

BARD® BRACHYSOURCE® 125 Implants with SOURCECAP™ Bioabsorbable Caps

RADIONUCLIDE BRACHYTHERAPY SOURCE, Model #: STM1251

Information for Use



Single use



Caution, consult
accompanying
documents.



Do not use if
package is
damaged.



Do not
resterilize

Rx only

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



Sterilized by radiation



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.



MR Conditional



Manufacturer:

Bard Brachytherapy, Inc.
Carol Stream, IL 60188 USA

Information for Use

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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 Seed/SOURCECAP™ 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.

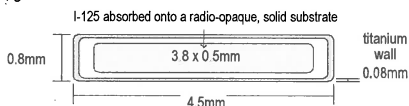
SOURCECAP™ caps are synthetic bioabsorbable monofilament components that are designed to be assembled onto each end of individual brachytherapy seeds. They are composed of 70% L-lactide and 30% D,L-lactide copolymer. The resulting brachytherapy seed / SOURCECAP™ assembly is approximately 0.9mm in diameter 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® Seed Implants in a separate screw-cap vial, loose BRACHYSOURCE® Seed Implants in a separate screw-cap vial, and/or individual packets of Biospacer™ synthetic spacers. All components are provided sterile.

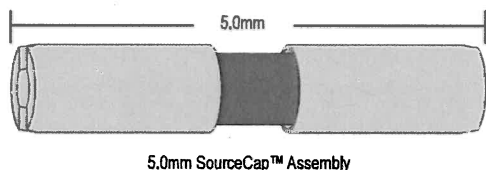
Physical Characteristics

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



Iodine-125 has a half-life of 59.6 days¹ 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.

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



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.

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. 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. The BioSpacer™ Seeding spacer is for use in seed approximation in brachytherapy procedures.

CONTRAINDICATIONS

As with other brachytherapy sources, treatment of tumors in generally poor condition [e.g. ulcerated] is not recommended with BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps due to the potential of brachytherapy source migration.

The BioSpacer™ seeding spacer, being bioabsorbable, should not be used where extended approximation of tissue is required. SOURCECAP™ Bioabsorbable Caps being bioabsorbable, should not be used where permanent spacing is required.

WARNINGS AND PRECAUTIONS

Warning: BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps contain radioactive materials.

BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps, 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.^{6,7,8,9} Any manipulation of the seeds or the needles should be performed behind shielding of adequate thickness. The seeds should be handled with forceps only, and with as much distance as practical between the seed and the operator. Initiate radiation surveys on all components upon completion of the seed implant.

Warning: Never implant visibly damaged BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps.

BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps should never be handled roughly or forced into any implant device, magazine or needle. Such force may damage the wall of the brachytherapy source, potentially causing release of I-125 into the tissues surrounding an implanted brachytherapy source or into the environment. 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.

Warning: SOURCECAP™ Bioabsorbable Caps and BioSpacer™ Seeding Spacer

As with any foreign body, prolonged contact of this or any other synthetic absorbable material with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Do not store the seed / SOURCECAP™ assemblies or BioSpacer™ Seeding Spacer at temperatures above 40° C.

The seed / SOURCECAP™ assemblies are 5.0mm long and are designed to provide accurate 1cm center-to-center spacing when used with 5.0mm BioSpacer™ Seeding Spacers. Use of spacers of other lengths (e.g. 5.5mm) will result in atypical spacing.

Warning: Mick® Cartridges

Do not handle Mick® cartridges by the spring loaded plunger. Do not exceed the maximum loading capacity per cartridges (15 seeds). Do not overtighten the round Mick® cartridges head. Do not let seeds drop into cartridges groove. Do not use force on seeds or cartridges. Do not force cartridges into applicator, and do not forcibly remove cartridges from applicator.

Caution: Biohazard

After use, the BRACHYSOURCE® seed implants, SOURCECAP™ Bioabsorbable Caps, BioSpacer™ Seeding Spacers, needles, Mick® cartridges, and accessories are potential biohazards. Handle and dispose of in accordance with acceptable medical practice and with applicable laws and regulations. Contact Bard Brachytherapy Customer Service, 800-977-6733, to receive instruction on how to dispose of radioactive seeds.

Information for Use

Caution: 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 9978, 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. If contamination is detected immediately segregate the contaminated articles or personnel and notify the Radiation Safety Officer. For contaminated personnel wash the skin with mild basic soap and water. If necessary the affected area and/or personnel should be further decontaminated per standard practice under the supervision of the Radiation Safety Officer

Caution: Radiation Protection:

BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps Preloaded in Needles or Mick® cartridges are shipped 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 with SOURCECAP™ Bioabsorbable Caps 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.

Caution: Restrictions on Use:

BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps and accessories 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 with SOURCECAP™ Bioabsorbable Caps should be used in those facilities that have been approved by the appropriate government authorities authorized to license the use of radioactive materials. Contact Bard Brachytherapy Customer Service, 800-977-6733, to receive instruction on how to dispose of excess seeds when necessary. See Accountability and Disposal section below.

Using the needle stylet with excessive force to manipulate lodged seeds in needles, cartridges, or applicators may damage the seed and result in patient or healthcare provider injury.

Needles are not intended to penetrate bone. If resistance is encountered, verify needle position. Do not push into bone; this may cause needle to bend or break. Replace needle if cannula or point is damaged. Check the device for completeness upon removal.

ADVERSE REACTIONS

This is a single use device. Do not sterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure and/or lead to injury, illness, or death of the patient.

BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps achieve their therapeutic effect through the delivery of radiation to target tissues. Any adverse event associated with tissue radiation damage may theoretically be associated with the use of BRACHYSOURCE® Seed Implants. Tissues which may experience unintended radiation damage include bladder, rectum, seminal vesicles, vasculature, lymphatic and nervous system.

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 reported¹⁴.

Adverse side effects associated with the use of the SOURCECAP™ Bioabsorbable Caps and BioSpacer™ Seeding Spacer include: minimal acute inflammatory tissue reaction, calculus formation in urinary and biliary tracts in the event of prolonged contact with salt solutions such as urine and bile, and transitory local irritation.

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.

BIOCOMPATIBILITY

BRACHYSOURCE® 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

BRACHYSOURCE® Seed Implants have passed a leak test per ISO 9978, Sealed Radioactive Sources – Leak Check Methods, showing <0.005µCi of removable I-125, as required by 32Ill. 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 retainer 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 with SOURCECAP™ Bioabsorbable Caps in Mick® Cartridges 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. BRACHYSOURCE® Seed Implants with SOURCECAP™ Bioabsorbable Caps in Cartridges have been designed to be compatible with Mick® brachytherapy applicators and needles. Per the customer's request, the order may also contain calibrated 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.^{13,20}

ADMINISTRATION AND DOSAGE

Established practice^{11,12,16,17,19} 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.^{3,4,5,15,18}

I-125 has a 59.6 day half life¹. 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 below²:

Days	Factor	Days	Factor	Days	Factor	Days	Factor
-7	1.085	10	0.890	27	0.731	44	0.599
-6	1.072	11	0.880	28	0.722	45	0.593
-5	1.060	12	0.870	29	0.714	46	0.586
-4	1.048	13	0.860	30	0.705	47	0.579
-3	1.036	14	0.850	31	0.697	48	0.572
-2	1.024	15	0.840	32	0.689	49	0.566
-1	1.012	16	0.830	33	0.681	50	0.559
0	1.000	17	0.821	34	0.673	51	0.553
1	0.988	18	0.811	35	0.666	52	0.546
2	0.977	19	0.802	36	0.658	53	0.540
3	0.966	20	0.792	37	0.650	54	0.534
4	0.955	21	0.783	38	0.643	55	0.527
5	0.944	22	0.774	39	0.635	56	0.521
6	0.933	23	0.765	40	0.628	57	0.515
7	0.922	24	0.756	41	0.621	58	0.509
8	0.911	25	0.748	42	0.614	59	0.504
9	0.901	26	0.739	43	0.606	60	0.498

Data on file at Bard Brachytherapy, Inc.

ACCOUNTABILITY AND DISPOSAL

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 significant 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, 2008.

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

- 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.

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