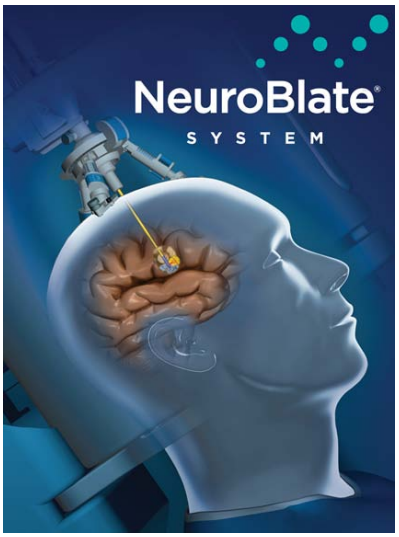
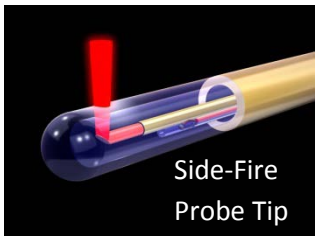
Summary

The NeuroBlate system (known earlier in its development as AutoLITT) is a MR guided, minimally invasive laser thermal therapy system developed for the treatment of brain tumors and other neurologicial applications. It provides the neurosurgeon with a new minimally invasive tool for thermal destruction of brain tumors rather than using ionizing radiation or invasive surgery. It is fully image guided in that the entire treatment procedure is done with the patient inside a MRI allowing the surgeon to visualize the thermal destruction of the target area in real time with MRI thermometry allowing conformal treatment of the entire region identified for treatment. As such, it interfaces with both diagnostic or intra-operative MRI suites either at 1.5 or 3 Tesla magnetic field strength commonly found in neuro-centers around the world.



The system includes several components developed to achieve accurate and targeted LITT (Laser Interstitial Thermal therapy):

1. Laser delivery probes providing either a side fire or diffuse energy pattern at their tip which are inserted into the tumor via stereotactic guidance. The side fire probe achieves a focal or directional energy pattern whereas the diffuse tip probe achieves a more rapidly expanding, larger ellipsoidal thermal lesion.

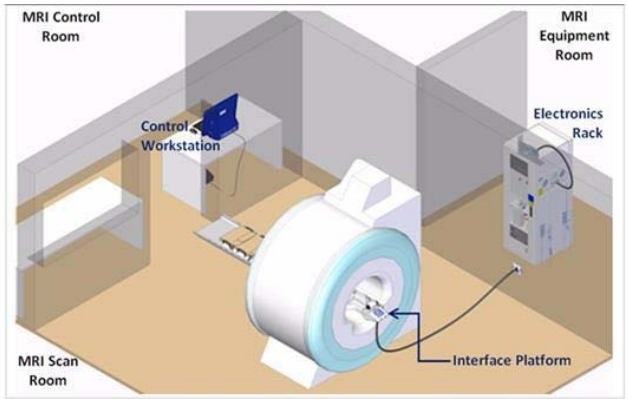


2. A MR compatible stereotactic miniframe (or "AxiiiS" device) which provides a platform for aligning the laser probe to the intracranial target via the skull burr hole. This device can be attached in the OR directly to the skull using standard neuronavigation procedures and then provides a MR compatible platform for supporting the probe and probe driver



3. A Probe Driver which interfaces to the probe and AXiiiS and allows the surgeon to remotely manipulate the rotation and translation of the probe during treatment to allow a precise and conformal thermal dose.

A supporting set of accessories integrated into the MR suite including an electronic rack, workstation, surgical laser, patient board with head fixation and software which completes the system and provides a turnkey solution for MR guided laser therapy.

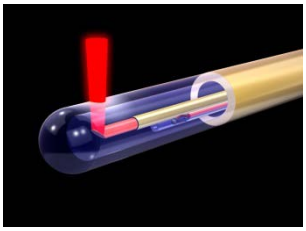


Description

The NeuroBlate System is a unique collection of MRI-compatible laser devices and accessories that create an MRI guided delivery of precision thermal therapy. Its initial application and the focus of its development was for the minimally invasive treatment of brain tumors. The NeuroBlate System components consist of:



- A gas-cooled Laser Delivery Probe (Probe) to deliver controlle energy to a target zone. Since the Laser Delivery Probe is onl mm in diameter, the NeuroBlate System allows a minimally ir approach to target tissue in the brain. When the Laser Deliver Probe is mechanically inserted through a stereotactic interfac (AxiiiS device) coupled to the Probe Driver, the surgeon can d the thermal therapy through a small burr hole. Target tissue heating is achieved by transmitting laser energy from a remote laser, through connecting fiber optics, and then out the end of the Probe. The Laser Delivery Probe is kept cool by allowing pressurized gas (CO_2) from a remote source to expand within the Laser Probe tip. This gas is vented outside the body.

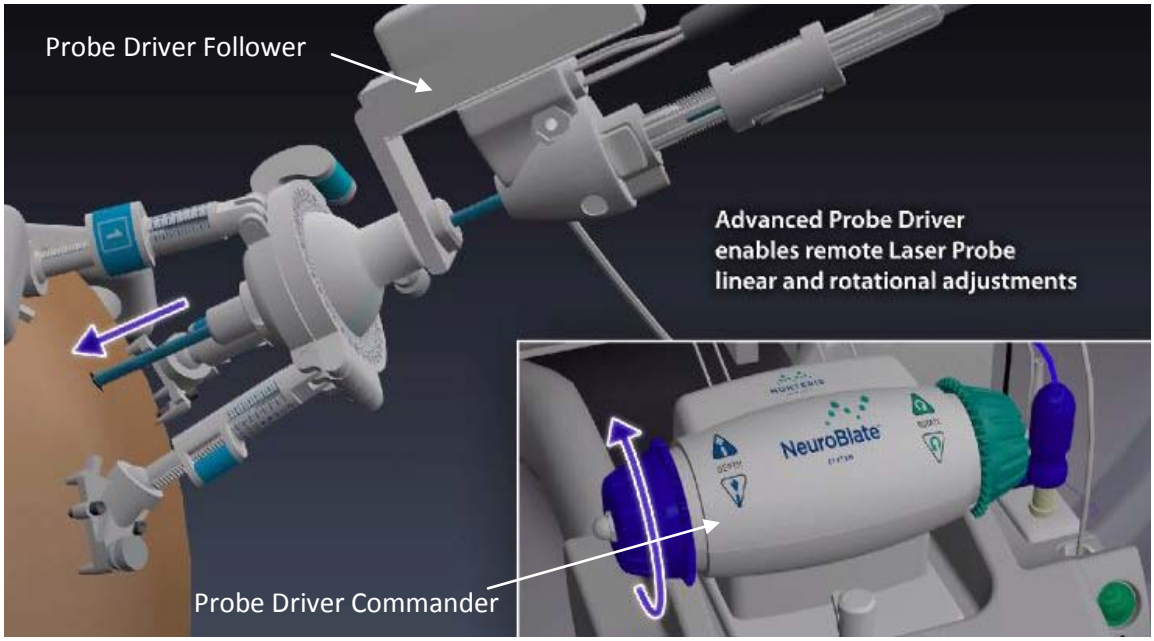


- A MR compatible stereotactic miniframe named the "AXiiiS" device. The AXiiiS is a MR compatible skull-mounted trajectory guide. It can be manipulated to provide a wide range of trajectories into the head. An Image-Guided Surgery (IGS) system loaded with preoperative image data is typically used to navigate the AXiiiS to the intended trajectory. Once the desired trajectory is obtained, the AXiiiS joints are locked to provide a stable and rigid platform for neurosurgical device or instrument delivery. The AXiiiS has three telescoping legs connected to a center ball joint. Each of the legs is attached to the patient's skull with one self-tapping titanium bone screw. By adjusting the height of each leg, and the alignment of the center ball, various trajectories can be obtained.

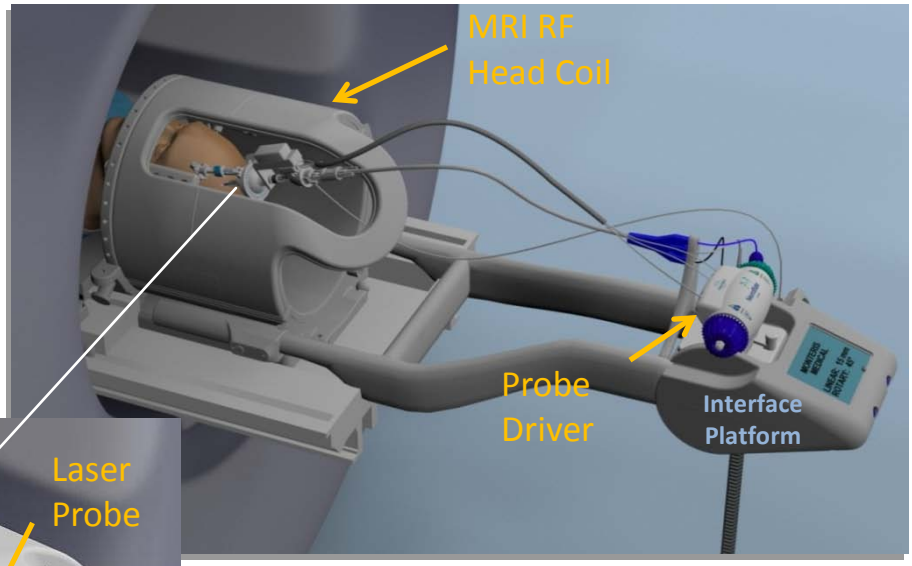


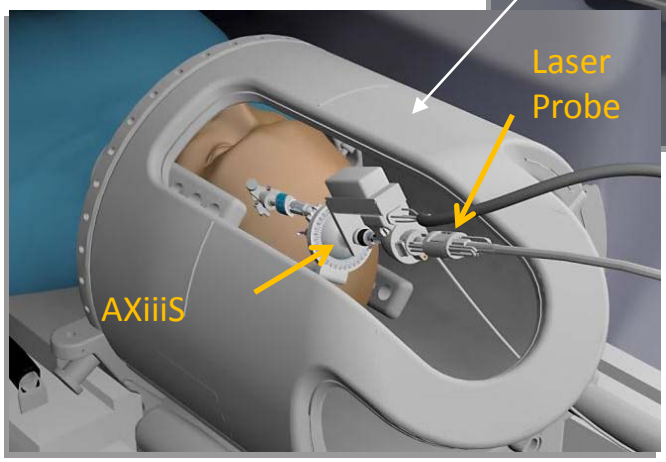
- A Probe Driver which allows the surgeon to precisely position, stabilize and manipulate the probe within the target zone. The probe driver has two components: (1) The "follower" attaches to the AXiiiS device and provides the interface to the probe to impart motion to the probe shaft. The follower is connected via push-pull cables to the (2) commander which includes two geared wheels

allowing either remotely automated (via motorized interaction of geared wheels) or manual (user interaction of geared wheels) manipulation of the follower.



- An Interface Platform, which attaches to the MRI system patient table and provides supporting electronics for the Probe Driver and interconnections for the Laser Delivery Probe

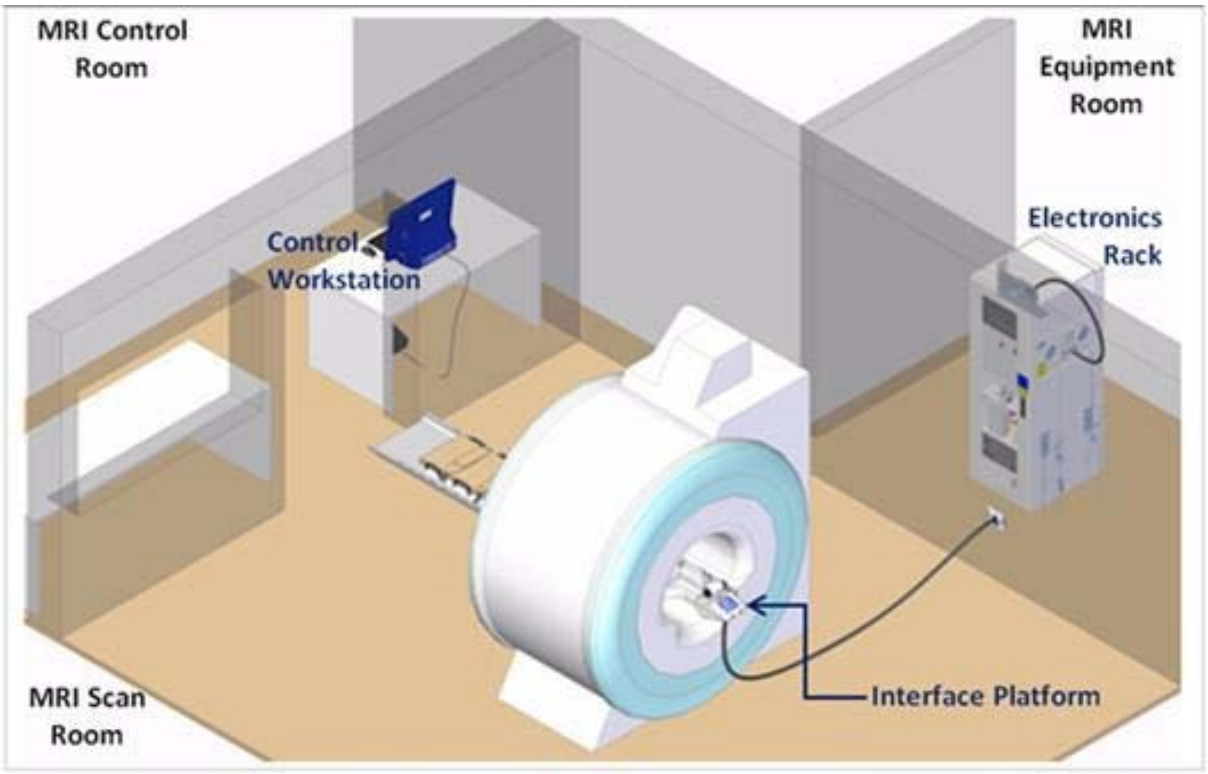




• A System Electronics Rack and Components, which includes necessary umbilicals, cables, penetration panels, and small hardware for system mechanical, electrical, and electronic operation, and

• A Control Workstation including the Software which includes a user interface for procedure planning, interactive monitoring of NeuroBlate procedures, and interfaces to the MRI and hardware subsystems.

This collection of components integrates within a MRI suite as shown below.



Cleveland Clinic

Gene H. Barnett, M.D., M.B.A., F.A.A.N.S., F.A.C.S.
Rose Ella Burkhardt Chair in Neurosurgical Oncology
Professor and Director,
Rose Ella Burkhardt Brain Tumor & Neuro-Oncology Center

November 27, 2013

Manning Award Committee
Suite 267, Alastair Ross Technology Centre
3553 – 31st Street N.W.
Calgary, AB T2L 2K7

Dear Sirs:

I am writing to the Committee today to endorse and offer my full support to the nomination of Mr. Richard Tyc and Dr. Mark Torchia and their innovation – NeuroBlate.

I have known Richard and Mark for more than 6 years and was the first neurosurgeon to be involved in the NeuroBlate (formerly AutoLITT) project. I initially provided neurosurgical expertise during the pre-clinical testing phase and during the development of clinical studies. The Cleveland Clinic was also chosen as one of two sites to conduct the first-in-man study of the system, a pivotal study that was key to a successful application to the Food and Drug Administration for approval of NeuroBlate. My current role also includes acting as Chief Medical Officer to Monteris Medical and as such I have continued to be involved in advising the company on the technology and its clinical application.

I would like to comment on each of the areas of interest of the Committee, in recognition of the efforts of Richard and Mark, but even more so to confirm the truly unique nature of the innovation and its value to the treatment of patients with life-threatening brain tumors.

NeuroBlate was conceived at a time when traditional thinking for laser interstitial thermal therapy was limited to that of a simple point source of energy. While this method allowed for distribution of heat, it was not until the unique approach of their side-firing probe, with the gas-cooled system, that any degree of surgical control over the deposition of heat could be produced. As for many important achievements in medicine and engineering, we often reflect post-invention on how “simple” the innovation, yet it is clear that this device not only required ingenuity in creating the first system, but the fact that the Joule-Thomson cooled-probe design has not required evolution during it’s entire lifetime, remaining highly effective, speaks to its power an as innovation.

The design, risk assessment, testing, and manufacturing of any device as complex as NeuroBlate, is a true challenge for any inventor. Add to that the consideration of seeking approval through the Food and Drug Administration and Health Canada for a neurosurgical device, by a small start-up company, and one quickly recognizes the challenges successfully faced. No such device could be used to treat such high-risk patients, in such a complex and delicate organ as the brain without careful consideration by its inventors. I was the first surgeon to use the device in a human patient – a galvanizing moment indeed, but it was clear that both Richard and Mark had guided the device carefully through its evolution and developed it along a path that insured its safety and efficacy.

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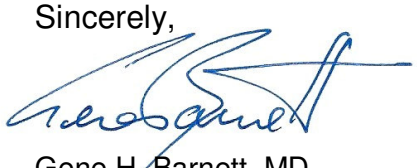
NeuroBlate has had a major positive impact in the treatment of patients with brain tumors for our neurosurgical group at the Cleveland Clinic, a recognized world leader. The addition of NeuroBlate to our armamentarium has allowed us to provide treatment to patients for which, 5 years ago, we had nothing to offer. We have treated tumors that were otherwise inaccessible, had already failed other modalities, and more recently, with continued demonstration of success and safety, this innovation has become one of our front-line therapies. The simple fact that patients treated with NeuroBlate are typically ready for discharge within 48 hours of the procedure not only reduces the cost of care for the patient and their insurers but also frees resources to treat other patients.

Interestingly, our experience in treating tumors has been so positive that we have now extended this innovative technology to another group of patients, namely those with medically refractory radiation necrosis. This condition occurs in about 5% of patients following radiotherapy or radiosurgery and is very difficult to treat. Our recent work has demonstrated that the NeuroBlate treatment results in near complete resolution of the edema and associated mass effect and the ability to quickly and completely wean patients off of steroids.

While I cannot comment directly on the social benefits to Canadian patients and the health system, I anticipate that the same benefits would be seen – reduced health care costs, greater resource availability, and quicker return of the patient to their families, jobs, and productivity. Certainly, having the company headquartered in Winnipeg for so long, has surely brought the economic advantage of many person-years of high-tech jobs (and resulting tax and spending benefits), and investment by Canadian firms and banks. Perhaps most importantly, Mark and Richard's integration with the local research and medical community in Manitoba has resulted in enhanced education of medical, engineering, and other graduate students as well as significant knowledge translation.

Overall, the NeuroBlate system and the innovation that Mark and Richard have created and developed speaks for itself – it has become a game-changer for patients with brain tumors. I wholeheartedly offer my support and endorsement of their application and of the NeuroBlate technology and highly recommend their recognition through the Manning Awards.

Sincerely,



Gene H. Barnett, MD

Washington University in St. Louis
SCHOOL OF MEDICINE

Eric C. Leuthardt, M.D.
Associate Professor of Neurological Surgery

Department of Neurological Surgery

November 27, 2013

Manning Award Committee
Suite 267, Alastair Ross Technology Centre
3553 – 31st Street N.W.
Calgary, AB T2L 2K7

Dear Sirs,

This letter represents my endorsement of the NeuroBlate innovation and that of Dr. Mark Torchia and Mr. Richard Tyc.

I have been involved with this project since I conducted the first commercial case with the AutoLITT (NeuroBlate) system in 2010 following its successful FDA clearance. Since that time, Barnes-Jewish Hospital has performed more than 30 NeuroBlate procedures on various types of brain tumors. More recently we have used the technology to treat a deep-seated epilepsy focus.

It is my belief that this innovation could, given that our early success and further evaluation of long-term efficacy over the next few years, replace open craniotomy for most patients and become a standard of care for brain tumors. Indeed, neurosurgery has not benefitted from new cytoreductive tools for some time that are as effective as the NeuroBlate system.

I have been involved in the development of many medical devices and continue to investigate new technologies in neurosurgery. It is clear to me that the NeuroBlate system stands far above the original concepts of laser interstitial thermal therapy. The early systems relied on point sources of heat, which would have been adequate if all tumors were spherical, the tissue homogeneous, and the brain behaved as an ideal thermal material. The innovators, rather than relying simply on available technology, envisioned the device from square one - the criteria of the brain and associated tumors. This resulted in the ingenious side-fire, Joule-Thomson cooled probe and associated control devices and systems that has proven to be so efficacious today.

From a clinical perspective, the NeuroBlate system has allowed our patients with superficial lesions to require only a single day stay in ICU, and those with deep grey matter lesions also see reduced ICU stays. Our quantitative analysis of outcomes at our centre has shown that recurrence-free survival after NeuroBlate is up to two-times longer than existing therapy. There is a paucity of surgical treatments for many deeply located brain tumors, and NeuroBlate has provided a new option to us as we recently demonstrated in the treatment of a metastatic adenocarcinoma in the subinsular region, which would have carried a high likelihood of paralysis, aphasia, and reduced quality of life using traditional surgical methods.

We believe that the NeuroBlate system is opening a wide range of other possibilities for treatment, including the ablation of epileptogenic foci. This therapy option opens new possibilities for select epilepsy patients in whom imaging or depth electrode data support LITT for ablation.

Barnes-Jewish Hospital was one of the first sites in the world to install a dual-room intraoperative MRI system (IMRIS – incidentally, also a Manning Award winner (2004) and also from Winnipeg!) The combination of this unique imaging platform with the NeuroBlate system has allowed us to expand our utilization of the iMRI suite and provide even more optimized therapy.

Furthermore, the System is providing a locus for other significant scientific and engineering developments. For instance, at Washington University in St. Louis, my team, in partnership with the nominees, is investigating the use of ultrasound imaging as a potential thermometry system for use with the next generation of NeuroBlate. This partnership has the ability to lead to advancing knowledge in the field and providing financial support to our team as well as graduate student and post-doctoral training.

The financial and social implications of NeuroBlate are many, but clearly include improved patient quality-of-life and therefore enhanced productivity. Reduced time in hospital and reduced morbidity compared to other therapy options leads directly to cost saving for the health system and the patient.

The NeuroBlate system has significantly changed my practice of neurosurgery. From our NeuroBlate Network meeting (a neurosurgical NeuroBlate-users group), I know that it has changed that of others as well, and will continue to do so in the future. NeuroBlate has provided hope and recovery to patients that otherwise have had no options.

Clearly, NeuroBlate is worthy of the Manning Award.

Sincerely,



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