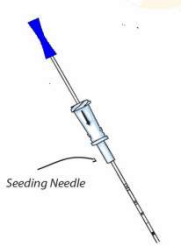
RADIOACTIVE SEED LOCALIZATION NEEDLE

⚠ Instructions for Use – This leaflet contains important product use and safety information. Please read carefully, and retain these instructions for future reference.

PRODUCT NAME:
I-125 RADIOACTIVE SEED LOCALIZATION NEEDLE

Description:
The IsoAid I-125 Radioactive Seed Localization Needle [RSLN] is a pre-sterilized 18-gauge stainless steel needle containing a low activity I-125 Iodine Seed (Advantage™ I-125 source). The ADVANTAGE™ I-125 source consists of a laser welded Titanium capsule, containing Iodine-125 chemically affixed (adsorbed), as silver iodide, onto a silver rod which acts as an x-ray detectable marker. The needle tip is occluded with bone wax and the iodine seed is loaded loose or stranded and is provided with or without a trailing spacer. The stainless-steel needles are provided in 5cm, 7cm, and 12cm lengths.

Indications for Use:
The RSLN is intended to be used on adult individuals with non-palpable tumors/lesions. The I-125 Radioactive Seed Localization Needle is indicated for the localization of (non-palpable lesions) in the breast, in transit melanoma metastases on the back and lymph nodes in the axilla or retro-peritoneum for excision with the use of radioactive seeds in adults.



The radioactive seed is intended to be excised within thirty (30) days of implant.

Physical Characteristics:
Iodine-125 has a half-life of 59.41 days and decays by electron capture with the emission of characteristic photons and electrons. The principal photon emissions are 27.2 KeV, 27.5 KeV, 31.0 KeV and 35.5 KeV with an average energy of 28.5 KeV. Table 1. shows the decay of I-125 seeds

Calibration:
ADVANTAGE™ I-125 sources are calibrated by direct comparison against a standard source of the same model that has been calibrated by the National Institute of Standards and Technology for Air Kerma Strength. The resulting calibration is reported in Air Kerma Strength (μGy m^2/h) as well as Apparent Activity (mCi).

ADVANTAGE™ I-125 sources are calibrated to the NIST SK99std WAFAC standards for I-125 seeds.

Sterilization:
The Radioactive Seed and Localization Needle are sterilized with a Sterility Assurance Level of 10^{-6} by Ethylene Oxide gas. The sterile packaging has a ninety (90) day shelf-life. If the products expiration date has been exceeded the product is considered non-sterile and therefore cannot be used. Do not re-sterilize the product.

Table 1. Iodine-125 Decay for RSLN

Day	Decay Factor	Day	Decay Factor	Day	Decay Factor	Day	Decay Factor
0	1.000	31	0.697	62	0.485	93	0.338
1	0.988	32	0.688	63	0.480	94	0.334
2	0.977	33	0.680	64	0.474	95	0.330
3	0.966	34	0.673	65	0.469	96	0.326
4	0.954	35	0.665	66	0.463	97	0.323
5	0.943	36	0.657	67	0.458	98	0.319
6	0.932	37	0.649	68	0.452	99	0.315
7	0.922	38	0.642	69	0.447	100	0.311
8	0.911	39	0.634	70	0.442	101	0.308
9	0.900	40	0.627	71	0.437	102	0.304
10	0.890	41	0.620	72	0.432	103	0.301
11	0.880	42	0.613	73	0.427	104	0.297
12	0.869	43	0.606	74	0.422	105	0.294
13	0.859	44	0.599	75	0.417	106	0.290
14	0.849	45	0.592	76	0.412	107	0.287
15	0.839	46	0.585	77	0.407	108	0.284
16	0.830	47	0.578	78	0.403	109	0.280
17	0.820	48	0.571	79	0.398	110	0.277
18	0.811	49	0.565	80	0.393	111	0.274
19	0.801	50	0.558	81	0.389	112	0.271
20	0.792	51	0.552	82	0.384	113	0.268
21	0.783	52	0.545	83	0.380	114	0.265
22	0.774	53	0.539	84	0.375	115	0.261
23	0.765	54	0.533	85	0.371	116	0.258
24	0.756	55	0.526	86	0.367	117	0.255
25	0.747	56	0.520	87	0.362	118	0.252
26	0.738	57	0.514	88	0.358	119	0.250
27	0.730	58	0.508	89	0.354	120	0.247
28	0.721	59	0.502	90	0.350		
29	0.713	60	0.497	91	0.346		
30	0.705	61	0.491	92	0.342		

In Vivo Characteristics:
During the excision procedure, the seed provides a radioactive localization point and acts as a marker to aid in the location and excision of the lesion. Verify the removal of seed at time of excision of the tumor/lesion using a gamma probe or similar instrument.

Instructions for Safe Use:
The radioactive seed is introduced via an 18-gauge needle using standard ultrasound or radiography guidance. Once guided to the desired location of the lesion, the seed is deployed through the bone wax with the aid of the needle stylet. If multiple lesions utilize more than one seed, then each seed shall be a minimum of >2 cm apart. Ultrasound or radiography confirms the appropriate placement of the seed. The seed is intended to be removed during the excision procedure.

Radiation Protection & Handling:
The 27- 35.5 KeV photons of I-125 are substantially absorbed by any high Z material but exhibit desirable penetration in tissue.

Half Value Layer Lead = 0.025 mm
Half Value Layer Tissue = 20.0 mm

Exposure can be reduced by 99.9% with a thin sheet of lead (0.25 mm or 0.01 inch). The shielding of I-125 results in a reduction of exposure to attending medical personnel and visitors. I-125 sources should be handled only by those individuals trained by an authorizing governmental agency in the safe use & handling of radioisotopes.

- Direct contact with I-125 sources should be avoided. The use of vacuum or reverse action tweezers is recommended. Proper precautions must be taken when handling the sources.
- Personnel monitoring is required. Dosimetry monitors, such as TLD devices, should be used to monitor hand and whole body exposure. During preparation and source implantation procedures, all practical steps should be taken to keep exposure as low as reasonably achievable. Limited exposure time, increasing distance, careful planning of the administration procedure and use of shielded barriers should be considered in meeting this goal.

Accidental Damage:
Do not use the product if there is suspicion that the product is damaged or if the sterile barrier has been breached. It is possible through rough handling (abrasion, incision, etc.), high temperatures or crushing that a seed could rupture and leak. The internal components of the seed are non-toxic, but the area should be closed off immediately and personnel limited to avoid radioactive contamination. The damaged seeds should be placed in a sealed container and the area should be decontaminated. In accordance with radiation regulations only authorized, specialized staff trained in handling radioactive substances may handle the I-125 seeds.

Accountability & Disposal:
Records of receipt, storage and disposal of Advantage™ I-125 sources should be maintained in accordance with government regulatory policies. I-125 sources should be strictly controlled and stored in a secured area.

When disposal is indicated, the Advantage™ I-125 sources should be transferred to an authorized radioactive waste disposal agency or returned to IsoAid for disposal. Advantage™ I-125 sources should not be disposed of in normal waste. Any discrepancies must be reported immediately to IsoAid Customer Service.

Licensing:
The Florida Department of Health (FDOH), Bureau of Radiation Control has approved this sealed source for distribution to persons licensed pursuant to Florida Administrative Code Chapter 64E-5, "Control of Radiation Hazard Regulations," Part VI or under equivalent licenses of the USNRC or issued by an Agreement State. IsoAid requires proof of USNRC radioactive materials license or respective government license as well as agreement state and licensing state information. Orders cannot be processed without license verification. Compliance with the applicable local, state, country, and/or government regulations

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concerning procurement, possession, use and disposal of radioactive materials is the responsibility of the customer.

Leak Testing:

ADVANTAGE I-125 Brachytherapy sources are 100% leak tested prior to shipment and have passed a leak test showing less than 185 Bq (5 nCi) of removable I-125 surface contamination as required by ISO 9978 "Radiation protection – Sealed radioactive sources." Advantage I-125 seeds do not require any additional leak testing provided the seeds are used within the use-by-date.

Localization Dosage and Administration:
The most commonly used source activity levels for localization is between 0.1 mCi and 0.3 mCi.

Adverse Reactions:

- Any adverse reaction associated with tissue radiation damage may be associated with use of I-125 sources. Proper precautions must be taken when handling the sources.
- As with any surgical procedure, complications may occur including: bruising, discomfort, prolonged bleeding or infection near the implant site.
- Although the risk of source migration is minimal it can be significantly reduced through the use of stranding that links the seed and spacer together prior to implantation.

Precautions:

- Use caution when patients are diagnosed with non-cancerous tumors/lesions. Implant and removal should occur within 24-hours to limit radiation exposure.
- Product should remain in leaded pouch until ready for use. Handle lead pouch and contents with care to prevent damage to product.

Contraindications:

- Do not use radioactive seed localization needles in neurological or cardiovascular tissues.
- The RSLN is sold sterile. Use of a non-sterile device may compromise patient care. Do not re-sterilize.
- Do not use a damaged seed or a seed that may have become damaged when using the device.
- Do not come in direct contact with the I-125 source. Use vacuum or reverse action tweezers to handle the I-125 sources.
- The needle is not to be used in an MRI environment.

⚠ **Warnings:**

- ⚠ Dispose of radioactive material per nuclear regulatory guidelines (for USA, 10 CFR 35.1000; for EU per EURATOM 1493/93)
- ⚠ Loss of a radioactive seed must be avoided. Protocols must be in place to ensure tracking of the seed throughout the process.
- ⚠ Any attempt to cut or segment stranded product may adversely result in radioactive contamination. Use product as intended.
- ⚠ Do not use if damaged. Discard if damaged during use or after use in accordance with waste disposal procedures.
- ⚠ Do not use when patients are pregnant or breastfeeding. An alternative non-radioactive device should be used to avoid radiation exposure.
- ⚠ Do not use on patients that are less than 18 years old, this product is intended for use in adults.
- ⚠ Do not use if needle is bent or broken.
- ⚠ Excessive Force is not required to expel seed.
- ⚠ Do not store without adequate leaded shielding/packaging
- ⚠ Healthy Tissue may be exposed to the RSLN device during implantation and excision.

MR-Conditional

The I-125 seed has been evaluated for safety in the MRI environment. The seeds are MR-Conditional as defined in ASTM F2503-13. The seeds have been tested for heating, migration, and image artifact in the MRI environment. IsoAid seeds are made with titanium shell with non-magnetic internal materials. Patients with the seeds may safely undergo MRI under the following conditions: 1) Static field of 3 T or less 2) Whole body SAR of 4 W/kg or less and head SAR of 3.2 W/kg or less 3) Normal or first level controlled mode of the MRI system for both RF and gradients 4) Maximum spatial gradient in the static field of 30 T/m (3000 Gauss/cm) 5) Maximum slew rate of the time-varying magnetic gradient for the seed is 200 [T/m/s], which is the high-end gradient slew rate and is worst-case for the seed that does not have any magnetic or transistors in the seed components, no conceivable negative impact.

⚠ The presence of other implants or the health state of the patient may require reduction of the MR limits.

⚠ Temperature rise of tissues surrounding the seed was calculated under a worst-case situation to be less than 50% above the background rise with no implant. Magnetic force and torque during MRI will be less than the values exerted by gravity. Image artifact is expected to extend less than 5 mm beyond the seeds.

⚠ CAUTION: Federal (USA) and State law(s) restrict this device to sale by or on the order of a physician.

⚠ Use and Distribution in the EU is governed by EURATOM *2013/59 and 1493/93.*

The excised RSLN seed is considered biohazardous and must be contained and disposed of in accordance with universal precautions.

The RSLN Product may be configured with or without a Spacer and/or Strand; and may be supplied in a 5cm, 7cm, or 12 cm stainless steel needle [where X = length of needle].

RSLN-X-SS	**Stranded, No Spacer**
RSLN-X-SS/S	**Stranded, With Spacer**
RSLN-X-LL	**Loose Load, No spacer**
RSLN-X-LL/S	**Loose Load, With Spacer**

Caution: Consult Accompanying Documents
Do Not Reuse
Consult Instructions for Use
STERILE EO Ethylene Oxide Sterilization
Use by Date
REF Catalog Number
Do not Resterilize
Biohazard
Radioactive

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