

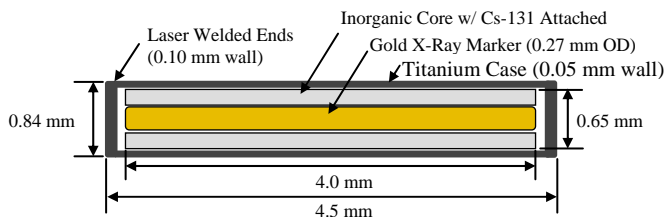
For Single Use, R_x ONLY

Description

Proxcelan™ Cesium-131 Brachytherapy Seeds, Non-sterile Model No. CS-1, (Rev. 2)

NONSTERILE – Seeds must be sterilized before use.

The Proxcelan brachytherapy seed consists of a welded titanium capsule containing the low energy gamma (X-ray) emitting isotope, Cesium-131, adsorbed onto an internal inorganic substrate. The seed configuration is designed to generate near isotropic emission of therapeutic radiation.



Physical Characteristics

Principle Radionuclide:	Cesium-131	(Cs-131)
Half-life of Cs-131:	9.69 days	(232.6 hr)
Radiation Energy:	29.5, 29.8, 33.6 keV	
Half-Value Thickness:	0.025 mm of Lead	
Average Dose Rate Constant:	1.059 cGy/U-Hr.	
Decay Mode:	Cs-131 decays by electron capture with the emission of characteristic low-energy X-ray photons and electrons. The electrons are absorbed by the titanium wall of the seed.	
Radionuclide Purity:	> 99.85%	Cs-131
	< 0.1%	Cs-132
	< 0.05%	All other radioisotopes

Indications

Proxcelan brachytherapy seeds are indicated for the treatment of malignant disease (e.g., head and neck, eye, brain, breast, prostate, etc.) and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. The seeds may be used as a primary treatment or in conjunction with other treatment modalities, such as external beam radiation therapy, chemotherapy or as treatment for residual disease after excision of primary tumors⁽¹⁾.

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g. ulcerated) is not recommended with Proxcelan brachytherapy seeds due to the potential for source migration.

Warnings

Warning: Proxcelan brachytherapy seeds are supplied non-sterile, in a tamper-evident container and must be sterilized prior to implantation using a qualified sterilization procedure.

Sterilization Procedure:

IsoRay recommends steam sterilization at 121° C (250°F) for 30 minutes. For adequate steam penetration, remove the lids from the stainless steel container or the outer lead shielding container and the inner glass vial containing the seeds. Sterilize the seeds in the stainless steel container or glass vial and lead container as well as the separated lids. USING ASEPTIC TECHNIQUE, replace the lids on the stainless steel container or glass vial and the lead container. The stainless steel container or glass vial and lead container should be upright during the sterilization process. As a precaution, the steam autoclave should be equipped to prevent seed loss through the condensate drain in the event that seeds are spilled inside the autoclave. DO NOT USE COLD CHEMICAL STERILIZATION. Some cold chemical sterilization solutions may leave a residue which can interfere with seed loading and implantation.

Warning: Never implant visibly damaged Proxcelan brachytherapy seeds. Proxcelan brachytherapy seeds should not be handled roughly or forced into (or from) any implant tube, needle, or cartridge, since this may breach the external

casing, potentially releasing free Cs-131 into the environment and/or body fluids if implanted. If this should happen, close off the area, seal the seeds in a shielded container, restrict personnel movement to avoid spread of any radioactive contamination, and survey/decontaminate the area and personnel according to established radiological procedures.

Precautions

Caution: Proxcelan brachytherapy seeds contain radioactive Cesium-131. Proxcelan brachytherapy seeds should only be handled in authorized, licensed facilities by experienced personnel who are fully trained and qualified in the safe use of radioactive materials by the appropriate regulatory agency. The seeds are quite small and are visually difficult to locate when dropped. All radiation and contamination surveys should be performed using calibrated equipment that is capable of detecting 30 keV photons (low energy X-rays). Personnel monitoring for radiation exposure is required (e.g., film badge, thermal luminescent dosimeter, finger rings, etc.). The half-value thickness of lead for Cesium-131 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide ~99.9% reduction of exposure.⁽²⁾

Caution: Proxcelan brachytherapy seeds exhibit a high surface dose rate. Appropriate precautions must be taken during handling. (e.g., keep sources shielded, away from personnel, and minimize exposure time). Plan the implantation procedure to minimize radiation exposure to personnel.⁽³⁻⁴⁾ The 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. SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

Caution: Do not expose seeds to extreme environmental conditions. The outer titanium shell of the Proxcelan brachytherapy seed has excellent biocompatibility and stability under normal use. Seeds are not affected by moderate pressure, vacuum, or temperature, common solvents (e.g., acetone, alcohol, etc.), or mild detergents. Do not expose seeds to strong acids or bases. Do not expose seeds to excessive temperatures greater than 300°C or pressures greater than 100 psi.

Caution: Caution is necessary if a post-implant transurethral resection of the prostate (TURP) is required due to the possibility of damaging the implanted seeds and the potential for a seed to be removed resulting in a risk of radiation exposure to staff.

Instructions for Use

Proxcelan brachytherapy seeds may be implanted using standard brachytherapy implant techniques, e.g., 18 gauge UTW brachytherapy needle, seed applicator, brachytherapy sleeves, etc. Radiological protection devices should be utilized during implantation procedures. When protective barriers are not practical, e.g., certain surgical stages, the user must rely on time and distance to minimize radiation exposure.

Determination of Source Shelf-Life

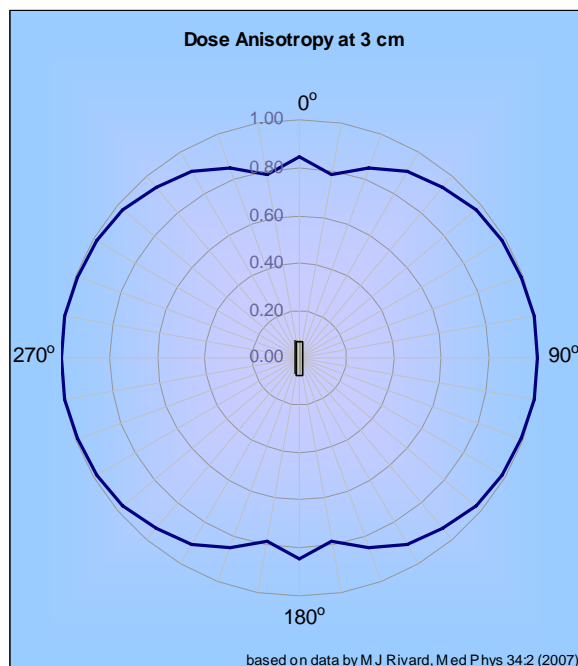
Proxcelan brachytherapy seeds contain Cesium-131 with a 9.69 day half-life and must be corrected for decay in order to properly calculate activity at the time of implantation as is shown in the table below:

<u>Day</u>	<u>Factor</u>	<u>Day</u>	<u>Factor</u>	<u>Day</u>	<u>Factor</u>
0	1.0000	11	0.4553	22	0.2073
1	0.9310	12	0.4238	23	0.1930
2	0.8667	13	0.3946	24	0.1796
3	0.8069	14	0.3673	25	0.1672
4	0.7512	15	0.3420	26	0.1557
5	0.6993	16	0.3184	27	0.1449
6	0.6510	17	0.2964	28	0.1349
7	0.6061	18	0.2759	29	0.1256
8	0.5643	19	0.2569	30	0.1170
9	0.5253	20	0.2392	31	0.1089
10	0.4890	21	0.2226	32	0.1014

Dosage and Administration

The total activity and placement of Proxcelan brachytherapy seeds required for any given treatment depends upon a number of well-established factors (e.g., treatment goals, tumor location/volume/shape, radiation history of the tumor site, concurrent treatments, etc). Established practice should be followed for the proper placement of the sources within the tissue, and for evaluation of the radiation dose distribution achieved during implantation.⁽⁵⁻¹⁰⁾

The Proxcelan brachytherapy seed is designed to produce a nearly isotropic dose distribution. The dose characteristics of the Proxcelan brachytherapy seeds have been confirmed through extensive Monte Carlo evaluations in accordance with American Association of Physicists in Medicine (AAPM) Task Group 43 (TG-43) guidelines^(5, 11). The radiation dose contour of the Proxcelan brachytherapy seed at a radius of 3 cm from the source appears in the figure below.



Proxcelan brachytherapy seeds are available with Air-Kerma strengths from 0.1 to 27 U, [microGray meter squared per hour ($\mu\text{Gy m}^2/\text{h}$)].⁽¹²⁻¹⁵⁾ AAPM guidelines for brachytherapy should be followed for independent verification of source output.⁽⁵⁻⁷⁾ A certificate of analysis is provided with each shipment that includes: customer order number, lot number, number of seeds, reference date, implant date, and average and total activities expressed as apparent activity (mCi) and Air Kerma strength ($\mu\text{Gy m}^2/\text{h}$) traceable to NIST (National Institute of Standards and Technology). Additional information, including patient and physician names, may be provided upon request.

Adverse Reactions

The potential for, and symptoms of, adverse events related to radiation exposure will vary depending on the radiosensitivity of the exposed tissue, the amount of radiation delivered, and the placement of the seeds themselves. The following information has been derived from articles published in the medical literature.

Mild to moderate genitourinary and gastrointestinal events have been documented in the general literature regarding the tolerability of brachytherapy. 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.⁽¹⁶⁾ These symptoms are usually treated supportively. Short-term urinary symptoms (e.g., frequent urination, discomfort, or difficulty voiding), similar to Iodine-125 brachytherapy have been reported with Proxcelan seeds. These symptoms are generally mild to moderate and often resolve quickly within 4 - 6 months.⁽¹⁷⁻²⁰⁾ Impotence has been noted as a possible long-term adverse effect of brachytherapy which may be age-related and often dependent on pretreatment factors.⁽²¹⁾ Long-term incontinence is uncommon,⁽²⁰⁻²²⁾ although patients who have previously undergone transurethral resection of the prostate (TURP) may be at a higher risk.^(20,23) Urethral stricture after brachytherapy has been reported in a small percentage of cases.^(20, 24) Rectal complications associated with prostate seed

implantation, (e.g. fecal incontinence and rectal bleeding), have been reported in the literature.^(17,25) Incidents of asymptomatic seed embolization to the lungs associated with brachytherapy seeds have been reported in the general literature.⁽²⁶⁾

Patient Counseling Information

All patients should be informed of the nature of Proxcelan brachytherapy 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 a Proxcelan brachytherapy seed implant. Guidelines for necessary precautions and patient release have been established.⁽²⁷⁻²⁹⁾

All patients should be advised of the possibility that, during a course of treatment, one or more seeds may be released into the urine or semen. Bandages or linens which come into contact with the implant site should be scrutinized for small metallic seeds (4.5 mm long). Patients should be advised that whenever seeds are found, they should be picked up with a spoon, placed in a jar or other container, and stored in an uninhabited area in the home. Patients should notify their health care provider as soon as possible after such an occurrence.

Patients should be informed to advise their physician of the implant if a transurethral resection of the prostate (TURP) is considered due to the possibility of damaging the implanted seeds and the potential for a seed to be removed resulting in a risk of radiation exposure to staff.

Accountability

Proxcelan brachytherapy seeds may only be distributed to persons licensed pursuant to Washington State Department of Health (WDOH) regulations or under equivalent licenses of the U.S. NRC or an Agreement State, and outside the United States, to persons authorized by the appropriate authority.

As with all radioactive materials, seeds must be controlled in accordance with approved procedures by authorized personnel in licensed facilities. When not in use, seeds should be stored in shielded containers in a controlled area (additional user requirements may also apply). If any radioactive material cannot be accounted for, the loss must be reported to the appropriate state or federal licensing agency.

Immediately report to IsoRay Customer Service any discrepancies between ordered and received shipments or any damaged or misrouted shipments. Dispose of damaged or unused seeds in compliance with local, state and federal regulations. If seed disposal services are desired, contact IsoRay Customer Service for return authorization at **1-509-375-5329**. Radioactive materials approved for return must comply with applicable U.S. Department of Transportation regulations (49 CFR 173) regarding packaging and labeling.

Leak Testing

Proxcelan brachytherapy seeds are leak tested prior to shipment and have passed a leak test showing $< 0.005 \mu\text{Ci}$ of removable Cs-131 as required by Washington State Department of Health (WDOH) regulations. This leak test date and value are printed on the Certification of Analysis that accompanies each shipment. The user is not required to perform additional leak testing.

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