

Battle Creek Health System  
300 North Avenue  
Battle Creek MI 49016

September 11, 2008

Attention: Robert Sieffert

Ms. Coleen Casey  
Materials Licensing Branch  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road , Suite 210  
Lisle , Illinois 60532-4352

RE: Amendment of License: 21-01354-04  
(Current Amendment No. 27)

Dear Ms. Casey

Battle Creek Health System is requesting that the referenced Materials License be amended as follows:

Item 7 Chemical or Physical Form

D. Sealed Sources

**Add: IsoAid LLC Model IAI 125 A**  
**Add: Bard Brachytherapy Inc. Model STM 1251**

Attached are copies of the Registry of Sealed Sources and Devices Safety Evaluation for these models of Brachytherapy Seeds.

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

Sincerely,



Robert Sieffert M.S.  
Radiation Safety Officer

RECEIVED SEP 18 2008



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

NO: IL-1074-S-101-S      DATE: September 13, 2005      PAGE: 2 of 8

SOURCE TYPE:      Therapeutic Sealed Source

DESCRIPTION:

The Bard Brachytherapy, Inc. Model STM1251 source contains I-125 absorbed on a solid nickel/copper coated, gold cored aluminum wire and singly encapsulated in a cylindrical titanium capsule which is sealed by laser welds at each end of the source capsule. The titanium capsule has an outside diameter of 0.8 mm and a wall thickness of 0.08 mm. The overall source length is 4.5 mm. The capsule attenuates very little of the low energy gamma radiation from I-125. The actual activity will not exceed the maximum stated 555 MBq (15 mCi). The "apparent activity" of these sources is assayed with a tolerance of 5%. The actual activity of the source can be determined by multiplying the apparent activity by a factor of 1.7.

LABELING:

Because of their small size, individual sources are not labeled. Sources are supplied as a group with "total activity" for a reference date and are packaged either in a vial or pre-loaded in a Mick® or Express™ cartridge, a needle or an isosleeve™ Delivery System, which are then placed in a heat-sealed plastic bag or pouch. The vials and preloaded cartridges are then placed in either a lead or a stainless steel container and a fiberboard box for shipment. Preloaded Express™ cartridges can also be shipped in a lead-lined cylindrical fiberboard container within a fiberboard box. The pouches containing preloaded needles and isosleeve™ Delivery Systems are placed inside a shielded steel box for shipment.

Each production lot is assigned a unique lot number and each customer order is assigned a unique certificate number. A label is affixed to the vial or pouch, as well as the shield container stating: "Caution - Radioactive Materials", isotope, quantity, midpoint activity, total activity, reference date, the trefoil radiation symbol and the manufacturer's name and address. An additional label is attached to the pouch stating the seeds are prescription only, sterilization information and a "use by" date. The label complies with the provisions of 32 Illinois Administrative Code 330.280(k) and 340.910 and 340.940 (10 CFR 32.74 and 10 CFR 20.1901 and 10 CFR 20.1904). See Attachment 1 for samples of labeling.

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

NO: IL-1074-S-101-S      DATE: September 13, 2005      PAGE: 3 of 8

SOURCE TYPE:      Therapeutic Sealed Source

DIAGRAMS:

See Attachment 2.

CONDITIONS OF NORMAL USE:

The Bard Brachytherapy, Inc. Model STM 1251 source is designed for permanent use in the interstitial, intracavitary or surface treatment of cancerous tumors. The placement of I-125 sources in tissue, which takes place in surgery, is facilitated by the use of one of several commercially-available implant tools. These implanters are used solely for source placement and are not designed either to store or to hold I-125 sources, as is the case with conventional applicators and cesium-137 sources. Sources may be provided in disposable Mick® cartridges with up to 15 sources per cartridge or Express™ cartridges with up to 12 sources per cartridge. The number of sources can be visually verified by the end-user without unloading the cartridge. Sources can also be preloaded into needles or the isosleeve™ Delivery System with absorbable spacers or SourceLink™ connectors. Given the potentially high surface dose rates associated with multiple sources, all preparatory actions should be conducted by a trained individual in an appropriately shielded area.

Loose sources in vials, sources preloaded in the isosleeve™ Delivery System or needles, and sources loaded into disposable Mick® cartridges are sterilized by gamma radiation prior to shipment. Sources in reusable cartridges or Express™ cartridges are not sterilized by gamma radiation prior to shipment. Sources in all of the aforementioned configurations can also be shipped nonsterile. The sources are designed to withstand normal autoclave temperature and pressure variations up to 134°C (273°F) and 30 psi and treatment with ethylene oxide. In addition, the sources should not be placed in concentrated acids or sterilized by dry heat methods.

Sources may be used for permanent implanting. Sources that retain clinical use after six months must be leak tested prior to use. The Recommended Working Life is based on the clinical efficacy of the product. This efficacy is to be determined at the discretion of the responsible physician but won't exceed 2 years based on physical decay of I-125.

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

**NQ:** IL-1074-S-101-S      **DATE:** September 13, 2005      **PAGE:** 4 of 8

**SOURCE TYPE:**      Therapeutic Sealed Source

**PROTOTYPE TESTING:**

Prototypes of the Model STM 1251 source were subjected to tests to demonstrate that the sources will maintain their integrity under stresses of use and accident conditions. The tests performed were in accordance with ANSI N43.6-1977. Bard Brachytherapy, Inc. reports that the prototypes passed the ANSI tests and achieved ratings of C64221. (NOTE: Test for puncture is not required.)

**EXTERNAL RADIATION LEVELS:**

External radiation levels from the Model STM 1251 were calculated by using a gamma constant of 2.75E-4 mR/hr  $\mu$ Ci @ 1 meter for a source of 15 mCi (8.8 mCi apparent activity) taken from the Handbook of Health Physics and Radiological Health, Third Edition, 1998:

| <u>Distance from<br/>The Source (cm)</u> | <u>Radiation Levels (mR/hr)</u>  |
|--|----------------------------------|
| 5  | 9.7 mSv/hr    (968 mR/hr)        |
| 30                                       | 269 $\mu$ Sv/hr    (26.88 mR/hr) |
| 100                                      | 24 $\mu$ Sv/hr    ( 2.4 mR/hr)   |

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

**NO:** IL-1074-S-101-S      **DATE:** September 13, 2005      **PAGE:** 5 of 8

**SOURCE TYPE:**      Therapeutic Sealed Source

**EXTERNAL RADIATION LEVELS:** (continued)

External radiation levels were measured from the Model STM 1251 with 10, 0.88 mCi sources loaded seed to seed in a needle. The measurements were taken with a Ludlum Model 17 ion chamber (window open) and a Ludlum model 19 microRmeter.

| <u>Distance from<br/>The Source (cm)</u> | <u>Radiation Levels (mR/hr)</u> | <u>Instrument</u> |
|--|---------------------------------|-------------------|
| 5  | 2.8 mSv/hr (280 mR/hr)          | Model 17          |
| 30                                       | 0.1 mSv/hr (10 mR/hr)           | Model 17          |
| 100                                      | 0.3 μSv/hr (0.03 mR/hr)         | Model 19          |

Dose rates from fully loaded cartridges may approach 41 mSv/hr (4,100 mR/hr) at 5 cm.

**QUALITY ASSURANCE AND CONTROL:**

Bard Brachytherapy, Inc. conducts the following quality control tests and inspection of the Model STM 1251 source prior to distribution: visual inspection, initial leak test, autoclave, second leak test and assay for radioactivity. A final wipe test is also performed on loaded needles and isosleeve™ Delivery Systems prior to shipment. The Bard Brachytherapy, Inc. quality system is compatible with U.S. NRC NUREG-1556 Vol. 3., Rev.1. Complete details of the quality control program are on file with the Illinois Emergency Management Agency.

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

**NO:** IL-1074-S-101-S      **DATE:** September 13, 2005      **PAGE:** 6 of 8

**SOURCE TYPE:**      Therapeutic Sealed Source

**LIMITATIONS AND OTHER CONSIDERATIONS OF USE:**

- The sealed sources shall be distributed only to specific licensees of the NRC, the Agency, an Agreement State or Licensing State.
- The licensing authority will have to obtain details on specific holders and any operational procedures, from the license applicant to make a licensing determination.
- Licensees should observe the manufacturer's instructions for handling and using the I-125 sources.
- When loading or removing I-125 sources from plastic or rubber afterloading catheters, licensees should use a vented chemical hood which has adequate air flow up the stack and a filtered exhaust. To assure that sources have not been damaged following removal from the afterloading catheters, a contamination survey should be conducted using a radiation monitor capable of detecting 30 keV photons. This survey should include wipe (or leak) tests of sources and an overall area survey.
- Sources should not be exposed to temperatures in excess of 134°C and pressures in excess of 30 psi.
- Bard Brachytherapy, Inc. supplies Model STM 1251 sources in reusable and in disposable Mick® applicator cartridges, with 1-15 sources per cartridge and Express™ cartridges with 1-12 sources per cartridge. The disposable Mick® cartridges may be shipped sterile or nonsterile. Cartridges that are not sterile when shipped should be sterilized before use. The disposable cartridge is not intended for re-use. Reusable cartridges and Express™ cartridges are not shipped sterile and should be sterilized before use. Dose rates from fully loaded cartridges may approach 41 mSv/hr (4,100 mR/hr) at 5 cm. Up to three cartridges may be placed in one sealed bag.
- Sources shall be leak tested at intervals not to exceed six months. The test shall be capable of detecting the presence of 185 Bq (0.005 microcurie) of I-125 on the test samples.

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

**NO:** IL-1074-S-101-S

**DATE:** September 13, 2005

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**SOURCE TYPE:** Therapeutic Sealed Source

**LIMITATIONS AND OTHER CONSIDERATIONS OF USE:** (continued)

- Unused sources may be returned to the manufacturer by prior arrangement.
- **Handling, Storage, Use, Transfer and Disposal:** Shall be determined by the licensing authority. In view that these sealed sources exhibit high surface dose rates when unshielded, these sealed sources should be handled by only experienced licensed personnel using adequate remote handling equipment and procedures.
- This registration sheet and the information contained with the references shall not be changed without the written consent of the Illinois Emergency Management Agency.

**REVIEWER NOTE:** For purposes of licensing STM 1251, source models manufactured under the new name, Bard Brachytherapy, Inc., can be considered identical to those sources manufactured previously as no changes were made to operations affecting source design or integrity.

**SAFETY ANALYSIS SUMMARY:**

Based on our review of the information, and test data cited below, we conclude that the Bard Brachytherapy, Inc. Model STM 1251 sealed source is acceptable for licensing purposes. Furthermore, we conclude that this source should maintain its integrity under normal conditions of use and accidental conditions, which might occur.

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

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SOURCE TYPE:      Therapeutic Sealed Source

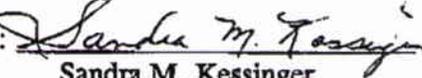
REFERENCES:

The following documents for the Bard Brachytherapy, Inc. Model STM 1251 therapeutic sealed sources are hereby incorporated by reference and are made a part of this registry document:

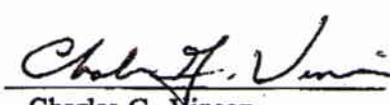
- Bard Brachytherapy, Inc. letters, with attachments, dated January 8, 1999, August 26, 1999, September 14, 1999, December 28, 1999, March 22, 2000, June 13, 2000, October 19, 2000, November 30, 2000, July 30, 2001, September 19, 2001, May 20, 2002 (signed May 23, 2002), August 14, 2002, March 7, 2003, September 17, 2003, May 17, 2005, July 11, 2005, July 25, 2005 and August 26, 2005.
- Telefacsimiles dated March 27, 2003, September 24, 2003 and September 13, 2005.
- Sample packaging received April 26, 2005 and August 22, 2005.
- Documents received August 22, 2005.

ISSUING AGENCY: Illinois Emergency Management Agency

DATE: 9/13/05

REVIEWED BY:   
Sandra M. Kessinger

DATE: 9/13/05

CONCURRENCE:   
Charles G. Vinson

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

**NQ:** IL-1074-S-101-S      **DATE:** September 13, 2005      **ATTACHMENT 1**

**SOURCE TYPE:** Therapeutic Sealed Source

**SAMPLE SHIELD LABEL - LOOSE STERILE SEEDS**

**Bard® BrachySource® <sup>125</sup>I Implant Seed**

Model# STM1251

|  |                          |                                |                              |
|--|--------------------------|--------------------------------|------------------------------|
| <b>Manufactured by:</b><br><b>Bard Brachytherapy, Inc.</b><br><b>Carol Stream, IL 60188 USA</b><br><b>800-977-6733</b>   | <b>Certificate #</b>     | <b>105346</b>                  |                              |
|  | <b>LOT</b>               | 150288H13                      |                              |
|  <b>Single Use</b><br>Caution - Federal Law restricts this device to sale by or on the order of a physician | <b>Quantity:</b> 35      | <b>Reference</b><br>08/16/2005 | <b>Implant</b><br>08/23/2005 |
|  | <b>Midpoint Activity</b> | 0.460mCi                       | 0.424mCi                     |
|  |                          | 17.02MBq                       | 15.69MBq                     |
|  | <b>Midpt Kerma</b>       | 0.74U                          | 0.55U                        |
| <br><b>Caution Radioactive Materials Iodine-125</b><br>PK0300675 08/05                                    | <b>Total Activity</b>    | 16.10mCi                       | 14.84mCi                     |
|  |                          | 595.7MBq                       | 548.1MBq                     |
|  | <b>Total Kerma</b>       | 25.84U                         | 23.91U                       |
|  | <b>Patient</b>           | Doc. J                         |                              |
|  | <b>Physician</b>         | Dr Smith                       |                              |

**SAMPLE POUCH LABEL - LOOSE STERILE SEEDS**

**Bard® BrachySource® <sup>125</sup>I Implant Seed**

**REF** Model# STM1251

**STERILE R**



**Manufactured by:**  
**Bard Brachytherapy, Inc.**  
**Carol Stream, IL 60188 USA**  
**800-977-6733**

Single Use

PK0300677 08/05

**Rx**  
Only

**Use By:**  
10/15/2005

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

NO: IL-1074-S-101-S

DATE: September 13, 2005

ATTACHMENT 2

SOURCE TYPE: Therapeutic Sealed Source

SCHEMATIC DIAGRAM OF I-125 SOURCE

MODEL STM 1251

All dimensions in millimeters



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

NO: FL-1146-S-101-S

DATE: June 25, 2002  
Revision 1 Amended Pages 1 and 4

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SEALED SOURCE TYPE:

Brachytherapy Seed

MODEL:

IAI-125A (Advantage™ I-125)

MANUFACTURER:  
& DISTRIBUTOR:

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

ISOTOPE:

MAXIMUM ACTIVITY:

Iodine 125

10 millicuries (370 MBq)

LEAK TEST FREQUENCY:

6 months

PRINCIPAL USE:

(V) General Medical Use

CUSTOM DEVICE:

\_\_\_\_ YES

\_\_\_\_ X \_\_\_\_ NO

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SEALED SOURCE TYPE:

Brachytherapy Seed

DESCRIPTION:

The IsoAid L.L.C. Model IAI-125A source is an interstitial brachytherapy seed. The Model IAI-125A seed contains iodine 125 adsorbed onto a 0.5 millimeter diameter, 3 millimeter long silver rod. The rod is encased in a 0.8 millimeter diameter, 4.5 millimeter length titanium tube with a wall thickness of 0.05 millimeter. The tube is laser welded shut at both ends, hermetically sealing the radioactive silver rod inside. See the diagram in attachment 1.

The Model IAI-125A 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 4 milliliter glass vial and a polyethylene lined lead brick for storage and 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 IAI-125A 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 can withstand a maximum temperature of 600°C (1112°F) and pressure of 290 psi.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
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**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. Six sources were selected for testing, with two 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 IAI-125A (Advantage™ I-125) brachytherapy seed has a classification designation of ISO/01/C53211.

**EXTERNAL RADIATION LEVELS:**

External radiation levels from the Model IAI-125A brachytherapy seed were determined by using an ionization chamber and the inverse square law with the following results:

Exposure Rate from a 0.191 mCi (7.03MBq) Seed

| Distance From Source (cm) | Exposure Rate<br>(mR/hr) – (µGy/hr) |     |
|---------------------------|-------------------------------------|-----|
| 5                         | 15.4                                | 154 |
| 15                        | 3.3                                 | 33  |
| 30                        | 0.7                                 | 7   |
| 50                        | 0.4                                 | 4   |
| 100                       | 0.2                                 | 2   |

Estimated dose from a 5 mCi (185MBq) seed

| Distance from source (cm) | Estimated Dose Rate<br>(mrem/hr) – (mSv/hr) |       |
|---------------------------|---|-------|
| 5                         | 2591.8                                      | 25.92 |
| 15                        | 288.0                                       | 2.88  |
| 30                        | 72.0  | 0.72  |
| 50                        | 25.9  | 0.26  |
| 100                       | 6.5   | 0.065 |

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

NO: FL-1146-S-101-S

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SEALED SOURCE TYPE:

Brachytherapy Seed

QUALITY ASSURANCE AND CONTROL:

IsoAid, L.L.C. conducts the following quality control tests and inspection of the Model IAI-125A 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.

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 138°C (280°F) and pressures in excess of 290 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 iodine 125.
- ⇒ 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 IAI-125A 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 IAI-125A brachytherapy seed are hereby incorporated by reference and are made a part of this registration document:

Correspondence dated: May 29, 2001 with attachments;  
July 18, 2001 with attachments; and  
June 5, 2002.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

NO: FL-1146-S-101-S

DATE: June 25, 2002  
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SEALED SOURCE TYPE:

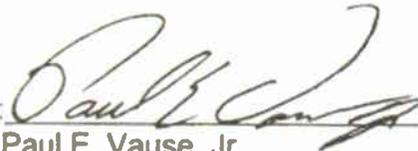
Brachytherapy Seed

The information provided by the manufacturer for distribution of the Model IAI-125A brachytherapy seed is incorporated into the IsoAid L.L.C., State of Florida, Radioactive Materials License Number 3196-1.

ISSUING AGENCY:

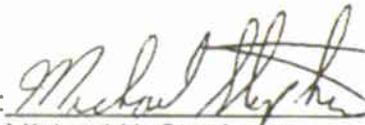
State of Florida  
Department of Health  
Bureau of Radiation Control  
Radioactive Materials Program  
Bin # C21  
4052 Bald Cypress Way  
Tallahassee, FL 32399-1741  
(850) 245-4545

Reviewed By:



Paul E. Vause, Jr.  
Environmental Manager

Concurrence:



Michael N. Stephens  
Environmental Administrator

Date: June 25, 2002

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION

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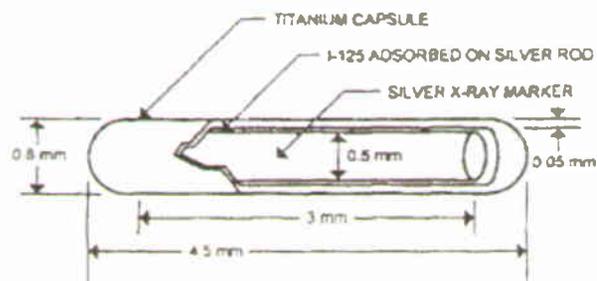
Revision 1

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DEVICE TYPE:

Brachytherapy Seed



ADVANTAGE™ I-125

Figure 1. Nominal Iodine-125 Seed.

Robert Sieffert M.S.  
Radiation Safety Officer  
Battle Creek Health Systems  
300 North Avenue  
Battle Creek, MI 49016

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FIRST CLASS



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Ms. Coleen Casey  
Materials Licensing Branch  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

605324352 0021

