



Instructions for the use of RAPID Strand for Interstitial Brachytherapy Treatments

Product Code: IMC7000

Warnings

For reasons of safety and to ensure correct usage, read these instructions carefully before unpacking, using, storing, transporting or disposing of the medical brachytherapy sources.

Medical brachytherapy sources must only be used by qualified persons or by trained assistants working under their direct supervision.

The sources must not be modified.

These instructions must always accompany the brachytherapy sources and be readily available to all persons using them.

You should be aware of the following:

- Radiation sources emit ionizing radiation
- Radioactive material may be released if the radiation sources are damaged

Before receiving, installing or using radiation sources or any radioactive material you must ensure that:

- You are complying with your national or state regulations (see section 19)
- You are aware of the necessary precautions required to ensure:
 - Safe handling of the radioactive material (see sections 12, 14, 15 and 17)
 - Safe use (see sections 16 and 17)
 - Safe storage (see section 13)
 - Safe transportation (see section 13)
 - Safe disposal of the radioactive material (see section 15)

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1. Product Description

1.1 Model 7000 RAPID Strand™ (code IMC 7000) consists of 11 violet colored absorbable seeding spacers and 10 Model 6711 seeds (IMC 6711 - welded titanium capsules containing iodine-125 adsorbed onto a silver rod) spaced at a fixed distance within an absorbable braided carrier, stiffened and then sterilized by ethylene oxide (see figure 1).

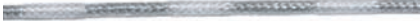


Figure 1: Model 7000 RAPID Strand (code IMC 7000)

1.2 The apparent activity of the ten seeds ranges from 0.191 to 1.016 mCi and corresponding air kerma strength values of 0.243 to 1.29 $\mu\text{Gy}/\text{h}$ per seed [To convert activity value from mCi to Megabecquerel (MBq), multiply by 37]. All Model 6711 seeds in each RAPID Strand have the same median activity (see figure 2 below).

1.3 RAPID Strand is sterilized by ethylene oxide gas and is sterile when shipped. **RAPID Strand should not be resterilized.**

1.4 The relative expanded uncertainty in the reported values of air kerma strength and apparent activity are estimated to be $\pm 7\%$ with a coverage factor of 2 corresponding to the 95% confidence interval. (For accounting and regulatory purposes, the activity content in mCi of a single RAPID Strand seed may be calculated by multiplying the apparent activity in mCi by 1.78).

1.5 RAPID Strand is designed to fit into an 18 gauge, thin walled needle (internal diameter 1 mm) using gentle pressure.

2. Physical Characteristics

- Principle Radionuclide: iodine-125
- Radionuclide Purity: > 99.9% iodine-125
< 0.005% iodine-126
- Half-life of Iodine-125: 59.43 days¹
- Types of Radiation: X-ray and Gamma
- Energy Level: X-ray/Gamma Photon 27.4 keV
X-ray 31.4 keV
Gamma 35.5 keV
Fluorescent X-Rays 22.1 keV

and
from the Silver Rod 25.2 keV

- Decay Mode:

Iodine-125 decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of Model 6711 seeds

2.1 Silver Rod

The silver rod inside the titanium capsule acts as an X-ray marker.

2.2 Shelf Life of Seeds

The useful "shelf life" of the seeds can be calculated by considering the day of use after the reference date and corresponding value of decay factor.

CAUTION: Unused RAPID Strand must be disposed of within six months of the leak test date shown on the certification form accompanying the product.

2.3 Physical Decay Calculation

To correct for the physical decay of iodine-125, the decay factors at selected days after the reference date are shown in the Decay Chart table on next page:

3. Mode of Action

3.1 The clinical efficacy of RAPID Strand derives solely from the interaction of the emitted ionizing radiation with the tissue being treated. The stiffened absorbable braided carrier holds seeds in place in the tissue being treated to aid proper placement and dosimetry and to minimize seed movement.

3.2 Dose distribution around each individual seed is not isotropic². This anisotropy should be included in dose distribution calculations.

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

3.4 Absorption of the carrier material is essentially complete between the 60th and 90th days¹⁰.

4. Indications/Intended Use

4.1 RAPID Strand is indicated for permanent interstitial implantation of selected localized tumors that are of low to moderate radio sensitivity.

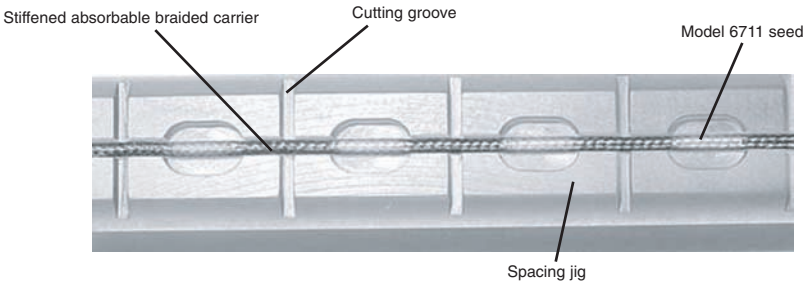


Figure 2: RAPID Strand

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

It may be used either as primary treatment (such as prostate cancer or unresectable tumors) or for the treatment of residual disease after excision of the primary tumor.

4.2 RAPID Strand may be indicated for use concurrent with or at the completion of other treatment modalities such as external beam radiation therapy or chemotherapy¹¹⁻¹³.

5. Contraindications

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

6. Warnings

- 1) RAPID Strand is shipped sterile and must not be resterilized. Do not use if package is open or damaged.**
- 2) Do not use visibly damaged RAPID Strand for implantation.**
- 3) Do not apply excessive force during loading/removing of RAPID Strand.**
- 4) Do not pick up seeds with the fingers, use forceps.**
- 5) For single use only.**
- 6) To minimize radiation exposure, use proper shielding in handling of RAPID Strand.**
- 7) Caution should be exercised in performing Transurethral Resection of the Prostate (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 residual radioactivity of the iodine-125 seed should be considered prior to the use of electrocautery.

7. Precautions

Customers should bring the warnings and instructions provided in this booklet to the notice and attention of users and operators prior to RAPID Strand being administered to a patient. If in doubt about how to proceed contact your adviser on radiation protection or Oncura.

7.1 Loading/Unloading

Do not force RAPID Strand into (or from) any spacing jig, afterloading catheter, or needle; doing so may damage radioactive seeds, potentially causing release of iodine-125 into the environment and into body fluids should the seed be implanted.

Under no circumstances should visibly damaged RAPID Strand be implanted.

7.2 Seed Corrosion

The titanium shell of Model 6711 seeds has excellent corrosion resistance under normal use. However, do not expose RAPID Strand to acid or alkaline solutions exceeding 1 molar. Seeds are not affected by common solvents such as acetone and alcohol or by mild detergents.

Do not use iodine-125 seeds in a concentrated hydrochloric acid environment.

7.3 Personnel Monitoring

RAPID Strand is 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 Thermoluminescent Dosimeter (TLD) worn on the body and a ring badge (during seed handling) is adequate.

8. Adverse Reactions

General

Since RAPID Strand delivers 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.

8.1 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 urine¹⁴. These symptoms are usually treated supportively. Incidents of asymptomatic seed embolization to the lungs have been noted in the literature³³.

8.2 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 months¹⁵⁻¹⁹. Generally, these are transient, mild effects which resolve spontaneously or require minor intervention.

8.3 Erectile dysfunction has been noted as a possible adverse effect, with an incidence ranging from 6 - 30%, as published by some groups^{15, 19-21}. The risk of impotence may be age-related¹⁹. Proctitis may occur, with several groups reporting a 2-6% incidence^{16, 19, 22, 23}. Long-term incontinence is uncommon^{15, 19, 22}, although patients who have previously undergone transurethral resection of the prostate (TURP) are at a higher risk^{24, 25}. Urethral stricture has been reported in a small percentage of cases^{15, 16, 19}.

9. Patient Counseling Information

9.1 All patients should be informed of the nature of RAPID Strand implants and the expected period of time during which radiation precautions will be necessary.

9.2 Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received a RAPID Strand implant²⁶.

9.3 Guidelines for necessary precautions have been established by European communities. *Medical and Dental Guidance Notes: A Good Practice Guide in all Aspects of Ionizing Radiation Protection in the Clinical Environment* (ISBN 19036 13094).

10. How Supplied

10.1 RAPID Strand is held within a plastic spacing (and cutting) jig and placed inside a stainless steel shielding tube. The shielding tube is placed in a plastic tray. The tray assembly is then placed in sterilization pouch, and later sealed in dust bags.

10.2 The label is affixed on the sterilization pouch showing the following information: Order I.D. number; apparent activity per seed in mCi and MBq; total apparent activity in mCi and MBq; number of seeds; reference date and expiration date. The lot number will be stamped on the sterilization pouch.

11. Directions for Use

General

11.1 RAPID Strand should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides.

11.2 Radiation detection equipment capable of detecting 30 keV photons should be available whenever RAPID Strand is being handled.

11.3 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 exposure²⁹⁻³².

On Receipt of Package

11.4 The package should be inspected on arrival and if any damage is observed which could have

resulted in damage to the product then the package must not be opened.

11.5 If the package is undamaged, check that the documentation and label description agrees with the order acknowledgment. If there are differences do not open the package, place in a secure area and notify Oncura or its authorized representative as soon as possible.

11.6 Notify the person responsible for radiation protection that the package has arrived. Update the official accountancy record for radioactive substances noting the identification, activity and date.

11.7 If the package is not opened immediately, a suitable secure store must be provided (see section 13 of these instructions).

Unpacking

11.8 Sources must only be unpacked in a specially designated area by trained, competent and authorized personnel. Radiation levels should be checked using an appropriate dose-rate meter at each stage of unpacking. Sections 11, 12 and 17 of these instructions should be read carefully and preparations made for using the sources or transferring them to a storage facility before unpacking them.

11.9 The package should be undamaged. If for any reason the white sterilization pouch has been damaged or become unsealed then do not proceed, as there will be a risk that the product is no longer sterile.

11.10 When unpacking the product for use, first remove the outer bags from the carton. Working in a clean, controlled environment open the outer plastic bag to access the inner bags. Open the inner bag and remove the sterilization pouch.

11.11 Using aseptic techniques peel open the gas sterilization pouch and remove the plastic tray (see figure 3). Remove the tray lid and place the shielding tube onto a flat working surface.

11.12 Remove the tube end cap and, using forceps, pull the spacing jig, flat face uppermost, out of the shielding tube far enough to expose the required number of seeds (see figure 4).

12. Handling

12.1 When preparing RAPID Strand for implantation, manipulation should be with forceps working behind shielding as far as practicable.

12.2 At the ends of each RAPID Strand there is excess absorbable braided carrier material used to locate the strand on the spacing jig. This excess material is not to be implanted and should be removed by cutting with a razor sharp scalpel in the perpendicular grooves on the spacing jig. If it is required to create a short section of RAPID Strand use a razor sharp scalpel to cut the absorbable braided carrier at the appropriate perpendicular groove on the spacing jig (see figure 5).

12.3 Any manipulation of RAPID Strand should be carried out in a clean environment behind shielding of adequate thickness. RAPID Strand should be handled gently, grasping one of the seeds (see figure 6) using forceps. Keep as much distance as practical between product and the operator.

Care must be taken to avoid cutting seed.

Do not grasp the absorbable braided carrier material between seeds.

12.4 If a razor blade, scalpel, or other sharp tool is used to remove RAPID Strand from the spacing jig, afterloading catheter, or needle, 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 iodine-125 into the environment.

12.5 It is not recommended to use an electrocautery device to cut RAPID Strand.

12.6 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 or its authorized representative.

12.7 All radioactive products should be handled, used, stored, transported or disposed of properly and in accordance with the appropriate regulations. To avoid danger it is essential that these instructions are strictly observed.

13. Storage and Transportation

13.1 Radioactive sources must be kept in a suitable receptacle and store at ambient temperature when not in use or being transported. This is a legal requirement in most countries.

13.2 The store must be adequately shielded, correctly labeled and fully secured against intrusion by any unauthorized persons. The dose rate on the outside of the store should not normally exceed 2.5 $\mu\text{Sv/h}$ (0.25mrem/h).

13.3 Care should be taken to ensure that sources are not trapped or bent when storage drawers are closed.

13.4 Although these sources are classed as sealed sources it is good practice to make regular checks for surface contamination in the area where they are handled and on any equipment with which they come into contact. These sources are intended for use at room temperature. Temperatures in excess of ambient temperature will lead to a change in the dose distribution around the seeds.

13.5 RAPID Strand should be stored in ambient conditions typically found in a laboratory environment i.e. temperature $<25^{\circ}\text{C}$ away from moisture and direct heat.

13.6 RAPID Strand will retain its sterile status as long as the sterile package is undamaged. Due to the radioactive decay of iodine-125 the product will normally be used considering the reference date and corresponding decay factor.

13.7 The stainless steel container effectively shields $>99.9\%$ of the photons from iodine-125 seeds. The stainless steel container may be used for storage and transport of RAPID Strand.

14. Accidental Damage or Loss

14.1 If the package is damaged or has been involved in an accident or exposed to adverse



Figure 3: Opening of sterilization pouch

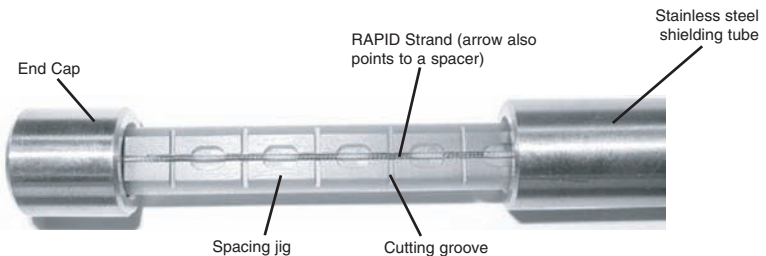


Figure 4: RAPID Strand in spacing jig and shield

conditions (see section 7.2) then appropriate precautions must be taken according to your contingency plans. Seeds that have been cut, bent or found to be leaking must not be used.

14.2 Oncura must be informed and further advice sought from the appropriate radiological protection service. In certain circumstances, inform the national regulatory authority and radiation protection service, providing contact information. In any case of doubt consult Oncura. If a seed is lost, the person responsible for radiation protection must inform the federal or state licensing agency. Records of any investigations taken to locate the lost seed must be kept for an appropriate period.

14.3 Although RAPID Strand has high structural integrity, it is possible through rough handling, exposure to excessive temperature, crushing or cutting to rupture a seed, causing it to release "free" iodine-125.

If this happens, the area of the accident should be closed off; the seeds should be sealed in a 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 iodine-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

15. Accountability/Storage/ Disposal

For U.S. Customers

15.1 Iodine-125 is an accountable radioactive material. RAPID Strand should, therefore, be strictly controlled and stored in a safe location. If any significant material cannot be accounted for, the loss must be reported to the federal or state licensing agency.

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

15.3 A RAPID Strand disposal service is provided by GE Healthcare. Customers wishing to dispose of RAPID Strand in this manner must contact Oncura Customer Care for instructions and authorization to return prior to shipment.

For Non-U.S. Customers

15.4 Where a radiation seed is re-sold, incorporated in other products or is transferred on in any other way, it is the responsibility of the seed user to ensure that all subsequent users are made aware of the nature of the seed and the specified use. Proper records must be kept of the transfer of the radioactive seeds.

15.5 All users must be supplied with a copy of the original GE Healthcare certification form, these instructions and any other relevant information that is required to ensure safe use and disposal of the seed and any product into which the seed is incorporated.

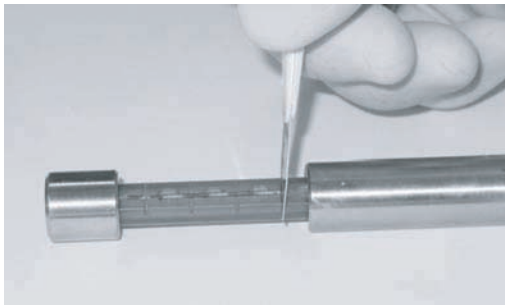


Figure 5: Cutting RAPID Strand using a perpendicular groove as a guide



Figure 6: Removing RAPID Strand from spacing jig

15.6 After use the seed and all materials intimately associated with the use of the seed (including any unused seed and its container) should be treated as potentially radioactive material. Where appropriate these materials should be decontaminated and checked before disposal. Any active or contaminated material (solid or liquid) should be disposed of in accordance with the conditions specified by the local competent authority and through an approved agency licensed to deal with radioactive waste. Such conditions should include specifications of the method or methods of disposal, maximum permitted activity levels and the nature of necessary containment.

15.7 When a seed is no longer required and is to be disposed of, contents must be properly packed and documented prior to being sent for disposal. Care should always be taken to minimize radioactive waste. Advice on the safe disposal of seeds is available from Oncura.

15.8 It is important that equipment which contains radioactive seeds is clearly designated as such and the possibility of accidental contamination or radiation exposure of the public by scrap disposal activities is avoided. Equipment that has contained radioactive material should be thoroughly checked for seeds and contamination before disposal.

15.9 If seeds have to be removed from a patient either at the end of the treatment or when a seed has been inadvertently displaced, they should be removed carefully to avoid seed damage. Patients must be checked with an appropriate radiation monitor to confirm that all the seeds have been removed.

15.10 Following removal, seeds should be inspected for damage and returned to the radioactive materials store where they should be counted and stock records updated.

16. Dosage and Administration

16.1 The total activity of Model 6711 seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice^{5-9, 27, 28} should be followed for the calculation of the total activity to be implanted, the proper placement of the seeds within the tissue, and the evaluation of the radiation dose distribution achieved.

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

16.2 RAPID Strand is commonly used to treat early stage prostate cancer. Special care should be taken when planning RAPID Strand implantation of those patients who have undergone, or may undergo, surgical treatment of the gland, to ensure that the prescribed location of seeds and radiation dose are achieved.

16.3 Each Model 6711 seed in RAPID Strand is measured by GE Healthcare and the median of activity range is noted on the certification form provided with the seeds. Decay calculations must be made to determine the activity of the seeds on the day of implantation.

It is recommended that the physician verify the values stated in the certification form before administering seeds to a patient³⁴.

Traceability

A record must be maintained of the quantity and lot numbers of each RAPID Strand used in each procedure. The lot number is printed on the product's packaging labels and certification report.

16.4 RAPID Strand may be used with a variety of appropriate accessories, e.g., needles and applicators. Never force RAPID Strand into or out of an accessory as doing so may damage the seed, potentially leading to a release of iodine-125.

16.5 In the United Kingdom customers should refer to the *Medical and Dental Guidance Notes: A Good Practice Guide in all Aspects of Ionizing Radiation Protection in the Clinical Environment (ISBN 19036 13094)*.

17. Radiological Protection

17.1 In the UK, a 'Controlled Area' may be required where instantaneous dose rates could exceed 7.5 $\mu\text{Sv/h}$. A particular room or building may be designated or an area marked out. The boundary of this area must be suitably labeled. Outside the UK customers should contact their adviser on radiation protection for advice.

17.2 Care must be taken to avoid inadvertent exposure to personnel and unintentional exposure to patients from the X-ray and gamma radiations.

17.3 Minimize personnel exposure using:

Time
Distance
Shielding

Time: Minimize time spent by personnel near the seed.

The total dose received in working with a seed is directly proportional to the time taken to carry out the work. If the work takes twice as long then the dose is twice as great.

Good planning helps to reduce exposure time to a minimum.

Distance: Maximize the distance between seeds and personnel.

Exposure is greatly affected by distance in accordance with the inverse square law. For example, if the distance is doubled the dose-rate is reduced to one quarter of its original value but if the distance is halved the dose-rate will increase fourfold.

Note that the dose rate at 1 mm is 10,000 times greater than it is at 100 mm.

Use forceps to handle a seed, do not touch with the fingers.

Shielding: Use shielding between seeds and personnel where possible.

Dense, high atomic number materials such as lead are preferred to reduce gamma radiations. Your adviser on radiation protection should be able to advise on shielding requirements as necessary. The half value thickness of lead for iodine-125 is approximately 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99.9% reduction in exposure.

17.4 A suitable calibrated dose rate meter must be used to check actual dose rates to personnel in the vicinity.

17.5 Check for contamination using an appropriate calibrated monitor in the working area after each operation. RAPID Strand is classed as sealed sources and as such, there should be no release of radioactivity during normal use, however, if contamination is found refer to your contingency plans.

17.6 Consideration must be given to taking precautions in the event of the death of a patient with a permanent implant. The Guidance Notes referenced in section 16.5 should be consulted. Outside the UK, contact your federal or state licensing agency.

18. Inspection and Testing

18.1 Capsule designs are assessed for their suitability for typical applications in accordance with the requirements of the International Organization for Standardization (ISO).

Please obtain advice from Oncura if in doubt as to the suitability of a seed for a particular application.

18.2 Model 6711 seeds are leak tested in accordance with ISO standards during manufacture prior to fabrication as RAPID Strand. Details of the tests performed are given in our certification.

18.3 Leak Testing

Prior to fabrication of RAPID Strand, all constituent seeds have passed a leak test showing <185 Bq, <0.005 µCi of removable iodine-125 as required by Illinois Emergency Management Agency 32 Ill. Adm. Code Part 335, Subpart C, 335.2050. This leak test date is printed on the Certification form that accompanies each shipment.

18.4 It is the user's responsibility to inspect RAPID Strand before use to ensure that there are no obvious signs of damage. Under no circumstances should visibly damaged RAPID Strand be used.

19. Regulations

The general information and instructions for safe use in this leaflet are applicable wherever the seeds are used. Specific advice is given to enable UK users to comply with UK regulations. In other countries the user should consider what additional steps may be needed to comply with their regulations.

19.1 Licensing (U.S.)

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.

19.2 Licensing (Europe)

Before ordering or using radiation seeds or any other radioactive material customers must take whatever actions are necessary to ensure that they are complying with their national or state regulations governing the use of such materials. In most countries regulations are closely related to the

International Atomic Energy Agency (IAEA) regulations and codes of practice.

If radioactive seeds have to be transported for use it is necessary to comply with the current IAEA Safety Standards Series - Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised). No. TS-R-1 (ST-1, Revised).

Depending on the mode of transport, it is also necessary to comply with the regulations of:

IATA- International Air Transport Association
and

ICAO- International Civil Aviation Organization
or

IMO- International Maritime Organization
or

ADR- European Road Regulations.

Road transport in Great Britain is governed by The Radioactive Material (Road Transport) (Great Britain) Regulations 1996.

19.3 UK Regulations

In the UK, the principal legislation governing the keeping and use of radioactive substances (including radiation sources) is the Radioactive Substances Act 1993 (RSA), the Health and Safety at Work Act 1974 (HSWA) and the Ionizing Radiation Regulations 1999 (IRR).

Before obtaining any radioactive substances or for the first time undertaking work with ionizing radiation in the UK, a person or organization must:

- register and obtain a certificate of registration from the appropriate Environment Agency in England and Wales, Scotland or Northern Ireland.

and

- notify the Health and Safety Executive (HSE) or the Department of the Environment in Northern Ireland of the intention to carry out the work at least 28 days before commencing the work.

and

- appoint a suitably qualified and experienced Radiation Protection Adviser (RPA), having given the HSE at least 28 days prior written notice of the intended appointment.

- Having appointed an RPA his advice must be sought on how the regulations are to be observed and, generally, as regards safety in the work to be done. In particular the RPA must be asked to advise on:

- the selection and training of Radiation Protection Supervisors (RPS) to supervise the work;

- the drawing up of written systems of work and local rules for the work to be done;

- appropriate training for the person(s) doing the work;

- appropriate dosimeters, dose-rate meters and contamination monitors;

- hazard assessments;

- contingency plans for dealing with any reasonably foreseeable accident occurrence or incident involving the seeds.

19.4 European Medical Device Regulations

RAPID Strand is an Active Implantable Medical Device as defined by the European Directive 90/385/EEC and carries the mark of conformity originally issued in 1996.



20. Feedback

Oncura strives at all times to provide products and services that are suitable for the required applications together with information which will ensure safe use of these products. Information from users regarding the performance of seeds in their specified applications is important to Oncura's continuing program of development and the company welcomes any such information.

Please contact the nearest Oncura representative for feedback or assistance. The contact information is provided on the last page of this booklet.

21. References

1. "X-Ray and Gamma Standards for Detector Calibration", International Atomic Energy Agency, Tech Doc-619, September, pp 149 (1991).
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