TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps

RADIONUCLIDE BRACHYTHERAPY SOURCE: TheraSeed Model 200

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 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.

BARD

Manufacturer:
Bard Brachytherapy, Inc.
Carol Stream, IL 60188 USA

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RADIONUCLIDE BRACHYTHERAPY SOURCE: TheraSeed® Model 200

DESCRIPTION

Presentation

TheraSeed® Palladium-103 Devices with SourceCaps are TheraSeed® Palladium-103 Devices 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.

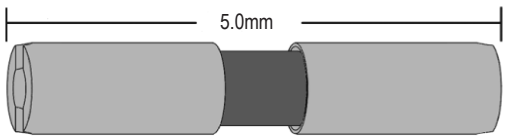
SourceCap™ Bioabsorbable Caps are synthetic bioabsorbable monofilament components that are designed to be assembled onto each end of individual brachytherapy seeds. They are composed of 70% L-lactide and 30% D,L-lactide copolymer. The resulting brachytherapy seed / SourceCap™ assembly is approximately 1.0mm 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 TheraSeed® Palladium-103 Devices in a separate screw-cap vial, loose TheraSeed® Palladium-103 Devices in a separate screw-cap vial, and/or individual packets of Biospacer™ synthetic spacers. All components are provided sterile.

Physical Characteristics

See manufacturer's Instructions for Use for the Palladium-103 seed for more information. The SourceCap™ Bioabsorbable Caps are assembled on the ends of brachytherapy seeds to provide seed / SourceCap™ assemblies:



5.0mm SourceCap™ Assembly

In-Vivo Characteristics

See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

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 absorbable BioSpacer™ seeding spacers occurs progressively and is essentially complete after 56 to 70 days.

As body fluids initially come into contact with the SourceCap™ Bioabsorbable Caps, 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

See manufacturer's Instructions for Use for the Palladium-103 seed. The BioSpacer™ Seeding spacer is for use in seed approximation in brachytherapy procedures.

CONTRAINDICATIONS

See manufacturer's Instructions for Use for the Palladium-103 seed. As with other brachytherapy sources, treatment of tumors in generally poor condition [e.g. ulcerated] is not recommended with TheraSeed® Palladium-103 Devices due to the potential of brachytherapy source migration. The BioSpacer™ seeding spacer, being absorbable, should not be used where extended approximation of tissue is required. SourceCap™ being absorbable, should not be used where permanent spacing is required.

WARNINGS AND PRECAUTIONS

Warning: TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps contain radioactive materials.

TheraSeed® Palladium-103 Devices 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.[1,2,3,4] 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 TheraSeed® Palladium-103 Devices.

TheraSeed® Palladium-103 Devices 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 Pd-103 into the tissues surrounding an implanted brachytherapy source or into the environment. TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps that have been visibly damaged in any way should be sealed in a container and the area monitored for potential Pd-103 contamination.

Warning: SourceCap™ 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 TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps, BioSpacer™ Seeding Spacers, Mick cartridges, needles 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.

Caution: Accidental Damage:

TheraSeed® Palladium-103 Devices are supplied with the radioactive Pd-103 hermetically sealed inside a titanium capsule. TheraSeed® Palladium-103 Devices are leak checked prior

to shipment per ISO 9978, Sealed Radioactive Sources – Leak Test Methods. TheraSeed® Palladium-103 Devices have high structural integrity, though rough handling or accidents may crush or rupture the TheraSeed® Palladium-103 Devices. In the event of such damage, the area containing the damaged TheraSeed® Palladium-103 Devices should be closed off and personnel movement should be controlled until the personnel and affected area can be monitored for evidence of Pd-103 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: Restrictions on Use:

TheraSeed® Palladium-103 Devices 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. TheraSeed® Palladium-103 Devices 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 or Mick® applicator stylet with excessive force to manipulate lodged seeds in needles, magazines 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.

Caution:

See manufacturer's Instructions for Use for the Palladium-103 seed for additional warnings and precautions.

ADVERSE REACTIONS

See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

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 the patient.

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 TheraSeed® Palladium-103 Devices 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. See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

BIOCOMPATIBILITY

See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

LEAK TESTING

See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

INSTRUCTIONS FOR USE

TheraSeed® Palladium-103 Devices 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 TheraSeed® Palladium-103 Devices 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.

TheraSeed® Palladium-103 Devices 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 TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps throughout the tumor volume according to a treatment plan for geometric arrangement. TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps in Mick® Cartridges have been designed to be compatible with Mick® brachytherapy applicators and needles. Per the customer's request, the order may also contain calibrated TheraSeed® Palladium-103 Devices in a separate screw-cap vial, loose TheraSeed® Palladium-103 Devices in a separate screw-cap via and/or individual packets of BioSpacers. All components are provided sterile.

PATIENT INFORMATION

TheraSeed® Palladium-103 Devices 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.[6,10]

See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

ADMINISTRATION AND DOSAGE

Established practice[5,7,8,9] 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 TheraSeed® Palladium-103 Devices 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. See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

ACCOUNTABILITY AND DISPOSAL

Palladium-103 is an accountable radioactive material. TheraSeed® Palladium-103 Devices 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 TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps must be maintained in accordance with requirements of government regulatory agencies. When disposal is indicated, TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps should be transferred to an authorized radioactive waste disposal agency. TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps should never be disposed of in normal waste.

Bard Brachytherapy, Inc. provides TheraSeed® Palladium-103 Devices with SourceCap™ Bioabsorbable Caps disposal service. Customers wishing to dispose of TheraSeed® Palladium-103 Devices 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

See manufacturer's Instructions for Use for the Palladium-103 seed for more information.

REFERENCES

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