



# FOCUSED ULTRASOUND

Using sound waves to  
**treat essential tremor**  
with no incisions and  
immediate and sustained  
tremor relief

INSIGHTEC

For use within the US

# What is Essential Tremor?

**Essential tremor (ET)** is a neurological condition that causes shaking of the hands, head and voice, but it can also cause the legs and trunk to shake. Some people even have a feeling of internal tremor. ET is often confused with Parkinson's disease although it's eight times more common, affecting an estimated **10 million Americans and millions more worldwide.**<sup>1</sup>

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## Symptoms

The primary symptoms associated with essential tremor include:

- Uncontrollable shaking that occurs for brief periods of time
- Begins gradually, usually on one side of the body
- Occurs in the hands first, affecting one hand or both
- Can include a shaking voice or tremor of the head
- Nodding head
- Worsening during periods of emotional stress and purposeful movement

<sup>1</sup>International Essential Tremor Foundation.

# What is Focused Ultrasound?

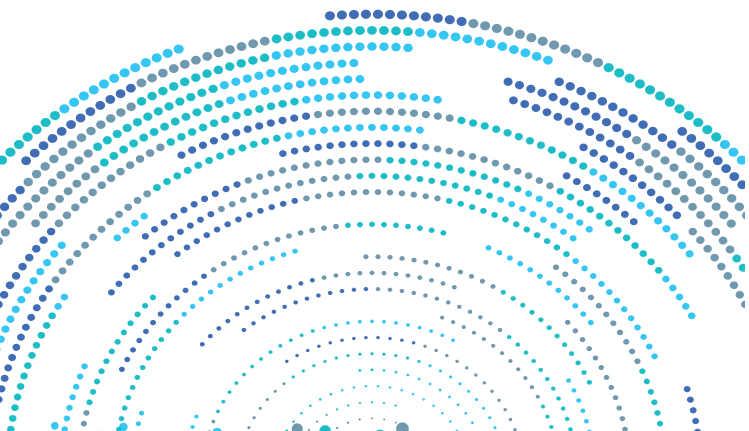
**Focused Ultrasound** is an incisionless treatment for essential tremor patients who have not responded to medication. It uses sound waves guided by MRI to treat deep in the brain with no incisions or permanent implants.

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 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.

Recently, Insightec received FDA approval for treatment of the second hand providing at least 9 months elapsed since the first uneventful treatment.

For intended use in each country, please see [insightec.com/regulatory-approvals/](https://www.insightec.com/regulatory-approvals/)





# Benefits of Focused Ultrasound



## Tremor Improvement

In an Insightec-sponsored clinical study, subjects reported an immediate improvement in tremor which was sustained for five years for treatment of the first hand<sup>2</sup> and at least six months for treatment of the second hand.<sup>3</sup>



## Incisionless

Focused ultrasound allows sound waves to pass safely through the skull with no incisions.



## Treats Both Sides

Focused ultrasound is FDA approved to treat both sides of the body. The procedures are staged by at least 9 months.



## Quick Recovery

With no surgical cuts, there is minimal to no risk of infection. The treatment is often performed on an outpatient basis and you can expect to resume normal activities within days.



## Important to share with your physician

It is extremely important to discuss all medical conditions with your physician so your suitability for the procedure can be properly evaluated.

<sup>2</sup>Pre-Market Approval (PMA) P150038

<sup>3</sup>(PMA) P150038-S022



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I always loved baking, so I decided to open my own bakery. One day, my right hand started to shake. Gradually I couldn't do daily activities like drink or eat, not to mention baking or serving coffee to my customers. I became completely dependent on my staff.

At first, the doctors prescribed medications, but they didn't work for me. Then they suggested the MRI-guided focused ultrasound treatment. I knew I would have to shave my head, but I just wanted to live my dream - to serve my customers again.

After a couple of hours or so, on the MRI bed, my hand didn't shake anymore.

”

**Haya Mendlebaum**, Focused Ultrasound Patient

Results may not be representative of all treatment outcomes.

# Is the treatment an option for me?

It is important to consult with your physician or a Focused Ultrasound Treatment Center to determine if the Focused Ultrasound treatment is right for you.

As part of the evaluation process, the severity of your tremor and your overall health will be evaluated.

Patients will need to undergo a CT scan in order to determine if they are candidates for the Focused Ultrasound treatment.

If you have metallic implants such as pacemakers, neuro-stimulators, spine or bone fixation devices, total joints, metal clips, screws, etc, you will need to consult with a physician to determine if Focused Ultrasound is an option for you. Any metallic implants must be MRI-compatible to prevent injury to the patient from the MRI's strong magnetic field.

Also, if you are not generally healthy enough to withstand the treatment and lie still in the same position for on average 1.5–2.5 hours, you may not be a good candidate for this treatment. There are additional limitations and a physician will do an assessment to verify if you are a candidate for the treatment.

For safety information, please visit:  
<https://insightec.com/safety-information>





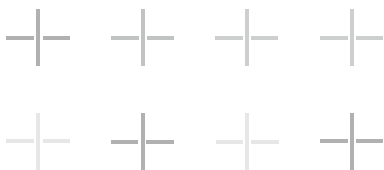
# What happens before, during, and after the treatment?

## Preparation

The Focused Ultrasound treatment requires that a patient have a cleanly shaven head. The Ultrasound waves will be transmitted into the brain from a helmet-like transducer. This is in order to ensure no interference of the sound waves. A local numbing medication will be applied and a head frame will be secured to your head so that your head does not move during treatment.

Your heart rate, blood pressure and blood oxygen levels may be monitored throughout the treatment. You will be awake, communicating with the treatment team throughout the treatment. You may be given additional medication to keep you comfortable.

Cool water will circulate in the helmet around the top of your head and you will be kept warm in case you get chilled. You will also be given a “stop sonication” button to indicate to the physician that you want to stop the treatment for any reason.





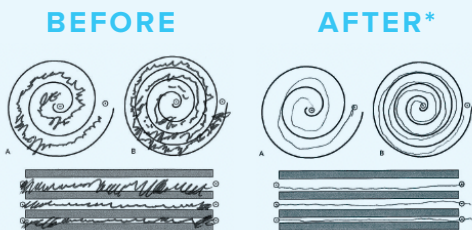
## Planning

A series of MRI images will be taken for planning the treatment according to your specific anatomy. The treating physician will first apply light doses of ultrasound energy. This helps to identify the precise spot in the brain for treatment by assessing temporary tremor improvement and any potential side effects.

After each application of energy, called a sonication, you will be asked to perform specific tasks to evaluate your tremor improvement. Tasks may include touching your nose with your finger and/or drawing spirals.

## Treatment

The treating physician will then gradually increase the energy to create a small lesion, usually resulting in a therapeutic effect, improvement of hand tremor in the treated side. Although individual results may vary, you should notice improvement during the treatment itself. The treatment lasts on average 1.5 - 2.5 hours.



## After Treatment

After treatment, the transducer and head frame will be removed, and you will go to the recovery room. The physician will let you know when you can go home and when you may need to return for a follow-up visit. Within days you should be able to return to normal activities. The treatment team will provide you with instructions related to your post-treatment recovery.

\*Results may not be representative of all treatment outcomes.

# What results can I expect?

For the first side treatment, outcomes of the Insightec sponsored clinical trial demonstrated an average of **73.1% improvement in tremor severity** at 5-year follow up in 40 patients.

For the second side treatment, outcomes of the Insightec sponsored clinical trial demonstrated an average of **80.2% improvement in tremor severity** at 6 month follow up in 51 patients.

## First Side Safety

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 study patients)
- Numbness/tingling (33%)
- Headache/head pain (51%).

Most of these events were classified as mild or moderate, and 48% of all adverse events resolved on their own within 30 days. Additional infrequent events include dizziness, taste disturbance, slurred speech, fatigue and vomiting.

**Adverse events recorded at 5 years were all mild or moderate and included:**

- Numbness/tingling (20% of study patients)
- Dysmetria (5%)
- Unsteadiness (5%)
- Gait disturbance (5%)
- Limb Weakness (5%)
- Dysgeusia (5%)

Additional infrequent events include slow movement and head pressure. If you experience a blood clot after the procedure that is not treated quickly, you may have long term related complications.

# Second Side Safety

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

- Slurred Speech (29% of study patients)
- Numbness/tingling (33%)
- Ataxia (23%)

About half of the related events were still ongoing at 6 months, but nearly all (95.7%) were mild.

**Complications that persisted in more than 2% of subjects at 6 months included:**

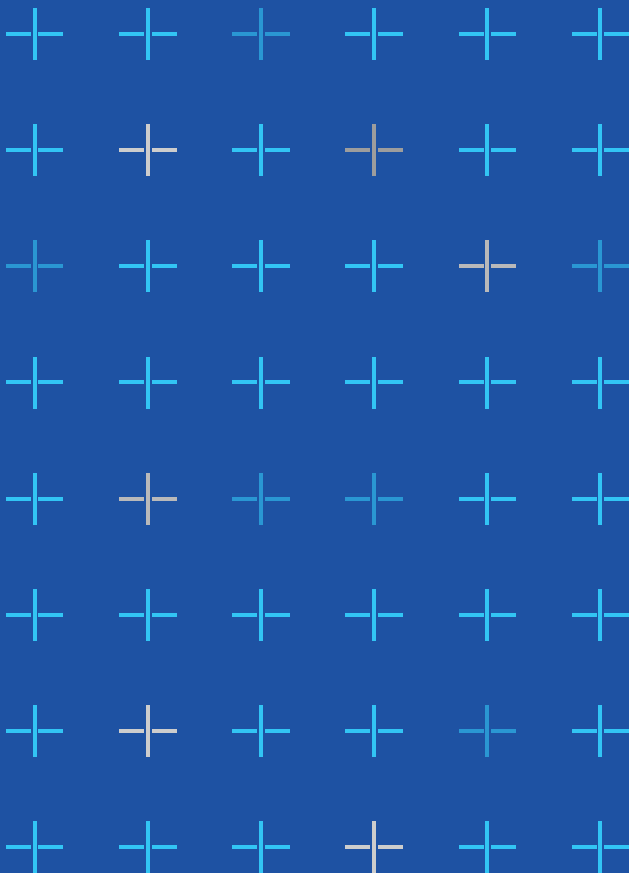
- Numbness / Tingling (16% of study patients)
- Slurred Speech (Dysarthria) (14%)
- Ataxia (14%)
- Hyogeusia (8%)
- Dysphagia (8%)
- Dysgeusia (6%)

If you experience a blood clot after the procedure that is not treated quickly, you may have long term related complications.

\*For additional safety information, please refer to: Pre-Market Approval (PMA) P150038-S022 for the second treated side. Again, you should discuss in detail the risks, benefits and treatment options with your physician prior to treatment.

For additional safety information, please refer to <http://www.insightec.com/safety-information>





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Device name: Exablate Neuro

Visit our website for more information about the  
focused ultrasound treatment for essential tremor:

[www.insightec.com/essential-tremor-treatment](http://www.insightec.com/essential-tremor-treatment)