Biocompatibles

Biocompatibles, Inc.
115 Hurley Road, Bldg. 3
Oxford, CT 06478

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www.biocompatiblesinc.com

March 22, 2012

Br.2

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

030 36099

Re: Amendment of License **06-30764-01** (Current Amendment No. 14)
Docket No. 030 36099

Dear Licensing Assistance Team

We have just received an urgent request from a facility to use a new Theragenics model I-125 seed for their brachytherapy cases.

Biocompatibles Inc. is requesting that I-125 Source Model Number AgX100 be added to our **possession license** as soon as possible.

I have enclosed the SSDR for this model.

12. Device/Series Model

Add Theragenics AgX100 100 millicuries

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

Sincerely,

Wayne Richardson
Radiation Safety Officer

J. Matons

James Matons
President

577196

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U.S. NUCLEAR REGULATORY COMMISSION Amendment No. 14

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated January 10, 2012,
1. Biocompatibles, Inc.	3. License number 06-30764-01 is amended in its entirety to read as follows:
2. 115 Hurley Road, Building 3 Oxford, Connecticut 06478	4. Expiration date December 31, 2012
	5. Docket No. 030-36099 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 57	A. Sealed Sources (Isotope Product Laboratories Model RV-057)	A. 5 millicuries per source and 15 millicuries total
B. Technetium 99m	B. Any	B. 40 millicuries
C. Palladium 103	C. Sealed Source (as specified in Condition 11)	C. 20,000 millicuries
D. Iodine 125	D. Sealed sources (as specified in Condition 12)	D. 20,000 millicuries
E. Cesium 131	E. Sealed sources (IsoRay Model Cserion Cs-1)	E. 65 millicuries (internal) per source and 130 curies total
F. Cesium 137	F. Sealed Sources (Isotope Products Laboratories Model RV-137)	F. 0.5 millicuries

9. Authorized use:

C., D. and E. Possession, storage, and packaging of sealed sources into a stranded or loose configuration for distribution to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

A., B. and F. Calibration and checking of the licensee's instruments.

CONDITIONS

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 06-30764-01

Docket or Reference Number 030-36099

Amendment No. 14

10. Licensed material may be used or stored only at the licensee's facilities located at 115 Hurley Road, Building 3A, Oxford, Connecticut.

11. The following products are authorized, provided the amount of palladium-103 contained in the source/device does not exceed the amounts specified in the following table:

Device/Series Model	Maximum Quantity per Source
IsoAid IAPd-103A	15 millicuries internal activity
Theragenics Model 200	10 millicuries internal activity
(NASI) MED3633	25 millicuries internal activity

12. The following products are authorized, provided the amount of iodine-125 contained in the source/device does not exceed the amounts specified in the following table:

Device/Series Model	Maximum Quantity per Source
Medi-Physics Inc. 6702	195 millicuries
Medi-Physics Inc. 6711	270 millicuries
Medi-Physics Inc. 6733 (EchoSeed)	71.2 millicuries
North American Scientific Inc. MED3631	25 millicuries
Best Medical International 2300 Series	110 millicuries
Bebig 125-S06	40 millicuries
Mills Biopharmaceuticals Inc. 125SL	1 millicurie
Mills Biopharmaceuticals Inc. 125SH	150 millicuries
IsoAid Inc. 1A1-125A	10 millicuries
Implant Sciences Corp. 3500	7.5 millicuries
Source Tech Medical LLC STM125	15 millicuries
Theragenics 125-S06	100 millicuries
Bebig 125-S06	40 millicuries

13. Licensed material shall be used by, or under the supervision of, Matthew Bouffard, Timothy Delaney, and Warren Rice.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
06-30764-01

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030-36099

Amendment No. 14

14. The Radiation Safety Officer for this license is Wayne Richardson.

15. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

16. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the

MATERIALS LICENSE SUPPLEMENTARY SHEET

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U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

    A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

    B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

    C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
06-30764-01

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20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated August 9, 2002 (ML022340699
B. Facsimile received September 5, 2002, except attachments (ML023580358)
C. Letter dated December 7, 2002 (ML023430482)
D. Letter dated July 28, 2003 (ML032100538)
E. Letter dated September 19, 2003 (ML032680907)
F. Application dated November 10, 2003 (ML033390297)
G. Letter dated January 27, 2004 (ML040490400)
H. Letter dated April 12, 2004 (ML041190045)
I. Letter dated April 29, 2004 (ML041260237)
J. Letters dated February 9, 2005 (2) (ML050610572)
K. Letter dated December 5, 2005 (ML053500305)
L. Letter dated February 10, 2006 (ML060600474)
M. Letter dated August 11, 2006 (ML062280111)

For the U.S. Nuclear Regulatory Commission

Date January 30, 2012

By ***Original signed by Thomas K. Thompson***

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406
Monday, January 30, 2012 08:32:43

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

(amended in its entirety)

NO. **GA-645-S-102-S** **DATE:** **March 17, 2011** **PAGE:** **1 of 15**

SOURCE TYPE: Therapeutic Brachytherapy Seed

MODEL: I-Seed – **refer to Description for package configurations**
Model I25.S06
Model AgX100

MANUFACTURER/DISTRIBUTOR: Theragenics Corporation
5203 Bristol Industrial Way
Buford, Georgia 30518

ISOTOPE:		**MAXIMUM ACTIVITY:**
Iodine 125	Model I25.S06	100 millicuries (3.7 GBq) – contained 76.9 millicuries (2.85 GBq) – apparent
	Model AgX100	**20 millicuries (0.74 GBq) – contained** **10 millicuries (0.37 GBq) – apparent**
	Typical activity ordered per seed:	**between 0.20 mCi [0.254 U] (apparent) and 0.60 mCi [0.762 U] (apparent)**

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: **(AA) Manual Brachytherapy**

CUSTOM DEVICE ___ YES _X_ NO

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

(amended in its entirety)

SOURCE TYPE: Therapeutic Brachytherapy Seed

DESCRIPTION:

The I-Seed Models I25.S06 **and AgX100** consist of **the following** component parts – a titanium tube capsule, a **cylindrical source rod containing** absorbed Iodine-125, and a radio-opaque marker. **The source models differ only in the material used for the source rod/marker combination.**

Iodine-125 is homogenously absorbed **on the source rod. The Model I25.S06 uses a source rod that** is **a** cylindrical **ceramic core with** a hollow core for the inclusion of a heavy metal x-ray marker for evaluating source position via radiography. **The Model AgX100 uses a silver source rod that also serves as the x-ray marker.** The **source rod is** then placed into a grade 2 biocompatible titanium tube. The titanium tube is laser welded. Refer to Figure 1**a** for a cross-sectional view of the Model I25.S06. **Refer to Figure 1b for a cross-sectional view of the Model AgX100.**

The dimensions of the source are as follows: wall thickness, 0.05 mm (0.002 in.); source diameter, 0.8 mm (0.03 in.); total length, 4.5 mm (0.18 in.).

The I-Seed is offered in a variety of package configurations:

- Loose I-Seed in glass vials, shipped in a lead container. May be delivered sterile or non-sterile.
- I-Seed pre-loaded in MICK® magazines **or Theragenics Vertical Seed Magazine (VSM)**, shipped in a lead container. May be delivered sterile or non-sterile.
- **I-Seed pre-loaded in IN-STANT stranding system magazine, shipped in a lead container. May be delivered sterile or non-sterile.**
- As TheraLoad®, brachytherapy needles custom loaded with I-Seed (I-125) and spacers according to a specific treatment plan. Delivered sterile in a ready-to-use kit
- As TheraStrand®, brachytherapy needles with customized strands of I-Seed (I-125) and spacers **embedded within a bio-absorbable suture**. Delivered sterile in a ready-to-use kit
- As TheraStrand® RT, which is TheraStrand™ configured with standard seed-spacer-seed spacing provided without a needle. Delivered sterile in a ready-to-use kit.
- **As TheraSleeve®, brachytherapy needles with customized sleeves of I-Seed (I-125) seeds and spacers. Delivered sterile in a ready-to-use kit.**

For each configuration, the final product is shipped in a DOT 7A Type A package, using the same package (and containers) as those used for shipping the TheraSeed® Model 200. The container used to ship the MICK® magazines holds a maximum of 8 magazines with a maximum of 15 seeds per magazine. **The container used to ship the VSM and IN-STANT stranding magazines holds a maximum of 8 magazines with a maximum of 20 seeds per magazine.** The container used to ship the TheraStrand® RT holds a maximum of 20 strands. **The TheraLoad®, TheraStrand®, and TheraSleeve® configurations are packaged into thermofoam plastic trays with a lead cover and sterilized via gamma irradiation, with a maximum of 16 needles per tray, and a maximum of 3 trays per container.**

The TheraLoad®, TheraStrand®, and TheraSleeve® kits contain a **variable number of** individual **components** (seeds and spacers – **maximum of 14 for the TheraLoad® and TheraSleeve®, 12 for TheraStrand®**), **custom loaded** per the treatment plan **into standard 18-gauge needles**. All stranded configurations begin and end with a half-cut spacer. Refer to Figure 2 for a view of the TheraStrand®.

SOURCE TYPE: Therapeutic Brachytherapy Seed

LABELING:

The actual sources are not large enough to be labeled individually.

The shipping containers are labeled with isotope, total activity, activity range, and assay date. This is in accordance with Georgia Rules and Regulations for Radioactive Material, Chapter 391-3-17-.03(12)(d), which is comparable to 10 CFR 20.1904. A certificate of calibration accompanies each shipment. Each production lot is assigned a unique lot number.

All labels have an adhesive backing and are printed with a font size and color that results in a legible copy. Copies of the labels are included in Figures 3 – **7**.

For seeds shipped loose, or in MICK®, **VSM, or IN-STANT** magazines, the inner packaging label (vial or magazine) will include the following information:

- product name (I-Seed I-125) with isotope
- an indication of sterile or non-sterile
- Manufacture's information (name & address)
- "Caution: Radioactive Material" with trefoil
- apparent activity range (in units of mCi)
- total apparent activity (in units of mCi)
- assay date
- LOT number
- "pig" number
- reference number (Theragenics Product Code)
- number of seeds
- order number

For orders that are being shipped sterile, the inner package label also includes patient name and method of sterilization.

The lead container ("pig") contains the above information, as well as the patient's name, an indication that the product is single use only, and a statement to refer to the package insert for handling and storage instructions.

For the TheraLoad®, TheraStrand®, **TheraSleeve®** or TheraStrand® RT, the labels that are applied to the tray and the "pig" contain the following information:

- product name (I-Seed) with isotope (I-125)
- Manufacture's information (name & address)
- "Caution: Radioactive Material" with trefoil
- Patient name
- order number
- "pig" number
- number of seeds

SOURCE TYPE: Therapeutic Brachytherapy Seed

LABELING: (continued)

- reference number (Theragenics Product Code)
- LOT number
- assay date
- apparent activity range (in units of mCi)
- total apparent activity (in units of mCi)
- method of sterilization
- an indication that the product is single use only

DIAGRAM:

Figure 1a	--	Cross sectional view, I-Seed Model I25.S06
Figure 1b	**--**	**Cross sectional view, I-Seed Model AgX100**
Figure 2	--	view of TheraStrand®, containing I-Seed
Figure 3	--	sample label, I-Seed, for non-sterile package
Figure 4	--	sample label, I-Seed, for sterile package
Figure 5	--	sample label, TheraLoad® (delivered sterile)
Figure 6	--	sample label, TheraStrand® or TheraStrand® RT (delivered sterile)
Figure 7	**--**	**sample label, TheraSleeve® (delivered sterile)**

CONDITIONS OF NORMAL USE:

The I-Seed Brachytherapy seeds are intended for clinical use in the treatment of superficial, intra-abdominal, and intrathoracic tumors with the seed in close proximity to or within a tumor site. The seeds may be used alone or in combination with external beam radiation.

The Brachytherapy seeds are directed to the tumor site via commercially available implant tools. Once implanted, the seeds are subjected to only mildly acidic or alkaline conditions within the human body. The titanium capsule has excellent corrosion resistance, but should not be exposed to concentrated hydrochloric acid.

Sources that are shipped non-sterile can be sterilized using standard autoclave (steam) methods of 132°C (270°F) and 35 psi, or via ethylene oxide sterilization at 55°C and 70% relative humidity. Recommended sterilization procedures are included in the manufacturer's instructions for use. Sources that are shipped sterile, including TheraLoad®, TheraStrand®, **TheraSleeve®** or TheraStrand® RT, should not be resterilized.

Care should be exercised when handling the sources to prevent accidental rupture of the seeds.

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

(amended in its entirety)

SOURCE TYPE: Therapeutic Brachytherapy Seed

PROTOTYPE TESTING:

A prototype of the I-Seed Model I25.S06 was constructed and subjected to the tests provided in ANSI 542-1977/ISO 2919 and achieved a classification of 77C63211. A listing of the testing requirements for this classification follows:

- Temperature: -40°F (-40°C) for 20 minutes, 1472°F (800°C) for 1 hour, thermal shock 1472°F to 68°F (800°C to 20°C)
- External Pressure: 25 kPa to 2 MPa (3.6 psi to 290 psi) absolute
- Impact: Hit by 50g (1.8 oz.) object from a height of 1m (3.28 ft), Survive 10 free drops onto a steel surface from a height of 1.5m (4.92 ft)
- Vibration: No test requirement
- Puncture: No test requirement

A prototype of the I-Seed Model AgX100 was constructed and subjected to the tests provided in ISO 2919:1999(E) and achieved a classification of C53211. ISO 2919 is equivalent to ANSI/HPS N43.6-1997, which replaced ANSI N542-1977. The listing for the temperature test criteria is included below; the other 4 tests are identical to that included above for the Model I25.S06.

- **Temperature: -40°F (-40°C) for 20 minutes, 1112°F (600°C) for 1 hour, thermal shock 1112°F to 68°F (600°C to 20°C)**

EXTERNAL RADIATION LEVELS:

The following dose rates were reported by the manufacturer for the I-Seed Model I25.S06 containing 100 millicuries (3.7 GBq) of Iodine-125. **Also included are the dose rates for a Model AgX100 seed containing a typically ordered apparent activity. Dose rates for a Model AgX100 seed containing the maximum activity were extrapolated from the typical seed dose rates.**

	Model I25.S06 100 mCi contained (79.6 mCi apparent)	**Model AgX100 Typical seed 0.551 mCi apparent**	**Model AgX100 20 mCi contained (10 mCi apparent)**
Distance from center of source	**Max. Radiation Level in mR/hr [mSv/hr]**	**Max. Radiation Level in mR/hr [µSv/hr]**	**Max. Radiation Level in mR/hr [µSv/hr]**
5 cm	2800 [28.0]	**10.50 [105.0]**	**190.58 [1905.8]**
30 cm	77.8 [0.778]	**0.50 [5.0]**	**9.08 [90.75]**
100 cm	7.0 [0.07]	**0.07 [0.7]**	**1.27 [12.71]**

Dose rates emanating from other configurations (in cartridges or needles) can be approximated conservatively by multiplying the above values by the number of individual sources present. The actual dose rates will be less because of absorption by the delivery container.

Radiation exposure can be reduced by 97% or more with a thin sheet of lead (0.06 mm).

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

(amended in its entirety)

SOURCE TYPE: Therapeutic Brachytherapy Seed

QUALITY ASSURANCE AND CONTROL:

Theragenics Corporation maintains a quality assurance and control program that has been deemed acceptable for licensing purposes by Georgia Radioactive Materials Program. A copy of the program is on file with the Program. Additionally, the manufacturer has a quality system that has been certified to ISO 9001 for development and manufacture of radioactive medical components. Excerpts of the quality system that are directly applicable to this Brachytherapy seed have been included in the application.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed to persons specifically licensed by the Georgia Radioactive Materials Program, the U.S. Nuclear Regulatory Commission, or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. Considering that these sources exhibit high surface dose rates when unshielded, these sources should only be handled by experienced licensed personnel using adequate remote handling equipment and procedures.
- Licensees should follow the instructions for use included with the sources.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 μCi (185 Bq) of removable contamination.
- The source shall not be subjected to conditions that exceed its ANSI 542-1977/ISO 2919 classification of 77C63211 **for the Model I25.S06, or C53211 for the Model AgX100** (refer to Prototype Testing section for a detailed listing of conditions). Additionally, the sources should not be subjected to concentrated acids or dry heat sterilization.
- Care should be taken when handling the sources to avoid cutting or crushing the sources. This includes the loading of cartridges or magazines into implant tools.
- The sources should remain in the lead shielding container ("pig") during storage. When transporting seeds within a facility, an appropriate carrier with adequate shielding should be used.
- **Sources that are shipped non-sterile can be sterilized using standard autoclave (steam) methods of 132°C (270°F) and 35 psi, or via ethylene oxide sterilization at 55°C and 70% relative humidity. Recommended sterilization procedures are included in the manufacturer's instructions for use.**
- Products that are delivered to the licensee as sterile should not be resterilized.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Georgia Radioactive Materials Program.

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

(amended in its entirety)

SOURCE TYPE: Therapeutic Brachytherapy Seed

SAFETY ANALYSIS SUMMARY:

This revision incorporated **an alternate design using a different substrate/marker within the seed, and also** other configurations in which the I-Seed can be provided to licensees. **This design change is internal to the individual seed and does not change its external physical appearance or dimensions.**

Based on review of the I-Seed Model I25.S06 **and Model AgX100** sealed sources, its ANSI/ISO classification, and the information and test data cited below, we continue to conclude that the source is acceptable for licensing purposes. **The Model I25.S06** sealed source was previously reviewed by the California Department of Health Services and was given certificate number CA-0406-S-191-S.

Furthermore, we continue to conclude that the sealed source, in any of its configurations, would be expected to maintain its containment integrity for normal conditions of use and accidental conditions that might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the I-Seed Model I25.S06 sealed source are hereby incorporated by reference and are made a part of this registry document.

- Theragenics Corporation's application dated February 10, 2003.
- Theragenics Corporation's letters with enclosures dated March 21, 2003, and March 31, 2003.
- Theragenics Corporation's letter with enclosures dated June 20, 2005.
- Theragenics Corporation's electronic correspondence dated August 1, 2005, 12:21:25 and August 25, 2005, 15:07:58.
- **Theragenics Corporation's letter with enclosures dated October 27, 2010 and signed by Joseph Rodgers, M.S., Director of Radiation Physics**

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

(amended in its entirety)

SOURCE TYPE: Therapeutic Brachytherapy Seed

ISSUING AGENCY: Georgia Department of Natural Resources
Radioactive Materials Program

This document is not a license to receive, possess or distribute radioactive material. Receipt, possession and distribution of radioactive material, sources and devices containing radioactive material, are subject to the terms and conditions of applicable regulations and licenses issued by the NRC or Agreement States.

Date: March 17, 2011 Reviewer: Eric Jameson

Eric T. Jameson

Date: March 17, 2011 Concurrence: Cynthia Sanders

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

(amended in its entirety)

NO. GA-645-S-102-S **DATE:** March 17, 2011 **Attachment 1**

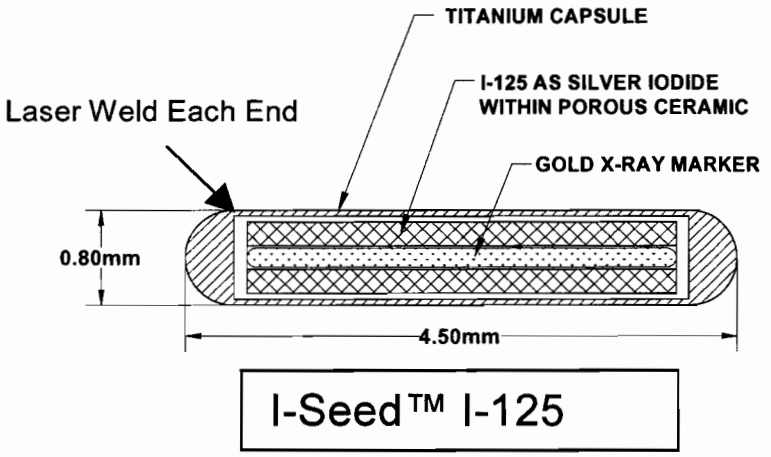

Figure 1a -- I-Seed Model I25.S06, cross sectional view

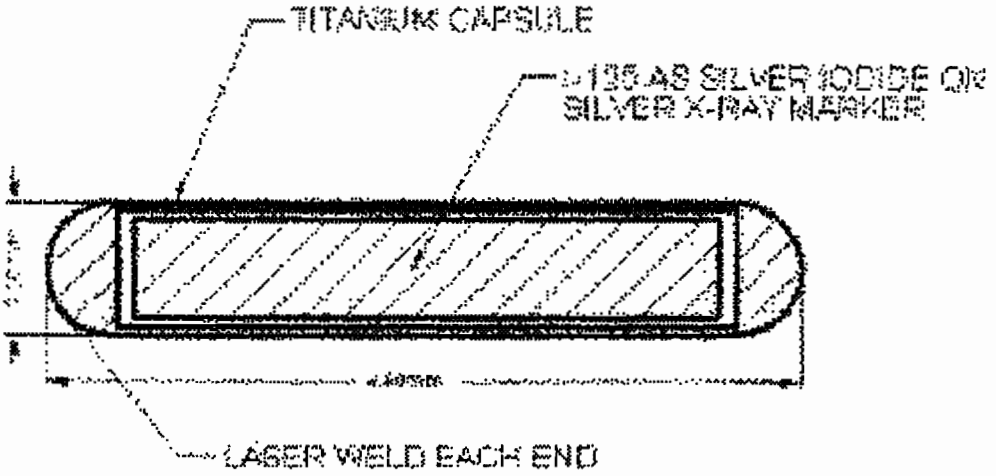

Figure 1b – I-Seed Model AgX100, cross sectional view

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

(amended in its entirety)

NO. GA-645-S-102-S **DATE:** March 17, 2011 **Attachment 2**

1. I-Seed
2. Spacer
3. Suture Material

Figure 2: TheraStrand™

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

(amended in its entirety)

NO. GA-645-S-102-S **DATE:** March 17, 2011 **Attachment 4**

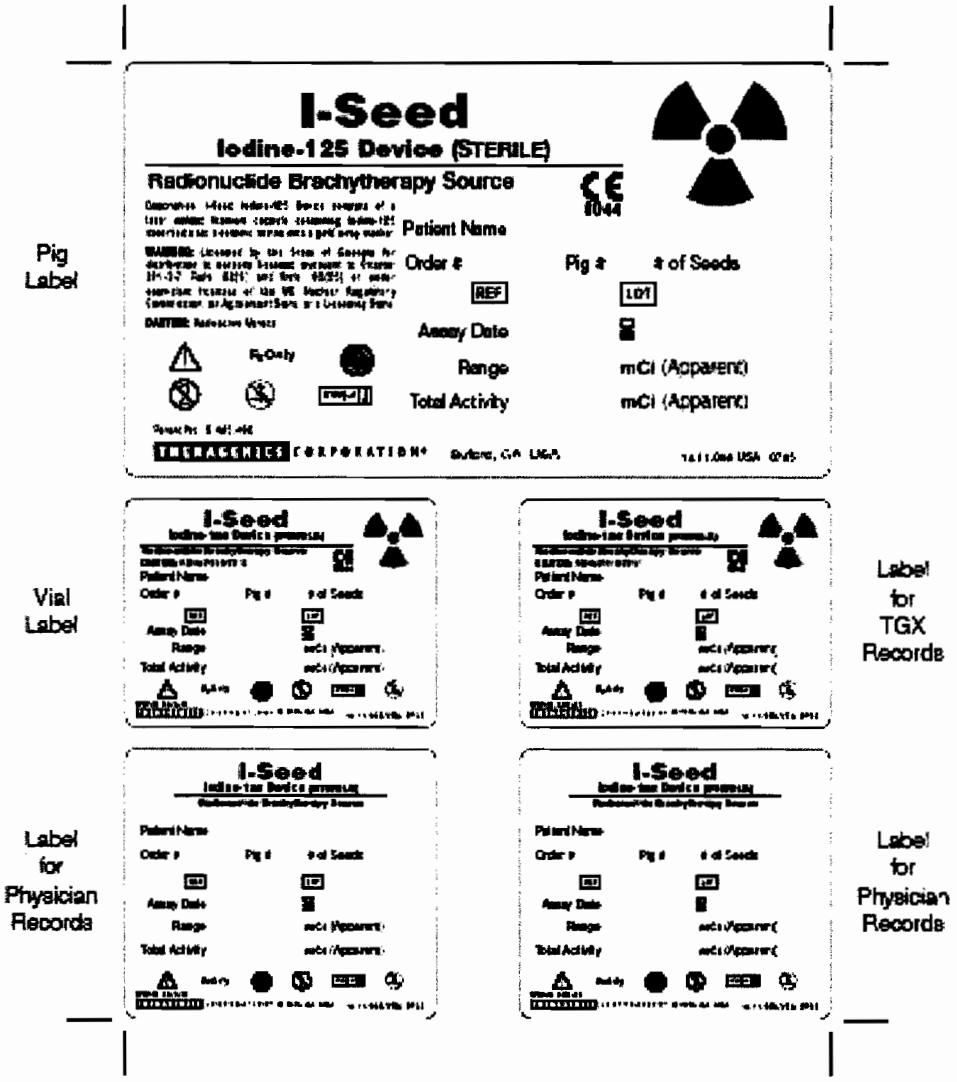

Figure 4 -- sample label, I-Seed (sterile shipment)

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

NO. GA-645-S-102-S **DATE:** March 17, 2011 **Attachment 5**

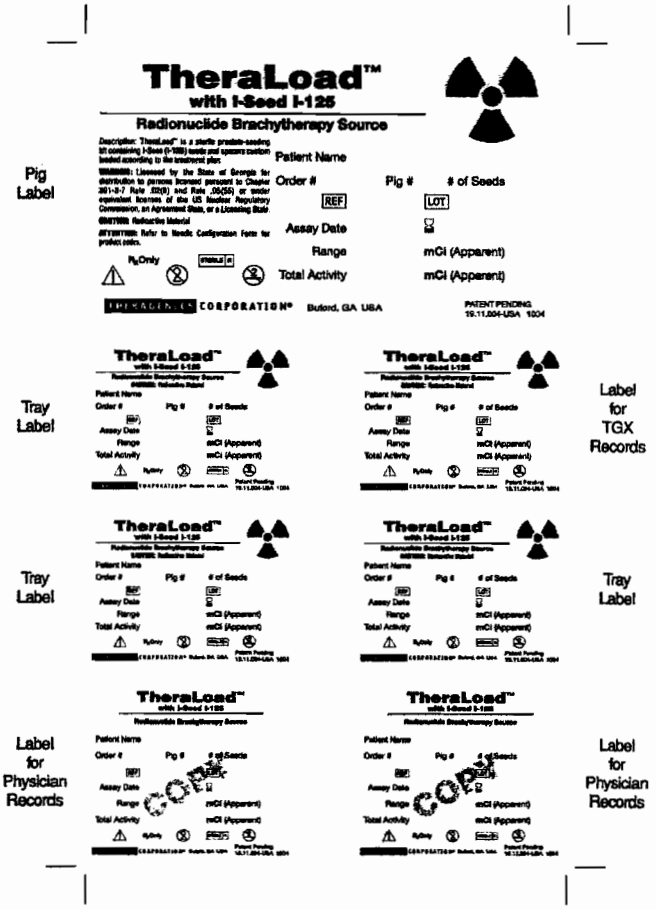

Figure 5 -- sample label, TheraLoad (sterile shipment)

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

(amended in its entirety)

NO. GA-645-S-102-S **DATE:** March 17, 2011 **Attachment 6**

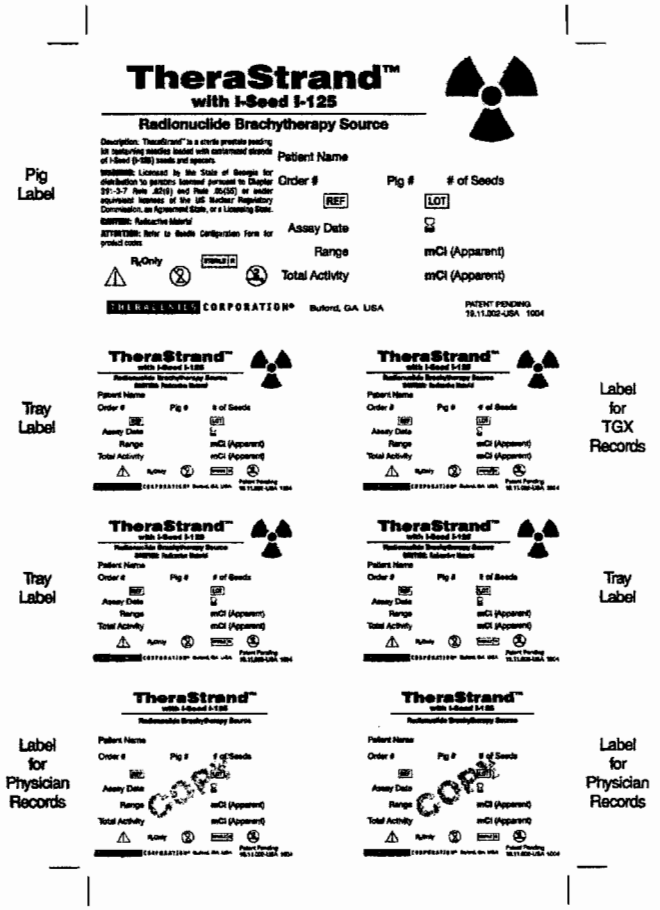

Figure 6 -- sample label, TheraStrand (sterile shipment)

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

NO. **GA-645-S-102-S** **DATE:** **March 17, 2011** **Attachment 7**

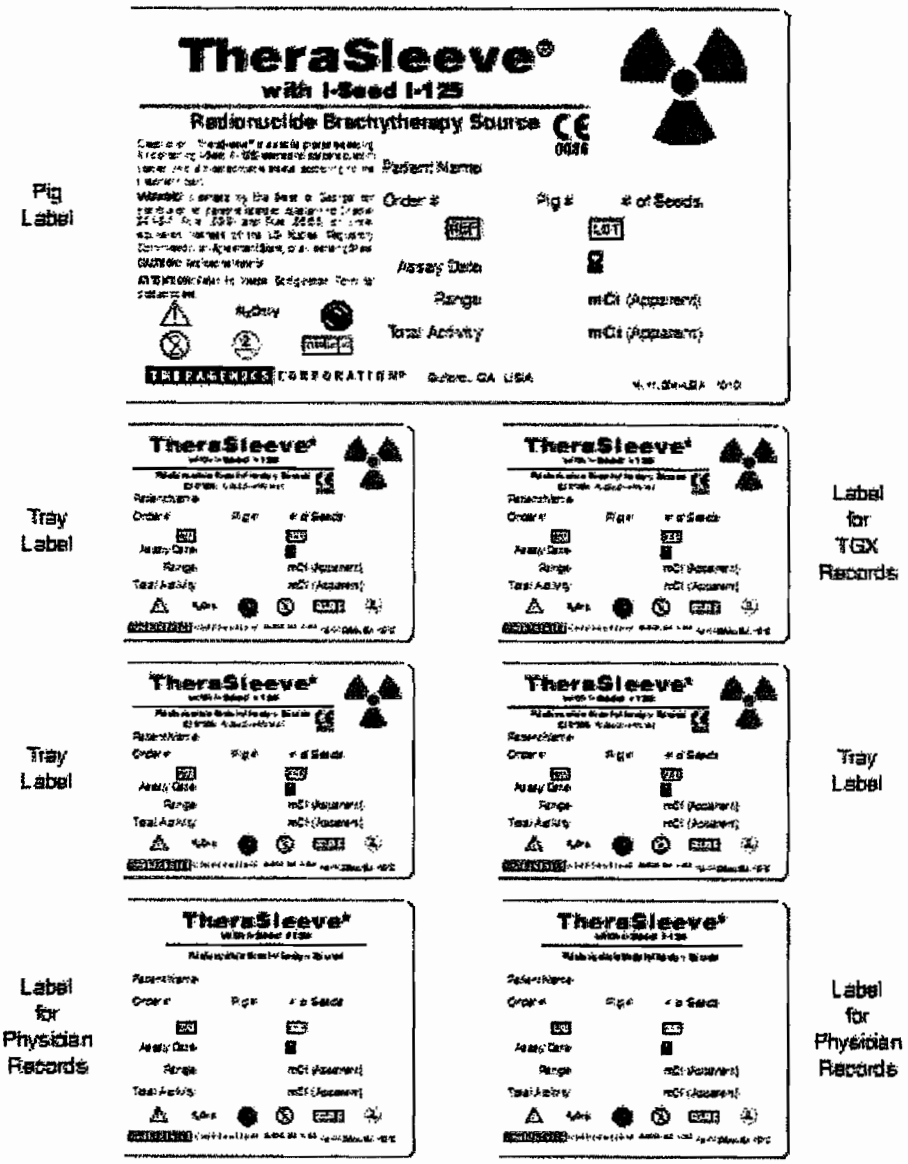

Figure 7 – sample labels, TheraSleeve (sterile shipment)

This is to acknowledge the receipt of your letter/application dated

3/22/12, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-30764-01)

[X] 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** 577196.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader