GT Medical TECHNOLOGIES
Tempe, AZ 85281

GammaTile®

MR Conditional

℞ Only

STERILE

For single use

Do not resterilize

Do not use if sterile packaging is damaged.

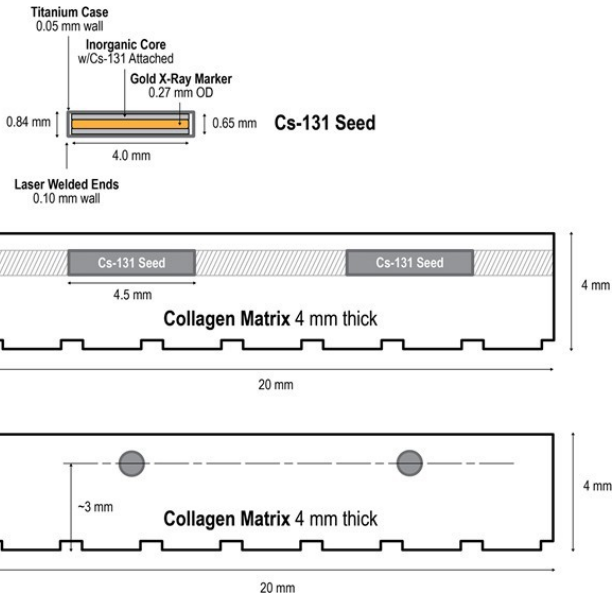
REF GT-001

Device Name: GammaTile®

Sterile, Implantable Brachytherapy Device
containing Model CS-1, (Rev.2) Seeds

Description

The radiation source component of GammaTile is the four (4) embedded Cs-131 brachytherapy seeds. Each 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. The seeds are spaced at a fixed distance within an absorbable braided strand (sleeve) and the strands spaced within an absorbable collagen matrix.
The carrier matrix used in GammaTile is a soft, white, pliable, nonfriable, porous collagen matrix with a mechanically strengthened collagen component.



Physical Characteristics

Principal 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

GammaTile is intended to deliver radiation therapy in patients with newly diagnosed malignant intracranial neoplasms and recurrent intracranial neoplasms.

Contraindications

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

GammaTile should not be used for patients with known history of hypersensitivity to bovine derived materials.

Possible complications can occur with any neurosurgical procedure and include cerebrospinal fluid leaks, infection, delayed hemorrhage and adhesion formation.

Warnings

Damaged Devices or Seeds: Never implant visibly damaged GammaTile or loose brachytherapy seeds

Any manipulation of GammaTile must be done very carefully to avoid damage to the seeds. The seeds must not be crushed or handled roughly since this may breach the external casing, potentially releasing Cs-131 into the environment. 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.

Sterilization: **Do not re-sterilize**. GammaTile are shipped sterile and must not be re-sterilized.

Warning: GammaTile and loose brachytherapy seeds should not be exposed to therapeutic levels of ultrasound energy, as the seeds may inadvertently concentrate the ultrasound field and cause harm.

Precautions

Caution: GammaTile and loose brachytherapy seeds contain radioactive Cesium-131.

GammaTile and loose 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 if 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 Cesium-131 half-value thickness of lead is 0.025 mm. Thus, a 0.25 mm lead sheet will provide ~99.9% reduction of exposure[1].

Caution: GammaTile and loose brachytherapy seeds exhibit a high surface dose rate.

Appropriate precautions must be taken during handling (e.g., keep devices shielded, away from personnel, and minimize exposure time). Plan the implantation procedure to minimize radiation exposure to personnel. [2,3] The devices should be handled behind shielding of adequate thickness. Forceps (either reverse or normal action) should be used to maintain adequate distance. If normal action forceps are used, gentle pressure should be applied so that the devices are not damaged. GAMMATILE OR LOOSE SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

Caution: Do not expose GammaTile or loose brachytherapy seeds to extreme environmental conditions.

Brachytherapy seeds have an outer titanium shell which has excellent biocompatibility and stability under normal use. Seeds are not affected by moderate pressure, vacuum, temperature, common solvents (e.g., acetone, alcohol, etc.), or mild detergents. Do not expose the seeds to strong acids or bases. The braided strand material is not compatible with steam or temperatures exceeding 55ºC (131ºF). Do not expose seeds to pressures greater than 100 psi.

How Supplied

GammaTile are an absorbable collagen embedded with Cesium-131 Brachytherapy Seeds spaced nominally 1 cm center to center in Polyglactin 910 absorbable braided strands. The collagen material is nominally 4mm thick with the seeds offset ~3mm from the textured side of the collagen. The collagen serves as a matrix to support the strands and provide a three-dimensional spacer during the implant procedure.

Instructions for Use

GammaTile must only be used by individuals who are qualified by training and experience in the safe use and handling of radionuclides. With the patient properly anesthetized, a qualified practitioner may line operative bed with the GammaTile. The implant of GammaTile does not require use of conventional brachytherapy seed applicators. The following cautions must be observed:

- Radiation detection equipment should be available when handling the GammaTile. **Use extreme care to avoid making contact with or cutting a seed**. A damaged seed may release radioactive Cesium-131 into the area.
- Any manipulation of the GammaTile must be done under strict aseptic conditions while working behind shielding and putting as much distance as feasible between tile and personnel.
- Hydrate suturable DuraGen in sterile saline or equivalent irrigating solution
- The textured side of the collagen should be placed against tissue in the resected cavity to offset the seeds from the surface of the brain.

- A contamination survey of the area should be performed after any manipulation of the GammaTile to ensure seeds have not been damaged. If contamination is found in the area, the seeds should be sealed in a container and a decontamination process should be followed for the area and the personnel in the area. **Do not implant GammaTiles with seeds that have been damaged**.

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.

Determination of Source Shelf-Life

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 following table:

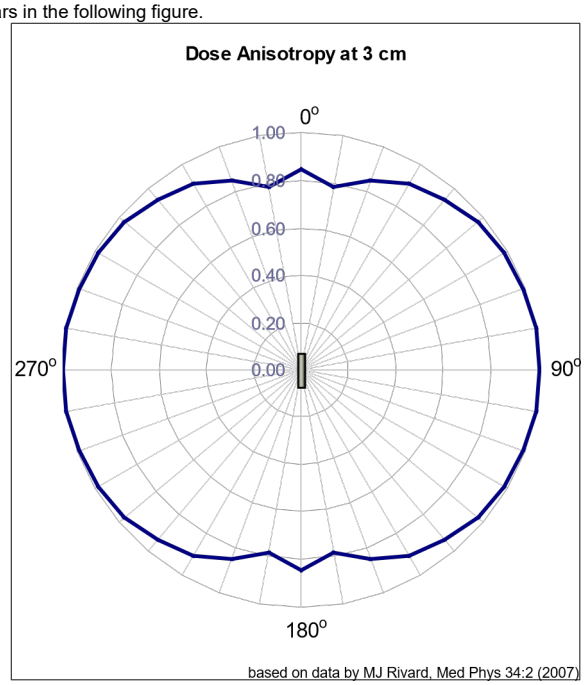
Cesium-131 Decay Chart (9.69 Day Half-Life)

Day	Factor	Day	Factor	Day	Factor
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 brachytherapy seeds required for any given treatment depends on 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 sources within the tissue and for evaluation of the radiation dose distribution achieved during implantation[4-8].

The brachytherapy seed is designed to produce a nearly isotropic dose distribution. The radiation dose contour of the brachytherapy seed at a radius of 3 cm from the source appears in the following figure.



The dose characteristics of GammaTile have also been confirmed through extensive Monte Carlo evaluations in accordance with American Association of Physicists in Medicine (AAPM) Task Group 43 guidelines[4, 9].

Each Cesium-131 brachytherapy seed contained in a GammaTile is targeted to provide Air-Kerma strength of 3.5 U [microGray meter squared per hour ($\mu Gym^2/h$)][12-15] at time of implant. AAPM guidelines for brachytherapy should be followed for independent verification of source output[4-6]. A certificate of analysis is provided with each shipment that includes: customer order number, lot number, patient identifier, physician name, number of seeds, number of GammaTiles, reference date/implant date, and average and total activities expressed as apparent activity (mCi) and Air Kerma strength ($\mu Gym^2/h$) traceable to NIST (National Institute for Standards and Technology).

Adverse Reactions

The Cesium-131 Brachytherapy Seeds contained in the GammaTile deliver a prescribed amount of radiation to the target tissue in order to provide therapy. 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.

Patient Counseling Information

All patients should be informed of the nature of GammaTile 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 GammaTile. Guidelines for necessary precautions and patient release have been established[14-16].

Accountability

Before ordering or using GammaTile containing Cesium-131 brachytherapy seeds, customers must comply with their national or state regulations regarding the use of radioactive materials. In most countries, regulations are closely related to the International Atomic Energy Agency (IAEA) regulations and codes of practice. In the U.S., 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 (Nuclear Regulatory Commission) or an Agreement State.

As with all radioactive materials, Cesium-131 brachytherapy seeds must be controlled in accordance with approved procedures by authorized personnel in licensed facilities. When not in use, GammaTile and loose 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 (national) licensing agency.

Immediately report any discrepancies between ordered and received shipments or any damaged or misrouted shipments to GT Medical Technologies Customer Service. Dispose of damaged or unused GammaTile or loose seeds in compliance with local, state and federal (national) regulations. If disposal services are desired, contact GT Medical Technologies Customer Service for return authorization at **1-833-662-0044**. Radioactive materials approved for return must comply with all applicable U.S. Department of Transportation regulations (49 CFR 173) regarding packaging and labeling.

Leak Testing

Each Cesium-131 brachytherapy seed contained in the GammaTile is leak tested prior to shipment and has passed a leak test showing < 0.005 µCi of removable Cs-131 as required by Washington State Department of Health (WDOH) regulations. The leak test date and value are printed on a certificate of analysis with each shipment.

MRI Safety Information

Non-clinical testing demonstrated that GammaTile is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode

Under the scan conditions defined, the GammaTile is expected to produce a maximum temperature rise of 2.8°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the GammaTile extends approximately 4-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Telsa MR system.

Literature Citations and References

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