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

NO: TX-1152-S-101-S DATE: November 21. 2001
(Previously TX-1068-S-101-S)
DEVICE TYPE: Therapeutic Seed Sources

MODEL IS- 125 Series
(IS-12500, IS-12501)

DISTRIBUTOR: **IsoStar Texas, Inc.**
dbn Imagyn Medical Technologies
3100 Jim Christal Rd.
Denton TX 76207-2600
(Formally know as International Isotopes, Inc.)

MANUFACTURER: **IsoStar Texas, Inc.**
dba Imagyn Medical Technologies
3100 Jim Christal Rd.
Denton TX 76207-2600
Phone (940) **591-1663**

ISOTOPE:	MAXIMUM ACTIVITY:
Iodine-125	10 per source

LEAK TEST FREQUENCY: 6 months, if a seed's activity was in excess of 800 microcuries at distribution.

PRINCIPAL USE: (V) General Medical Use

CUSTOM DEVICE: _____ YES __X__ NO

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DESCRIPTION:

The **IsoStar Texas, Inc.**, Model IS-12500 (previously listed as Model IS 125) seed consists of iodine-125 deposited on a silver coated titanium sphere with subsequent metallic over-lays applied with vacuum sputtering and electroplating techniques. The **IsoStar Texas, Inc.**, Model IS-12501 seed consists of iodine-125 deposited on a silver sphere with subsequent metallic over-lays applied with vacuum sputtering and electroplating techniques. Finally, several (typically five) of the matching coated spheres are loaded into a pure titanium tube and welded into a cylindrical, shiny, metallic-gray seed with an outer dimension of approximately 4.5 mm length and 0.8 mm diameter. The wall thickness of the tube or welded sleeve is 0.05 mm. The average thickness of each laser weld (located at both ends) is about 0.5 mm.

LABELING:

Because of their small size, individual seeds are not labeled. The seeds are supplied as a group of seeds with an activity within a stated range and are packaged in either a screw cap glass, one-dram vial, or pre-loaded into administration needles called an iso-sleeve assembly. When seeds are supplied in the iso-sleeve assembly, they have been pre-loaded with bovine gut spaces and would be gamma-sterilized prior to distribution. A final image of each loaded needle with a corresponding identification number will be provided to the costumer to visually identify spacing and a starting seed inventory traceable by individual needle assembly. Each production lot is assigned a unique lot number. A label is affixed to the vial stating: "Caution-Radioactive Material, isotope, total activity, activity range, assay date, lot number, the trefoil radiation symbol, non-sterile, manufacturer, model number, and marketed by." The iso-sleeve assembly label (see diagram) located on the needle drape and outer pouch, uniquely identifies that it is, "Sterile: For single use only," and specifies a patient name. An additional label is attached to the lead storage container which includes the same information on the glass vial and a warning that regulated distribution is limited to specific radioactive material licensees subsequent to a physician's order.

DIAGRAMS:

See Attachments 1 (seed design) and 2 (iso-sleeve assembly and label).

CONDITIONS OF NORMAL USE:

The model IS-125 series brachytherapy source is intended to be used as a permanent interstitial implant in the treatment of selected localized tumors. Licensed physicians in a clinical environment (surgery) use the device. The placement of the seeds in the tumor is facilitated by the use of one of several commercially available implant tools. These tools are used solely for source placement and not designed either to store or hold the seeds. The seeds are designed to withstand normal autoclave temperatures and pressure variations not to exceed 135° C and 35 psi for 30 minutes. Steam sterilization instructions are provided in the Instructions-for-Use that accompanies the product.

PROTOTYPE TESTING:

Prototypes of both model seeds were subjected to tests for demonstration that the sources would maintain their integrity under stresses of use and accident. The tests performed were in accordance with ISO 2919-1980, Annex C (Medical: interstitial and intracavitary appliances), with a resulting classification of ISO/C53211. This model source has not been tested to satisfy the testing criteria to be declared "special form," as described in 49 CFR 173.469. The impact test was performed striking against the conical end of the seeds, in a manner determined as the source's most vulnerable area. The manufacturer provided additionally testing of the seeds to include autoclaving at 135° C at 34 psi for 30 minutes, without evidence of source failure. These autoclaving values are in excess of the manufacturer's recommendations, and where offered as the seeds are provided non-sterilized.

EXTERNAL RADIATION LEVELS:

Single ten-millicurie seed at:	Upper exposure rate
5 cm	73 mR/hr
30 cm	6 mR/hr
100 cm	0.529 mR/hr

7 one-millicurie seeds (with spaces) in an iso-sleeve in needle assembly	Upper Exposure rate
5 cm	12.6 mR/hr
30 cm	1.95 mR/hr
100 cm	0.50 mR/hr

QUALITY ASSURANCE AND CONTROL:

IsoStar Texas, Inc., conducts quality control tests and inspection of the Model IS-12500 and IS-12501 sources prior to distribution, that include: visual inspection, leak testing, radioassay, and physical outer dimensions. Incoming inspections of raw materials includes: labeling, physical and chemical attributes. Manufacturing quality control includes measurements, radiochemical, and radioassay.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- These sources shall be distributed only to persons specifically licensed by the United States Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State.
- The source shall not be subjected to environmental or other conditions of use which exceed ISO 2919.

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Continued (LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE)

- The licensing authority will have to obtain details on specific holders, measuring equipment, and any operational procedures from the license applicant to making a licensing determination. Based on exhibited, unshielded surface dose rates and the frequent number of sources handled during a typical procedure, these sealed sources should be handled by only experienced licensed personnel equipped with remote handling equipment and appropriate low-energy photon detection equipment.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Texas Department of Health.
- In spite of the excellent corrosion resistance of titanium, exposure to strong acids and/or bases should be avoided.
- The sources are designed to withstand temperatures and pressures of 275° F (133° C) and 30 psi for 30 minutes. Higher temperatures and pressures are not recommended. Nominal autoclaving conditions are 250° F (121° C) at 15 psi for 15 minutes. Sources should not be sterilized by dry heat.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information, test data cited below, we conclude that the **IsoStar Texas, Inc.**, Model IS-125 Series, 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 plausible within the medical laboratory/surgery environment. The United States Food and Drug Administration (FDA) shall have determined the efficacy and granted authorization for the therapeutic use of these seeds in humans.

REFERENCES: Supporting information for the creation of this summary was obtained from letters supplied by the manufacturer, dated: July 1, 1998, August 31, 1998, October 7, 1998, December 14, 1998, April 28, 1999, May 23, 2001, June 19, 2001, July 5, 2001, September 28, 2001, October 25, 2001 and November 13, 2001.

ISSUING AGENCY: Texas Department of Health's Bureau of Radiation Control

Date: December 7, 2001 REVIEWED BY: David M. Wood
David M. Wood

Date: December 7, 2001 CONCURRENCE: D. Ray Jisha
D. Ray Jisha

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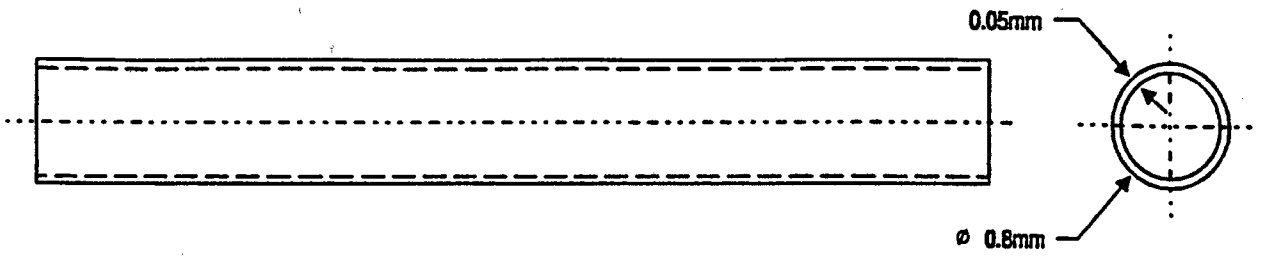
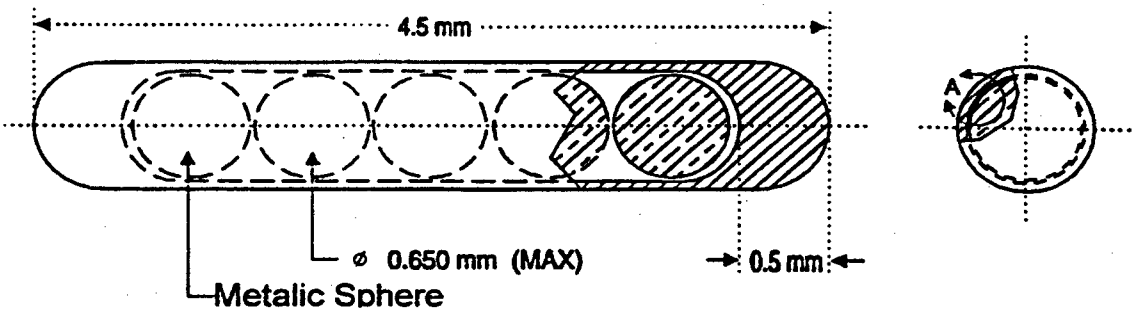
ATTACHMENT 1

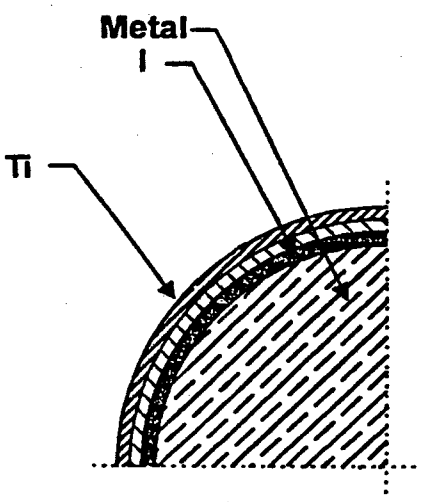
TITANIUM TUBE BEFORE WELD



TITANIUM TUBE AFTER WELD



SINGLE SPHERE CUT-AWAY



Details of a Sphere

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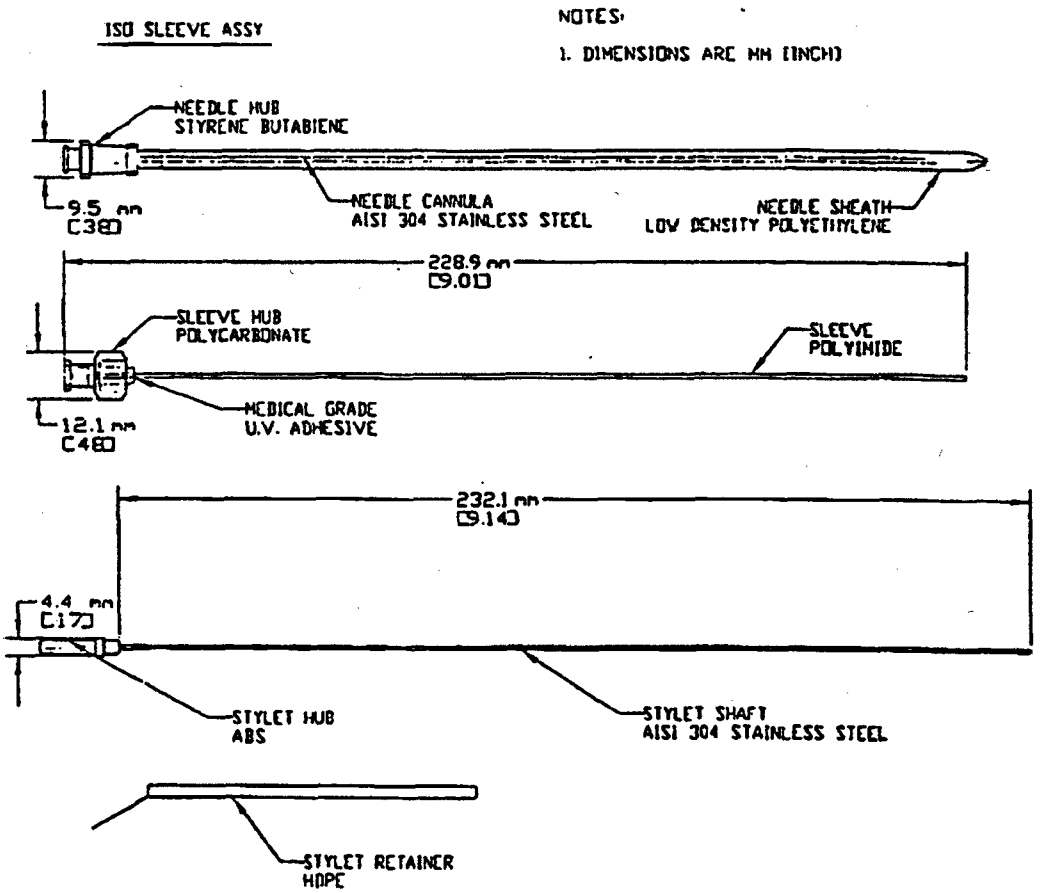
ATTACHMENT 2

ISO-SLEEVE ASSEMBLY



LABEL FOR ISO-SLEEVE ASSEMBLY