



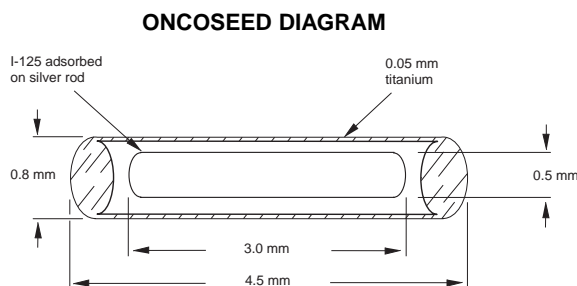
OncoSeed™ (Iodine-125 Seeds)

Model 6711 Non-Sterile OncoSeed Model 6715 Sterile Convenience Pack Rx ONLY

DEVICE DESCRIPTION

Model No. 6711

OncoSeed seeds consists of a welded titanium capsule containing Iodine-125 adsorbed onto a silver rod.



Model No. 6715

The OncoSeed Sterile Convenience Pack contains fifteen OncoSeed Seeds (Model 6711) loaded into a Mick® Disposable Cartridge and steam sterilized Ready to Use.

Physical Properties

- Principle Radionuclide: ¹²⁵I (Iodine)
- Radionuclide Purity: > 99.9% ¹²⁵I
< 0.005% ¹²⁶I
- Half-life of ¹²⁵I: 59.43 days
- Types of Radiation: X-ray and Gamma
- Energy Level:

Photon	27.4 keV
X-ray	31.4 keV
Gamma	35.5 keV
Fluorescent X-Rays from the Silver Rod	22.1 keV and 25.2 keV
- Decay Mode: ¹²⁵I decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of an OncoSeed.

Shelf Life

The useful "shelf life" of the source and convenience pack can be calculated by considering the day of use after the assay date and corresponding value of decay factor. Unused seeds must be disposed of within six months of the leak test date shown on the certification form accompanied with the product.

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.

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-Life¹)**

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

INTENDED USE/INDICATIONS

OncoSeed seeds with apparent activities from 0.191 to 1.01 mCi are 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 for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intraabdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

OncoSeed seeds with total apparent activities greater than 1.01 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants.

OncoSeed seeds are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with OncoSeed seeds.^{10, 11}

CONTRAINDICATIONS

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

WARNINGS

- 1) Do not use visibly damaged seeds for implantation.
- 2) Do not apply excessive force during loading/removing of seeds.
- 3) Do not pick up seeds with the fingers, use forceps.
- 4) Do not use dry heat or chemical sterilization.
- 5) To minimize radiation exposure, use vented chemical hood and proper shielding in handling of seeds.
- 6) Caution should be exercised in performing Transurethral Resection (TURP) with electrocautery in patients who have undergone prostatic radioactive seed implantation. Because the integrity of the seed capsule can potentially be breached by electrocautery, the patient and surgical personnel should be monitored for any possible radioactive contamination after the procedure. Additionally the radioactive half-life of the seed should be considered prior to the use of electrocautery.

PRECAUTIONS

1) Loading/Unloading of Seed

Sterile Convenience Pack (Model 6715) is loaded Ready to Use. No special loading/unloading is required.

Do not force an OncoSeed into (or from) any implant tube, needle, or cartridge; doing so may damage the wall or end welds of the seed, potentially causing release of I-125 into the environment and into body fluids should the seed be implanted. **UNDER NO CIRCUMSTANCES SHOULD VISIBLY DAMAGED SEEDS BE IMPLANTED.**

When loading or removing an OncoSeed from plastic or rubber afterloading catheters, it is advisable to use a vented chemical hood which has adequate air flow up the stack and a filtered exhaust. If a chemical hood is not available, a plastic glove box specifically designed for work with radioactive iodine may be substituted, provided it is properly vented.

If a razor blade, scalpel, or other sharp tool is used to remove an OncoSeed from the afterloading catheters, use extra care to avoid contacting or cutting a seed. A seed which has been damaged (nick, cut, slice, or other type of damage) will release I-125 into the environment.

To assure that seeds have not been damaged following removal from the afterloading catheters, a contamination survey should be conducted using a radiation monitor capable of detecting 30 keV photons. This survey should include wipe (or leak) tests of seeds and an overall area survey. For seed leak test details, contact Amersham Health (Medi-Physics, Inc.), Customer Service at 1-800-228-0126. Residents of Canada call 905-847-1166 or 1-800-387-7146.

2) Seed Corrosion

The titanium shell of an OncoSeed has excellent corrosion resistance under normal use. However, do not expose a seed to acid or alkaline solutions exceeding 1 molar. Seeds are not affected by common solvents such as acetone and alcohol or by mild detergents.

3) Personnel Monitoring

OncoSeed seeds are radioactive, and appropriate precautions must be taken when handling the sources. 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.

4) Storage and Transportation

The lead seed container effectively shields >99.9% of the photons from I-125. The lead seed container may be used for storage and transport of seeds.

5) Seed Handling

OncoSeed seeds should be handled behind shielding of adequate thickness. Forceps, either reverse or normal action, should be used to maintain operator to seed distance. If normal action forceps are used, gentle pressure should be applied so that seeds are not damaged. **ONCOSEED SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.**

OncoSeed Convenience Pack is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use. No special handling is required.

6) Seed Sterilization

OncoSeed seeds are not sterilized when shipped and must be sterilized prior to use. Only the steam sterilization method must be used

Sterile Convenience Pack is shipped sterilized. In the event resterilization is required, only the steam sterilization method must be used using the following conditions: 120°C-122°C, 14-18 psi, 30-33 minutes

DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION.

7) Accidental Damage to Seed

Although an OncoSeed has a high structural integrity, it is possible through rough handling, exposure to excessive temperature, or crushing 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 lead 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.

ADVERSE REACTIONS

General

Since I-125 seeds deliver radiation to the target tissue in order to provide therapy, any adverse effect associated with tissue radiation damage theoretically may be associated with their use. The potential for and symptoms of such damage will vary depending on the nature and location of the target tissue.

Prostate Brachytherapy

The following adverse event information has been derived from published articles listed in the reference section.

Immediately subsequent to transperineal seed implantation for prostate brachytherapy, there is often procedure-related bleeding or burning beneath the scrotum, or passage of blood in the urine.¹² These symptoms are usually treated supportively. Incidents of asymptomatic seed embolization to the lungs have been noted in the literature.¹³

Short-term irritative or obstructive urinary symptoms, such as frequent, urgent or uncomfortable urination, dribbling, or difficulty voiding, may be experienced after implantation, and may last for several weeks to a few months.¹⁴⁻¹⁸ Generally, these are transient, mild effects which resolve spontaneously (as seed radiation levels decrease) or require minor intervention.

Impotence has been noted as a long-term adverse effect, with an incidence ranging from 6-30%, as published by some groups.^{14, 18-20} The risk of impotence may be age-related.¹⁸ Proctitis may occur, with several groups reporting a 2-6% incidence.^{15, 18, 21, 22} Long-term incontinence is uncommon,^{14, 18, 21} although patients who have previously undergone transurethral resection of the prostate (TURP) are at a higher risk.^{23, 24} Urethral stricture has been reported in a small percentage of cases.^{14, 15, 18}

PATIENT COUNSELING INFORMATION

All patients should be informed of the nature of OncoSeed seed 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 an OncoSeed seed implant. Guidelines for necessary precautions have been established.²⁵

All patients should be advised of the possibility that, during a course of treatment, one or more OncoSeed seeds might slough off and become detached as a tumor regresses and becomes smaller. Under these circumstances, any bandages or linens which come into contact with the site of the implant should be scrutinized for small metallic seeds (1/4 of an inch long). Patients should be advised that whenever seeds are found, they should be picked up with a spoon and placed in a jar or other container, and placed in an inaccessible area in the home. The radiation center should be notified of such an event as soon as possible after its occurrence.

HOW SUPPLIED

Model No. 6711 OncoSeed seeds are shipped in a shrink wrapped, screw-cap glass vial which is inside a sealed lead "securitainer" The lead securitainer can be opened by pulling off the plastic ring seal. OncoSeed seeds are supplied non-sterile and loose with apparent activities from 0.191 to 6.24 mCi per seed and, by special request, from 6.24 to 40 mCi per seed. Please contact Amersham Health (Medi-Physics, Inc.), Customer Service for further details.

Model No. 6715 OncoSeed seeds in the Sterile Convenience Pack contains fifteen Model 6711 OncoSeeds loaded into a Mick Disposable Cartridge and steam sterilized Ready to Use. Each Sterile Convenience Pack is placed in a primary sterility barrier and held in a lead container, which holds a maximum of ten convenience packs. OncoSeed Sterile Convenience Pack are available with apparent activities from 0.27 mCi to 0.673 mCi per seed. Please contact Amersham Health (Medi-Physics, Inc.), Customer Service for further details.

Both seed models are packaged with labeling information on air kerma strength and apparent activity per seed, total air kerma strength and apparent activity, reference date, number of seeds, and order I.D. number. Air kerma strength is specified in units of microGray meter squared per hour ($\mu\text{Gy}\cdot\text{m}^2/\text{h}$), and apparent activity has units of milliCurie (mCi). The label contains precautionary regulatory statements pertaining to licensing of the seeds. Any discrepancies noted upon receipt of the product, from that which was ordered, must be reported immediately to Amersham Health (Medi-Physics, Inc.), Customer Service at 1-800-228-0126. In Canada call 905-847-1166 or 1-800-387-7146.

LEAK TESTING

OncoSeed seeds are leak tested prior to shipment and have passed a leak test showing $<0.005 \mu\text{Ci}$ 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.

OncoSeed seeds that retain clinical utility for more than six months must be leak tested at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State, except for sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer, as prescribed in Illinois Department of Nuclear Safety 32 Ill. Adm. Code Part 335, Subpart C, 335.2050.

OncoSeed seeds intended for temporary implants (1 to 40 mCi) might fall into the above category and, if so, would need to be leak tested. Additionally, since the higher activity seeds are often reused, leak testing at more frequent intervals is recommended. For leak test details, contact Amersham Health (Medi-Physics, Inc.), Customer Service at 1-800-228-0126. Residents of Canada can call 905-847-1166 or 1-800-387-7146.

Unused OncoSeed seeds intended for permanent implants (nominal strength of 0.50 mCi) will not require additional leak testing providing they are disposed of within six months of the date shown on the Seed Certification form.

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.

DIRECTIONS FOR USE

General

OncoSeed seeds and Convenience Pack should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Radiation detection equipment, capable of detecting 30 keV photons, should be available whenever I-125 Seeds seeds are being handled. The seeds are quite small and it may be difficult to locate a dropped seed visually.

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.²⁸⁻³¹

OncoSeed seeds can be implanted directly with an 18 or larger gauge needle or using a seed applicator attached to the needle. Common seed applicators are the Mick, Henschke and Scott. The Royal Marsden Gold Grain gun can be used to implant seeds provided a special modification is requested of the manufacturer.

For temporary implant, OncoSeed seeds are usually loaded into plastic tubing or other devices (e.g., gold eye plaques) to facilitate afterloading procedures and seed recovery.

OncoSeed seeds are shipped with a source output strength certificate. However, if verification of source output is considered necessary, the AAPM guidelines should be followed.⁷

OncoSeed Convenience Pack (Model 6715) is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use.

STEAM STERILIZATION (AUTOCLAVE):

Model 6711

Use the normal cycle (121 degrees C at 15 psi for 15 to 30 minutes) or the flash cycle (133 degrees C at 30 psi for about 3 minutes). DO NOT EXPOSE SEEDS TO TEMPERATURES AND PRESSURES IN EXCESS OF 138 DEGREES C and 35 PSI. Autoclaves should be equipped with traps or other means to prevent seed loss through the drain hole.

When in doubt about compatibility of steam heat with various seed containers, load them with non-radioactive seeds to determine the effect of steam on the container material and on seed recovery.

Model 6715

Sterile Convenience Pack is shipped sterilized Ready to Use. Refer to the Precautions section, item six, for resterilization.

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^{5-9, 26, 27} 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.²⁻⁹ This anisotropy should be considered in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility, and together with the silver rod, results in a total self-absorption of approximately 35%.

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

ACCOUNTABILITY/DISPOSAL

Iodine-125 is an accountable radioactive material. OncoSeed seeds 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 appropriate federal or state licensing agency.

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

If a seed has been visibly damaged in any way, seal it in a container and discard it immediately to radioactive waste and check the area for contamination.

An OncoSeed disposal service is provided by Amersham Health (Medi-Physics, Inc.). Customers wishing to dispose of OncoSeed seeds in this manner must contact Amersham Health (Medi-Physics, Inc.), Customer Service 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,

Shipments are to be directed to: Amersham Health (Medi-Physics, Inc.), 3350 N. Ridge Ave., Arlington Heights, IL 60004.

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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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Customer Service (800) 228-0126
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