MINIMALLY INVASIVE ROBOTIC LASER THERMOTHERAPY

SYSTEM OVERVIEW
**NeuroBlate Fusion Software**

NeuroBlate Fusion Software is the exclusive software intelligence behind the NeuroBlate® System. NeuroBlate Fusion allows neurosurgeons to plan, deliver, and monitor MRI-guided robotic laser thermotherapy.

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**ADVANCED IMAGE CO-REGISTRATION TOOLS**

**Precisely Shape Ablation Margins for Assured Surgical Accuracy**

NeuroBlate Fusion Software accepts image data processed by other imaging software, delivering surgeons needed information to optimize visibility and accuracy of the intended ablation target.

Enhanced image fusion tools allow for the import of pre-operatively planned, 3D objects, such as auto-segmented ablation target(s), post-processed fMRI data and DTI (fibertracking data). These objects can be fused to the treatment day MRI, and create 3D volumes in NeuroBlate Fusion superimposed on the background imaging during ablation.

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**TRUTEMP™ TECHNOLOGY**

Proton resonance phase drift, which is inherent with all MRI scanners and can account for a several degree temperature variance over short time intervals, is mapped, corrected, and holds baseline temperature.

The NeuroBlate System detects patient motion and significant RF noise events, and will automatically shut off the laser when appropriate for added safety.

NeuroBlate removes pixels which exhibit unstable MRI signal and can cause inaccurate thermography.

Actual baseline body temperature is used as an input, rather than assuming 37° C. This assures that the ablation temperature is accurate for cell death.

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**ENHANCED VISUALIZATION OF THE ABLATION TARGET**

Additionally, NeuroBlate Fusion Software offers the ability to delineate the target ablation area or structures to avoid with interactive, multi-planar volume contouring tools.

Monitor the intended ablation area in three orthogonal planes, as well as perpendicular slice planes above and below the center of the ablation zone. This eliminates the uncertainty associated with a "blind" ablation with no defined ablation zone.
FINALLY, PRECISION DELIVERED THROUGH A MINIMALLY INVASIVE SURGICAL OPTION

NeuroBlate® is the only minimally invasive, robotic, laser thermotherapy that uses MRI-guided surgical ablation technology designed specifically for use in the brain. NeuroBlate provides precise and maximal tumor reduction for patients without the invasiveness of an open neurosurgical procedure. The precise nature of the procedure helps lessen the likelihood of harm to nearby healthy tissue.1,2,3,4
THE NEUROBLATE® SYSTEM
IS USED IN A WIDE RANGE OF LESIONS

NeuroBlate Keeps a Patient’s Options Open
If repeat surgery is determined to be required, NeuroBlate offers a minimally invasive surgical option. At this time, there are no contraindications for NeuroBlate that would limit the number of procedures a patient may undergo.

NeuroBlate is Minimally Invasive
Generally, minimally invasive procedures are well tolerated, have a short recovery time, and patients typically require 1-2 stitches to close the incision.

More than 1,800 NeuroBlate procedures since 2008 have been performed in 59 centers.
NEUROBLATE DELIVERS A COMPREHENSIVE SYSTEM WITH OPTIONS AND CONTROL

The NeuroBlate System portfolio offers a comprehensive, full solution laser ablation system that includes patient stabilization and transport (AtamA™ Patient Board), probe trajectory (Mini-Bolt Access - available in 2.2 mm and 3.3 mm inner diameters), therapy planning and analysis (NeuroBlate Fusion Software™), and a versatile set of tools for robotic laser thermotherapy (NeuroBlate Robotic Probe Driver, SideFire™ and FullFire™ laser probes).

NeuroBlate offers two robotically controlled probe options to deliver laser energy during ablation:

**NeuroBlate SideFire Laser**
Probe provides focused, directional ablation

**NeuroBlate FullFire**
Diffusing Tip Laser Probe provides fast, volumetric ablation
Economic Value

Hospitals may see a variety of benefits from adding NeuroBlate® capability. Multiple studies describe a short hospital stay after the LITT procedure. In a single center economic analysis, LITT was found to be less costly or a similar cost to traditional surgical methods. As physicians experience with NeuroBlate increases, the procedure time and MRI time decreases – further increasing efficiency in the procedure room.

Support and Services

- Dedicated technical and clinical staff delivering training and case support
- NeuroBlate peer-to-peer mentoring opportunities

Indications

The NeuroBlate System is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures, through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers.

The NeuroBlate System is intended for planning and monitoring thermal therapies under MRI visualization. It provides MRI based trajectory planning assistance for the stereotaxic placement of MRI compatible (conditional) NeuroBlate Laser Delivery Probes. It also provides real-time thermographic analysis of selected MRI images.

When interpreted by a trained physician, this System provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of the NeuroBlate System analysis.

Risks

The NeuroBlate System is a surgical tool used in brain surgery to heat and destroy targeted tissue. There are no known or reported contraindications. Patients must be able to undergo MRI exposure. All brain surgeries carry risk. There are potential benefits and risks, e.g., device malfunction, bleeding, edema and unintended major brain tissue damage and permanent neurological deficits.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse event.

For full prescribing information please visit monteris.com.

REFERENCES

8. Monteris data on file CL100 87 Rev A.