons who are specifically licensed.
- ⇒ The sources shall not be exposed to temperatures in excess of 400°C (752°F) and pressures in excess of 290.1 psi.
- ⇒ Sources shall be leak tested at intervals not to exceed 6 months. The test shall be capable of detecting the presence of 0.005 microcurie of palladium 103.
- ⇒ Handling, storage, use, transfer and disposal of these specifically licensed sources are to be determined by the licensing authority.
- ⇒ Sources are supplied non-sterile. Sterilization must be performed prior to implantation.
- ⇒ This registration sheet and the information contained within the references shall not be changed without the written consent of the State of Florida, Bureau of Radiation Control.

SAFETY ANALYSIS SUMMARY:

Based on the review of the information and test data cited below, and the past history of the design of similar sources, we conclude that the Model IAPd-103A brachytherapy seed is acceptable for specific licensing purposes. Furthermore, we continue to conclude that these sources are expected to maintain their containment integrity for normal and accidental conditions of use, which might occur during the uses specified in this registration certificate.

REFERENCES:

The following supporting documents for the Model IAPd-103A brachytherapy seed are hereby incorporated by reference and are made a part of this registration document:

Correspondence dated: January 9, 2004 with attachments;
February 20, 2004 with attachments; and
April 13, 2004 with attachments.

The information provided by the manufacturer for distribution of the Model IAPd-103A brachytherapy seed is incorporated into the IsoAid L.L.C., State of Florida, Radioactive Materials License Number 3196-1.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION

NO: FL-1146-S-102-S

DATE: September 7, 2007

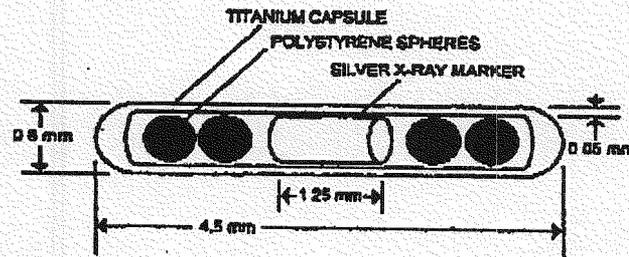
PAGE 6 of 6

Attachment 1

Revision 1 (Amended in its entirety)

DEVICE TYPE:

Brachytherapy Seed



ADVANTAGE™ Pd-103

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION

NO: FL-1146-S-102-S

DATE: September 7, 2007
Revision 1 (Amended in its entirety)

PAGE 5 of 6

SEALED SOURCE TYPE:

Brachytherapy Seed

ISSUING AGENCY:

State of Florida
Department of Health
Bureau of Radiation Control
Radioactive Materials Program
Bin # C21
4052 Bald Cypress Way
Tallahassee, FL 32399-1741
(850) 245-4545

Reviewed By: Tristan Timm
Tristan Timm
Environmental Specialist III

Concurrence: Paul Vause
Paul Vause
Environmental Administrator

Date: September 7, 2007

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 1 of 8

SEALED SOURCE TYPE:

Sealed brachytherapy source

MODEL: 200

(Old Model No. 100)

MANUFACTURER/DISTRIBUTOR:

Theragenics Corporation
900 Atlanta Drive, N.W.
Atlanta, Georgia 30318

ISOTOPE: Palladium-103

MAXIMUM ACTIVITY: Not to exceed 10 millicuries each

LEAK TEST FREQUENCY:

PRINCIPLE USE: General Medical Use

CUSTOM SOURCE: _____ YES _____ X _____ NO

CUSTOM USER:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 2 of 8

SEALED SOURCE TYPE: Sealed brachytherapy source

DESCRIPTION:

The Model 200 Palladium Seed consists of a cylindrical titanium tube sealed at both ends with laser welded titanium end cups. Enclosed in the tube are two palladium-103 plated graphite cylinders and a lead rod X-ray marker to identify the position of implanted seeds on a radiograph. The cylindrical tube is 0.177 inch (4.5 mm) in overall length and 0.032 inch (0.81 mm) in diameter. All of the titanium material is commercially pure ASTM B265-78, Grade 2. The lead and graphite are both 99.99±% pure. The radioactive palladium-103 is electrolytically plated upon all outer surface of the graphite substrate.

LABELING:

The size of the Model 200 Palladium Seed precludes any engraved, etched or printed labeling. The seeds will be shipped in a small vial inside a lead vial holder. The lead vial holder will be placed inside. Labeling that will be affixed to each of these containers are illustrated in Figures 1, 2, 3, and 4.

DIAGRAM:

Figure five shows the material of construction, dimensions, method of sealing, and the relationship of all major components for the Model 200 palladium Seed.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 3 of 8

SEALED SOURCES TYPE: Sealed brachytherapy source

CONDITIONS OF NORMAL USE:

The Model 200 Palladium Seed is intended to be used as a permanent interstitial implant. The soft therapeutic X-ray (20-23kev) emitted by the Palladium Seed interact with the tissue to be treated.

Palladium Seeds are indicated for tumors with the following characteristics:

- o Localized
- o **Unresectable**
- o Low to moderate radiosensitivity

The tumors may be of the following types:

- o Superficial
- o Intrathoracic
- o Intraabdominal
- o Lung, Pancreas, Prostrate (Stage A or B)
- o Residual following external radiation
- o Recurrent

The seeds are designed to withstand temperatures and pressures up to 272°F (133°C) and 30 psig for 30 minutes. Nominal autoclaving conditions are 250°F (121°C) at 15 psig for 15 minutes. The seeds are capable of withstanding moderate to severe challenges to their integrity. It is possible through rough handling, high temperatures or crushing that a seed could leak or be ruptured. If such an occurrence does happen, there is little or no biological hazard due to the non-toxic nature and physical form of the internal components.

PROTOTYPE TESTING:

The Palladium Seeds were subjected to four prototype tests to demonstrate their integrity under expected stresses of use or accidents. These tests provided evaluation under the following conditions: 1) Autoclave; 2) Impact, 3) Percussion and 4) Bend. The tests were conducted generally as suggested in NBS Handbook 126, ANSI N542-1977, Appendix C and ANSI N44.1-1973. Brachytherapy seeds containing Pd-103 sealed in a tube of dimensions as shown in figure 5 do not entirely fit the Classifications or Definitions in the referenced ANSI standards. Some modifications of the test conditions were required. These prototype tests for the Model 200 Palladium Seed follow closely the modified ANSI prototype tests that were performed by the 3M® Company for their approved I-125 Seeds®.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 4 of 8

SEALED SOURCE TYPE: Sealed brachytherapy source

EXTERNAL RADIATION/LEVELS:

Model 200 Seed Activity	Average Dose Rate (mR/hr)	
	at 5 cm	at 30 cm
0.5 mCi (Comp)	25.86	0.718
5.0 mCi (Comp)	258.60	7.180

QUALITY ASSURANCE AND CONTROL:

The major quality control tests that are used include the following:

After Completion of Seed Assembly

Visual inspection to verify proper seating of the titanium end cups in the titanium tubes and verify overall seed integrity.

After Laser Welding

Visual optical inspection to check cleanliness and soundness of welds and verify overall seed integrity.

Dimensional checks performed to verify that the seeds are within specifications.

X-ray to verify the seed was loaded correctly.

After Irradiation

Autoclave leak test performed to verify no leakage of radioactive palladium.

The radiation activity level of each seed is measured using a Capintec Dose Calibration apparatus or, equivalent so seeds of the same Curie level can be grouped together.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE**

(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 5 of 8

SEALED SOURCE TYPE: Sealed brachytherapy source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- A. Palladium seeds are licensed by the State of Georgia for distribution to persons licensed pursuant to (9)(c) and (2)(c) of Chapter 290-5-23, Schedule C, Group VI or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.
- B. The seeds will be 100% leak tested by the manufacturer prior to distribution. No further leak testing is necessary due to the 16.97 day half-life.
- C. The vial should remain in the lead pig during storage. When transporting seeds within the hospital, an appropriate carrier with adequate shielding should be used.
- D. Adequate radiation protection should be used during implantation procedures, however, in many instances in surgery, radiation protective barriers are not practical, thus the medical personnel must rely upon speed and distance to minimize radiation exposure.
- E. The titanium encapsulation provides very good biocompatibility along with excellent corrosion resistance but it is not designed to be used in a concentrated acid environment due to the chemical reaction.
- F. The use of Palladium Seeds, as with other brachytherapy sources, is not recommended for the treatment of tumors in generally poor or ulcerated condition.
- G. The radioactive Palladium Seeds are not sterile when shipped, hence a sterilization process must be performed. Sterilization may be accomplished by either ethylene oxide (EtO) or by steam (autoclave) prior to implantation.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 6 of 8

SEALED SOURCE TYPE: Sealed brachytherapy source

SAFETY ANALYSIS SUMMARY:

The Model 200 Palladium Seeds were subjected to Autoclave, Impact, Percussion, and Rend tests to verify their structural integrity under both normal and abnormal usage. The seeds successfully passed these tests which generally follow ANSI N524-1977, ANSI N44.1-1973 and ANSI N44.2-1973.

The Model 200 Palladium Seeds should not be subjected to temperatures greater than 272°F (133°C) or pressures greater than 30 psig. Under the abnormal conditions of fire or explosion, these conditions undoubtedly will be exceeded. Failure or rupture of a seed could permit release of the palladium pellets. This physical form of the radioactive content of the seed has no tendency to pulverize into airborne respirable particles (see ANSI N44.1-1973, Section 5.2). Release of Pd-103 as a vapor is considered very remote. As a member of the platinum group of metals, it has a characteristically low vapor pressure of 1.6×10^{-4} atm. at its melting point of 2826°F (1550°C). Chemically, the palladium is insoluble in water. Although not designed for a concentrated acid environment, it is only slightly attacked by sulfuric and hydrochloric acids. In the event of seed failure when implanted in the body tissue, it has been shown that palladium is biocompatible.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: GA645S101S

DATE: June 6, 1988

PAGE: 7 of 8

SEALED SOURCE TYPE:

Sealed brachytherapy source

REFERENCES :

This Certificate of Registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made a part of this registry document:

1. Hilaris, B.S. ed Handbook of Interstitial Brachytherapy. Publishing Sciences Group, Inc., Acton MA. 1975.
2. NCRP Report No. 37 NCRP Publication, P. O. Box 30175, Washington, DC 20014.
3. NCRP Report No. 40 NCRP Publication, P. O. Box 30175, Washington, DC 20014.
4. NCRP Report No. 41 NCRP Publication, P. O. Box 30175, Washington, DC 20014.
5. NCRP Report No. 48 NCRP Publication, P.O. Box 30175, Washington, DC 20014.
6. NCRP Report No. 49 NCRP Publication, P.O. Box 30175, Washington, DC 20014.
7. Ling, C. Proceedings of Fourth International Conference on Medical Physics, Ottawa, Canada, July 1976.
8. Harper, Paul V. and Lathrop "Palladium-103 as Therapeutic Radiation Source" Nuclear Medicine, Stuttgart, F.R.G., 1965.
9. Theragenics Corporation application dated March 3, 1986 and enclosures thereto.
10. Letter from Theragenics Corporation dated March 5, 1986 and enclosures thereto.
11. Letter from Theragenics Corporation dated July 3, 1986.
12. Letter from Theragenics Corporation dated March 15, 1988 and enclosure thereto.
13. Letter from Theragenics Corporation dated March 21, 1988.
14. Letter from Theragenics Corporation dated May 13, 1988 and enclosures thereto.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

(Amended in its entirety)

NO: GA645S101S

DATE: June 6, 1988

PAGE: 8 of 8

SEALED SOURCE TYPE:

Sealed brachytherapy source

ISSUING AGENCY:

Georgia Department of Human Resources
Radiological Health Section

DATE: 6-6-88

REVIEWER: Cynthia A. Sanders

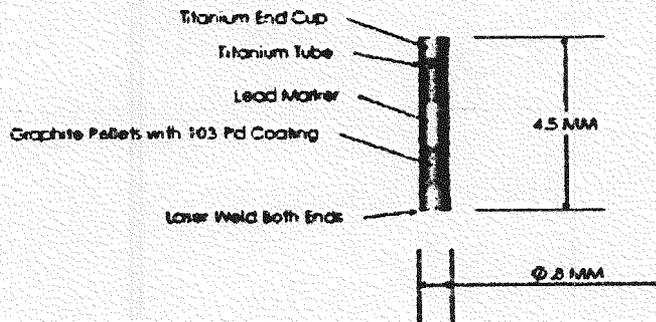
DATE: 6-6-88

CONCURRENCE: Jerry W. Manis

Palladium - 103 seeds

TheraSeed®
model 200

TheraSeed® MODEL 200 IMPLANT



Theragenics Corporation,
Buford, 5203 Bristol Industrial Way, Georgia 30518
(800) 458-4372

<http://www.theragenics.com/>

distributed by: Theragenics Corporation

· Jeffrey F. Williamson, Bert M. Coursey, Larry A. DeWerd, William F. Hanson, Ravinder Nath, Mark J. Rivard, Geoffrey Ibbott, "Recommendations of the American Association of Physicists in Medicine on ^{103}Pd interstitial source calibration and dosimetry: Implications for dose specification and prescription," *Medical Physics* – April 2000 – Volume 27, Issue 4, pp. 634-642



· Jeffrey F. Williamson, "Monte Carlo modeling of the transverse-axis dose distribution of the Model 200 ^{103}Pd interstitial brachytherapy source," *Medical Physics* – April 2000 – Volume 27, Issue 4, pp. 643-654

· Weaver K., "Anisotropy functions for ^{125}I and ^{103}Pd sources," *Med. Phys.*, 25 (12) 2271-2278, December 1998.

· Ravinder Nath, Ning Yue, Kambiz Shahnazi, and Paul J. Bongiorni. Measurement of dose-rate constant for ^{103}Pd seeds with air kerma strength calibration based upon a primary national standard. *Medical Physics* – April 2000 – Volume 27, Issue 4, pp. 655-658

TOP

added to Registry March 1, 2001; Updated May 16, 2002

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

NO.: CA0510S126S

DATE: December 18, 1998

PAGE: 1 of 6

SEALED SOURCE TYPE: Brachytherapy Source

MODEL: MED3631 and MED3633

MANUFACTURER/DISTRIBUTOR:

North American Scientific, Inc.
7435 Greenbush Avenue
North Hollywood, CA 91605
Phone: (818) 503-9201
Fax: (818) 503-0764

ISOTOPE: Iodine 125 or Palladium 103

MAXIMUM ACTIVITY: 25 millicuries

LEAK TEST FREQUENCY: Not to exceed six (6) months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: _____ YES X NO

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

NO. CA0510S126S

DATE. December 18, 1998

PAGE: 2 of 6

SEALED SOURCE TYPE: Brachytherapy Source

DESCRIPTION:

The Models MED3631 and MED3633 are the same source design. The Nuclide in the Model MED3631 is Iodine 125 and the nuclide in the Model MED3633 is Palladium 103. The Model MED3631 or MED3633 consists of a welded titanium capsule. The active element for the MED3631 consists of iodine absorbed onto silver wire or absorbed on ion exchange resin beads. The Model MED3633 active element consists of palladium electroplated on a metallic substrate or absorbed on ion exchange resin beads. The active element is then placed inside of the capsule with fusion welds on each end to complete containment. The maximum outer dimensions of the capsule are 5mm in length by 0.8mm in diameter. Wall thickness shall not be less than 0.05mm.

LABELING:

The physical size of the Model MED3631 and MED3633 prevents direct labeling of the individual source. Each source or set of sources shall be packaged with the minimum identifying information provided on the package label:

Company Identification	(ex: North American Scientific)
Activity	(ex: 0.5 mCi each)
Lot No.	(ex: A001)
Isotope	(ex: I-125 or Pd-103)
Calibration Date	(month and year ex: May 1, 1997)

DIAGRAM: (See attachment 1)

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

NO.: CA0510S126S

DATE: December 18, 1998

PAGE: 3 of 6

SEALED SOURCE TYPE: Brachytherapy Source

CONDITIONS OF NORMAL USE:

The Model MED3631 and MED3633 is designed and intended for use as a source of nuclear radiation for the therapy treatment of malignant disease by means of interstitial, intercavitary or surface application. The radioactive I-125 or Pd-103 is encapsulated in titanium-a biocompatible material. The MED3631 and MED3633 is intended to be used under controlled clinical laboratory or medical surgery room conditions. They should not be subjected to conditions exceeding those specified by the ANSI 77C64221 rating.

PROTOTYPE TESTING:

Two inactive prototype capsules were subjected to the testing in accordance with ANSI N542-1977 and passed the requirement of 77C64221. Additionally, sources met the testing requirement specified in American National Standard N44.1-1973 Integrity and Test Specification for Selected Brachytherapy Sources for Temperature, Impact and Percussion.

EXTERNAL RADIATION LEVELS:

External radiation levels were calculated using gamma radiation constants provided in the Radiological Health Handbook. The value provided for I-125 is given as $\sim 0.7 \text{ Rcm}^2/\text{hr/mCi}$. Based on this value the expected radiation levels for 1 mCi of I-125 are shown below. Containment of 1mCi within a welded titanium capsule with corresponding wall thickness of 0.05 mm would attenuate the output by approximately 15%.

	<u>5 cm</u>	<u>10 cm</u>	<u>30 cm</u>
Unencapsulated	28 mR/hr	7 mR/hr	0.8 mR/hr
Encapsulated	24 mR/hr	6 mR/hr	0.7 mR/hr

Radiation levels for a maximum loading of 25 mCi would be proportionately higher. The values for Pd-103 will be less than the I-125 because of the energy difference.

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

NO.: CA0510S126S

DATE: December 18, 1998

PAGE: 4 of 6

SEALED SOURCE TYPE: Brachytherapy Source

QUALITY ASSURANCE AND CONTROL:

Each source manufactured by North American Scientific, Inc. is governed by the quality assurance program of the company specifically, ASME NQA-1-1989 Edition. This information includes examples of specific procedures for a typical manufacturing operation. Specific QA/QC information regarding source activity, radiopurity and leak testing is given below.

1. **LEAK TESTING:** These sources are leak tested in accordance with procedures SP-1000, "Soak Test". All sources manufactured will be considered leak free if the measured value is less than 0.001 microcurie.
2. **ACTIVITY LEVEL:** Activity levels of each source supplied shall be kept to within -10%/+10% of the stated value.
3. **RADIOPURITY:** Isotopes used for manufacturing shall have a radiopurity of 97% or better with respect to other nuclides (associated daughters not included) as determined by gamma spectroscopy of the batch materials used prior to production.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. **License requirements:** These sources shall be distributed to specific licensees of the NRC or Agreement States.
2. **Leak Testing:** These sources shall be tested for leakage at time intervals not to exceed 6 months. Leak testing shall be in accordance with the individual license requirements issued by the NRC or Agreement States.
3. **Environmental Limitations:** These sources are designed for use in controlled laboratory or medical surgery room conditions and should not be subjected to conditions exceeding those specified by the ANSI 77C64221 rating.

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

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SEALED SOURCE TYPE: Brachytherapy Source

4. **Handling:** These sources should be handled only by qualified and certified individuals as defined in the specific license. In keeping with the ALARA philosophy, remote handling and localized shielding should always be used.
5. **Storage:** When not in use the sources should be stored in the shielded container supplied with each source or set of sources.
6. **Use:** These sources are designed for medical brachytherapy under controlled clinical laboratory conditions. They should be used by qualified individuals as noted in the specific NRC or Agreement State License.
7. **Transfer and Disposal:** Transfer and disposal shall be in accordance with the user's specific license issued by the NRC or Agreement State.
8. **Cleaning:** Normal use would not subject these sources to conditions which would require cleaning. Cleaning of the source can be done using water and a mild detergent or appropriate solvent (ethanol or acetone). It should be performed in accordance with limitations described above (i.e. handling and use).
9. This registration sheet and the information contained within the references, shall not be changed without the consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

The prototype capsule passed the test requirements and achieved a classification of ANSI 77C64221. Additionally, sources also met the testing requirements specified in ANSI N44.1 - 1973, "Integrity and Test Specification for Selected Brachytherapy Sources", for Temperature, Impact and Percussion. This source configuration has been used extensively for brachytherapy use without known incident and North American Scientific has received approval from the U.S. Food and Drug Administration to distribute the product. Based on our review of the information and data submitted, we conclude that the sources are safe for general medical use and are acceptable for licensing and distribution.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
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SEALED SOURCE TYPE: Brachytherapy Source

REFERENCES:

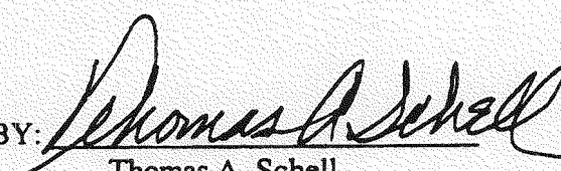
The Certificate of Registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this Registry Document.

1. North American Scientific, Inc. letters dated April 1, 1991 with associated attachments thereto (QC documents and procedures) and April 18, 1991 with associated attachments thereto.
2. North American Scientific, Inc. letter dated April 25, 1997 with attachments thereto.
3. North American Scientific, Inc. letters dated July 27, 1997 and October 23, 1998 with attachments thereto.

ISSUING AGENCY: California Department of Health Services

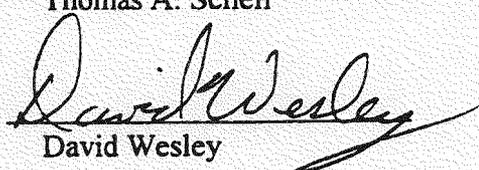
DATE: December 18, 1998

REVIEWED BY:


Thomas A. Schell

DATE: December 18, 1998

CONCURRED BY:


David Wesley

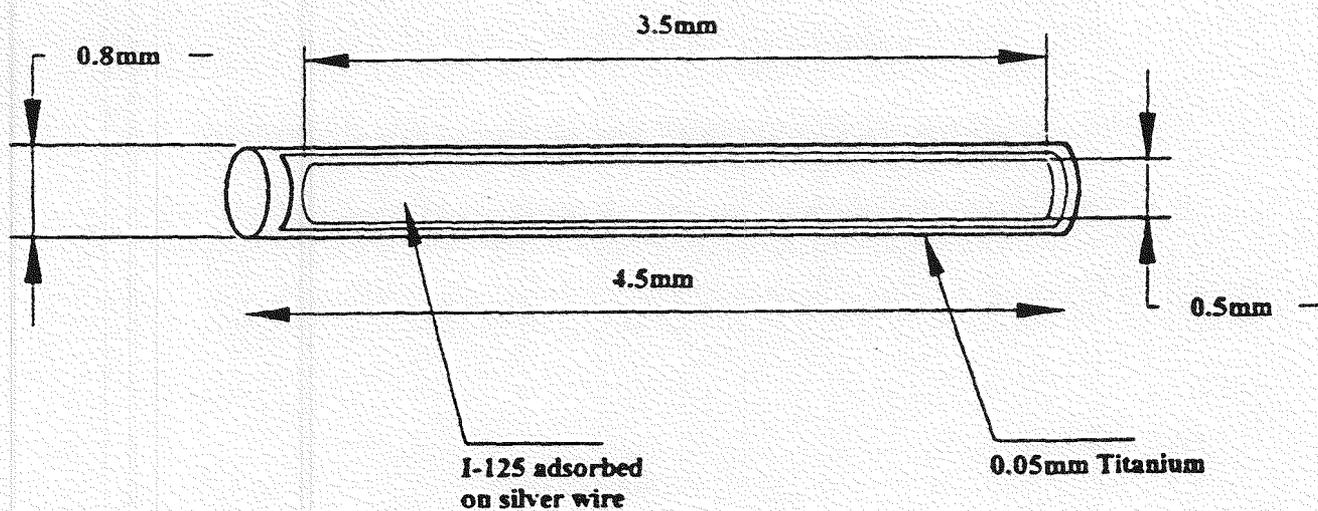
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

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ATTACHMENT 1

SEALED SOURCE TYPE: Brachytherapy Source



This is to acknowledge the receipt of your letter application dated

8/3/2009, and to inform you that the initial processing which includes an administrative review has been performed.

/ AMMIS, 06-30764-01 / 06-30764-0210
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143991/143992
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.