

BARD® BRACHYSOURCE® I-125 Implants Preloaded in Needles

RADIONUCLIDE BRACHYTHERAPY SOURCE, Model #: STM1251



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

PK0319934 11/2018



Single Use



Caution



Do not use if package is damaged.



Do Not Re-sterilize



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



Sterilized using irradiation



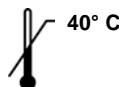
Caution: Radioactive materials
Iodine-125



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.



MR Conditional



Upper Limit of Temperature



Use By



Serial Number



Reference Number

DESCRIPTION

Presentation

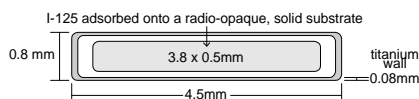
BRACHYSOURCE® Seed Implants Preloaded in Needles are BRACHYSOURCE® Seed Implants loaded with BARD® SOURCELINK™ Connectors synthetic absorbable seeding spacer links or with SOURCELINK™ Spacers synthetic spacers in a requested patient-specific order within brachytherapy implant needles.

SOURCELINK™ Connectors are synthetic absorbable monofilament seeding spacers that are designed to be assembled with BRACHYSOURCE® seeds into connected trains of variable lengths and with seed-to-seed spacing as predetermined by the physician. SOURCELINK™ Spacers are synthetic absorbable monofilament spacers that are placed between seeds to provide non-connected seed-to-seed spacing as predetermined by the physician. Both the SOURCELINK™ Connectors and SOURCELINK™ Spacers are composed of 70% L-lactide and 30% D,L-lactide copolymer. SOURCELINK™ Connectors are approximately 0.9mm in diameter and come in various sizes to provide accurate spacing of seeds in 0.5cm center-to-center increments. SOURCELINK™ Spacers are approximately 0.8mm in diameter and are available in lengths of 5.0mm and 5.5mm.

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 SOURCELINK™ Connectors or synthetic spacers (see individual IFUs for further information regarding SOURCELINK™ Connectors and synthetic seeding spacers). All components are provided sterile.

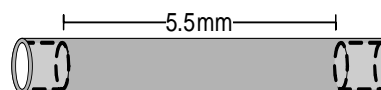
Physical Characteristics

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

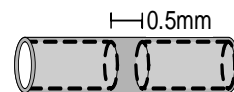


Iodine-125 has a half-life of 59.6 days¹ and decays by electron capture with the emission of characteristic photons and Auger electrons. The principal photon emissions are 27.4 and 31 keV x-rays and a 35.5 keV gamma. The titanium wall of the BRACHYSOURCE® Seed Implants absorbs the electrons.

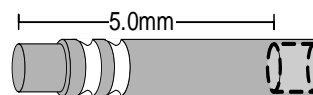
SOURCELINK™ Connectors consists of three distinct components, designed to give seed spacing in 0.5cm increments. The components are:



5.5mm Standard SOURCELINK® Connector



0.5mm Seed-to-Seed SOURCELINK® Connector



5.0mm Extension SOURCELINK® Connector

Information for Use

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.

As body fluids initially come into contact with the SOURCELINK™ Connectors or SOURCELINK™ Spacers, they chemically react with the polymer to break the polymer chains through hydrolysis. The material is then metabolized.

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. SOURCELINK™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures. SOURCELINK™ Spacers are indicated for non-connected seed spacing 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 due to the potential of brachytherapy source migration.

SOURCELINK™ Connectors and SOURCELINK™ Spacers, being absorbable, should not be used where permanent spacing or linking is required.

WARNINGS AND PRECAUTIONS

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} 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.

BRACHYSOURCE® Seed Implants 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 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.

Warning: SOURCELINK™ Connectors and SOURCELINK™ Spacers

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 SOURCELINK™ Connectors or SOURCELINK™ Spacers at temperatures above 40°C.

Caution: Biohazard

After use, the BRACHYSOURCE® seed implants, SOURCELINK™ Connectors, SOURCELINK™ Spacers, needles and accessories are potential biohazards. Handle and dispose of in accordance with acceptable medical practice and with applicable laws and regulations.

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, *Radiation Protection – Sealed Radioactive Sources – Leakage 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 Preloaded in Needles 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 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 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 should be used in those facilities that have been approved by the appropriate government authorities authorized to license the use of radioactive materials.

Using the stylet with excessive force to manipulate lodged seeds may damage the seed and result in patient or health care 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 resterilize 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 patient.

BRACHYSOURCE® Seed Implants 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 the trans-urethral resection of the prostate prior to or after implantation.¹⁰ Proctitis, transient dysuria and increased urinary frequency have also been reported.

Adverse side effects associated with the use of the SOURCELINK™ Connectors and SOURCELINK™ Spacers 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 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, *Radiation Protection – Sealed Radioactive Sources – Leakage Test Methods*, showing <0.005µCi of removable I-125, as required by 32Ill. Adm. Code, Sec. 340.410.

INSTRUCTIONS FOR USE

BRACHYSOURCE® Seed Implants 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 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.

Information for Use

- The needle assemblies should be removed from the needle card, and the stylet retainer removed by grasping the tab and gently pulling.
- Prior to performing the procedure, verify that the loaded needle components have not prematurely dislodged from the needle.

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 SOURCELINK™ Connectors or synthetic spacers (see individual IFUs for further information regarding SOURCELINK™ Connectors and synthetic seeding spacer). All components are provided sterile.

PATIENT INFORMATION

BRACHYSOURCE® 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.¹⁴

ADMINISTRATION AND DOSAGE

Established practice^{12,13} 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 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 is not isotropic, as with other I-125 brachytherapy sources.^{3,4,5}

I-125 has a 59.6 day half life¹. Decay corrections must be made to properly calculate the activity of the BRACHYSOURCE® Seed Implants 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:

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	0.820	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

ACCOUNTABILITY AND DISPOSAL

I-125 is an accountable radioactive material. BRACHYSOURCE® 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 appropriate licensing agency.

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

Bard Brachytherapy, Inc. provides BRACHYSOURCE® Seed Implants disposal service. Customers wishing to dispose of BRACHYSOURCE® Seed Implants 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

- 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

- [A Handbook of Radioactivity Measurement Procedures](#), Second Edition, NCRP Report No. 58, NCRP Publications, Bethesda, MD, 1985.
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- Ling, C.C., Schell, M.C. and Yorke, E.D., [Two Dimensional Dose Distribution of I-125 Seeds](#), *Med Phys* 12, Number 5:652-655, 1985.
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- [Specification of Gamma-Ray Brachytherapy Sources](#): NCRP Report No. 41, NCRP Publications, Bethesda, MD, 1974.
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- [Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10MeV](#): NCRP Report No. 49, NCRP Publications, Bethesda, MD, 1976.
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- Hilaris, B.S. (Hilaris, B.S. and Nori, D., ed.), [Brachytherapy Treatment Planning](#): *Brachytherapy Oncology Update*, pp. 5-10, Memorial Sloan-Kettering Cancer Center, New York, NY, 1984.
- Anderson, L.L., Kuan, H.M. and Ding, I.Y., [George III, F.W., ed.] [Clinical Dosimetry With I-125](#), *Modern Interstitial and Intraoperative Radiation Cancer Management*, pp. 9-15, MASSON Publishing USA, Inc., New York, NY, 1981.
- [Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides](#): NCRP Report No. 37, NCRP Publications, Bethesda, MD, 1970.



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