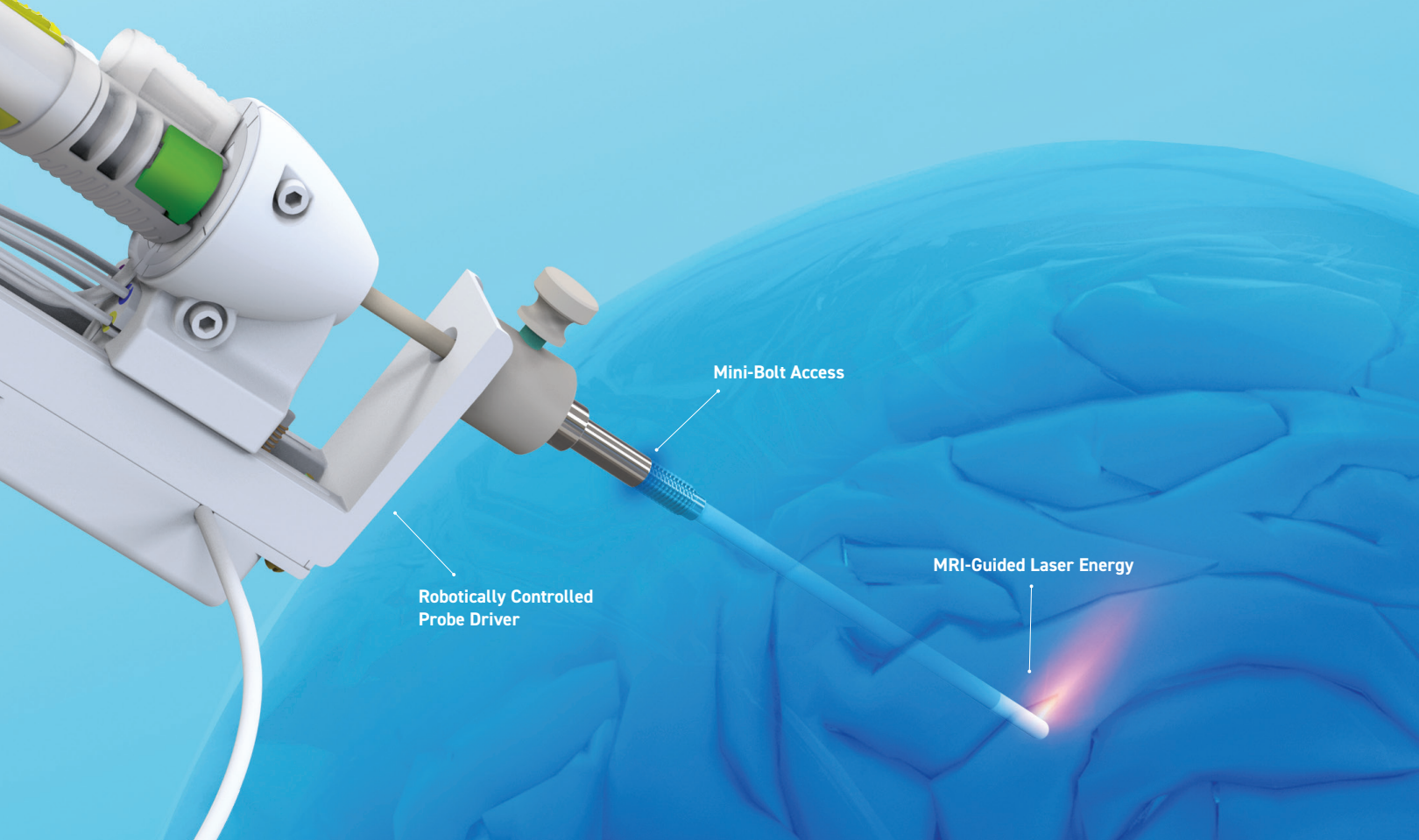




SYSTEM OVERVIEW

MINIMALLY INVASIVE ROBOTIC LASER THERMOTHERAPY



PRECISION AND CONFIDENCE DELIVERED THROUGH A MINIMALLY INVASIVE SURGICAL OPTION

The NeuroBlate® System is the only minimally invasive, robotic, laser thermotherapy tool 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}

For Tumor Patients, Safe Cytorreduction with NeuroBlate Sets the Stage

When precious time matters, achieving safe cytorreduction for patients deemed poor surgical candidates, NeuroBlate provides a minimally invasive option. The Stupp Protocol is widely accepted as the standard of care for glioblastoma (GBM). Cytorreduction of the tumor followed by temozolomide and radiotherapy provides a statistically significant survival advantage.⁵

For Refractory Epilepsy Patients, NeuroBlate Offers an Alternative

NeuroBlate achieves maximum ablation of epileptic foci. For those patients who are resistant to drug therapy, and whose epileptic focus can be identified, laser ablation offers a minimally invasive and repeatable option.⁶

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.

NEUROBLATE® SYSTEM: THE MINIMALLY INVASIVE SURGICAL CHOICE

INOPERABLE BRAIN TUMORS

- Difficult to access tumors
- Recurrence
- Surgical option at time of biopsy
- Fragile patients*

EPILEPSY

- Epileptic foci

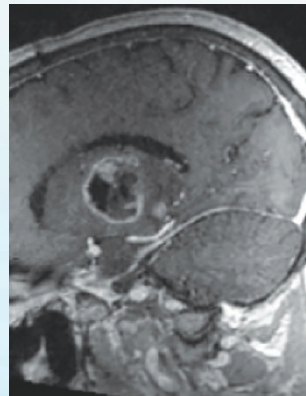
* Fragile patients are not optimal open surgical candidates due to health or age concerns



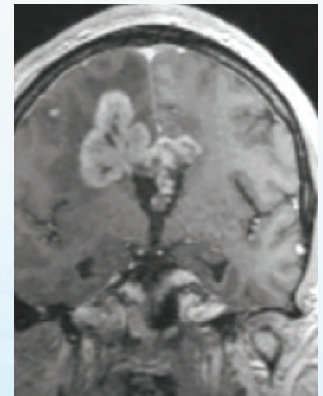
PROGRESSION AFTER STEREOTACTIC RADIOSURGERY (SRS)

- Inflammatory response to radiation (necrosis)
- Progressive metastatic tumors (METS)

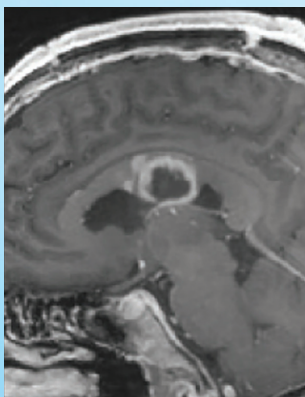
THE NEUROBLATE SYSTEM
IS USED IN A WIDE RANGE
OF **LESIONS, INCLUDING
BRAIN TUMORS** AND
EPILEPTIC FOCI



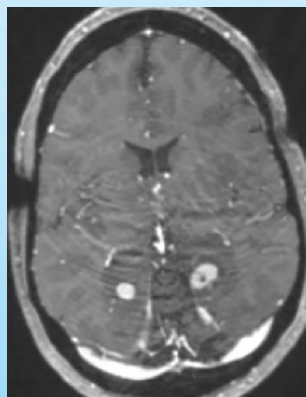
Symmetrical



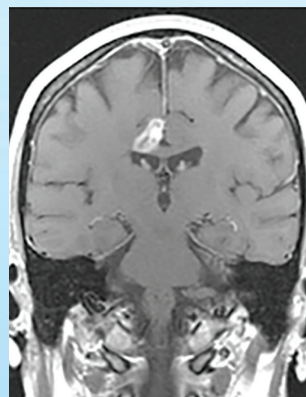
Asymmetrical



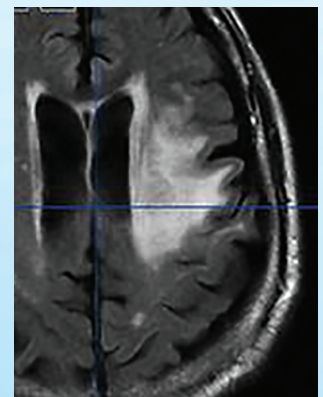
Difficult to Access



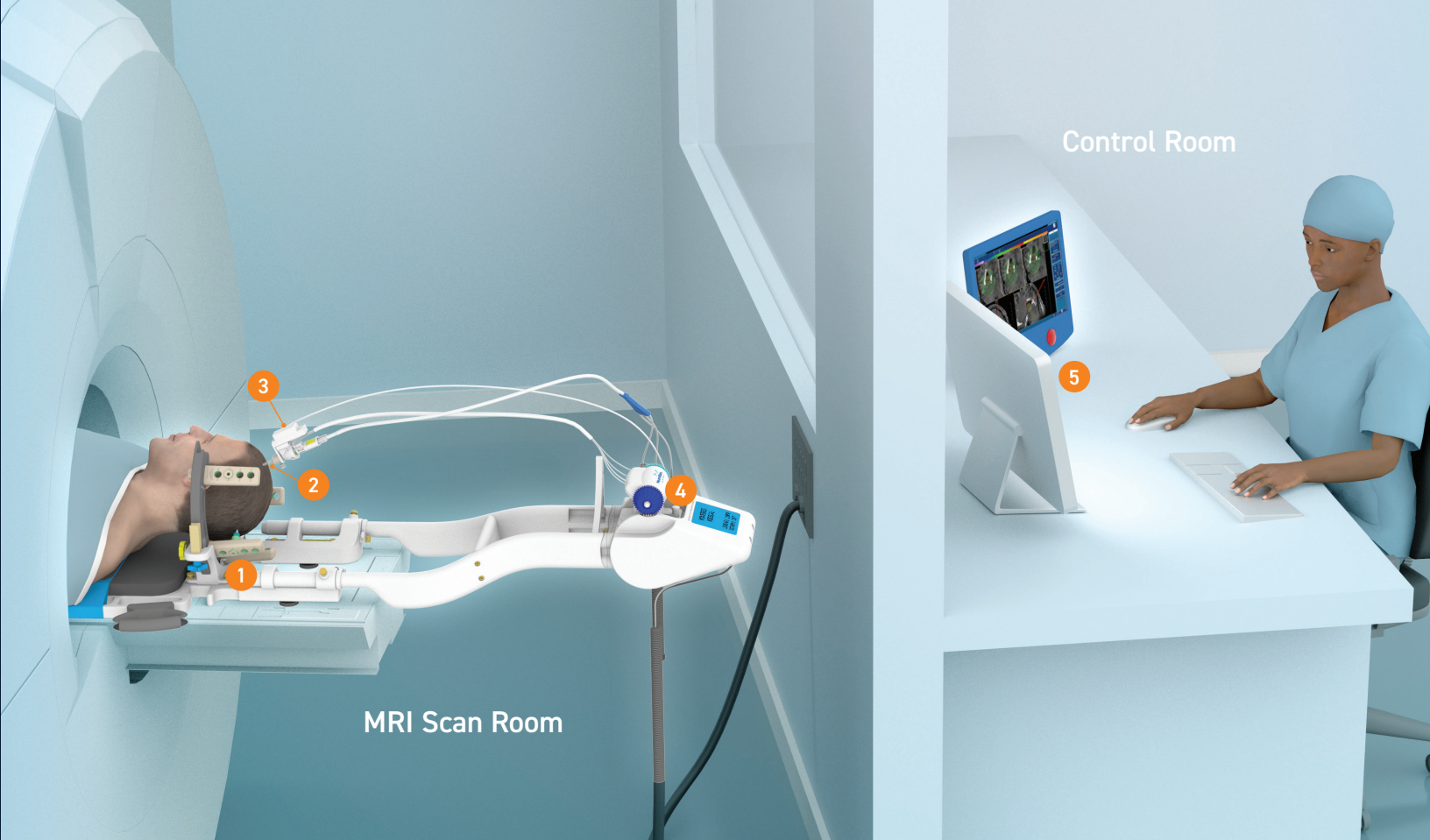
Multiple



METS



Radiation Necrosis

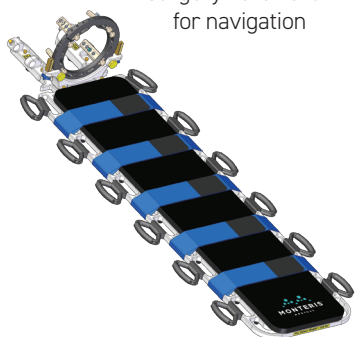


NEUROBLATE DELIVERS A **COMPREHENSIVE SYSTEM WITH OPTIONS AND CONTROL**

1

ATAMA® SYSTEM

- Patient transfer and head stabilization system for the MRI
- Enables attachment of NeuroBlate System hardware
- Integrates versatile head fixation into a patient transfer board for efficient patient transport from OR to MRI
- 1.5 T or 3.0 T MR conditional
- Secured patient head position ensures temporal and spatial imaging accuracy for MRI-guided neuro- interventions
- Starburst Adapter enables attachment of image guided surgery hardware for navigation



2

MONTERIS® MINI-BOLT

- Rigid skull fixation for neurosurgical devices
- Solid titanium construction
- Available in 2.2 mm and 3.3 mm inner diameter
- 4.5 mm diameter hole
- Allows a direct interface to the NeuroBlate Robotic Probe Driver for precise laser probe control and laser delivery
- Accessories and adapters allow on-trajectory placement using an array of stereotactic frames and navigated articulated arms
- 1.5 T or 3.0 T MR conditional

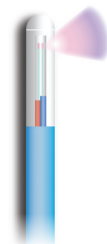


3

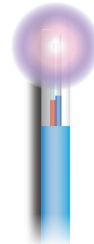
NEUROBLATE® OPTIC™ LASER PROBE

- NeuroBlate Optic Laser Probe is the only commercially available laser probe with fiber optic controlled cooling
- Available in two configurations:
 - SideFire® Directional Laser Probe: the industry's only laser probe for the brain providing focused, directional ablation
 - FullFire® Diffusing Tip Laser Probe: providing fast, volumetric ablation

SideFire
Probe



FullFire
Probe



4

NEUROBLATE® ROBOTIC PROBE DRIVER

- Low profile delivery platform for robotic laser thermotherapy
- Precise robotic linear positioning prevents laser probe misplacement
- Probe can be directed from the work station during the procedure
- Hands-off laser manipulation reduces multiple trips into MR scan room and procedure delays





MRI Equipment Room/
Electronics Rack

NEUROBLATE'S EXCLUSIVE TECHNOLOGY

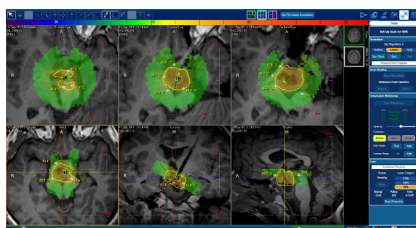
PRECISION & CONFIDENCE DELIVERED WITH TRUTEMP™ TECHNOLOGY

TruTemp Technology may mitigate the factors that negatively influence MRI thermometry, providing confidence in the accuracy of the ablation zone and added safety assurance.

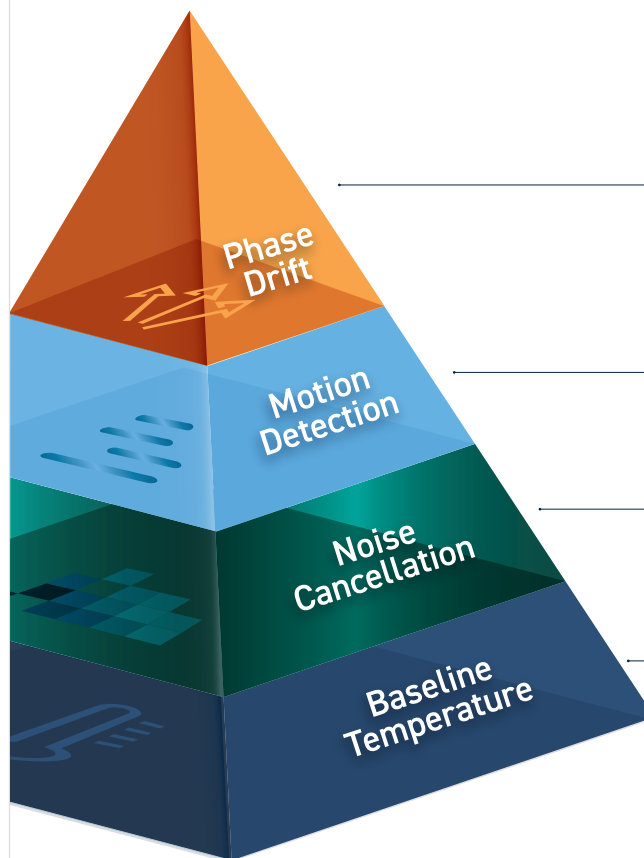
5

NEUROBLATE® FUSION-S™ SOFTWARE

- NeuroBlate Fusion-S Software, the exclusive software intelligence behind the NeuroBlate System, delivers superior visualization to see more of the procedure
- 3-D anatomical views allow the user to closely monitor the procedure and tailor laser delivery to conform to the intended ablation boundaries
- Unlimited number of temperature pick points and intuitive color display enable the user carefully monitor ablation progression and avoid eloquent structures



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 and corrected.

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 that 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.

Thermography is accurate within 1.5 ± 0.7 mm of displayed thermal dose threshold (TDT) lines. Thermometry accuracy is $\pm 3.0^\circ$ C.

Economic Value

Hospitals may see a variety of benefits from adding NeuroBlate® capability. Multiple studies describe a short hospital stay after the LITT procedure.^{7,8} In a single center economic analysis, LITT was found to be less costly or a similar cost to traditional surgical methods.⁹ As physicians experience with NeuroBlate increases, the procedure time and MRI time decreases – further increasing efficiency in the procedure room.¹⁰

Support and Services

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

Disclosures

The NeuroBlate® System is intended for ablating intracranial soft tissue, including brain structures. Patients must be able to undergo MRI exposure and be surgical candidates. The technology is not appropriate for every lesion type and location. It may be difficult to use the technology on certain large or irregularly shaped lesions.

All brain surgeries carry risk. Possible adverse events include, but are not limited to, hematoma, embolic events, edema, bleeding, unintended major 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 events. For full prescribing information, please visit monteris.com.



**Contact Monteris Medical Corporation for more information.
Not available for sale outside the U.S. or Canada.**

REFERENCES

1. Wilson TA, Karajannis MA, and Harter DH. Glioblastoma multiforme: State of the art and future therapeutics. *Surg Neurol Int.* 2014 May 8;5:64. doi: 10.4103/2152-7806.132138
2. Mohammadi, A.M. & Schroeder, J.L. Laser interstitial thermal therapy in treatment of brain tumors – the NeuroBlate System. *Expert Rev Med Devices.* 11(2): 109-119 (2014). doi:10.3171/2013.1.JNS1291
3. Sloan AE, Ahluwalia MS, Valerio-Pascua J, et al. Results of the NeuroBlate System first-in-humans phase I clinical trial for recurrent glioblastoma: clinical article. *J Neurosurg.* 2013;118(6):1202-1219. doi:10.3171/2013.1.JNS1291
4. Carpentier A, McNichols RJ, Stafford RJ, et al. Laser thermal therapy: real-time MRI-guided and computer-controlled procedures for metastatic brain tumors. *Lasers Surg Med.* 2011;43(10):943-950. doi:10.1002/lsm.21138
5. Stupp R, Mason WP, van den Bent MJ, et al. Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma. *New England Journal of Medicine.* 2005;352(10):987-996. doi:10.1056/NEJMoa043330
6. Gross RE, Stern MA, Willie JT, et al. Stereotactic laser amygdalohippocampotomy for mesial temporal lobe epilepsy: SLAH outcomes for MTLE. *Annals of Neurology.* 2018;83(3):575-587. doi:10.1002/ana.25180
7. Mohammadi AM, Hawasli AH, Rodriguez A, et al. The role of laser interstitial thermal therapy in enhancing progression-free survival of difficult-to-access high-grade gliomas: a multicenter study. *Cancer Med.* 2014;3(4):971-979. doi:10.1002/cam4.266
8. Jethwa PR, Barrese JC, Gowda A, Shetty A, Danish SF. Magnetic resonance thermometry-guided laser-induced thermal therapy for intracranial neoplasms: initial experience. *Neurosurgery.* 2012;71(1 Suppl Operative):133-144; 144-145. doi:10.1227/NEU.0b013e31826101d4
9. Leuthardt EC, Voigt J, Kim AH, Sylvester P. A single-center cost analysis of treating primary and metastatic brain cancers with either brain laser interstitial thermal therapy (LITT) or craniotomy. *PharmacoEconomics - Open.* November 2016. doi:10.1007/s41669-016-0003-2
10. Monteris data on file CL100 87 Rev A.

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