



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

**PRODUCT NAME:**  
**ADVANTAGE MAGAZINE® / ADVANTAGE PD-103 SEED®**

**(ADVANTAGE MAGAZINE® LOADED PD-103 SEEDS)**

**Description:**  
 The Advantage Magazine™ is a shielded, disposable seed delivery device (accessory) comprised of two major components; a carrier magazine and a shielding magazine head. The design of the Advantage Magazine™ reduces unintended exposure to ionizing radiation, especially to the hands and fingers. The Advantage Magazine™ can be ordered pre-sterilized or non-sterile containing one to fifteen sources each of Advantage PD-103. The ADVANTAGE PD-103® source consists of a laser welded Titanium capsule, containing Palladium-103chemically affixed (adsorbed), as silver iodide, onto a silver rod which acts as an x-ray detectable marker.

**Indications for Use:**

**Refer to the Advantage PD-103® Instructions for Use (IFU)**

The IsoAid Advantage Magazine™ is intended for the adult population for treatment of selected localized tumors, by facilitating the implantation of active ADVANTAGE PD-103 seeds as a nuclear radiation source for therapy. The Advantage Magazine™ is intended to be used with a seed applicator, and seed applicator needle. Brachytherapy is indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.



**Advantage Magazine™ Specifications & Features:**

- Advantage Magazine Specifications & Features:**
- Shielded Magazine Head
  - Disposable (one-time use only)
  - 15 Seed Maximum Capacity
  - Compatible with industry Applicator
  - Autoclavable
  - Cost Effective

**Indications for Use (Secure Seed®):**  
**Refer to the Advantage PD-103® Instructions for Use (IFU).**

The Advantage Magazine with the is indicated for use in the loading and delivery of radioactive seeds as an accessory. Tumors of the head, neck, breast, lung, pancreas, and prostate are commonly treated. It is intended to be used on individuals with tumors that are localized, unresectable, or have low to moderate radiosensitivity. The IsoAid Advantage Magazine is intended for the treatment of selected localized tumors. The radioactive seeds are intended to be a permanent implant.

The ADVANTAGE PD-103 sources consist of a laser welded Titanium capsule, containing Palladium-103chemically affixed (adsorbed), as silver iodide, onto a silver rod which acts as an x-ray detectable marker. Note: See Advantage PD-103 Instructions For Use.

**⚠ Contraindications:**

⚠ Do not use a non-sterile magazine to implant sources. Do not use a damaged seed or a seed that may have become damaged when loading the applicator. Direct contact with seeds should be avoided. Use vacuum or reverse action tweezers to handle seeds.

**Physical Characteristics:**  
 Palladium-103has 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 PD-103 seeds.

**Calibration:**  
 ADVANTAGE PD-103 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<sup>2</sup>/h) as well as Apparent Activity (mCi).

ADVANTAGE PD-103 sources are calibrated to the NIST SK99std WAFAC standards for PD-103 seeds.

**Sterilization:**  
 When the Advantage Magazine™ is provided sterile, product is sterilized to a Sterility Assurance Level of 10<sup>-6</sup> by Ethylene Oxide gas. The sterile packaging has a thirty-one (31) day shelf-life. If the products expiration date is exceeded the product's sterility may be compromised and the product is considered not sterile. Do not use and do not re-sterilize the product.

⚠**WARNING:** If Advantage Magazine™ is supplied non-sterile, sterilization must be performed prior to implant. Always refer to the sterilizer manufacturer's instructions or those provided by the health care institution.

⚠**WARNING:** Temperature should not exceed 280°F / 138°C

**CAUTION:** DO NOT autoclave Advantage Magazine™ in plastic tubing or containers which have a low melting point as it may prevent source recovery.

**The parameters for sterilization by steam are based on the following sterility information:**

<b>Validation Method</b>	<i>-ANSI/AAMI/ISO 17665-1 Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices</i>  <i>-ISO 17664 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.</i>
<b>SAL</b>	10 <sup>-6</sup>

**When Advantage Magazine™ is supplied sterile, product is sterilized by Ethylene Oxide with a Sterility Assurance Level [SAL] of 10<sup>-6</sup>**

**In Vivo Characteristics:**  
 Clinical efficacy results from the interaction of the emitted ionizing radiation from ADVANTAGE PD-103® source with the tissue being treated. Dose calculations should account for a moderate anisotropic dose distribution around each ADVANTAGE PD-103® source. Appropriate parameters should be included in treatment planning.

Titanium encapsulation provides biocompatibility. If Secure Seed is used in the Magazine the absorability of the polymer is expected to extend to 18 months.

**Instructions for Safe Use:**  
 The radioactive seed is introduced via an 18-gauge needle using standard ultrasound or radiography guidance with the compatible Mick® Applicator: Mick® 100, Mick® 200-TP and Mick® 200-TPV Applicators, compatible with Advantage® 1-125 Seeds. Once guided to the desired location of the lesion, the seeds are deployed via the applicator stylet, through the applicator needle cannula.



Ultrasound or radiography confirms the appropriate placement of the seed.

**Directions for Use:**

If Advantage Magazine is supplied nonsterile; and must be sterilized prior to use. A qualified practitioner trained in brachytherapy should place the sources within the tumor according to the treatment plan to achieve the desired tissue dose distribution. The seeds will fit in a standard 18-gauge (1.2 mm) applicator needle. When using commercially available applicators refer to the instructions for use to determine compatibility with the device. Ultrasound or radiography confirms the appropriate placement of the seeds. "The Advantage Seeds are licensed by the department for distribution to persons licensed pursuant to 64E-5, F.A.C., Part VI or under equivalent licenses of the United States Nuclear Regulatory Commission, an agreement state or a licensing state."

**Radiation Protection & Handling:**

The 27- 35.5 KeV photons of PD-103 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 PD-103 results in a reduction of exposure to attending medical personnel and visitors. PD-103 sources should be handled only by those individuals trained by an authorizing governmental agency in the safe use & handling of radioisotopes.

- Direct contact with PD-103 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 PD-103 seeds.

**Accountability & Disposal:**

Records of receipt, storage and disposal of ADVANTAGE PD-103® sources should be maintained in accordance with government regulatory policies. PD-103 sources should be strictly controlled and stored in a secured area.

When disposal is indicated, the ADVANTAGE PD-103® sources should be transferred to an authorized radioactive waste disposal agency or returned to IsoAid for disposal. ADVANTAGE PD-103® 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 concerning procurement, possession, use and disposal of radioactive materials is the responsibility of the customer.

**Canada- Canadian Nuclear Safety Commission**

Application of REGDOC-2.12.3, Security of Nuclear Substances: Sealed Sources for typical uses of sealed sources, Brachytherapy - low dose rate is a category 4 source. Category 4 Sources that are very unlikely to permanently injure anyone. However, this amount of unshielded radioactive material, if not safely managed or securely protected, could possibly – although it is unlikely – temporarily injure someone who handled it or was otherwise in contact with it, or who was close to it for a period of many weeks. This Code of Conduct on the Safety and Security of Radioactive Sources was approved by the Board of Governors of the International Atomic Energy Agency (IAEA) on 8 September 2003. It replaces the version published (with the symbol IAEA/CODEOC/2001) by the IAEA in March 2001. It reflects the important findings produced by the International Conference on Security of Radioactive Sources held in Vienna in March 2003 (the Hofburg Conference). Member States to be encouraged to join and effectively implement these Conventions. Canada is already a signatory to these conventions, together with codes of conduct on nonproliferation, research reactors and the safety and security of radioactive sealed sources, along with the Comprehensive Nuclear Test-Ban Treaty.

Canadian Nuclear Safety Commission  
280 Slater Street P.O. Box 1046  
Station B Ottawa, Ontario K1P 5S9 CANADA  
Tel.: 613-995-5894 or 1-800-668-5284 (in Canada only) Facsimile: 613-995-5086 Email: [info@cnsccsn.gc.ca](mailto:info@cnsccsn.gc.ca)  
Web site: [nuclearsafety.gc.ca](http://nuclearsafety.gc.ca)

**Australia- Australian Radiation Protection and Nuclear Safety Agency**

The establishment of a NRWMF is governed by the National Radioactive Waste Management Act 2012. A NRWMF also needs to adhere to the Environment Protection and Biodiversity Conservation Act 1999, the Nuclear Non-Proliferation (Safeguards) Act 1987 and the Australian Radiation Protection and Nuclear Safety Act 1998.

The proposed National Radioactive Waste Management Facility would be a controlled facility under the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act). Under the Act, licences are required to prepare a site for, construct, or operate a controlled facility. The decision to submit a licence application is a matter for the applicant. Before an application is made to the CEO of ARPANSA for a licence to prepare a site for the National Radioactive Waste Management Facility, the applicant will have to obtain approval from the Minister for the Environment under the Environment Protection and Biodiversity Conservation Act 1999. Before any radioactive material is allowed to be transported it must be packed, shielded, labelled and marked as set out in the ARPANSA Code: Safe Transport of Radioactive Materials. This code is based on the International Atomic Energy Agency's (IAEA) Regulations for Safe Transport of Radioactive Material. [nrwmfsupport@arpansa.gov.au](mailto:nrwmfsupport@arpansa.gov.au); [www.arpansa.gov.au](http://www.arpansa.gov.au).

A radioisotope is considered to be for medical use when it is intended to be:

1. administered to humans or used for any therapeutic procedure or purpose in any planned exposure of humans to ionising radiation
2. used in any in vitro medical diagnosis or test
3. used in research which is either directly or indirectly related towards medical diagnosis or therapy in humans.

**Note: Sealed and unsealed radioactive sources that are used to calibrate instruments in medical practices and pathology laboratories are also included as medical radioisotopes for permit purposes. The applicant/"end user" declares that he/she holds an appropriate licence issued by the relevant Commonwealth, State or Territory radiation regulatory authority to deal with the above radioisotopes. The applicant/"end user" also undertakes not to supply any of the above radioisotopes to an unapproved user. The applicant/"end user" should contact the relevant Commonwealth, State or Territory radiation regulatory authority for advice on legislative requirements. [medicalpermits@arpansa.gov.au](mailto:medicalpermits@arpansa.gov.au) ; [www.arpansa.gov.au](http://www.arpansa.gov.au).**

ARPANSA, like other regulatory bodies in Australia and abroad, has been working on developing capability in holistic safety. Charged with the function of protecting the health and safety of people under the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act), ARPANSA proposes to use a holistic approach to assess and monitor the safety of licence



holders and applicants. These guidelines outline ARPANSA's vision and expectations for holistic safety.

**⚠ Adverse Reactions:**

- Any adverse reaction associated with tissue radiation damage may be associated with use of Advantage PD-103 sources. Proper precautions must be taken when handling the sources.
- As with any surgical procedure, complications may occur including: bruising, discomfort, prolonged bleeding, inflammation 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/or spacer together prior to implantation.
- As brachytherapy sources achieve therapeutic results through radiation, any adverse event associated with tissue radiation damage may be associated with use of Advantage sources.
- Adverse reactions associated with implant usage in the prostate. Bladder, uterus, anal and colon implant usage have been reported to include irritative uropathy symptoms including increased urinary frequency, urgency, incontinence, and obstruction.
- Complications have also included cystitis, urethritis, superficial urethral necrosis, hematuria, stricture/contracture, incontinence, proctitis, and impotence, bleeding and discharge, fibrosis and necrosis.
- Seed migration to other parts of the body is possible.
- Allergic reaction to Iodine.

**⚠ Precautions:**

- ⚠ Use caution when patients are diagnosed with non-cancerous tumors/lesions.
- ⚠ 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 Advantage Magazine and the Advantage PD-103 seeds in neurological or cardiovascular tissues.
- ⚠ The Advantage Magazine 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 use bent or broken applicator needle.

- ⚠ Do not come in direct contact with the Advantage PD-103 source. Use vacuum or reverse action tweezers to handle the Advantage PD-103 sources.
- ⚠ The applicator needles, Advantage Magazine Cartridge, Advantage Magazine are not to be used in an MRI environment
- ⚠ The Advantage Cartridge and the Advantage Magazine are 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 Advantage I-125 Seed 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 if package has any signs of damage. Properly discard package if damaged 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 re-sterilize! Single use only.
- ⚠ The Advantage Magazine is not designed to screw into or out of the applicator.
- ⚠ Do not handle the Advantage Magazine by the protruding spring-loaded plunger.
- ⚠ THE SEED MAGAZINE IS DESIGNED TO SEAT INTO THE MICK APPLICATOR BY

SIMPLY PUSHING IT INTO THE MAGAZINE RECEPTOR WITH A NOTICEABLE "CLICK".

- ⚠ Do not exceed the maximum loading capacity Per cartridge. (Max. 15 seeds / cartridge)
  - ⚠ Do not overtighten the round magazine head.
  - ⚠ Do not let seeds drop into the magazine groove.
  - ⚠ Do not use force on seeds; handle seeds gently!
  - ⚠ Initiate radiation surveys on all components upon completion of seed implants.
  - ⚠ Use appropriate radiation protection and precautions when handling radioactive materials.
  - **⚠ ASCERTAIN THAT CARTRIDGE IS "EMPTY" PRIOR TO DISPOSAL. "CONDUCT RADIATION SURVEY"**
- Sterilization:**
- ⚠ WARNING: If Advantage Magazine™ is supplied nonsterile, sterilization must be performed prior to implant.
  - ⚠ Always refer to the sterilizer manufacturer's instructions or those provided by the health care institution.
  - ⚠ WARNING: Temperature should not exceed 280°F /138°C
  - ⚠ CAUTION: DO NOT autoclave Advantage Magazine™ in plastic tubing or containers which have a low melting point as it may prevent source recovery.

# ISOAID

The parameters for sterilization by steam are based on the following sterility information:

<b>Validation Method</b>	-ANSI/AAMI/ISO 17665-1 Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices -ISO 17664 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
<b>SAL</b>	10 <sup>-6</sup>

When Advantage Magazine is supplied sterile, product is sterilized by Ethylene Oxide with a Sterility Assurance Level [SAL] of 10<sup>-6</sup>

### Patient Education:

Patients and people who come into contact with the patient must be informed of the nature of the PD-103 implants and follow radiation precautions as outlined by the National Council on Radiation Protection and Measurements, federal (US), state, and/or other government regulations. In the event that an implanted source has dislodged and become separated from the patient, instruction should be given in proper handling of the loose implant. The implant should not be picked up by hand. A spoon or tweezers can be used to place it into a container such as a glass jar with lid. The jar should then be placed in an isolated area in the home until a local regulatory center or hospital radiation department can be contacted.



**MR-Conditional:**

The Advantage PD-103 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 Advantage PD-103 seeds has been evaluated for safety in the MRI environment. It is MR-conditional and has been

tested for heating, migration, and image artifact in the MRI environment.

⚠ 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.**

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

⚠ **CAUTION: Canadian National and Regional/State law(s) restrict this device to sale by or on the order of a physician.**

⚠ **CAUTION: Australian National and Regional/State law(s) restrict this device to sale by or on the order of a physician.**



The expelled Advantage™ Seed is considered biohazardous and must be contained and disposed of in accordance with standard precautions.

<b>#3008S</b>	<b>Advantage Magazine® loaded with Advantage PD-103 Seeds</b>
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	Caution: Consult Accompanying Documents
	Do Not Reuse
	Consult Instructions for Use
	Ethylene Oxide Sterilization
	Use by Date
	Catalog Number
	Do not Resterilize
	Date of Manufacture

	Biohazard
	Radioactive
	MR Conditional
	Do not use if package is damaged

### Leak Testing:

ADVANTAGE™ PD-103 Brachytherapy sources are 100% leak tested prior to shipment and have passed a leak test showing less than 185 Bq (5 nCi) of removable PD-103 surface contamination as required by ISO 9978 "Radiation protection – Sealed radioactive sources." ADVANTAGE PD-103 seeds do not require any additional leak testing provided the seeds are used within the use-by-date.

### Dosage and Administration:

The most commonly used source activity levels for prostate cancer treatment is between 0.2 mCi and 0.7 mCi. Other source strengths are available by special order.

### Adverse Reactions:

- Any adverse reaction associated with tissue radiation damage may be associated with use of PD-103 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.
- Adverse reactions associated with implant usage in the prostate have been reported to include irritative uropathy symptoms including increased urinary frequency, urgency and obstruction.
- Complications for prostate brachytherapy may include cystitis, urethritis, superficial urethral necrosis, hematuria, stricture/contracture, incontinence, proctitis and impotence.
- Although the risk of source migration is minimal it can be significantly reduced through the use of the Secure Seed, which provides additional adhesion to tissue once implanted.

### Precautions:

- Product should remain in shielded pouch until ready for use. Handle shielded pouch and contents with care to prevent damage to product.

### Contraindications:

- Do not use radioactive seed needles in neurological or cardiovascular tissues.
- The Advantage Magazine™ may be sold sterile. If packaging is damaged the sterile barrier may be compromised. Use of a non-sterile device may compromise patient care.





- Caution should be taken when using an MRI to aid in delivery of the seed. The needles used to deliver the seeds are stainless steel and may affect the quality of the diagnostic information.
- 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 PD-103 source. Use vacuum or reverse action tweezers to handle the PD-103 sources.

The use of ADVANTAGE™ PD-103 sources is not recommended for the treatment of tumors in generally poor or ulcerated condition.

**⚠ 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.
- ⚠ Do not use if damaged. Discard if damaged during use or after use in accordance with waste disposal procedures.
- ⚠ Do not use on patients that are less than 18 years old, this product is intended for use in adults.
- ⚠ Do not attempt to screw the Advantage Magazine™ into, or out of the applicator.
- ⚠ Do not handle the Advantage Magazine™ by the protruding spring-loaded plunger.

**Patient Education:**

Patients and people who come into contact with the patient must be informed of the nature of the PD-103 implants and follow radiation precautions as outlined by the National Council on Radiation Protection and Measurements, federal (US), state, and/or other government regulations. In the event that an implanted source has dislodged and become separated from the patient, instruction should be given in proper handling of the loose implant. The implant should not be picked up by hand. A spoon or tweezers can be used to place it into a container such as a glass jar with lid. The jar should then be placed in an isolated area in the home until a local regulatory center or hospital radiation department can be contacted

**⚠ MR MR-conditional**

Magnetic force on the seeds in the MR systems with 3T or less and with maximum spatial gradient in the static field of less than 30 T/m (3000 G/cm) is not expected to pose an added risk to the patient. The PD-103 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.

⚠ Do not use needle, applicator needle, Advantage Magazine Cartridge and Advantage Magazine in MRI Environment

⚠ The PD-103 seed has been evaluated for safety in the MRI environment. The seeds are MR-conditional and have been tested for heating, migration, and image artifact in the MRI environment.

⚠ **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.**

**☣ Seeds that have become separated from their host are considered biohazardous and must be contained and disposed of in accordance with standard precautions.**

	Caution: Consult Accompanying Documents
	Do Not Reuse
	Consult Instructions for Use
	Ethylene Oxide Sterilization
	Use by Date
	Catalog Number
	Do not Resterilize
	Date of Manufacture
	Biohazard
	MRI Conditional
	Radioactive
	Do not use if package is damaged

**Manufacturer:**  
**IsoAid LLC**  
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 Port Richey, Florida 34668  
 United States of America  
 Ph: +1-727-815-3262