CADILLAC MERCY HOSPITAL

PARTNERING WITH MUNSON HEALTHCARE

PELLS IMAGING CENTER/RADIOLOGY FAX TRANSMISSION

MERCY HOSPITAL
400 HOBART ST,
CADILLAC, MI 49601
231-876-7260
FAX: 231-876-7855

TO: Jim Mullauer (NRC Health physicist) DATE: 8-16-07
1-630-829-9873
FAX # 1-708-361-9533 PAGES: 5 INCLUDING COVER SHEET

FROM: Mercy Hospital - Cadillac, MI

SUBJECT: 35.400 - materials

COMMENTS: Info you requested for License No. 21-10717-01. Manufacturers and model numbers and possession limits. Please let us know if you have any questions. You can call Laura Luna @ MPC.

Thank you,

Kelli Schuette, CNMT
Mercy Hospital - Cadillac
231-876-7264.

Fax to his house

231-876-7455 - Lake

******Facsimile Request******
Date: July 27, 2007

Message For: Laura Luna

Of: MPC

Facsimile Number: 734-662-9224

Number of Pages (including this form): 2

From
James R. Mullauer, M.H.S.
Health Physicist
United States Nuclear Regulatory Commission
2443 Warrenville Road
Lisle, IL 60532-4351

Current Telephone Number: (623) 214-5213 **Fax Number: (630) 829-9873**

E-mail: jrm1@nrc.gov

Dear Laura, this regards Mercy Hospital - Cadillac, License No. 21-10717-01 and their request to add Dr. Crosby to their license. That is no problem, however, their license authorizes 35,400 material and there is no possession limit or manufacturers names and model numbers of the sources they have. Please provide this information. Please call with any questions.

Thanks, Jim

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

THERAGENICS CORPORATION®

THERASEED® Pd-103 Device

(*) Model 200

Instructions for Use

(*) Possession Limit : 400 mCi

Theragenics Corporation®
5203 Bristol Industrial Way
Buford, GA 30518
877-444-7333

10-11-007/0106

7 PRODUCT SPECIFICATIONS

7.1 Testing/Standards Compliance

- The Sealed Source Device Registration Number for TheraSeed® is **GA 645S101S.**
- The ISO Sealed Source Classification for TheraSeed® is **ISO/99/C53211** according to ISO 2919:1999(E), *Radiation Protection – Sealed radioactive sources – General requirements and classification.*
- TheraSeed® is leak tested during manufacturing in accordance with internal procedures and ISO 9978:1992. *Radiation protection – Sealed radioactive sources – Leakage Test Methods*. The internal acceptance criterion for leak testing is less than 4 nCi.
- The steam sterilization method used to sterilize TheraSeed® packaged in vials or MICK® magazines was validated in accordance with AAMI/ANSI/ISO 11134:1993, *Sterilization of Healthcare products – Requirements for Validation and Routine Control – Industrial Moist Heat Sterilization.*
- TheraSeed® is classified as "MR Safe" in accordance with ASTM F 2052, *Standard Test Method For Measurement Of Magnetically Induced Displacement Force On Passive Devices In The Magnetic Resonance Environment.*

7.2 Source Limitations

It is possible through rough handling (abrasion, incision, etc.), high temperatures, or crushing that a TheraSeed® device could rupture and leak. If this happens, contact your facility Radiation Safety Officer. The area should be closed off immediately and personnel limited to avoid radioactive contamination. The damaged device should be placed in a sealed container and the area should be decontaminated.

7.3 Source Characteristics/Dosimetry

Pd-103 has a half-life of 16.991 days and decays by electron capture with the emission of characteristic x-rays of 20-23 keV and Auger electrons. To correct for physical decay of the Pd-103, decay factors at selected days after the reference date are shown in Table 2.

Refer to the AAPM Task Group No. 43 (TG43) update for a dosimetric characterization of TheraSeed® (Model 200).[1]

Table 2: Decay of Palladium-103

Day	Decay Factor	Day	Decay Factor	Day	Decay Factor	Day	Decay Factor	Day	Decay Factor
1	0.9600	8	0.7215	15	0.5423	22	0.4076	29	0.3063
2	0.9216	9	0.6927	16	0.5206	23	0.3913	30	0.2941
3	0.8848	10	0.6650	17	0.4998	24	0.3757	31	0.2823
4	0.8494	11	0.6384	18	0.4798	25	0.3606	32	0.2711
5	0.8155	12	0.6129	19	0.4607	26	0.3462	33	0.2602
6	0.7829	13	0.5884	20	0.4422	27	0.3324	34	0.2498
7	0.7516	14	0.5649	21	0.4246	28	0.3191		

BrachySource® Seed Implants

RADIONUCLIDE BRACHYTHERAPY SOURCE, Model #: STM1251

Manufactured by:

Bard Brachytherapy, Inc.

(*) Possession Limit = 400 mCi

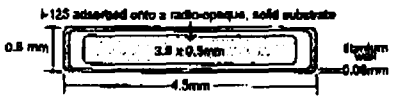
Caution:

Federal law restricts this device to sale by or on the order of a physician.

DESCRIPTION

Physical Characteristics

BrachySource® Seed Implants consist of a welded titanium capsule containing Iodine-125 adsorbed onto a nickel/copper coated, gold cored aluminum wire.



Iodine-125 has a half-life of 59.6 days[1] and decays by electron capture with the emission of characteristic photons and Auger electrons. The principal photon emissions are 27.4 and 31 keV x-rays and a 35.5 keV gamma. The titanium wall of the BrachySource® Seed Implants absorbs the electrons.

In-Vivo Characteristics

Clinical efficacy derives solely from the interaction of the emitted ionizing radiation from the BrachySource® Seed Implants with the tissue being treated. Titanium encapsulation provides good biocompatibility. Total photon transmission is approximately 59%[2] after accounting for attenuation by the titanium capsule and the radio-opaque solid substrate.

Dose distribution around BrachySource® Seed Implants is moderately anisotropic, as is common with other brachytherapy sources,[3,4,5] and should be accounted for in dose calculations.

INDICATIONS

BrachySource® Seed Implants are indicated for permanent interstitial treatment of selected localized tumors such as: head and neck, lung, pancreas, and early stage prostate. BrachySource® Seed Implants may be used in superficial, intra-abdominal and intra-thoracic locations. BrachySource® Seed Implants are indicated to treat residual tumors following completion of a course of external radiation therapy and for recurrent tumors.

CONTRAINDICATIONS

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g. ulcerated) is not recommended with BrachySource® Seed Implants due to the potential of brachytherapy source migration.

WARNINGS AND PRECAUTIONS

Warning: BrachySource® Seed Implants are supplied non-sterile and must be sterilized prior to use.

Caution: Do not sterilize BrachySource® Seed Implants in tubing or containers unable to withstand the conditions of sterilization, as it may prevent recovery.

BrachySource® Seed Implants are supplied non-sterile. Sterilization must be performed prior to implant using a qualified sterilization process such as steam sterilization or ethylene oxide sterilization. Glutaraldehyde based cold sterilization solutions have been reported to be unsuitable due to adherent films which form around the brachytherapy sources. BrachySource® Seed Implants should be sterilized in an adequately shielded container with an opening sufficient for sterilant penetration.

Warning: BrachySource® Seed Implants contain radioactive materials.

BrachySource® Seed Implants, like all radioactive materials, must be handled with care. Appropriate safety measures should be used to minimize exposure to clinical personnel. Personnel monitoring is required. Typically a film badge or TLD dosimeter worn on the body and a ring badge(s) is adequate. Care should be taken to minimize radiation exposure to patients and other individuals consistent with proper therapeutic management. During the implantation procedure, all practical steps should be employed to maintain radioactive exposure as low as reasonably achievable. In circumstances such as surgery when protective barriers are not practical, operators must rely upon proper use of applicators, distance and speed to minimize radiation exposure.[7,8,9,10]

Warning: Never implant visibly damaged BrachySource® Seed Implants.

BrachySource® Seed Implants should never be handled roughly or forced into any implant device or needle. Such force may damage the wall of the brachytherapy source, potentially causing release of I-125 into the environment or tissues surrounding an implanted brachytherapy source. BrachySource® Seed Implants that have been visibly damaged in any way should be sealed in a container and the area monitored for potential I-125 contamination.

Accidental Damage:

BrachySource® Seed Implants are supplied with the radioactive I-125 hermetically sealed inside a titanium capsule. BrachySource® Seed Implants are leak checked prior to shipment per ISO Technical Report 4826, Sealed Radioactive Sources – Leak Test Methods. BrachySource® Seed Implants have high structural integrity, though rough handling or accidents may crush or rupture the BrachySource® Seed Implants. In the event of such damage, the area containing the damaged BrachySource® Seed Implants should be closed off and personnel movement should be controlled until the personnel and affected area can be monitored for evidence of I-125 contamination. Such monitoring should be performed in accordance with standard practice. If necessary, the affected area and/or personnel should be decontaminated per standard practice under the supervision of a qualified health physicist.

Radiation Protection:

BrachySource® Seed Implants are shipped non-sterile in a shielded shipping container designed to attenuate >99.9% of the photons from I-125. Following removal from the shipping container, store BrachySource® Seed Implants behind appropriate shielding until their use. The half-value thickness of lead for I-125 is 0.025mm. Thus, a 0.25mm lead sheet will provide >99.9 % reduction in exposure.

Restrictions on Use:

BrachySource® Seed Implants should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclide brachytherapy sources and whose experience and training has been approved by the appropriate government authorities authorized to license the use of radioactive materials. BrachySource® Seed Implants should be used in those facilities that have been approved by the appropriate government authorities authorized to license the use of radioactive materials.

Tamper Resistance:

BrachySource® Seed Implants are shipped within a tamper evident shielded shipping container.

ADVERSE REACTIONS

BrachySource® Seed Implants achieve their therapeutic effect through the delivery of radiation to target tissues. Any adverse event associated with tissue radiation damage theoretically may be associated with the use of BrachySource® Seed Implants.

Following prostate implant of I-125 brachytherapy sources, some cases of impotence, urinary incontinence and urethral strictures have been reported. The frequency of these adverse reactions shows significant correlation to mitigating factors such as the age of the patient and the performance of a trans-urethral resection of the prostate prior to or after implantation.[11] Proctitis, transient dysuria and increased urinary frequency have also been reported.

LICENSING

The Illinois Emergency Management Agency (IEMA), Division of Nuclear Safety has approved BrachySource® Seed Implants for distribution to persons pursuant to 32Ill. Adm. Code, Sec. 330.260(a) and 32Ill. Adm. Code Sec. 335.7010, or under equivalent licenses of the NRC, an Agreement State or a Licensing State, and [outside the United States] to persons authorized by the appropriate authority.

Federal law restricts this device to sale by or on the order of a physician.