INCISIONLESS BRAIN SURGERY

Exablate Neuro
MR-guided Focused Ultrasound for Essential Tremor and Tremor-Dominant Parkinson's Disease
Incisionless brain surgery is now possible.

The award winning Exablate Neuro™ delivers up to 1024 ultrasound waves to precisely heat and ablate deep brain targets with no surgical incisions or burr holes. Treatment is guided by MR imaging for patient-specific planning, real-time temperature monitoring as well as immediate confirmation of treatment outcome.

First, low energy is applied for locating the ultrasound to the anatomic target followed by physiologic evaluation of patient response including tremor relief as well as potential side effects.

Once the target is confirmed, the energy is gradually increased to create a highly accurate and controllable lesion. The result for many patients is immediate improvement of tremor with no overnight hospital stay.

THE FOREFRONT OF INNOVATION

MR-guided focused ultrasound can help position you and your medical facility at the forefront of innovation, providing a new treatment option for patients.

- FDA-approved focused ultrasound treatment for Essential Tremor and Tremor-Dominant PD.
- No craniotomy with low to no risk of infection or bleeding.
- No implanted hardware or multiple follow up visits.
- Quick recovery and rapid return to daily activities for patients.

1 Information for Prescribers: https://www.insightec.com/media/31393/exablateneuroinformationforprescribers0usa.pdf
INCISIONLESS THALAMOTOMY

MR-guided focused ultrasound (MRgFUS) can be an option for medication-refractory Essential Tremor (ET) and Tremor-Dominant Parkinson's Disease (PD) patients who are not candidates or not willing to have invasive surgery.

Incisionless treatment
- No invasive burr holes or implants
- No general anesthesia required
- Little to no risk of infection
- Minimal hospitalization

Personalized treatment
- Neurologic evaluation of patient response and potential side effects before final lesion
- Enables sub-millimeter target movement

Tremor improvement
- Immediate tremor improvement post-procedure
- ET tremor stably maintained at 3 years
- Improved quality of life

Safe and effective
- Real-time thermal feedback to continuously monitor patient safety and temperature at target
- Majority of adverse events in the pivotal study were minor or moderate and transient

RISKS
- Risks associated with Exablate Neuro thalamotomy include transient and/or sensory paresthesias, numbness, imbalance, and/or gait disturbance. These events are mild or moderate in severity and may resolve over time.
- Risks and adverse events also associated with the Exablate Neuro treatment include brief sonication-related pain, brief sonication-related dizziness and nausea.
- For complete risk information: https://www.insightec.com/us/safety-information
INNOVATION IS NO LONGER CUTTING EDGE

SURGICAL PRECISION WITHOUT INCISIONS:

- Phase array, piezoceramic helmet with 1024 elements.
- Advanced focusing algorithms that adjust according to patient’s skull to ensure beams converge at target.
- Precise focal spot location controlled in size (2-5mm) and location (<1mm accuracy).
- Continuous flow of water actively cools patient’s skull.
- Advanced software interface for treatment monitoring and control.
- Compatible with certain GE Healthcare and Siemens Healthineers MR scanners
TREATMENT STAGES: SEE. TREAT. MONITOR.

Focused ultrasound is usually performed as an outpatient procedure without sedation. Treatment time is approximately 3 hours including patient preparation and scans.

1 PATIENT PREPARATION
Several days before treatment, a CT scan is done to detail the shape, thickness and density of the patient’s skull for final confirmation of patient eligibility and to guide treatment. On the day of treatment, the patient’s head is shaved and a local anesthetic is applied for affixing the stereotactic frame. The patient is positioned on the treatment bed with their head in the Exablate Neuro helmet. Cold water is circulated around the scalp.

2 PLANNING
Pre-operative and/or intraoperative (fused) MRI images are taken to plan the treatment and identify the target.

3 TARGET VERIFICATION
Prior to treatment, low energy sonications (application of ultrasound energy) are used to adjust the focal point to the intended target. Energy is gradually increased to allow assessment of patient response and potential adverse effects.

4 TREATMENT
High energy is applied to make the final lesion. The ultrasound waves precisely converge at the target in the Vim. At the focal point, temperatures increase to near 140°F/60°C, causing thermal ablation of the target tissue. The treatment is continuously guided by MRI for real-time thermal feedback of temperature changes at the target.

5 ASSESSMENT & POST-OPERATIVE CARE
Spirals or other testing methods are used to assess tremor improvement throughout the treatment. After final sonication, the ablation area is confirmed using MR imaging. The frame is removed and after a short recovery time, patients can return home.
CLINICAL EVIDENCE

3 YEAR FOLLOW UP PIVOTAL STUDY OF FOCUSED ULTRASOUND FOR ESSENTIAL TREMOR

POPULATION
Of the total 75 subjects in the pivotal trial, 57 are included in the 2-year and 54 are included in the 3-year analysis of the long term study results.

SAFETY
Persistent adverse events (AEs) at 3 years were mild or moderate and included gait disturbance (2%), imbalance (4%), musculoskeletal weakness (2%), unsteadiness (4%) and numbness (9%). The number in parenthesis is the percentage of active subjects experiencing these adverse events. Long-term safety profile confirms that 74% of AEs were mild and the rest were moderate. Of the total AEs, 48% resolved within 30 days of the procedure.

EFFICACY
The tremor severity score (CRST Part A) improved 75.1% and 76.5% over baseline at 2- and 3-year follow-up, respectively, for combined (Exablate Neuro and crossover) subjects.

Additionally, improvement in tremor/motor function (CRST Part A & B) was 39.6% at one year and 53.1% at three years. Functional disability (CRST Part C) showed a 64.0% improvement at one year with some decline to 56.9% improvement from baseline at three years.

The graph above represents the long term results for thalamotomy for ET. Corresponding results for thalamotomy for tremor-dominant Parkinsons Disease are limited to one year follow up and are available at:
https://www.insightec.com/media/31393/exablateneuroinformationforprescribers0usa.pdf
I don't shake anymore and I got my self esteem back.”

ET Patient: Gregg Ley, Electronics technician from Georgia

Disclaimer: This quote may not be representative of all patient outcomes.
INSIGHTEC is a global medical technology innovator transforming patient lives through incisionless brain surgery. The company’s award-winning Exablate Neuro™ is used by neurosurgeons to perform the MR-guided focused ultrasound treatment for immediate tremor relief in patients. Research for future applications in the neuroscience space is underway in partnership with leading academic and medical institutions.

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