

The NeuroBlate™ System MRI-Guided Neurosurgical Ablation

Monteris Medical, Inc.®

Monteris Medical Inc. was founded in 1999 to address unmet needs of brain cancer patients. Monteris has focused on developing and converging three core medical technologies: controlled, focused application of laser interstitial thermal therapy (LITT), real-time Magnetic Resonance Imaging (MRI) thermometry, and minimally-invasive, MRI-guided surgical procedures. The Monteris product portfolio includes the NeuroBlate™ System, the AXiiiS® Stereotactic Miniframe, and the Atama™ Headcoil and Stabilization System. Monteris has locations in Winnipeg, Manitoba, Canada and Minneapolis, MN, USA.

Overview

Monteris Medical is focused on providing innovative MRI-guided solutions for neurosurgeons treating brain tumors. The NeuroBlate™ System (formerly known as the AutoLITT® System) applies focused laser energy to ablate tumors from the inside, with little or no effect on surrounding healthy tissue. NeuroBlate users have access to new levels of control and visualization during tumor destruction. The NeuroBlate procedure is currently the only neurosurgical procedure done in an active MRI magnet.

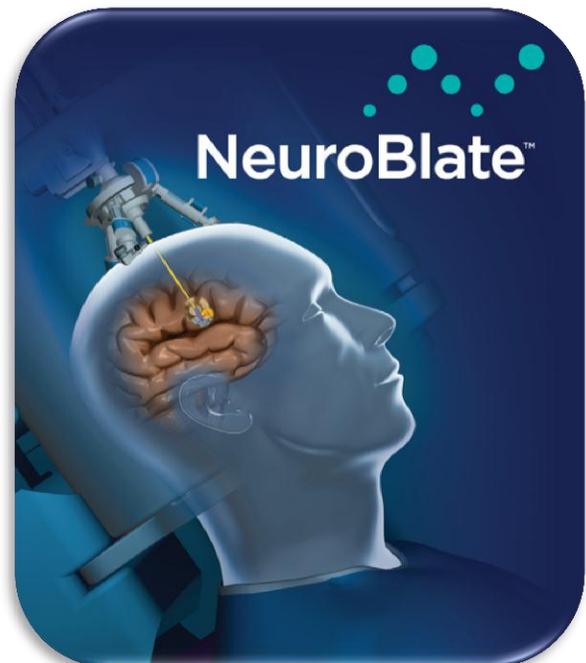
The NeuroBlate System procedure is minimally-invasive, surgeon controlled, and provides immediate target tumor coagulation (cell death) with minimal patient side-effects. The procedure employs a unique, side-firing laser probe, real-time MRI-thermometry, and proprietary software to enable the treating neurosurgeon to precisely “sculpt” the ablation to conform to irregular tumor margins. With traditional brain tumor surgery surgeons use MRI after a procedure to determine if the entire tumor has been removed. NeuroBlate allows the surgeon to use MRI visualization *during live surgery*, offering a new set of metrics for surgical decision making. The small diameter NeuroBlate laser probe can reach most areas of the brain, potentially expanding the number of patients who can have their tumor treated.

This new approach may benefit the brain tumor patient who has been told he/she is not a candidate for traditional surgical excision of a life threatening malignant tumor, based on tumor size or location.

The NeuroBlate™ System

The NeuroBlate™ System is a 510(k) cleared, commercially available device in the U.S. The system includes an installed, capital component and an assortment of consumable patient care items. The NeuroBlate™ System includes

- 1064nm solid state laser, computerized cooling and electronics system
- Remote controlled laser delivery with surgeon workstation and monitor
- Proprietary MRI-compatible positioning devices and consumable items which enable minimally-invasive access in cranial neurosurgery.



The NeuroBlate System can be used with both 1.5 Tesla and 3.0 Tesla MRIs to ablate brain tumors under direct visualization. MRI-compatible, remote controlled components send information to the surgeon via Monteris proprietary M°Vision software. Monteris has adapted and incorporated MRI thermometry into M°Vision to display an accurate, near-real-time temperature and predictive thermal damage display of the entire treatment region.

The system enables a treating neurosurgeon to access the brain through a small burr hole in the skull, to deliver thermal energy selectively on a specific portion of the tumor and to limit the thermal damage to that portion only. The procedure promises to be an alternative option for brain tumors when surgical resection and/or radiosurgery may be sub-optimal or contraindicated.

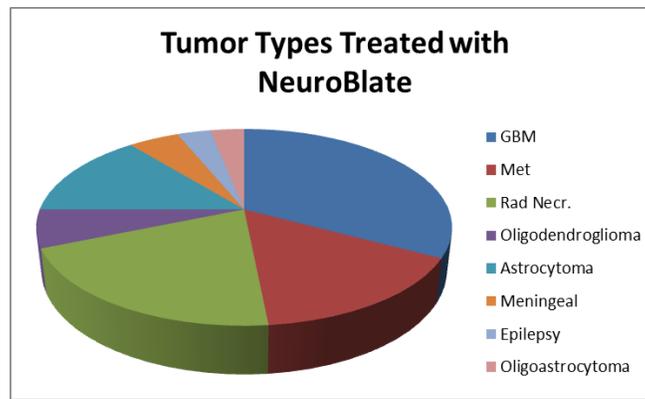
Reimbursement

CMS has established a specific ICD-9 code (17.61: “MRI-guided laser interstitial thermal therapy (LITT) of lesion or tissue of brain”) for NeuroBlate. This code tracks to Diagnosis Related Groups (DRG’s) 25, 26, 27: “Craniotomy & Endovascular Intracranial Procedures”. Hospitals are being reimbursed by Medicare for use of the NeuroBlate System.

New Technology Distinction from CMS: Effective October 1st, 2010 a New Technology Add-On Payment of \$5,300 was approved by the Center for Medicare and Medicaid Services (CMS) for use of the NeuroBlate System in brain neoplasm cases, diagnosis Glioblastoma Multiforme (GBM). In August, 2012, CMS extended this New Technology Add-On for an additional year. Medicare patients diagnosed with GBM and treated with NeuroBlate will trigger this additional payment to their hospital provider.

Clinical Experience

The NeuroBlate System has been used to treat many types of tumors and brain lesions. This is consistent with our broad 510(k) clearance for use to “necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 lasers”.



Information

More information on the NeuroBlate™ System and on Monteris Medical can be found at www.monteris.com

