

PROSPERA® Pd-103 BRACHYTHERAPY SOURCE

Model MED3633 Effective May 2002

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

DESCRIPTION

Each PROSPERA® Pd-103 Brachytherapy Source (Model MED3633) consists of a welded titanium capsule containing Pd-103 absorbed onto four resin beads with two inactive gold beads serving as x-ray markers identifying source location and orientation. The two markers are located at the center of the capsule. (see Fig. 1) PROSPERA® Pd-103 Sources are supplied non-sterile when shipped and must be sterilized prior to use.

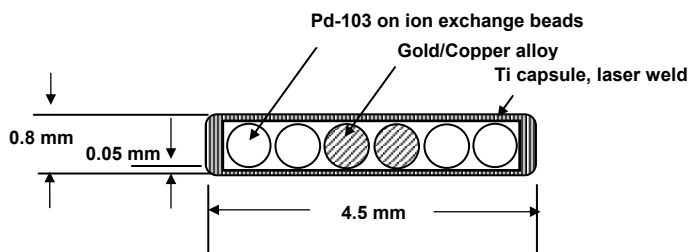


Fig 1. Schematic drawing of the MED3633 source. The two markers are located at the center. Dimensions shown are nominal.

Physical Characteristics

Pd-103 has a half-life of 16.99 days and decays by electron capture with the emission of characteristic x-rays at 20-23 keV and Auger electrons. Decay correction factors for activity calculations are provided in the "Palladium-103 Decay Chart".

In Vivo Characteristics

Clinical efficacy results from the interaction of the emitted ionizing radiation from PROSPERA® Pd-103 Brachytherapy Source with the tissue being treated. Titanium encapsulation provides good biocompatibility.

Total photon transmission, after accounting for attenuation resulting from the titanium capsule and the internal components, is approximately 55%.

Dose calculations should account for a moderate anisotropic dose distribution around each Pd-103 Source, as with other brachytherapy sources (see Fig 2). Appropriate parameters should be included in treatment plan.

CLINICAL INDICATIONS

PROSPERA® Pd-103 sources are indicated for treatment of selected localized tumors such as the following: head and neck; lung; pancreas; early stage prostate. They may be used in superficial, intraabdominal, or intrathoracic locations. They may also be used at completion of external beam radiation therapy and for recurrent tumors.

CONTRAINDICATIONS

As with other brachytherapy sources, it is not recommended that PROSPERA® Pd-103 sources be implanted in tissue sites whose structural instability (e.g. ulceration) is likely to lead to significant brachytherapy source migration.

WARNINGS AND PRECAUTIONS

WARNING: SOURCES ARE SUPPLIED NON-STERILE AND MUST BE STERILIZED PRIOR TO USE.

The brachytherapy sources may be sterilized by steam autoclaving or ethylene oxide. North American Scientific has validated the following steam sterilization cycles for seeds in the shipping container with the shipping container lid and vial cap removed.

Configuration	Standard Autoclave Cycle	Flash Autoclave Cycle
Loose seed in vial	121°C, 15 psi, 20 minutes	132°C, 30 psi, 3 minutes

For ethylene oxide sterilization, use a cycle that is within the range recommended by the sterilization unit manufacturer and which has been validated by the hospital.

Glutaraldehyde based cold sterilization has been reported to be unsuitable because of adherent films which form around the brachytherapy source.

CAUTION: DO NOT AUTOCLAVE THE PROSPERA® Pd-103 SOURCES IN LOW MELTING POINT PLASTIC TUBING OR CONTAINERS AS IT MAY PREVENT SOURCE RECOVERY.

Brachytherapy sources, like all radioactive materials, must be handled with care and appropriate safety measures should be used to minimize exposure to clinical personnel. Personal monitoring is required. Typically a film badge or TLD dosimeter worn on the body and a ring badge during source handling is adequate. Care should also 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 radiation exposure as low as reasonably achievable. In circumstances such as surgery when protective barriers are not practical, operators must rely upon proper use applicators, distance and speed to minimize radiation exposure.

WARNING: NEVER IMPLANT VISIBLY DAMAGED BRACHYTHERAPY SOURCES.

PROSPERA® Pd-103 Brachytherapy Sources should never be handled roughly or forced into any implant device or needle; such force may damage the wall of the source, potentially causing release of radioactive contents into the environment or into body fluids surrounding an implanted damaged source. Sources which have been visibly damaged in any way should be sealed immediately into a container and the area monitored for possible contamination.

Accidental damage: PROSPERA® Pd-103 Brachytherapy Source are supplied with the radioactive source material welded inside sealed titanium tubes to prevent any loss of radioactive material. All sources are checked for leakage prior to shipment. Although the MED3633 sources have high structural integrity, rough handling or accidents theoretically may crush or rupture the sealed sources. In the event of such an accident, the area of the source should be closed off and personnel movement should be controlled until the area and personnel can be monitored for evidence of any contamination in accordance with standard practice. If required, the area and personnel should be decontaminated according to established procedures, under the supervision of a qualified health physicist.

The Brachytherapy sources are shipped non-sterile in a shielded shipping container. The shielding is designed to attenuate > 99.9% of the photons from Pd-103. After sterilization, sources can be stored behind appropriate shielding until their use. Note that 0.25 mm thick layer of lead will reduce the 20-23 keV photon flux of Pd-103 by > 99%.

Brachytherapy sources should be used only by physicians who are qualified by training and experience in safe use and handling of such materials and whose experience and training has been approved by the appropriate governmental authorities authorized to license the use of radioactive materials.

ADVERSE REACTIONS

Since the brachytherapy source achieves its therapeutic effect through the delivery of radioactivity to target tissues, any adverse event associated with tissue radiation damage theoretically may be associated with the use of the radioactive sources. With implantation of sources in the prostate, impotence may result in about 25% of cases; urinary incontinence and proctitis have been reported in about 1% of cases. After prostate implants, transient dysuria and increased urinary frequency have been reported in about 15% of patients.

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 sources 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 seed is not isotropic, as with other brachytherapy sources (see Fig 2).

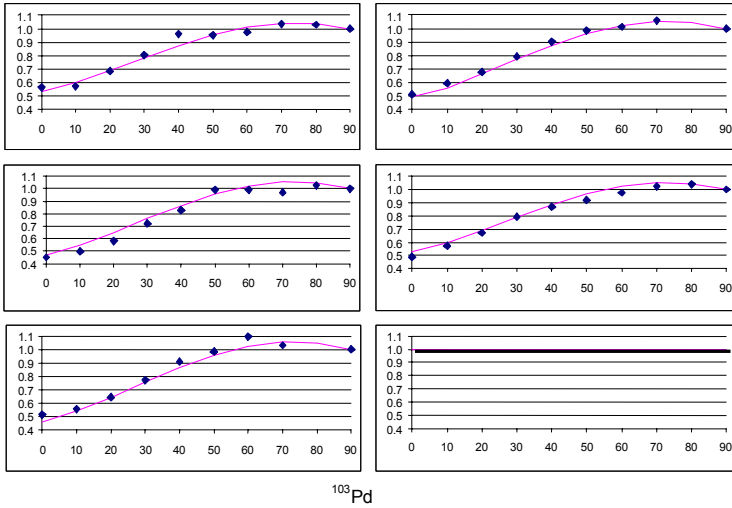


Fig 2. TLD experimental study(8) and theoretical fitting(9) obtained the anisotropic functions, providing the two dimensional dose distributions around the MED3633 source. In the figure are fits for $r = 1, 2, 3, 4, 5, 50$ cm, from top to bottom and left to right respectively

Pd-103 has a 16.99 day half-life. Decay corrections must be made in order to calculate properly the activity of the Sources from the "reference date" to the day they are implanted. Factors for decay calculation are provided in the Palladium 103 decay chart below.

PALLADIUM-103 DECAY CHART

DAYS	DECAY FACTOR	DAYS	DECAY FACTOR
1	0.9600	18	0.4798
2	0.9216	19	0.4606
3	0.8848	20	0.4422
4	0.8494	21	0.4245
5	0.8155	22	0.4076
6	0.7829	23	0.3913
7	0.7516	24	0.3756
8	0.7215	25	0.3606
9	0.6927	26	0.3462
10	0.6650	27	0.3324
11	0.6384	28	0.3191
12	0.6129	29	0.3063
13	0.5884	30	0.2941
14	0.5649	31	0.2823
15	0.5423	32	0.2710
16	0.5206	33	0.2602
17	0.4998	34	0.2498

NOTE: Reference date is indicated on the product labeling and certification.

INSTRUCTIONS FOR USE

PROSPERA[®] Pd-103 Brachytherapy Sources are supplied as NON-STERILIZED individual units. All sources must be sterilized prior to use. Pd-103 sources should be removed from shielded containment and plastic vial. They should be placed under either steam or gas sterilization. During treatment procedure, the patient must be appropriately anesthetized. A qualified practitioner may place the Pd-103 brachytherapy sources throughout the tumor volume according to a treatment plan for geometric arrangement. Commercially available applicators and needles, such as the Mick, may be used since the Pd-103 brachytherapy sources are designed to fit them.

PATIENT INFORMATION

Since PROSPERA[®] Pd-103 is radioactive source, prior to implant, patients should be informed about radiation safety procedures and the expected time during which such precautions should be observed. Examples of precautionary guidelines have been established by the NCRP.

ADDITIONAL PRODUCT INFORMATION

1) BIOCOMPATIBILITY

The North American Scientific PROSPERA[®] Pd-103 Brachytherapy Sources are enclosed in sealed titanium capsules. Years of clinical experience have shown that when titanium is used to encapsulate a radioactive source for implant, the danger of adverse tissue reaction is not significant.

2) ACCOUNTABILITY AND DISPOSAL

Records of receipt, storage and disposal of brachytherapy sources should be maintained in accordance with requirements of government regulatory agencies. When disposal is indicated, Pd-103 sources should be transferred to an authorized radioactive waste disposal agency. Pd-103 Brachytherapy Sources should never be disposed of in normal waste.

REFERENCES:

- Hilaris, B.S., (ed) Handbook of Interstitial Brachytherapy. Publishing Science Group Inc., Acton, Massachusetts (1975)
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- Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. NCRP Report No. 37. Washington, D.C. (1970)
- R. Nath, L.L. Anderson, G. Luxton, K.A. Weaver, J.F. Williamson, and A.S. Meigooni, " Dosimetry of interstitial brachytherapy sources: Recommendations of the AAPM Radiation Therapy /Committee Task Group No. 43", Med. Phys. **22**, 209-234
- R. E. Wallace and J. J. Fan, "Dosimetric Characterization of a New Design Pd-103 Brachytherapy Source, Submitted for publication in Medical Physics.
- Furhang and Wallace, work in progress, private communications.

Note: The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1026, Bethesda, MD 20814.



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