TheraSeed® Palladium-103 Devices Preloaded in Needles
RADIONUCLIDE BRACHYTHERAPY SOURCE: TheraSeed® Model 200

Sterile Presentation Prepared by: Bard Brachytherapy, Inc. Carol Stream, IL 60188 USA www.bardmedical.com 800-977-6733

PK0304828 07/2016

Single Use

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

Caution: Radioactive materials Palladium-103

Use By

Serial Number

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DESCRIPTION

Presentation
Palladium-103 Devices Preloaded in Needles are Palladium-103 Devices (seeds) loaded with Bard SOURCELink™ Connectors synthetic absorbable seeding spacer links or with CP Medical BioSpacer™ synthetic spacers in a requested patient-specific sequence within brachytherapy implant needles.

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 CP Medical BioSpacer™ synthetic spacers are synthetic, absorbable monofilament seeding spacers comprised of 90% glycolide and 10% L-lactide copolymer. The spacer is approximately 5.5mm in length and 0.78mm diameter.

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® applicator cartridge and/or individual packets of SOURCELink™ Connectors or BioSpacer™ synthetic spacers (See manufacturer’s Instructions for Use for the Palladium-103 seed, Mick® applicator cartridge, SOURCELink™ Connectors and/or BioSpacer™ seeding spacer for more information.) All components are provided sterile.

Physical Characteristics
See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELink™ Connectors and/or BioSpacer™ seeding spacer for more information.

IN-VIVO Characteristics
See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELink™ Connectors and/or BioSpacer™ seeding spacer for more information.

INDICATIONS
Needles are indicated for the delivery of brachytherapy seeds and spacers during implantation of radioactive seeds in selected localized prostate tumors. See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELink™ Connectors and/or BioSpacer™ seeding spacer for more information.

CONTRAINDICATIONS
See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELink™ Connectors and/or BioSpacer™ seeding spacer for more information.

WARNINGS AND PRECAUTIONS
Warning: Palladium-103 Seeds contain radioactive materials.

Palladium-103 seeds, 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. Any manipulation of the seeds or the needle system 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: SOURCELink™ Connectors 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.
Information for Use

Do not store the SOURCELINK™ Connectors or BioSpacer™ Synthetic Spacers at temperatures above 40°C.

Caution: Biohazard:
After use, the Palladium-103 seeds, 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:
When handling SOURCELINK™ Connectors and BioSpacer™ seeding spacers, care should be taken to avoid any damage to the material. Avoid crushing or crimping damage caused by the application of surgical instruments such as forceps or needle holders. Using the stylet with excessive force to manipulate lodged seeds may damage the seed. 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.

Caution: Restrictions on Use:
Palladium-103 seeds 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. Palladium-103 seeds should be used in those facilities that have been approved by the appropriate government authorities authorized to license the use of radioactive materials.

Caution:
See manufacturer's Instructions for Use for the Palladium-103 seed, SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for additional warnings and precautions.

ADVERSE REACTIONS
See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for more information.
Adverse side effects associated with the use of the SOURCELINK™ Connectors 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 Palladium-103 Devices Preloaded in Needles for distribution to persons pursuant to 32 Ill. Adm. Code, Sec. 330.260(a) and 32 Ill. 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. See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for more information.

BIOCOMPATIBILITY
See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for more information.

LEAK TESTING
See manufacturer’s Instructions for Use for the Palladium-103 seed.

INSTRUCTIONS FOR USE
Palladium-103 Devices Preloaded in Needles are supplied sterile. During the treatment procedure, the patient must be appropriately anesthetized. A qualified practitioner may place the Palladium-103 Devices throughout the tumor volume according to a treatment plan for geometric arrangement.
The preloaded needles arrive ready for use: needles are preloaded, prestereitized and preassayed. Prior to performing the procedure, verify that the loaded needle components have not prematurely dislodged into the needle sheath. The pouch containing the preloaded needles on insert cards should be opened using sterile technique. The needle assemblies should be removed from the insert card, and the stylet retainer removed by grasping the tab and gently pulling. An image of the treatment plan is provided with each order for visual verification of the loading pattern.
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 BioSpacer™ synthetic spacers (See manufacturer’s Instructions for Use for the Palladium-103 seed, Mick® applicator cartridge, SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for more information.) All components are provided sterile.

PATIENT INFORMATION
Palladium-103 seeds 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.

See manufacturer’s Instructions for Use for the Palladium-103 seed, SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for more information.

ADMINISTRATION AND DOSAGE
Established practice 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 Palladium-103 seeds 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. See the manufacturer’s Instructions for Use for the Palladium-103 seed and SOURCELINK™ Connectors and/or BioSpacer™ seeding spacer for more information.

ACCOUNTABILITY AND DISPOSAL
Palladium-103 is an accountable radioactive material. Brachytherapy seed implants containing Palladium-103 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 brachytherapy seed implants containing Palladium-103 must be maintained in accordance with requirements of the appropriate government regulatory agencies. When disposal is indicated, brachytherapy seed implants containing Palladium-103 should be transferred to an authorized radioactive waste disposal agency. Brachytherapy seed implants containing Palladium-103 should never be disposed of in normal waste.
Contact Bard Brachytherapy Customer Service, 800-977-6733 for assistance with questions regarding disposal of unused brachytherapy seed implants.

REFERENCES

Bard and SourceLink are trademarks and/or registered trademarks of C. R. Bard, Inc.
CP Medical and BioSpacer are trademarks of CP Medical Corporation.
Mick is a registered trademark of Mick RadioNuclear Instruments, Inc.
TheraSeed is a registered trademark of the Theragenics Corporation.

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