

OncoSeed (Iodine-125 Seeds)  
**RAPID Strand**<sup>TM</sup>  
 Rigid Absorbable Permanent Implant Device  
**No. 7000**

**DESCRIPTION**

RAPID Strand<sup>TM</sup> consists of ten Model No. 6711 OncoSeed<sup>TM</sup> seeds (welded titanium capsule containing I-125 adsorbed onto a silver rod) spaced at a fixed distance within polyglactin 910 absorbable suture. The suture material containing OncoSeed is stiffened, then sterilized by ethylene oxide. The seeds are housed in a plastic spacing jig within a stainless steel shielding tube which attenuates >99% of the I-125 photons. RAPID Strand is sterile when shipped.

**PHYSICAL CHARACTERISTICS**

Iodine-125 has a half-life of 59.43 days<sup>1</sup> and decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of an OncoSeed. The principal photon emissions are 27.4 and 31.4 keV x-rays and a 35.5 keV gamma. Also emitted are 22.1 and 25.2 keV fluorescent x-rays from the silver rod.<sup>2</sup>

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below.

**Iodine-125 Decay Chart  
 (59.43 day Half-Life<sup>1</sup>)**

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.657
2	0.977	38	0.642
4	0.954	40	0.627
6	0.932	42	0.613
8	0.911	44	0.599
10	0.890	46	0.585
12	0.869	48	0.571
14	0.849	50	0.558
16	0.830	52	0.545
18	0.811	54	0.533
20	0.792	56	0.520
22	0.774	58	0.508
24	0.756	60	0.497
26	0.738	62	0.485
28	0.721	64	0.474
30	0.705	66	0.463
32	0.689	68	0.452
34	0.673	70	0.442

**RADIATION PROTECTION**

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide >99% reduction in exposure.

**ACTIONS**

The clinical efficacy of RAPID Strand derives solely from the interaction of the emitted ionizing radiation with the tissue being treated. The stiffened suture material holds the seeds in place in the tissue being treated to ensure proper dosimetry and minimize seed movement/shedding.

Dose distribution around each individual seed is not isotropic.<sup>2, 3, 4, 5, 6, 7, 8, 9</sup> This anisotropy should be included in dose distribution calculations.

Intramuscular implantation studies in rats show that non-stiffened sutures containing OncoSeed seeds are minimally absorbed until about the 40th postoperative day. Absorption is essentially complete between the 60th and 90th days.<sup>10</sup>

**INDICATIONS**

RAPID Strand is indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor.

RAPID Strand may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.<sup>11, 12, 13</sup>

**CONTRAINDICATIONS**

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g., ulcerated) is not recommended with RAPID Strand.

**WARNINGS**

RAPID Strand is shipped sterile and must not be resterilized.

Do not use if package is open or damaged.

**PRECAUTIONS**

**1) Personnel Monitoring**

RAPID Strand is radioactive, and appropriate precautions must be taken during handling. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel.

Personnel monitoring is required. Typically a film badge or TLD dosimeter worn on the body and a ring badge (during Seed handling) is adequate.

**2) RAPID Strand Shipping Container**

RAPID Strand is shipped sterile in a stainless steel shielding tube which attenuates >99.9% of the photons from I-125.

**3) Handling**

Any manipulation of RAPID Strand should be carried out in a clean environment behind shielding of adequate thickness. RAPID Strand should be handled with forceps only and with as much distance as practical between Seeds and the operator.

The implant procedure may require that RAPID Strand be cut into sections. CARE MUST BE TAKEN TO AVOID CUTTING SEEDS. STORE SEEDS AT AMBIENT TEMPERATURE.

**4) Seed Sterilization**

RAPID Strand is sterilized using ethylene oxide, and is sterile when shipped. RAPID Strand SHOULD NOT BE RESTERILIZED.

**5) Accidental OncoSeed Damage**

Although each OncoSeed has a high structural integrity, it is possible through rough handling, exposure to excessive temperature, crushing or cutting to rupture a seed, causing it to release "free" I-125. If this happens, the area of the accident should be closed off; the seeds should be sealed in a container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to established procedures. Personnel working in or near the accident should also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

**APPLICATION TO PATIENT**

RAPID Strand should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides.

Radiation detection equipment capable of detecting 30 keV photons should be available whenever RAPID Strand is being handled.

All practical physical protection should be provided during the implantation procedure. Frequently, however, protective barriers are not practical in the surgery. In this circumstance, operators must rely upon distance and speed to minimize radiation exposure.<sup>14, 15, 16, 17</sup>

**TREATMENT OF PATIENT**

All patients should be informed of the nature of RAPID Strand implants and the expected period of time during which radiation precautions will be necessary. Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received a RAPID Strand implant. Guidelines for necessary precautions have been established.<sup>18</sup>

**ACCOUNTABILITY/STORAGE/DISPOSAL**

Iodine-125 is an accountable radioactive material. RAPID Strand should, therefore, be strictly controlled and stored in a locked safe. If any significant material cannot be accounted for, the loss must be reported to the federal or state licensing agency.

Store at room temperature. Avoid storing RAPID Strand at conditions of excessive heat or humidity. Studies have demonstrated that RAPID Strand is stable when exposed to 40°C, 104°F and 75% relative humidity for two weeks.

When disposal is indicated, RAPID Strand should be transferred to an authorized radioactive waste disposal agency. RAPID Strand should never be disposed of in normal waste.

A RAPID Strand disposal service is provided by Medi-Physics, Inc. Customers wishing to dispose of RAPID Strand in this manner must contact Medi-Physics, Inc., Customer Service at 1-800-228-0126 prior to returning the sources; residents of Canada call 1-800-387-7146 or 1-905-847-1166 (Toronto), for approval and specific shipping container and forms.

Material approved for return must comply with Department of Transportation regulations (49 CFR Parts 171-177) regarding packaging and labeling.

## LEAK TESTING

Prior to fabrication of RAPID Strand, all OncoSeed seeds have passed a leak test showing <185 Bq, <0.005  $\mu$ Ci of removable I-125 as required by Illinois Department of Nuclear Safety 32 Ill. Adm. Code Part 335, Subpart C, 335.2050. This leak test value is printed on the Certification form that accompanies each shipment.

## ADVERSE REACTIONS

No adverse reactions involving OncoSeed in suture have been reported.

## DOSAGE AND ADMINISTRATION

The total activity of OncoSeed seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice<sup>5, 6, 7, 8, 9, 19, 20</sup> should be followed for the calculation of the total activity to be implanted, the proper placement of the sources within the tissue, and the evaluation of the radiation dose distribution achieved.

Dose distribution around each individual seed is not isotropic.<sup>2, 3, 4, 5, 6, 7, 8, 9</sup> This anisotropy should be considered in dose distribution calculations.

Iodine-125 has a 59.43 day half-life. Decay corrections must be made in order to calculate properly the activity of the seeds on the day they are implanted.

## DIRECTIONS FOR USE

The RAPID Strand product is designed to be opened in the operating room and used immediately.

With the patient appropriately prepared for implantation surgery, a qualified practitioner may place the RAPID Strand throughout the tumor volume according to a preplanned geometric arrangement. The use of RAPID Strand requires the use of disposable needles. Implantation techniques using disposable needles have been previously described.<sup>21, 22, 23, 24</sup>

## HOW SUPPLIED

RAPID Strand is shipped sterile, having ten OncoSeed seeds spaced 1 cm center to center in a polyglactin 910 suture which has been stiffened and then gas (ethylene oxide) sterilized. The usual apparent activity range of the ten seeds is 7.06 to 24.9 MBq, 0.191 to 0.673 mCi per seed. All seeds within each RAPID Strand are within the same activity range. Other apparent activity ranges up to 37 MBq, 1.0 mCi may be available upon request.

RAPID Strand is held within a plastic spacing jig which is inside a stainless steel shielding tube. The assembled RAPID Strand, plastic spacing jig and steel shielding tube in a plastic tray are sealed within a white sterilization pouch which is sealed in a bag.

Affixed to the bag is a label showing the following information: Apparent median activity in mCi; total apparent activity; number of seeds; reference date; order I.D. number/lot number. Affixed to the sterilization pouch is a label showing the following information: Lot number and "Sterility guaranteed unless package is damaged or opened."

RAPID Strand is sterile when shipped.

## LICENSING

The Illinois Department of Nuclear Safety (IDNS) has approved this sealed source for distribution to persons licensed pursuant to 32 Ill. Adm. Code 330.260(a) and Part 335 Subpart H 335.7010 or under equivalent licenses of the USNRC or an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

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

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**Note:** The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

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