For single use  
Do not re-sterilize  
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

**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 should be available (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.

**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 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. GAMMATEIL 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 55°C (131°F). 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 place 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.
- Tiles should not overlap each other. If a tile needs to be cut, cut the tile with sterile surgical scissors, using forceps to hold the tile as it is cut, and being careful to cut parallel to the braided strand lines.
- 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 collagen carrier in sterile saline or equivalent irrigating solution.

**Indications**

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

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**GammaTile® GT-001 Rev 0**

Tempe, AZ 85281
The total activity and placement of brachytherapy seeds required for any given treatment must be corrected for decay in order to properly calculate activity at the time of implantation as shown in the following table:

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</table>

**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.

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 Physicians in Medicine (AAPM) Task Group 43 guidelines.
Literature Citations and References