

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

NO.: NR-0645-S-102-S DATE: March 31, 2015 PAGE: 2 of 15
(Supersedes GA-0645-S-102-S)

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 I25.S06 has been discontinued and is no longer manufactured or distributed as of May 2012.

The Model AgXI00 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.

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 Models I25.S06 and AgX100 are offered in a variety of 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.

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SOURCE TYPE: Therapeutic Brachytherapy Seed

DESCRIPTION (Cont.):

- As TheraLoad[®], brachytherapy needles custom loaded with loose I-Seed (1-125) 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 (1-125) 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 contained in a bio-absorbable suture provided without a needle. Delivered sterile in a ready-to-use kit.
- As TheraSleeve[®], brachytherapy needles with customized sleeves of I-Seed (1-125) seeds and spacers contained in a bio-absorbable sleeve suture provided in a brachytherapy needle. Delivered sterile in a ready-to-use kit.

The I-Seed Models AgX100 is also offered in the following configurations:

- I-Seed preloaded in C20[®] magazines capable of holding 20 seeds.
- I-Seed preloaded needle distributed as Lesion-Loc I-125 Needle.

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

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SOURCE TYPE: Therapeutic Brachytherapy Seed

DESCRIPTION (Cont.):

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 or ethylene oxide (EO), with a maximum of 16 needles per tray, and a maximum of 3 trays per container. The container used to ship C20® magazines holds a maximum of 20 seeds per magazine.

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.

The AgX100 seeds will be manually inserted into the slots of a seed carrier for eye plaques. The eye plaque is comprised of a Silastic (silicon) seed carrier either circular or notched design with a standardized seed pattern used to hold pre-determined number of I-Seed Model AgX100. The maximum number of seeds per plaque configuration is shown in Table 1. The I-Seeds Model AgX100 are manually inserted into the slots of a seed carrier for eye plaques.

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SOURCE TYPE: Therapeutic Brachytherapy Seed

DESCRIPTION (Cont.):

Table 1: Seed Carriers Diameters and Maximum Number of Seeds

Carrier Diameter (mm)	Maximum Number of seeds	
	Circular Seed Carrier	Notched Seed Carrier
10	5	4
12	8	7
14	13	12
16	13	12
18	21	20
20	24	23
22	21	20

The I-Seed Model AgX100 will be used for localization of Non-Palpable Lesions also known as Radioactive Seed Localization (RSL). The Model AgX100 will be distributed in a preloaded 18 gauge brachytherapy needle, in four lengths (5, 7, 10, 15 cm), with a single seed containing a maximum activity of 0.270 mCi-apparent (0.540 mCi-contained). The loaded needle is placed in a stainless steel tube with thickness of 0.020 inches and then placed in a Tyvek pouch for sterilization via Ethylene Oxide (EO). The RSL needle will be manufactured and distributed by Theragenics for IntraMedical Imaging under the name Lesion-Loc I-125 Seed/Needle.

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. A certificate of

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SOURCE TYPE: Therapeutic Brachytherapy Seed

LABELING (Cont.):

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 result in a legible copy.

For seeds shipped loose, in MICK[®], VSM, IN-STANT, or C20[®] magazines or Seed Carrier for Eye Plaques, the inner packaging label (vial or magazine) will include the following information:

- product name (I-Seed 1-125) 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:

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SOURCE TYPE: Therapeutic Brachytherapy Seed

LABELING (Cont.):

- product name (I-Seed) with isotope (1-125)
- Manufacture's information (name & address)
- "Caution: Radioactive Material" with trefoil
- Patient name
- order number
- "pig" number
- number of seeds
- 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

See Attachment 10 for label sample of AgX100 used for RSL.

DIAGRAM:

See Attachments 1 - 10.

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

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SOURCE TYPE: Therapeutic Brachytherapy Seed

CONDITIONS OF NORMAL USE (Cont.):

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.

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 77C6321 1. 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 1 m (3.28 ft), Survive 10 free drops onto a steel surface from a height of 1.5m (4.92ft)
- Vibration No test requirement
- Puncture No test requirement

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SOURCE TYPE: Therapeutic Brachytherapy Seed

PROTOTYPE TESTING (Cont.):

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.

Table 2: Maximum Radiation Level, in mR/hr [μ Sv/hr]

	Model I25.S06 100 mCi contained (79.6 mCi apparent)	Model AgX100 Typical seed 0.551 mCi apparent	Model AgX100 40mCi Contained (20 mCi apparent)
Distance from center of the source	Max. Radiation Level in mR/hr [mSvr/hr]	Max. Radiation Level in mR/hr [μ Svr/hr]	Max. Radiation Level in mR/hr [μ Svr/hr]
5 cm	2800 [28.0]	10.50 [105.0]	381.16 [3811.6]
30 cm	77.8 [0.778]	0.50 [5.0]	18.16 [181.6]
100 cm	7.0 [0.07]	0.07 [0.7]	2.54 [25.4]

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

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SOURCE TYPE: Therapeutic Brachytherapy Seed

EXTERNAL RADIATION LEVELS (Cont.):

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

The dose rates shown in Table 3 were reported by the manufacturer for the Seed Carrier for Eye Plaques containing the maximum number of sources.

Table 3: Maximum Radiation Levels for a 20mm "Seed Carrier for Eye Plaques" containing a 24 Seeds

Radiation levels (mR/hr) for 24 seeds in a 20 mm diameter seed carrier	
Distance	I-seed Model AgX100 0.405 mCi (0.514 U)
5 cm	200
10 cm	27
100 cm	1

Table 4: Maximum Radiation Levels for RSL (Lesion-Loc Needle)

Calculated Radiation Levels (mR/hr) for one (1) I-Seed Model AgX100 loaded in a shielded needle. (0.270 mCi-apparent (0.540 mCi-contained))	
Distance	mR/hr
5 cm	0.444
30 cm	0.017
100 cm	0.017

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SOURCE TYPE: Therapeutic Brachytherapy Seed

QUALITY ASSURANCE AND CONTROL:

All manufacturing of I-Seed Models sources and related operations are to be carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR Part 820, under the supervision of the Quality Assurance group at Theragenics Corporation. Theragenics Corporation Quality System is compliant with good manufacturing practices for medical devices and is certified to ISO 13485:2003.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed to persons specifically licensed by 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 AgX1 00 (refer to Prototype Testing section for a detailed listing of

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SOURCE TYPE: Therapeutic Brachytherapy Seed

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd):

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 NRC.
- The I-Seed Model **I25.S06** has been discontinued and is no longer manufactured or distributed as of May 2012.

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SOURCE TYPE: Therapeutic Brachytherapy Seed

FDA APPROVAL:

Models I25.S06 Series sealed sources were approved by the US FDA, Approval No. K021343, Form 510(k) dated 20 May 2002.

The model AgX100 was approved by the U.S. Food and Drug Administration Approval No.K103319, Form (510K), dated January 3, 2010.

The use of model AgX100 (Lesion-Loc Seed/Needle) for Radioactive Seed Localization was approved by the U.S. Food and Drug Administration Approval No.K142668, Form (510K), dated November 21, 2014.

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 conclude that the I-Seed Model I25.S06 and Model AgX100, 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.

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REFERENCES:

The following supporting documents for the I-Seed Model I25.S06 and Model AgX100 sealed sources 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 letters with enclosures dated November 10, 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.
- Theragenics Corporation's e-mails dated January 15, 2014, with enclosure thereto.
- Theragenics Corporation's letters dated August 18, 2014, and September 25, 2014, with enclosures thereto.
- Theragenics Corporation's e-mail dated November 7, 2014, with enclosures thereto.

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SOURCE TYPE: Therapeutic Brachytherapy Seed

REFERENCES (Cont'd):

- Theragenics Corporation's application dated November 12, 2014, with enclosures thereto.
- Theragenics Corporation's e-mails dated January 27, 2015, February 2, 2015, and two e-mails dated February 6, 2015, with enclosures thereto.
- **Theragenics Corporation's email dated March 20, 2015, (ML15084A200 and ML15084A217) with enclosures thereto.**

ISSUING AGENCY:

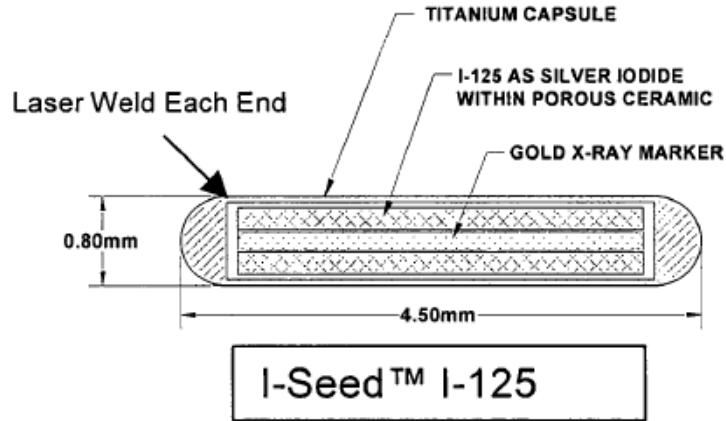
U.S. Nuclear Regulatory Commission

DATE: March 31, 2015 REVIEWER: **/RA/**
Tomas Herrera

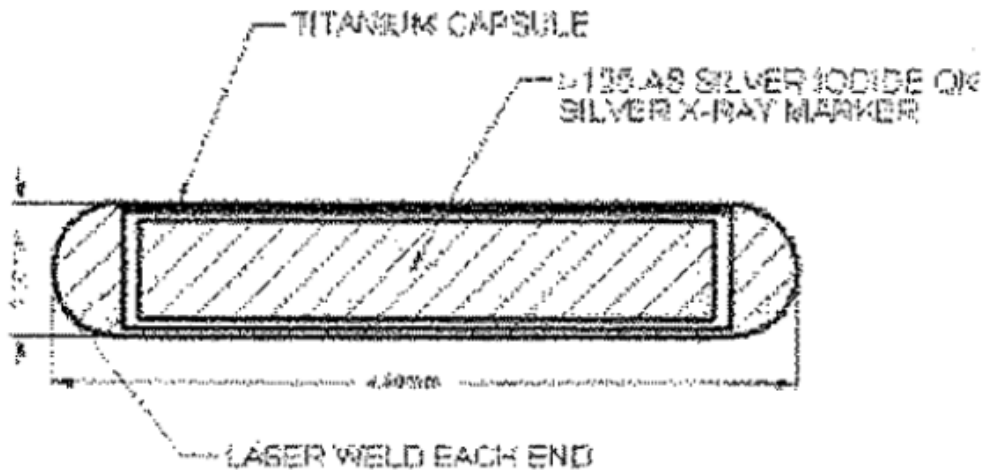
DATE: March 31, 2015 CONCURRENCE: **/RA/**
Lymari Sepulveda

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I-Seed Model I25.S06, cross sectional view
(Discontinued as of May 2012)



I-Seed Model AgX100, cross sectional view

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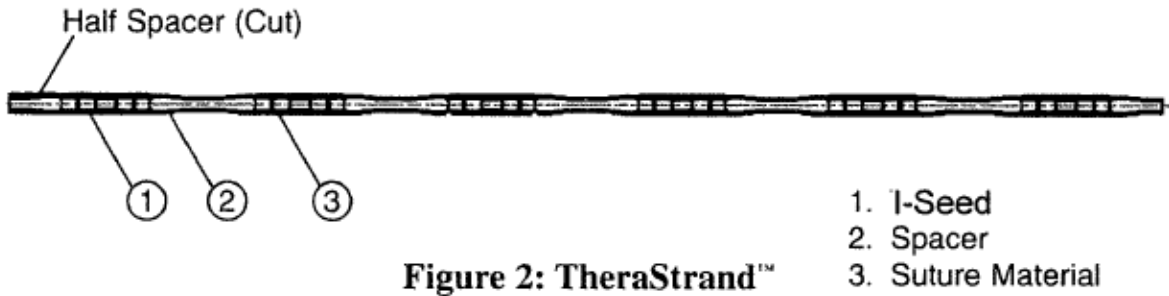



Figure 2: TheraStrand™

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I-Seed I-125

IODINE-125 SOURCE 125.S06
(NON STERILE)

Radionuclide Brachytherapy Source

FOR INFORMATION PURPOSES ONLY
 Do not use for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

WARNING: Labels are not to be used for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

CAUTION: Labels are not to be used for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

Order No. REF

Pig No. LOT

Range mCi (Apparent)

Total Activity mCi (Apparent)

Number of Seeds

Assay Date

Patient Name

Single Use

See package insert for instructions on handling and storage of I-Seed

Caution: RADIOACTIVE MATERIAL

Theragenics Corporation
 Buford, GA 30518 U.S.A.
 Form No. 6-MS-08
 11-11-08 USA 1250

I-Seed I-125 (Distributed by Theragenics Corporation, Buford, GA 30518 U.S.A.)

Caution: RADIOACTIVE MATERIAL

Range mCi (Apparent)

Total Activity mCi (Apparent)

Assay Date LOT

Pig No. No. of Seeds

Order No.

Form No. 6-MS-08 Caution: Labels are not to be used for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

I-Seed I-125 (Distributed by Theragenics Corporation, Buford, GA 30518 U.S.A.)

Caution: RADIOACTIVE MATERIAL

Range mCi (Apparent)

Total Activity mCi (Apparent)

Assay Date LOT

Pig No. No. of Seeds

Order No.

Form No. 6-MS-08 Caution: Labels are not to be used for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

I-Seed I-125 (Distributed by Theragenics Corporation, Buford, GA 30518 U.S.A.)

Caution: RADIOACTIVE MATERIAL

Range mCi (Apparent)

Total Activity mCi (Apparent)

Assay Date LOT

Pig No. No. of Seeds

Order No.

Form No. 6-MS-08 Caution: Labels are not to be used for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

I-Seed I-125 (Distributed by Theragenics Corporation, Buford, GA 30518 U.S.A.)

Caution: RADIOACTIVE MATERIAL

Range mCi (Apparent)

Total Activity mCi (Apparent)

Assay Date LOT

Pig No. No. of Seeds

Order No.

Form No. 6-MS-08 Caution: Labels are not to be used for any other purpose than that intended. Do not use for any other purpose than that intended. Do not use for any other purpose than that intended.

I-Seed I-125

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Fig Label

I-Seed
 Iodine-125 Device (STERILE)
 Radionuclide Brachytherapy Source

CE
 IEC 60601-2-1

Caution: Iodine-125 emits gamma rays of a low energy. Handle source carefully avoiding Iodine-125 contamination. Do not touch source with bare hands.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 101-02 State Code and State Statute or under any other license of the US Nuclear Regulatory Commission, or Agreement State, or its licensing body.

CAUTION: Radioactive Material

REF

LOT

Assay Date

Range

Total Activity

of Seeds

mCi (Apparent)

mCi (Apparent)

Patent No. 6,426,466

TECHNICALS CORPORATION® Atlanta, GA USA 1611668 USA ©2015

Vial Label

I-Seed
 Iodine-125 Device (STERILE)
 Radionuclide Brachytherapy Source

Caution: Iodine-125 emits gamma rays of a low energy. Handle source carefully avoiding Iodine-125 contamination. Do not touch source with bare hands.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 101-02 State Code and State Statute or under any other license of the US Nuclear Regulatory Commission, or Agreement State, or its licensing body.

CAUTION: Radioactive Material

REF

LOT

Assay Date

Range

Total Activity

of Seeds

mCi (Apparent)

mCi (Apparent)

Patent No. 6,426,466

TECHNICALS CORPORATION® Atlanta, GA USA 1611668 USA ©2015

Label for TGX Records

I-Seed
 Iodine-125 Device (STERILE)
 Radionuclide Brachytherapy Source

Caution: Iodine-125 emits gamma rays of a low energy. Handle source carefully avoiding Iodine-125 contamination. Do not touch source with bare hands.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 101-02 State Code and State Statute or under any other license of the US Nuclear Regulatory Commission, or Agreement State, or its licensing body.

CAUTION: Radioactive Material

REF

LOT

Assay Date

Range

Total Activity

of Seeds

mCi (Apparent)

mCi (Apparent)

Patent No. 6,426,466

TECHNICALS CORPORATION® Atlanta, GA USA 1611668 USA ©2015

Label for Physician Records

I-Seed
 Iodine-125 Device (STERILE)
 Radionuclide Brachytherapy Source

Caution: Iodine-125 emits gamma rays of a low energy. Handle source carefully avoiding Iodine-125 contamination. Do not touch source with bare hands.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 101-02 State Code and State Statute or under any other license of the US Nuclear Regulatory Commission, or Agreement State, or its licensing body.

CAUTION: Radioactive Material

REF

LOT

Assay Date

Range

Total Activity

of Seeds

mCi (Apparent)

mCi (Apparent)

Patent No. 6,426,466

TECHNICALS CORPORATION® Atlanta, GA USA 1611668 USA ©2015

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

NO.:NR-0645-S-102-S DATE: March 31, 2015 ATTACHMENT: 5 of 10
 (Supersedes GA-0645-S-102-S)

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source

Development: TheraLoad™ is a sterile, sealed, non-leaking, low-activity (1-Seed I-125) source and contains custom metal according to the license plan.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 281-1-1 Rule 400(s) and Rule 400(d) or other regulatory sources of the US Nuclear Regulatory Commission, an Agreement State, or a Licensee State.

CAUTION: Radioactive Source

ATTENTION: Refer to Handle Configuration Form for model codes.

Patient Name _____

Order # _____ **REF**

Assay Date _____

Range _____

Total Activity _____

Pig # _____ **LOT**

of Seeds _____

mCi (Apparent) _____

mCi (Apparent) _____

ENERGENICS CORPORATION® BURNS, GA, USA **INFORMEDOM**
 18-1-004-USA-1004

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source
Labeled Labeled Source

Patient Name _____

Order # _____ Pig # _____ # of Seeds _____

Assay Date _____ **REF** **LOT**

Range _____ mCi (Apparent) _____

Total Activity _____ mCi (Apparent) _____

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source
Labeled Labeled Source

Patient Name _____

Order # _____ Pig # _____ # of Seeds _____

Assay Date _____ **REF** **LOT**

Range _____ mCi (Apparent) _____

Total Activity _____ mCi (Apparent) _____

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source
Labeled Labeled Source

Patient Name _____

Order # _____ Pig # _____ # of Seeds _____

Assay Date _____ **REF** **LOT**

Range _____ mCi (Apparent) _____

Total Activity _____ mCi (Apparent) _____

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source
Labeled Labeled Source

Patient Name _____

Order # _____ Pig # _____ # of Seeds _____

Assay Date _____ **REF** **LOT**

Range _____ mCi (Apparent) _____

Total Activity _____ mCi (Apparent) _____

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source

Patient Name _____

Order # _____ Pig # _____ # of Seeds _____

Assay Date _____ **REF** **LOT**

Range _____ mCi (Apparent) _____

Total Activity _____ mCi (Apparent) _____

TheraLoad™

with I-Seed I-125

Radionuclide Brachytherapy Source

Patient Name _____

Order # _____ Pig # _____ # of Seeds _____

Assay Date _____ **REF** **LOT**

Range _____ mCi (Apparent) _____

Total Activity _____ mCi (Apparent) _____

Pig Label

Tray Label

Tray Label

Label for Physician Records

Label for TGX Records

Tray Label

Label for Physician Records


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





NO.:NR-0645-S-102-S DATE: March 31, 2015 ATTACHMENT: 6 of 10
 (Supersedes GA-0645-S-102-S)

TheraStrand™

with I-Seed I-125

Radionuclide Brachytherapy Source



Description: TheraStrand™ is a sterile sealed source for permanent prostate implant with nominal activity of 9 Seed (I-125) seeds and spacers.
WARNING: Licensed in the State of Georgia for distribution to licensed hospitals pursuant to Chapter 301-2-7 Rule (200) and Part 2400 in strict compliance with the U.S. Nuclear Regulatory Commission, or Agreement State, or Licensing State.
CAUTION: Radioactive Material
ATTENTION: Refer to Isotope Dispensation Form for product uses.
 Radioactive hazard symbols:    

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

TheraStrand™
with I-Seed I-125
Radionuclide Brachytherapy Source

Tray Label

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

TheraStrand™
with I-Seed I-125
Radionuclide Brachytherapy Source

Label for TGX Records

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

TheraStrand™
with I-Seed I-125
Radionuclide Brachytherapy Source

Tray Label

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

TheraStrand™
with I-Seed I-125
Radionuclide Brachytherapy Source

Tray Label

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

TheraStrand™
with I-Seed I-125
Radionuclide Brachytherapy Source

Label for Physician Records

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

TheraStrand™
with I-Seed I-125
Radionuclide Brachytherapy Source

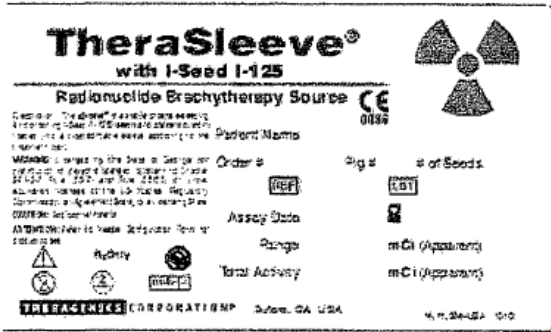

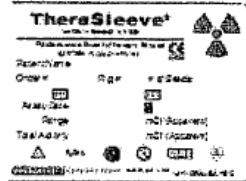




Label for Physician Records

Patient Name	Order #	Pig #	# of Seeds
	REF	LOT	
	Assay Date		
	Range		mCi (Apparent)
	Total Activity		mCi (Apparent)

THERAGENICS CORPORATION® Suwanee, GA USA **PATENT PENDING**
 1511.002 USA 100A

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

NO.:NR-0645-S-102-S DATE: March 31, 2015 ATTACHMENT: 7 of 10
(Supersedes GA-0645-S-102-S)

		
Pig Label		
Tray Label	<div style="width: 48%;">  </div> <div style="width: 48%;">  </div>	Label for TGX Records
Tray Label	<div style="width: 48%;">  </div> <div style="width: 48%;">  </div>	Tray Label
Label for Physician Records	<div style="width: 48%;">  </div> <div style="width: 48%;">  </div>	Label for Physician Records

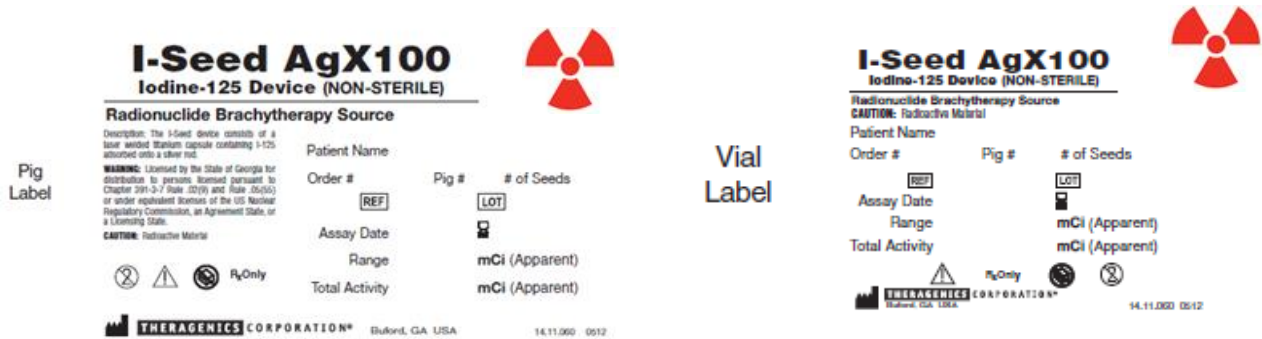
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.:NR-0645-S-102-S DATE: March 31, 2015 ATTACHMENT: 8 of 10
(Supersedes GA-0645-S-102-S)



Theragenics Label (Sterile)

(Loose seeds, MICK[®] magazines, C20[®] magazines, and Seed Carriers for Eye Plaques)



Theragenics Label (Non-Sterile)

(Loose seeds, MICK[®] magazines, C20[®] magazines, and Seed Carriers for Eye Plaques)

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

NO.:NR-0645-S-102-S DATE: March 31, 2015 ATTACHMENT: 9 of 10
 (Supersedes GA-0645-S-102-S)

TheraLoad®
with AgX100® I-125

Radionuclide Brachytherapy Source

Description: TheraLoad® is a sterile prostate-seeding kit containing AgX100® (I-125) seeds and spacers custom loaded according to the treatment plan.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 291-3-7 Rule (22)(3) and Rule (22)(5) or under equivalent licenses of the US Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

CAUTION: Radioactive Material

ATTENTION: Refer to Needle Configuration Form for product codes.

Pig Label

Order # REF

Assay Date

Range

Total Activity

THERAGENICS CORPORATION® Buford, GA USA



TheraLoad®
with AgX100® I-125

Radionuclide Brachytherapy Source

CAUTION: Radioactive Material

Tray Label

Patient Name

Order # REF

Assay Date REF

Range

Total Activity

Pig #

of Seeds LOT

mCi (Apparent)

mCi (Apparent)

THERAGENICS CORPORATION® Buford, GA USA



Theraload Label

TheraStrand®
with AgX100® I-125

Radionuclide Brachytherapy Source

Description: TheraStrand® is a sterile prostate seeding kit containing needles loaded with customized strands of AgX100® (I-125) seeds and spacers.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 291-3-7 Rule (22)(3) and Rule (22)(5) or under equivalent licenses of the US Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

CAUTION: Radioactive Material

ATTENTION: Refer to Needle Configuration Form for product codes.

Pig Label

Order # REF

Assay Date

Range

Total Activity

THERAGENICS CORPORATION® Buford, GA USA



TheraStrand®
with AgX100® I-125

Radionuclide Brachytherapy Source

CAUTION: Radioactive Material

Tray Label

Patient Name

Order # REF

Assay Date REF

Range

Total Activity

Pig #

of Seeds LOT

mCi (Apparent)

mCi (Apparent)

THERAGENICS CORPORATION® Buford, GA USA



TheraStrand® and TheraStrand® RT Label

TheraSleeve®
with AgX100® I-125

Radionuclide Brachytherapy Source

Description: TheraSleeve® is a sterile prostate-seeding kit containing AgX100® (I-125) seeds and spacers custom loaded into a bioabsorbable sleeve according to the treatment plan.

WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to Chapter 291-3-7 Rule (22)(3) and Rule (22)(5) or under equivalent licenses of the US Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

CAUTION: Radioactive Material

ATTENTION: Refer to Needle Configuration Form for product codes.

Pig Label


Order # REF

Assay Date

Range

Total Activity

THERAGENICS CORPORATION® Buford, GA USA



TheraSleeve®
with AgX100® I-125

Radionuclide Brachytherapy Source

CAUTION: Radioactive Material

Tray Label

Patient Name

Order # REF

Assay Date REF

Range

Total Activity


Pig #

of Seeds LOT

mCi (Apparent)

mCi (Apparent)

THERAGENICS CORPORATION® Buford, GA USA



TheraSleeve Label

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

NO.:NR-0645-S-102-S DATE: March 31, 2015 ATTACHMENT: 10 of 10
(Supersedes GA-0645-S-102-S)



WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to NRC 10 CFR 35.1000 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Manufactured by Theragenics for:

IntraMedical Imaging

12569 Crenshaw Blvd.
Hawthorne, CA 90250
(424) 456-7316

Lesion-Loc I-125 Seed / 5cm Needle
One Seed at XX.XX mCi Apparent on YYYY-MM-DD

Seed Model AgX100

REF L125-5

LOT XXXXXX

YYYY-MM-DD

CAUTION - Radioactive Material



STERILE EO Rx Only

US Patents: 6,496,717 & 7,881,775

14-11-600-02

Unit Label w/sample variable data



WARNING: Licensed by the State of Georgia for distribution to persons licensed pursuant to NRC 10 CFR 35.1000 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

Manufactured by Theragenics for:

IntraMedical Imaging

12569 Crenshaw Blvd.
Hawthorne, CA 90250
(424) 456-7316

Reference Date: YYYY-MM-DD

Total Activity: XX.XX mCi Apparent

Lesion-Loc I-125 Seed / 5cm Needle

Seed Model AgX100

REF L125-5

QTY XXXX / Single Packs

LOT XXXXXXXX

YYYY-MM-DD

CAUTION - Radioactive Material



STERILE EO Rx Only

US Patents: 6,496,717 & 7,881,775

14-11-600BX-02

Box Label w/sample variable data

Radioactive Seed Localization Label