GammaTile®

GammaTile® Tile-Based Radiation Therapy (TBRT) – Redefining the Operable Brain Tumor Treatment Paradigm

Brain metastases affect up to 40% of all cancer patients and significantly impact survival and quality of life.[1] While surgery followed by stereotactic radiation therapy (SRT) has been the standard of care for patients with operable tumors, its limitations are well-recognized, with a 1-year tumor recurrence rate of approximately 16%.[2] Brain metastases present great risk to patients and require novel interventions that can improve outcomes. In addition, up to one third of patients miss or significantly delay postoperative radiation due to access barriers, fragmented care pathways, or logistical challenges,[3] creating a critical gap in care that GammaTile fills.

HOW GAMMATILE® ADDRESSES THE GAP IN CARE

GammaTile is a bioresorbable, FDA-cleared collagen tile embedded with Cesium-131 radiation seeds. By placing the tile directly into the surgical cavity at the exact time of tumor removal, it eliminates the standard multi-week delay typically required for surgical healing before traditional external radiation can begin.

- **Immediate Treatment:** Radiation begins on "Day 0" at the time of surgery, targeting residual microscopic tumor cells when they're at their weakest.
- **Guaranteed Treatment Initiation:** Because the therapy is implanted during surgery, it eliminates the risk of patients missing or delaying their radiation due to care fragmentation, insurance delays, or access barriers.
- **Streamlines the Radiation Treatment Course:** For patients receiving radiation to the surgical site, GammaTile consolidates that component of treatment into the surgical procedure itself, eliminating the treatment gap and need for additional outpatient radiation sessions to the resection cavity.

The ROADS Randomized Clinical Trial

The ROADS (Randomized Controlled Trial of Resection [Surgery] and GammaTile® versus Standard of Care) (NCT04365374) clinical trial is a pivotal phase 3 study. The trial, which completed randomization of 230 patients in 32 leading cancer centers in the United States in August 2025, evaluated whether implanting GammaTile immediately at the time of surgery, with no waiting or time lost, could improve outcomes compared with the current standard of care (surgery followed by SRT). The standard approach requires a recovery period before radiation can begin, during which remaining microscopic tumor cells may regrow.

KEY TOPLINE FINDINGS

Data from the ROADS clinical trial, presented as a Late-Breaking Abstract at the 2026 Annual Meeting of the American Society of Clinical Oncology (ASCO26), demonstrated that patients who received GammaTile at the time of surgery had significantly lower rates of tumor regrowth, were more likely to live longer without recurrence, and had significantly improved overall survival compared to patients who received standard radiation therapy after surgery.[3]

GammaTile TBRT showed superior performance in the study's co-primary endpoints[3]

- Surgical bed recurrence rate was dramatically lower with GammaTile vs. standard radiation therapy (1.0% vs. 11.9%, HR: 0.06, p=0.007)
- Patients who received GammaTile were more than 50% less likely to experience tumor recurrence or death compared to standard radiation therapy (HR: 0.48, p=0.002).

GammaTile TBRT provided benefit in key secondary endpoints[3]

- Overall survival was significantly improved with GammaTile: estimated 24-month survival was 61.7% (GammaTile) vs. 35.7% (standard radiation therapy) (HR: 0.59, p=0.032)
- Total cranial radiation to the resected tumor was completed in a median of 1 day (GammaTile) vs. 30 days (standard radiation therapy) (p<0.001)
- Rates of radiation necrosis, leptomeningeal disease, adverse events, functional status, and quality of life were similar between arms

GammaTile TBRT ensured patients received their prescribed radiation therapy[3]

- All patients in the GammaTile arm received complete radiation therapy
- In contrast 82.1% patients in the standard radiation therapy arm received their prescribed postoperative SRT - consistent with published data showing that incomplete or delayed postoperative radiation is a known and documented limitation of the current standard of care[4,5]

REFERENCES

1. Lamba N, et al. *Neuro-Oncology.* 2021;23(9):1447–1456.
2. Weinberg J. J Clin Oncol 44, 2026 (suppl 17; abstr LBA2000).
3. Roth O'Brien, et al. *J Neurosurg.* 135:1695–1705 (2021).
4. Brennan C, et al. *Int J Radiat Oncol Biol Phys.* 2014;88:130–136.
5. Yeboa DN, et al. *JAMA Oncol.* 2025;11(8):890–899.

GammaTile

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GammaTile® is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms. The potential for, and symptoms of, adverse events related to radiation exposure vary depending on the radiosensitivity of the exposed tissue, the amount of radiation delivered, and the placement of GammaTile(s). GammaTile should not be used for patients with a known history of hypersensitivity to bovine-derived materials. More information on indications, contraindications, warnings, and instructions for use can be found in the GammaTile Instructions for Use.