Information for Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Do not resterilize. Do not use if package is damaged. Single use. Sterilized using irradiation.

Caution: Radioactive materials Iodine-125. Caution: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

**BARD® BRACHYSOURCE® I-125 Implants with SOURCECAP™ Bioabsorbable Caps**

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

**DESCRIPTION**

**Presentation**

**BRACHYSOURCE®** Seed Implants with SourceCaps are **BRACHYSOURCE®** Seed Implants fitted on each end with **SOURCECAP™** Bioabsorbable Caps. These Seed / **SOURCECAP™** assemblies are loaded with CP Medical BioSpacer™ synthetic spacers in a requested patient-specific order within brachytherapy implant needles. The **SourceCapTM** assemblies may also be loaded into custom Mick® cartridges (1-15 assemblies per cartridge) and are designed for use with the Mick® 200-TP and 200-TPV Applicators and with applicator implant needles supplied for use by Bard.

**SOURCECAP™** caps are synthetic bioabsorbable monofilament components that are designed to be assembled onto each end of individual brachytherapy seeds. They are composed of 70% L-lactide and 30% D,L-lactide copolymer. The resulting brachytherapy seed / **SOURCECAP™** assembly is approximately 0.9mm in diameter and with a length of 5.0mm.

The CP Medical BioSpacer™ synthetic spacers are synthetic, absorbable monofilament seeding spacers comprised of a blend of glycolide and L-lactide copolymer with a monomer residue (lactic acid). The spacer is approximately 5.0mm in length and 0.78mm in diameter.

Per the customer’s request, the order may also contain calibrated **BRACHYSOURCE®** Implants in a separate screw-cap vial, loose **BRACHYSOURCE®** Implants in a separate screw-cap vial, and/or individual packets of BioSpacer™ synthetic spacers. All components are provided sterile.

**Physical Characteristics**

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

- **I-125** absorbed onto a radio-opaque, solid substrate

![I-125 Assembly](image)

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®** Implants absorbs the electrons.

**SOURCECAP™** Bioabsorbable Caps are assembled on the ends of brachytherapy seeds to provide seed / **SOURCECAP™** assemblies:

![5.0mm SourceCap™ Assembly](image)

**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.

The BioSpacer™ seeding spacer elicits a minimal acute inflammatory reaction in tissues, which is followed by the gradual encapsulation of the spacer by fibrous connective tissue. Absorption of the synthetic bioabsorbable BioSpacer™ seeding spacers occurs progressively and is essentially complete after 56 to 70 days.

As body fluids initially come into contact with the **SOURCECAP™**, they chemically react with the polymer to break the polymer chains through hydrolysis. The material is then metabolized and excreted via the renal system.

**INDICATIONS**

**BRACHYSOURCE®** Seed Implants with **SOURCECAP™** Bioabsorbable Caps are indicated for permanent interstitial treatment of selected localized tumors such as: head and neck, lung, pancreas, and early stage prostate.
LEAK TESTING

BrachySource® 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 32 Ill. Adm. Code, Sec. 340.410.

INSTRUCTIONS FOR USE

BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps Preloaded in Needles are supplied sterile. During the treatment procedure, the patient must be appropriately anesthetized. A qualified practitioner may place the BrachySource® Seed Implants with SourceCap™ bioabsorbable caps throughout the tumor volume according to a treatment plan for geometric arrangement.

1. The preloaded needles arrive ready for use: needles are preloaded, presterilized and preassayed.
2. An autoradiograph image of the loaded needles is provided with each order for visual verification of the loading pattern.
3. The tray containing the preloaded needles should be opened using sterile technique.
4. The needle assemblies should be removed from the needle card, and the stylet retained removed by grasping the tab and gently pulling.
5. Prior to performing the procedure, verify that the loaded needle components have not prematurely dislodged.

BrachySource® Seed Implants in a separate screw-cap vial, loose BrachySource® Seed Implants in a separate screw-cap vial and/or individual packets of synthetic spacers. All components are provided sterile.

PATIENT INFORMATION

BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps 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 by the patient, patient’s family and healthcare professionals. Examples of precautionary guidelines have been established by the NCRP.12,23

ADMINISTRATION AND DOSAGE

Established practice12,16,17,18 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 BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps 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 BrachySource® Seed Implant with SourceCap™ Bioabsorbable Caps is not isotropic, as with other I-125 brachytherapy sources.3,4,5,13,18

I-125 has a 59.6 day half life. Decay corrections must be made to properly calculate the activity of the BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps from the labeled reference date to the day they are implanted. To correct for the physical decay of iodine-125, the decay factors at selected days before and after the assay date are shown in the table below:

<table>
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<th>Days</th>
<th>Factor</th>
<th>Days</th>
<th>Factor</th>
<th>Days</th>
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Data on file at Bard Brachytherapy, Inc.
I-125 is an accountable radioactive material. BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps 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 appropriate licensing agency.

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

Bard Brachytherapy, Inc. provides BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps disposal service. Customers wishing to dispose of BrachySource® Seed Implants with SourceCap™ Bioabsorbable Caps in this manner must contact Bard Brachytherapy Customer Service, 800-977-6733. Bard Brachytherapy, Inc. will provide you with the instructions, forms and shipping containers required for shipment to Bard Brachytherapy, Inc.

MRI INFORMATION

The BrachySource® 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 BrachySource® 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**

- Maximum 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**

MRI 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.