Medtronic Engineering the extraordinary

Visualase[™] MRI-Guided Laser Ablation Do more for more patients.

With a minimally-invasive option to ablate epileptic foci and tumors in the brain, you can give your patients an alternative to craniotomy. Because less time in the hospital is more time for living.



Visualase[™] MRI-guided laser ablation offers your patients a minimally invasive option to ablate brain tumors, radiation necrosis, and epileptic foci.

Visualase[™] is an MRI (Magnetic resonance imaging)-guided laser ablation system used to perform Laser Interstitial Thermal Therapy (LITT), a minimally invasive surgical alternative to open craniotomy. LITT may benefit patients with brain tumors, radiation necrosis, or medically-refractory focal epilepsy.

The Visualase[™] system delivers laser energy through a small catheter into unwanted soft tissue targets in the brain. When laser energy is absorbed by the target tissue, temperature rises and, over time, creates an irreversibly damaged thermal lesion.

Minimally invasive. Significantly faster recovery.⁵⁻⁷ Higher patient satisfaction.^{5,8,9}

Together, we prioritize the patient. First line medical therapies, radiation-based therapies, and invasive surgical interventions may not be appropriate in all cases. The Visualase[™] system offers a minimally invasive option for you to reach more patients.

Advantages of Visualase[™] laser ablation system

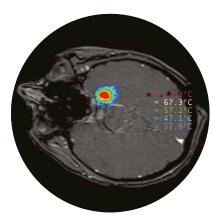
Physicians experience precise ablation control¹⁰⁻¹⁴ using best-in-class thermal image resolution, automatic laser shut off near critical structures, and Visualase[™] is the only LITT thermal damage model to have proven accuracy compared to histology. ^{10,11,15,16}

Patients experience minimal hair shaving, a small incision with little scarring, a significantly shorter hospital stay,^{5,6,17-22} decreased risk of infection,^{3,4} and higher patient satisfaction^{5,8,9} when they receive surgical intervention using Visualase[™].

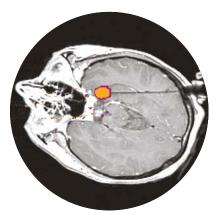
Precise

Best-in-class thermal image resolution and refresh rate give you the precision you need^{1,2}.

Visualase[™] is the only LITT system to offer voxel size of 1x1x3mm and a thermal image refresh every 5-7 seconds, which allows surgeons to monitor the ablation with unmatched precision and speed.



Thermal Monitoring



Thermal Damage

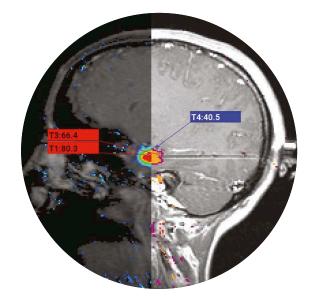


Post-Op Thermal Lesion

Controlled

Automatic laser shut-off and histology-proven tissue damage visualizations provide the control you need for accurate ablation while minimizing risk.

Visualase[™] Temperature Targets automatically turn the laser off as soon as a critical area's temperature reading exceeds a set threshold. Additionally, the Visualase[™] Thermal Damage Estimate accurately displays zones of complete necrosis and transitional tissue, enabling surgeons to ablate target tissue with confidence while protecting critical structures.



Efficient

Minimize your time in the MRI and maximize efficiency with one-time image setup and 2-3 minute ablations^{3,4}.

Visualase[™] in-plane thermometry displays heating anywhere along the laser catheter, eliminating the need for thermal image adjustment when the laser is moved. Additionally, Visualase[™] 360° diffusing tips deliver 980nm laser energy, keeping each ablation to only a few minutes.^{3,4}

Flexible

Plan the trajectory that best serves your patient using the most flexible LITT system available.

The Visualase[™] low-profile bone anchor and flexible laser catheter allow broad surgical access and maximize patient positioning options, enabling surgeons to reach even the most challenging locations.

The mobile cart-based system allows easy configuration with the leading brands of MRI scanners. Simply wheel the Visualase[™] cart to its location and connect to the MRI with a standard ethernet cable on the day of surgery.



A workflow that works for your hospital.

We believe that innovative technology should enable, not limit, your clinical decisions when it comes to your patient. The unique challenges of performing a procedure within the MRI bore must be carefully considered, and every design aspect of the Visualase[™] system supports these procedures by featuring:

- Small, flexible laser catheter and low profile bone anchor for more patient positioning options
- Mobile system and a low-impact installation
- In-plane thermometry and a diffusing laser tip design
- Efficient laser design is broadly applicable to most ۲ target locations and simplifies inventory management

Part Number	Description
9735559	3mm laser diffusing tip
9735560	10mm laser diffusing tip
9735566	MRI-Conditional Stylet
9735571	Neuro Accessory Kit



5

Plan

The surgeon plans the approach using stereotactic planning software, taking into account ablation coverage and catheter placement trajectory.

Laser Placement

A small, flexible laser catheter is inserted in the target area. Visualase[™] is compatible with many common stereotactic platforms so the surgeon and staff can stick to a workflow that is most familiar to them.

Transport to MRI

The patient is transported to the MRI in radiology, or an intraoperative MRI is brought to the patient.

MRI-Guided Laser Ablation

A pre-ablation scan is obtained. The surgeon then selects the preferred thermal imaging planes, identifies temperature check points, and starts the ablation. As tissue heats up, the system displays the thermal damage progress.

Close

The laser applicator is removed and the small incision is typically closed with just one suture required.^{23,24} The patient is then moved to recovery and in many cases goes home the next day.^{5,17-22}

- Medtronic. Visualase™ MRI Guided Laser Ablation System IFU. D00418382_A_9736415_02DEC2021.
- 2. Monteris Medical. NeuroBlate® System Instructions for Use 80512 Rev C. Published online November 2022. Accessed February 3, 2023. https://www.monteris.com/ wp-content/uploads/2021/12/80512-Rev-B-NeuroBlate-
- System-IFU-SW-3.16.pdf Fabiano AJ, Alberico RA. Laser-interstitial thermal thera-3 Fabiano AJ, Alberico KA. Laser-interstitial thermal thera-py for refractory cerebral edema from post-radiosurgery metastasis. World Neurosurg. 2014;81(3-4):652.e1-652. e6524. doi:10.1016/j.wneu.2013.10.034 Carpentier A, McNichols RJ, Stafford RJ, et al. Laser
- 4. thermal therapy: real-time MRI-guided and comput-er-controlled procedures for metastatic brain tumors. Lasers Surg Med. 2011;43(10):943-950. doi:10.1002/ lsm.21138
- Kang JY, Wu C, Tracy J, et al. Laser interstitial thermal therapy for medically intractable mesial temporal lobe epilepsy. Epilepsia. 2016;57(2):325-334. doi:10.1111/ epi.13284
- Waseem H, Osborn KE, Schoenberg MR, et al. Laser ablation therapy: An alternative treatment for medically resistant mesial temporal lobe epilepsy after age 50. Epilepsy Behav. 2015;51:152-157. doi:10.1016/j.
- yebeh.2015.07.022 Leuthardt EC, Voigt J, Kim AH, Sylvester P. A Single-Cen-ter Cost Analysis of Treating Primary and Metastatic Brain Cancers with Either Brain Laser Interstitial Thermal 7. Therapy (LITT) or Craniotomy. Pharmacoecon Open 2017;1(1):53-63. doi:10.1007/s41669-016-0003-2
- 8 Khu KJ, Doglietto F, Radovanovic I, et al. Patients perceptions of awake and outpatient craniotomy for brain tumor: a qualitative study. J Neurosurg. 2010;112(5):1056-1060. doi:10.3171/2009.6.JNS09716
- Medtronic

Europe

Medtronic International Trading Sarl. Route du Molliau 31 Case postale CH-1131 Tolochenaz www.medtronic.eu Tel: +41 (0)21 802 70 00 Fax: +41 (0)21 802 79 00

medtronic.eu

- Kim AH, Tatter S, Rao G, et al. Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (LAANTERN): 12-Month Outcomes and Quality of Life After Brain Tumor Ablation. Neurosurgery
- 2020;87(3):E338-E346. doi:10.1093/neuros/nyaa071 10.Graham SJ, Chen L, Leitch M, et al. Quantifying tissue damage due to focused ultrasound heating observed by MRI. Magn Reson Med. 1999;41(2):321-328. doi:10.1002/(SICI)1522-2594(199902)41:2<321::AID-MRM16>3.0.CO;2-9.
- 11. Sherar MD, Moriarty JA, Kolios MC, et al. Comparison of thermal damage calculated using magnetic resonance thermometry, with magnetic resonance imaging post-treatment and histology, after interstitial microwave thermal therapy of rabbit brain. Phys Med Biol. 2000;45(12):3563-3576. doi:10.1088/0031-9155/45/12/304
- 12. Youngerman BE, Save AV, McKhann GM. Magnetic resonance imaging-guided laser interstitial thermal therapy for epilepsy: systematic review of technique, indications, and outcomes. Neurosurg. 2020;86(4):E366-E382. doi:10.1093/neuros/nyz556.
- Kang JY, Sperling MR. Magnetic resonance imag-ing-guided laser interstitial thermal therapy for
- treatment of drug-resistant epilepsy. Neurotherapeutics. 2017;14(1):176-181. doi:10.1007/s13311-016-0498-3.
 14. Franzini A, Moosa S, Servello D, et al. Ablative brain surgery: an overview. International Journal of Hyperthermia. 2019;36(2):64-80. doi:10.1080/02656736.20 9.1616833.
- 15. Patel NV, Frenchu K, Danish SF: Does the thermal damage estimate correlate with the magnetic resonance imaging predicted ablation size after laser interstitial thermal therapy? Oper Neurosurg (Hagerstown)
- 15:179-183, 2018. doi: 10.1093/ons/opx191. 16.Munier SM, Desai AN, Patel NV, Danish SF. Effects of intraoperative magnetic resonance thermal imaging signal artifact during laser interstitial thermal therapy on thermal damage estimate and postoperative magnetic resonance imaging ablative area concordance. Operative Surg. 2020;18(5):524-530. doi:10.1093/ons/opz182.

- 17. 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 Opera-tive):133-145. doi:10.1227/NEU.0b013e31826101d4 18 Jawie C. Weil AG. Duchowww.M. Photie S. Pachet.
- Lewis EC, Weil AG, Duchowny M, Bhatia S, Ragheb J, Miller I. MR-guided laser interstitial thermal therapy for pediatric drug-resistant lesional epilepsy. Epilepsia 2015;56(10):1590-1598. doi:10.1111/epi.13106 19. Patel P, Patel NV, Danish SF. Intracranial MR-guided
- laser-induced thermal therapy: single-center experience with the Visualase thermal therapy system. J Neurosurg. 2016;125(4):853-860. doi:10.3171/2015.7.JNS15244
- Wilfong AA, Curry DJ. Hypothalamic hamartomas: optimal approach to clinical evaluation and diagnosis. Epilepsia. 2013;54 Suppl 9:109-114. doi:10.1111/ oi.12454
- 21. Willie JT, Laxpati NG, Drane DL, et al. Real-time magnetic resonance-guided stereotactic laser amygdalo hippocampotomy for mesial temporal lobe epilepsy. Neurosurgery. 2014;74(6):569-585. doi:10.1227/ NEU.000000000000343
- 22. Petito GT, Wharen RE, Feyissa AM, Grewal SS, Lucas JA, Tatum WO. The impact of stereotactic laser ablation at a typical epilepsy center. Epilepsy Behav. 2018;78:37-44. doi:10.1016/j.yebeh.2017.10.041
 23. Jethwa PR, Lee JH, Assina R, Keller IA, Danish SF. Treatment of a supratentorial primitive neuroectodermal
- tumor using magnetic resonance-guided laser-induced thermal therapy. J Neurosurg Pediatr. 2011;8(5):468-475. doi:10.3171/2011.8.PEDS11148 24. Torres-Reveron J, Tomasiewicz HC, Shetty A, Amankulor
- NM, Chiang VL. Stereotactic laser induced thermothera-py (LITT): a novel treatment for brain lesions regrowing after radiosurgery. J Neurooncol. 2013;113(3):495-503. doi:10.1007/s11060-013-1142-2



See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precations, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

UC201502921h-visualase-mri-guided-laser-ablation-hcp-brochure-en-we-8174194 © 2022 Medtronic. All rights reserved. Medtronic, Medtronic logo and Engineering the extraordinary are trademarks of Medtronic.

All other brands are trademarks of a Medtronic company