

# BARD® READYLINK™ Delivery System with BRACHYSOURCE® I-125 Implants RADIONUCLIDE BRACHYTHERAPY SOURCE, Model #: STM1251RL



**Manufacturer:**  
Bard Brachytherapy, Inc.  
Carol Stream, IL 60188 USA  
www.bardmedical.com  
800-977-6733  
PK0319935 07/2018



Single Use



Do not use if package is damaged.



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



Caution: Radioactive materials Iodine-125



Upper Limit of Temperature 40° C



Serial Number



Use By



Caution



Do Not Re-sterilize.



Sterilized using irradiation.



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



Reference Number

## DESCRIPTION

### Presentation

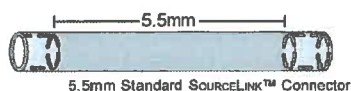
The BARD® READYLINK™ delivery system includes BRACHYSOURCE® Seed Implants pre-connected with BARD® SOURCELINK™ Connectors synthetic absorbable seeding spacer links in requested patient-specific order configurations.

SOURCELINK™ Connectors are synthetic absorbable monofilament seeding spacers that are designed to be assembled with BRACHYSOURCE® seeds into trains of variable lengths and with seed-to-seed spacing as predetermined by the physician. They 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.

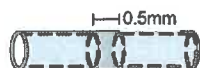
The READYLINK™ delivery system is provided per customer and/or patient specific instructions. The SOURCELINK™ connectors and seeds can be prepared in three distinct configurations: 1.) in standard spacing with 10 seeds and spacers connected in standard 1.0 cm seed to seed spacing; 2.) in variable spacing with 3, 4, or 5 seeds and spacers connected in standard 1.0 cm seed to seed spacing; and 3.) in prescription spacing with trains of seeds and spacers in connected trains no longer than 8.0 cm in length for each needle position on the treatment plan. In addition, the variable and standard spacing configurations allow for additional trains of seeds and sources pre-connected to customer defined configurations to allow for special loading patterns.

### Physical Characteristics

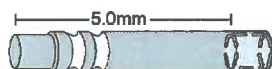
SOURCELINK™ Connectors consists of three distinct components, designed to give seed spacing in 0.5cm increments. The components are;



5.5mm Standard SOURCELINK™ Connector



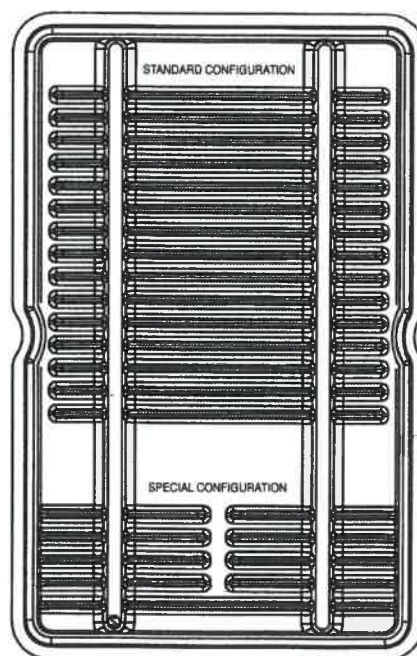
0.5mm Seed-to-Seed SOURCELINK™ Connector



5.0mm Extension SOURCELINK™ Connector

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

READYLINK™ System consists of three distinct delivery trays, designed to maintain structure of the pre-connected seed and spacer trains during shipping. The tray designs are:



### Standard Configuration tray

The Standard Configuration tray allows for up to 15 pre-connected trains of 10 seeds and SOURCELINK™ Connectors, up to 8 custom trains of seeds and SOURCELINK™ Connectors no longer than 5.0 cm in length, and 1 custom train no longer than 10.0 cm in length.

## Information for Use

### WARNINGS AND PRECAUTIONS

#### Warning: SOURCELINK™ Connectors

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.

Discard open unused SOURCELINK™ Connectors. Store unopened packages at room temperature. Do not store SOURCELINK™ Connectors at temperatures that exceed 40°C.

#### ADVERSE REACTIONS

Adverse side effects associated with the use of the SOURCELINK™ Connectors 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.

#### INSTRUCTIONS FOR USE

Please consult Seed Implant specific product inserts and labels for any indications, hazards, warnings, cautions and instructions for use. During the treatment procedure, the patient must be appropriately anesthetized. A qualified practitioner may place the Seed Implants throughout the tumor volume according to a treatment plan for geometric arrangement.

Per the customer's request, the order may also contain calibrated Seed Implants in a separate screw-cap vial, loose Seed Implants in a separate screw-cap vial (sterile or non-sterile) and/or individual packets of SOURCELINK™ Connectors or synthetic spacers (see individual IFUs for further information regarding BRACHYSOURCE® seeds, SOURCELINK™ Connectors and seeding spacers.) All non-seed components are provided sterile.

#### 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 Bar Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428.

Non-clinic 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 these 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

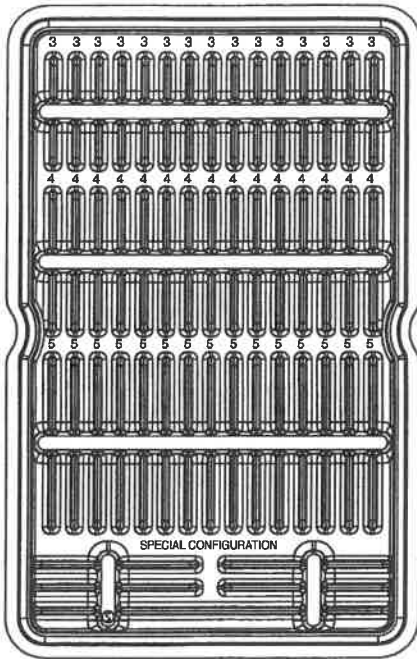
In non-clinical testing, the BRACHYSOURCE® Model STM1251 I-125 brachytherapy seed produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

*Highest temperature* +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 average 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.

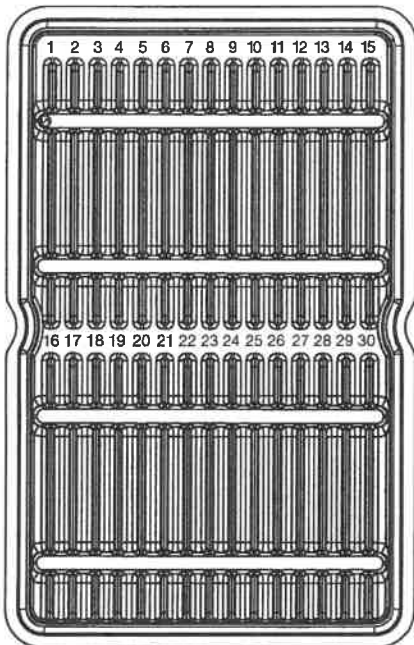
#### ARTIFACT INFORMATION

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.



#### Variable Configuration Tray

The Variable Configuration tray allows for up to 15 pre-connected trains of 3 seeds and SOURCELINK™ Connectors, up to 15 pre-connected trains of 4 seeds and SOURCELINK™ Connectors, up to 15 pre-connected trains of 5 seeds and SOURCELINK™ Connectors, up to 4 custom trains of seeds and SOURCELINK™ Connectors no longer than 5.0 cm in length, and 1 custom train no longer than 10.0 cm in length.



#### Prescription Configuration Tray


The Prescription Configuration tray allows for up to 30 pre-connected trains of seeds and SOURCELINK™ Connectors no longer than 8.0 cm in length.

#### INDICATIONS

SOURCELINK™ Connectors are indicated for use in seed spacing and linking in brachytherapy procedures.

#### CONTRAINDICATIONS

SOURCELINK™ Connectors that are absorbable, should not be used where permanent spacing or linking is required.

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US Patent No. 5,928,130 and 6,530,875. Patents Pending.

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