FOCUSED ULTRASOUND
Incisionless Outpatient Procedure

INSIGHTEC

Focused ultrasound offers a next generation incisionless outpatient procedure for patients with Essential Tremor or Parkinson's Disease who don't get acceptable tremor relief from medications.

With no incisions or implants, there is little to no risk of infection and patients usually return home the same day.

Benefits for your Patients

Incisionless treatment

- Treatment available on both sides (staged, unilateral with 9 months separation) for ET patients
- No invasive burr holes or implants
- No general anesthesia required
- Little to no risk of infection[1]
- Minimal hospitalization

Tremor improvement

- Immediate tremor improvement post-procedure
- Improved quality of life[1] and functional disability[2]
- Durable tremor improvement maintained to at least 3 years for first side[1] and to 6 months for second side[2]

Personalized treatment

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

Safe and effective

- Real-time thermal feedback to continuously monitor patient safety and temperature at target
- Majority of adverse events were mild and moderate[1,2]

Thermal ablation of the ventral intermediate nucleus (Vim) of the thalamus is done under MR guidance for visualization of patient anatomy, real-time thermometry as well as immediate confirmation of treatment outcome. During the procedure, patients are awake and responsive to assist in evaluating response including tremor improvement and potential side effects. Many patients report immediate and lasting improvement of the tremor in their treated hand with minimal complications.

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I just wanted a chance to get my life back. I was shaking so much. Nobody knows what that's like, unless you've lost a part of your life and then you regain it. I'm so thankful.

Carol Klein, Focused Ultrasound Patient

Patient disclaimer: This patient testimonial may not be representative of all treatment outcomes.

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Focused Ultrasound has really revolutionized our treatments of tremor, because patients are now coming in and asking for focused ultrasound.

Andres Lozano, MD, University of Toronto, NeuroNews July 2021

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I was just floating [in the MRI]. It was the most peaceful feeling. That's when I knew those tremors were gone. That peace I felt was unbelievable.

Marie Baker, Focused Ultrasound Patient

Patient disclaimer: This patient testimonial may not be representative of all treatment outcomes.

[1]Premarket Approval P150038
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038

[2]Premarket Approval P150038-S022
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038S022

TRANSFORMING PATIENT CARE

Exablate Neuro

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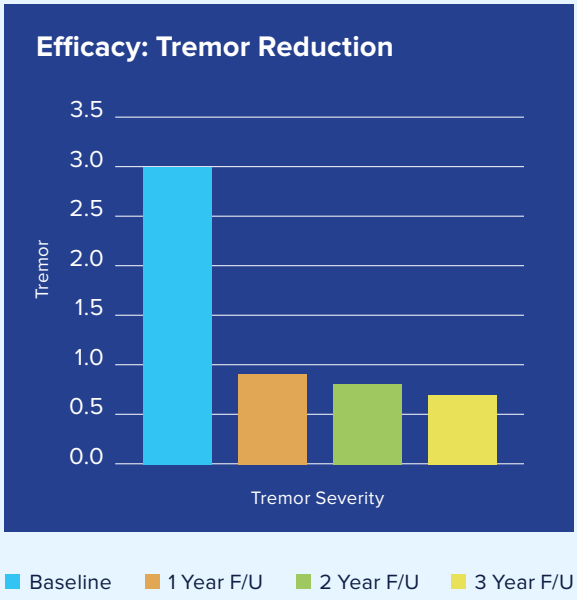
Facts About Focused Ultrasound

- The procedure was FDA approved for the first side of Essential Tremor patients in 2016, with over 4,000 procedures performed worldwide in 2022. The second side procedure was FDA approved in 2022.
- Exablate Neuro is covered by Medicare in all 50 states for essential tremor first side treament. Aetna and CIGNA cover treatment for essential tremor first side treatment nationally, and 80% of Blue Cross Blue Shield plans provide access for essential tremor first side treatment. Please contact your treatment team for coverage information on Second Side treatment.
- Focused ultrasound treatment is patient specific, stimulating at a low temperature, fine-tuning position until the patient gets tremor relief.
- Focused ultrasound is available and offered at treatment centers throughout the country. For more information, visitour website: insightec.com/global/treatment-centers/

Clinical Evidence: First Side

3-year follow-up of subjects in the pivotal study of focused ultrasound for essential tremor.[1]



Safety

- The most common adverse events reported by subjects in Insightec-sponsored clinical studies after treatment included: imbalance/gait disturbance (26% of study subjects), numbness/tingling (33%), and headache/head pain (51%).
- Most complications were classified as mild or moderate, and 48% resolved on their own within 30 days. Additional infrequent events include dizziness, taste disturbance, slurred speech, fatigue and vomiting. Persistent adverse events at three-years included: numbness/tingling (9% of study subjects), imbalance (4%), unsteadiness (4%), gait disturbance (2%), and musculoskeletal weakness (2%).
- Patients should discuss in detail the risks, benefits and treatment options with their physician prior to treatment. For more safety information, please go to https://insightec.com/safety-information

*Data on file with Insightec. Premarket Approval P150038
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038

Note: The system may only be operated by licensed Neurosurgeons that have successfully completed the Exablate training program.

TRANSFORMING PATIENT CARE
Exablate Neuro

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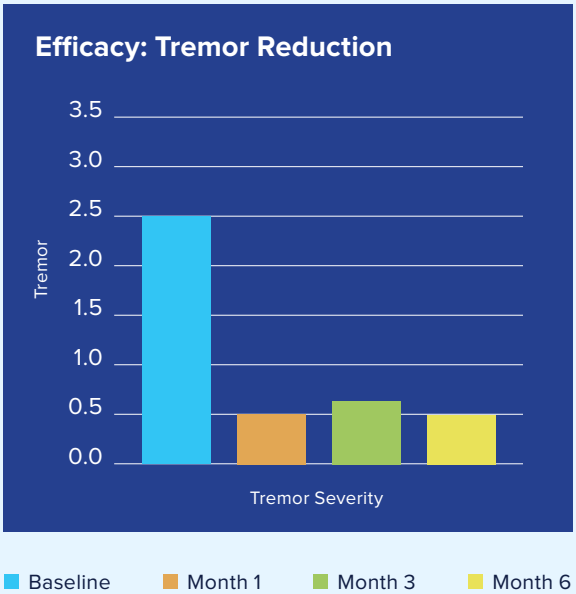
Clinical Evidence: Second Side

6-month follow-up of subjects in the pivotal study of focused ultrasound for essential tremor for contralateral side.[2]



There was one procedural related serious adverse event - a urinary tract infection following the use of a catheter during the procedure.

The most common adverse events experienced during and after treatment were:

- Numbness / Tingling (31% of subjects)
- Dysarthria (29% of subjects)
- Ataxia (24% of subjects)
- Dysgeusia (14% of subjects)
- Imbalance (10% of subjects)
- Unsteadiness (10% of subjects)
- Gait Disturbance (10% of subjects)
- Dysphagia (10% of subjects)
- Hypogeusia (10% of subjects)
- Dysmetria (4% of subjects)
- Fatigue (4% of subjects)

Safety

The safety profile of the second side treatment is similar to the safety profile of the treatment of the first side. In an Insightec-sponsored clinical study that included 51 subjects at seven leading academic medical centers in the US, 85% of the adverse events reported were mild and 98% of the adverse events were mild or moderate.

Patients should discuss in detail the risks, benefits and treatment options with their physician prior to treatment. For more safety information, please go to https://insightec.com/safety-information

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Device name: Exablate Neuro