**BARD® BRACHYSOURCE® I-125 Seed Implants, Non-Sterile**

**RADIONUCLIDE BRACHYTHERAPY SOURCE, Model #: STM1251**

**Manufacturer:**
Bard Brachytherapy, Inc.
Carol Stream, IL 60188 USA
www.bardmedical.com
800-977-6733

PK0304819 07/2016

**Single Use**

Do not use if package is damaged.

**Rx Only**

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

**Caution: Radioactive materials**

Iodine-125

**MR Conditional**

**Serial Number**

**Information for Use**

**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 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% 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, 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 steriliton 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.

**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:

BRACHY SOURCE® Seed Implants are supplied with the radioactive I-125 hermetically sealed inside a titanium capsule. BRACHY SOURCE® Seed Implants are leak checked prior to shipment per ISO 9978, Radiation Protection – Sealed Radioactive Sources – Leakage Test Methods. BRACHY SOURCE® Seed Implants have high structural integrity, though rough handling or accidents may crush or rupture the BRACHY SOURCE® Seed Implants. In the event of such damage, the area containing the damaged BRACHY SOURCE® 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:

BRACHY SOURCE® 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 BRACHY SOURCE® 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:

BRACHY SOURCE® 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. BRACHY SOURCE® 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:

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

ADVERSE REACTIONS

BRACHY SOURCE® 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 BRACHY SOURCE® 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. Proctitis, transient dysuria and increased urinary frequency have also been reported.

LICENSED

The Illinois Emergency Management Agency (IEMA), Division of Nuclear Safety has approved BRACHY SOURCE® Seed Implants for distribution to persons pursuant to 32Ill. Adm. Code Sec. 330.200(a) and 32Ill. Adm. Code Sec. 335.7010, or under equivalent licenses of the NRC, an Agreement State and [outside the United States] to persons authorized by the appropriate authority.

BIOCOMPATIBILITY

BRACHY SOURCE® Seed Implants are hermetically sealed in a welded titanium capsule consisting of ASTM F67, Grade 2 unalloyed titanium, providing exceptional tissue biocompatibility. The danger of adverse tissue reactions is not significant.

LEAK TESTING

BRACHY SOURCE® Seed Implants have passed a leak test per ISO 9978, Radiation Protection – Sealed Radioactive Sources – Leakage Test Methods, showing <0.005µCi of removable I-125, as required by 32Ill. Adm. Code Sec. 340.410.

ADMINISTRATION AND DOSAGE

Established practice should be followed for the calculation of the total activity to be implanted, the evaluation of the radiation dose distribution and the proper placement of the BRACHY SOURCE® Seed Implants within the tissue. The tumor volume and the previous radiation history of the tumor site should be considered for the total activity calculation for any given treatment. The anisotropy should be considered in dose calculations for treatment planning since dose distribution around each individual BRACHY SOURCE® Seed Implant is not isotropic, as with other I-125 brachytherapy sources.

I-125 has a 59.6 day half life. Decay corrections must be made to properly calculate the activity of the BRACHY SOURCE® Seed Implants from the labeled reference date to the day they are implanted.

To correct for the physical decay of iodine-125, calculate the decay factors at selected days before and after the assay date as shown in the table below:

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<th>Days</th>
<th>Factor</th>
<th>Days</th>
<th>Factor</th>
<th>Days</th>
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INSTRUCTIONS FOR USE

BRACHY SOURCE® Seed Implants are supplied non-sterile. BRACHY SOURCE® Seed Implants must be sterilized prior to use. During the treatment procedure, the patient must be appropriately anesthetized. A qualified practitioner may place the BRACHY SOURCE® Seed Implants throughout the tumor volume according to a treatment plan for geometric arrangement. BRACHY SOURCE® Seed Implants have been designed to be compatible with commercially available brachytherapy applicators and needles.

PATIENT INFORMATION

BRACHY SOURCE® Seed Implants are radioactive. Prior to performing an implant, patients should be informed about radiation safety procedures and the expected time during which such precautions should be taken. Examples of precautionary guidelines have been established by the NCRP. 34

ACCOUNTABILITY AND DISPOSAL

I-125 is an accountable radioactive material. BRACHY SOURCE® Seed Implants should be strictly controlled and stored in a locked safe. If any radioactive material cannot be accounted for, the loss must be reported to the federal or state licensing agency.

Records of receipt, storage and disposal of BRACHY SOURCE® Seed Implants must be maintained in accordance with requirements of government regulatory agencies. When disposal is indicated, BRACHY SOURCE® Seed Implants should be transferred to an authorized radioactive waste disposal agency. BRACHY SOURCE® Seed Implants should never be disposed of in normal waste.

Bard Brachytherapy, Inc. provides BRACHY SOURCE® Seed Implants disposal service. Customers wishing to dispose of BRACHY SOURCE® Seed Implants in this manner must contact Bard Brachytherapy Customer Service, 800-977-8733. Bard Brachytherapy, Inc. will provide you with the instructions, forms and shipping containers required for shipment to Bard Brachytherapy, Inc.

MRI INFORMATION

The BRACHY SOURCE® Model STM1251 I-125 brachytherapy seed was determined to be MR-Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428.

Non-clinical testing demonstrated that the BRACHY SOURCE® Model STM1251 I-125 brachytherapy seed is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

STATIC MAGNETIC FIELD

-Static magnetic field of 3-Tesla or less
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less
MRI-RELATED HEATING

In non-clinical testing, the BrachySource® Model STM1251 I-125 brachytherapy seed produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +0.5°C

Therefore, the MRI-related heating experiments for the BrachySource® Model STM1251 I-125 brachytherapy seed at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 3.0-W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +0.5°C.

ARTIFACT INFORMATION

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the BrachySource® Model STM1251 I-125 brachytherapy seed. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

REFERENCES

2. Data on file with Bard Brachytherapy, Inc.

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