

CLINICAL STUDY RESULTS

FOR PATIENTS

Focused Ultrasound for Essential Tremor

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What is Focused Ultrasound?

Focused Ultrasound is an incisionless treatment for essential tremor patients who have not responded to medication. It uses sound waves guided by MRI to treat deep in the brain with no incisions or permanent implants.

The ultrasound waves are focused on a small spot in the brain, the Vim of the thalamus, considered to be responsible for tremor. The temperature at the target rises high enough to create a small ablation or burn, providing a therapeutic effect. The patient lies down on a table which moves in and out of the MRI scanner. The MRI is the eyes of the treatment, enabling the physician to plan, guide and target the area for treatment. It also acts like a thermometer, providing continuous temperature monitoring to verify that only the targeted tissue is destroyed.

For intended use in each country, please see insightec.com/regulatory-approvals/

Efficacy Results

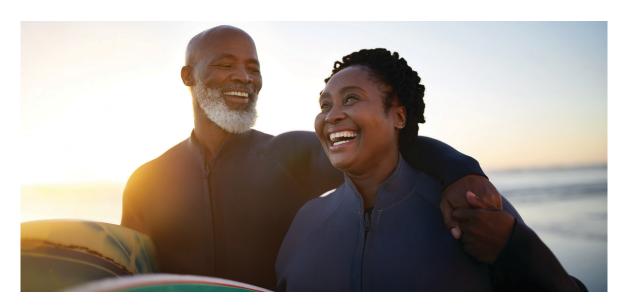
During an Insightec-sponsored clinical trial, 56 subjects received focused ultrasound treatment and 19 received a sham procedure and then crossed over to the focused ultrasound treatment arm. Of these 75 subjects, a total of 54 are included in the 3-year analysis.

Hand Tremor: The tremor severity score (CRST Part A) **improved 76.5%** over baseline at 3-year follow-up for combined (focused ultrasound and crossover) subjects.

Functional disability and quality of life: Improvement in tremor/motor function (CRST Part A & B) was 53% at three years. Functional disability (CRST Part C) showed a **56.9% improvement** from baseline at three years.







Safety Results

Overall, the focused ultrasound treatment has been shown to be safe for treating essential tremor with minimal risk, but as with any medical procedure, there are risks. You should have a detailed conversation with your physician regarding complications, also known as adverse events, that you may experience.

Insightec-sponsored clinical studies have shown that the most common adverse events after treatment are:

- Imbalance/Gait Disturbance (26% of subjects)
- Numbness/Tingling (33% of subjects)
- Headache/Head Pain (51% of subjects).

Most of these events were classified as mild or moderate, and 48% of all complications resolved on their own within 30 days.

Additional infrequent events include dizziness, taste disturbance, slurred speech, fatigue and vomiting.

Adverse events that persisted at 3 years were all mild or moderate and included:

- Numbness/Tingling (9% of subjects)
- Imbalance (4% of subjects)
- Unsteadiness (4% of subjects)
- Gait Disturbance (2% of subjects)
- Musculoskeletal Weakness (2% of subjects)

For additional safety information, please refer to: <u>Pre-Market Approval (PMA) P150038.</u> Again, you should discuss in detail the risks, benefits and treatment options with your physician prior to treatment.

If a blood clot or deep vein thrombosis (DVT) occurs after the procedure and is not treated urgently it could lead to long term muscle, heart, brain, or lung damage. There is a possibility that your tremor may return months or years after treatment. This procedure does not treat the underlying disease nor prevent its progression. For more information on the focused ultrasound treatment, including warnings, precautions, potential side effects and contraindications, please see the Safety Information page: insightec.com/safety-information/









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