

IsoAid Advantage® Radioactive Seed Localization (RSL)

Patient Information Leaflet

Introduction and Indications for Use

You have been implanted with an IsoAid Advantage® I-125 low activity radioactive seed. The I-125 Radioactive Seed Localization Needle is indicated to aid in the diagnosis of non-palpable tumors, lesions or associated lymph nodes in the breast by defining tumor, lesion or node location with a radioactive seed in preparation for excision. (Non-palpable means that it cannot be found during a clinical examination, but can be identified by ultrasound, mammogram or MRI.) The Advantage RSL is intended to be used on adult individuals with non-palpable tumors/lesions/nodes in the breast. The radioactive seed is intended to be excised within 30 days of implant.

Materials in the I-125 Radioactive Seeds

In addition to the radioactive I-125, depending on the configuration of the I-125 radioactive seed ordered by your physician, you may be exposed to the following materials:

- Titanium
- Violet synthetic absorbable 90% glycolide and 10% L-lactide copolymer monofilament
- Poly-L/D lactic acid (70L/30DL) absorbable copolymer
- Bone Wax consisting of beeswax, isopropyl palmitate, paraffin

The above materials have been commonly used in medical implant applications for many years and have undergone biocompatibility testing to assure their safe use in humans.

Warnings and Precautions:

MRI Environment

In the event you require an MRI, you should inform your physician that you have an I-125 radioactive seed implanted. The seeds have been tested and are considered “MR Conditional” according to industry standards. You may safely undergo an MRI under certain conditions. Please inform the MRI facility of your RSL implant and physician information so that your attending physician can be contacted prior to undergoing an MRI.

Airport Radiation Detectors

If you will be traveling, it is safe to go through the radiation scanner, but radiation may be detected.

Radiation Exposure

The I-125 seed contains a very low dose of radiation. The seed is not intended to deliver therapy or treatment; it is used as a marker so your physician can detect the exact location of your tumor, lesion or node when ready for excision.

In Case of Emergency

In case of an emergency, please notify emergency personnel that you have radioactive seed implanted.

If you have any other questions, or experience any pain or discomfort, please speak to your physician.

Manufactured by:

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