



# EchoSeed™

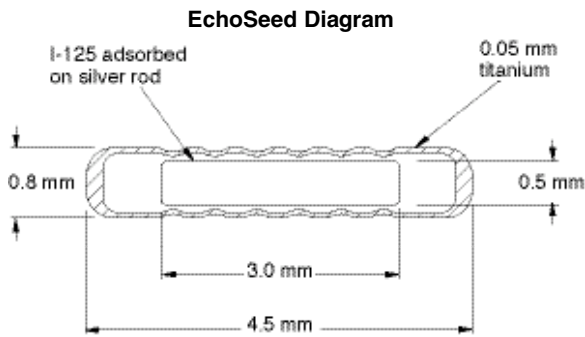
(Iodine-125 Seeds)

**Model 6733**  
**Non-Sterile EchoSeed**  
**Model 6735**  
**Sterile Convenience Pack**  
**Rx ONLY**

**DEVICE DESCRIPTION**

**Model No. 6733**

EchoSeed seeds consist of a welded titanium capsule containing Iodine-125 adsorbed onto a silver rod. The specifically designed grooves on the outer surface of the capsule allow enhanced visualization under ultrasound.



**Model No. 6735**

The EchoSeed Sterile Convenience Package contains fifteen EchoSeed seeds (Model 6733) loaded into a Mick® Disposable Cartridge and steam sterilized Ready to Use.

**Visualization under Ultrasound**

EchoSeed seeds are specifically designed to offer enhanced visualization of implanted seeds under ultrasound.

**Physical Characteristics**

- Principle Radionuclide: <sup>125</sup>I (Iodine)
- Radionuclide Purity: > 99.9% <sup>125</sup>I  
< 0.005% <sup>126</sup>I
- Half-life of <sup>125</sup>I: 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: <sup>125</sup>I decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of an EchoSeed.

**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 accompanying 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-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

**INTENDED USE/INDICATIONS**

EchoSeed seeds with apparent activities from 0.297 to 0.673 mCi are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used as primary treatment of prostate cancer.

EchoSeed 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 EchoSeed seeds.<sup>9,10</sup>

**CONTRAINDICATIONS**

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

## WARNINGS

- 1) EchoSeed seeds are intended as a Single Use Permanent Implant.
- 2) Do not use visibly damaged seeds for implantation.
- 3) Do not apply excessive force during loading/removing of seeds.
- 4) Do not pick up seeds with the fingers, use forceps.
- 5) Do not use dry heat or chemical sterilization.
- 6) To minimize radiation exposure, use vented chemical hood and proper shielding in handling of seeds.
- 7) 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.
- 8) Do not over tighten base in the Mick Cartridge.

## PRECAUTIONS

### 1) Loading/Unloading of Seed

Sterile Convenience Pack (Model 6735) is loaded Ready to Use. No special loading/unloading is required.

Do not force an EchoSeed 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 EchoSeed 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 EchoSeed 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 Oncura Customer Care at (877) 639-8060.

### 2) Seed Corrosion

The titanium shell of an EchoSeed 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

EchoSeed 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

EchoSeed 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. ECHOSEED SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

EchoSeed Sterile Convenience Pack contains fifteen EchoSeed seeds loaded into a Mick Disposable Cartridge and steam sterilized Ready to Use. No special handling is required.

### 6) Seed Sterilization

EchoSeed seeds are not sterilized when shipped and must be sterilized prior to use. Before implantation, they must be sterilized using steam or ethylene oxide (EtO).

Sterile Convenience Pack is shipped sterilized. In the event resterilization is required, use a steam sterilization method with the following conditions: 120 - 122°C, 14 - 18 psi, 30 - 33 minutes. If a second resterilization is required, the seeds should be removed from the cartridge and sterilized as loose seeds (Model 6733) per the Directions for Use, Steam Sterilization (Autoclave) section on page 3 of this document. Multiple resterilization of the Mick® Disposable Cartridge is not recommended.

For Sterile Convenience Pack: DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION.

### 7) Accidental Damage to Seed

Although an EchoSeed 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.<sup>11</sup> These symptoms are usually treated supportively. Incidents of asymptomatic seed embolization to the lungs have been noted in the literature.<sup>12</sup>

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.<sup>13-17</sup> 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.<sup>13, 17-19</sup> The risk of impotence may be age-related.<sup>17</sup> Proctitis may occur, with several groups reporting a 2-6% incidence.<sup>14, 17, 20, 21</sup> Long-term incontinence is uncommon,<sup>13, 17, 20</sup> although patients who have previously undergone transurethral resection of the prostate (TURP) are at a higher risk.<sup>22,23</sup> Urethral stricture has been reported in a small percentage of cases.<sup>13, 14,17</sup>

## PATIENT COUNSELING INFORMATION

All patients should be informed of the nature of EchoSeed 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 EchoSeed seed implant. Guidelines for necessary precautions have been established.<sup>24</sup>

All patients should be advised of the possibility that, during a course of treatment, one or more EchoSeed 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. 6733 EchoSeed 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. EchoSeed seeds are supplied non-sterile and loose with apparent activities from 0.297 to 0.673 mCi per seed.

Model No. 6735 EchoSeed Sterile Convenience Pack contains fifteen Model 6733 EchoSeeds 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. EchoSeed Sterile Convenience Pack is available with apparent activities from 0.297 mCi to 0.673 mCi per seed. Please contact Oncura Customer Care 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 ( $\mu\text{Gym}^2/\text{h}$ ), 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 Oncura Customer Care at (877) 639-8060.

## LEAK TESTING

EchoSeed 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 Emergency Management Agency 32 Ill. Adm. Code Part 335, Subpart C, 335.2050. This leak test value is printed on the Certification form that accompanies each shipment.

EchoSeed 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 Emergency Management Agency 32 Ill. Adm. Code Part 335, Subpart C, 335.2050.

Unused EchoSeed 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 Emergency Management Agency (IEMA) 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

EchoSeed seeds and the Sterile 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.<sup>28-30</sup>

EchoSeed 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.

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

EchoSeed Convenience Pack (Model 6735) is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use.

## STEAM STERILIZATION (AUTOCLAVE):

Model 6733

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 6735

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 EchoSeed seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice<sup>4-8, 25, 26</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>2-8</sup> 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. EchoSeed 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, EchoSeed seeds should be transferred to an authorized radioactive waste disposal agency. EchoSeed 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 EchoSeed disposal service is provided by GE Healthcare (Medi-Physics, Inc.). Customers wishing to dispose of EchoSeed seeds in this manner must contact Oncura Customer Care 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: GE Healthcare (Medi-Physics, Inc.), 3350 N. Ridge Ave., Arlington Heights, IL 60004.

## REFERENCES

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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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