

# BARD® READYLINK™ Delivery System with Palladium-103 Implants

RADIONUCLIDE BRACHYTHERAPY SOURCE: TheraSeed® Model 200



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

**TheraSeed® Model 200 Palladium-103 Device**  
**Manufactured By:**  
**Theragenics Corporation**  
 Buford, GA 30518  
 (770) 271-0233

PK0319938 07/2018



**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 Palladium-103**



**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.**



**Upper Limit of Temperature**



**Reference Number**



**Serial Number**

## DESCRIPTION

### Presentation

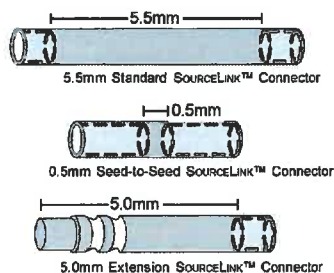
The BARD® READYLINK™ Delivery System with Palladium-103 Devices includes Palladium-103 Devices (seeds) pre-connected with BARD® SOURCELINK™ Connectors synthetic absorbable seeding spacer links in requested patient-specific order configurations.

SOURCELINK™ Connectors are synthetic absorbable monofilament seeding spacers that are designed to be assembled with Palladium-103 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 to 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

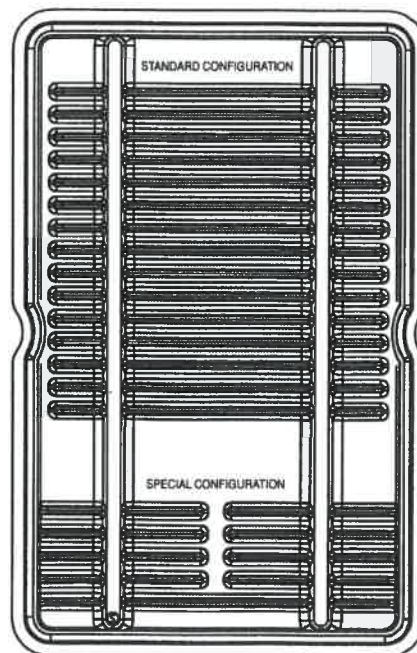
SOURCELINK™ Connectors consists of three distinct components, designed to give seed spacing in 0.5 cm increments. The components are;



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.

See manufacturer's Instructions for Use for the Palladium-103 Device and/or SOURCELINK™ Connectors for more information.

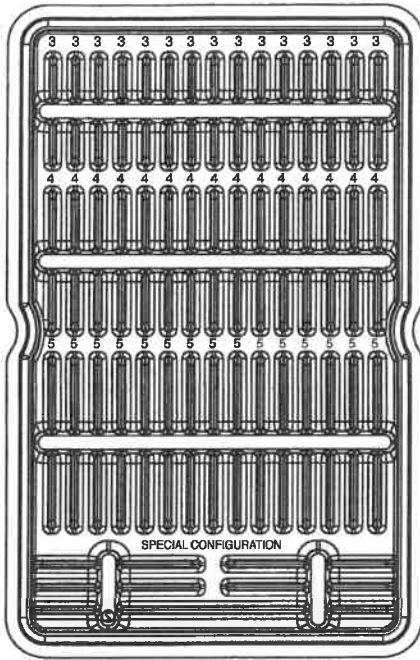
READYLINK™ System consists of three distinct delivery trays, designed to maintain structure of the pre-connected seed and spacer trains during shipping. The tray designs are:



Standard Configuration tray

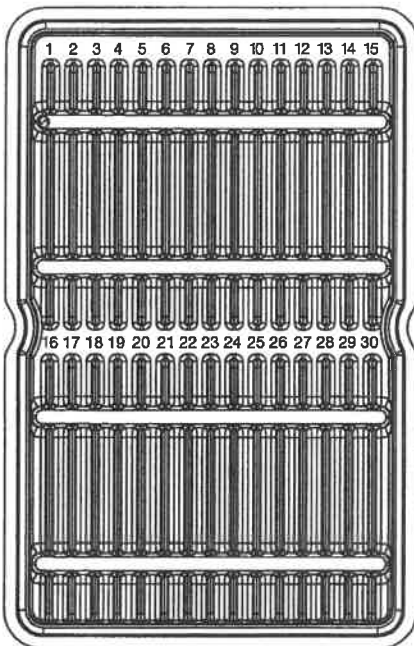
## Information for Use

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.



### 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. See manufacturer's Instructions for Use for the Palladium-103 Device and/or SOURCELINK™ Connectors for more information.

## CONTRAINDICATIONS

SOURCELINK™ Connectors that are absorbable, should not be used where permanent spacing or linking is required. See manufacturer's Instructions for Use for the Palladium-103 Device and/or SOURCELINK™ Connectors for more information.

## 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.

### Caution:

See manufacturer's Instructions for Use for the Palladium-103 Device and/or SOURCELINK™ Connectors for more information.


## 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. See manufacturer's Instructions for Use for the Palladium-103 Device and/or SOURCELINK™ Connectors for more information.

## INSTRUCTIONS FOR USE

Please consult the Palladium-103 seed 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 Palladium-103 seeds in a separate screw-cap vial, loose Palladium-103 seeds in a separate screw-cap vial, Palladium-103 seeds in Mick® cartridges and/or individual packets of SOURCELINK™ Connectors or synthetic spacers (See manufacturer's Instructions for Use for the Palladium-103 seed, Mick® applicator cartridge, and/or SOURCELINK™ Connectors and synthetic spacers for more information.) All components are provided sterile.

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