



INSIGHTEC

FOCUSED ULTRASOUND FREQUENTLY ASKED QUESTIONS

For Patients with Essential Tremor



ABOUT FOCUSED ULTRASOUND

1 What is Focused Ultrasound?

Focused Ultrasound is an incisionless treatment for essential tremor patients who have not responded to medications. It is based on MR-guided Focused Ultrasound (MRgFUS) technology which uses sound waves to precisely treat deep in the brain guided by MR imaging.

2 How long has this procedure been approved by the FDA?

The FDA approved the Exablate Neuro device for treating essential tremor at the end of 2016 and for treating patient's second side essential tremor in 2022.

3 Where is this procedure done in the USA?

There are Treatment Centers performing Exablate Neuro procedures across the USA. For a complete list visit: <https://insightec.com/treatment-centers/>

To find out if the center is trained to perform a specific procedure, please contact the center.

4 Is this treatment being done in other countries besides the USA?

Yes, treatments are being performed in centers in a growing list of countries around the world.

5 Why is the treatment limited to age 22 and older?

The limitation is based on the FDA approval that is based on the clinical study that was performed and its criteria.

6 Is this effective with head tremors?

The treatment is FDA approved to treat hand tremor.

7 If I have it in both hands, do I need two treatments for each hand?

The treatment is FDA approved for staged unilateral treatment - treating one side at a time with at least 9 months between treatments for eligible patients and without significant clinical events from the first treatment.

8 If the thalamus is in the center of the brain, why doesn't this treatment affect the rest of the brain?

The ultrasound waves pass through the rest of the brain. Only where they converge in the thalamus does the temperature rise, heating and creating a lesion that helps disrupt what is causing the tremor.

9 Is there a possibility of missing the target?

The possibility is rare, because MR imaging allows the treating physician to continuously see the treatment area and monitor the temperatures.



CANDIDACY PROCESS

1

Do I have to visit a doctor before visiting the treatment center?

Yes, you need to have a definitive diagnosis of essential tremor, often done by your healthcare provider, primary care physician, a neurologist, or a movement disorder specialist. Other criteria are described below and should be discussed with your physician.

3

If I am found to be suitable for treatment, how soon can the treatment be done?

This will depend on the treatment center. You can call Insightec Educators at [1-800-775-5073](tel:1-800-775-5073) for more information on the Incisionless treatment.

2

Should I try medications first?

In order to be a candidate for the incisionless treatment, you must have a confirmed diagnosis of essential tremor that does not respond or are ineligible for at least two standard of care medications. Please discuss with your physician.





ABOUT INSURANCE COVERAGE

1

In which states is there Medicare coverage for the treatment for essential tremor?

Effective July 12, 2020, the MR-guided focused ultrasound treatment for medication-refractory essential tremor is a Medicare covered benefit in all 50 states.

2

Is Focused Ultrasound covered under Medicare Part A, Medicare Part B, or a supplemental Medicare plan?

The focused ultrasound treatment (also known as Magnetic Resonance guided Focused Ultrasound (MRgFUS) for treatment of essential tremor) is covered under Medicare Part B.

3

Do private health insurance plans cover the treatment?

Aetna and many Blue Cross Blue Shield Association plans cover MR-guided focused ultrasound treatment for medication-refractory Essential Tremor. For up-to-date information on insurance coverage, please visit <https://usa.essential-tremor.com/insurance-coverage/>

4

Can I travel to other states to receive the treatment if my state is not covered by Blue Cross Blue Shield?

It is our understanding that under the Blue Card Network, patients traveling outside of their home state for treatment at a facility providing MRgFUS would be subject to their home plan coverage decision. We recommend confirming coverage determination with your health plan and the treatment center prior to treatment.

5

What about other private insurance plans?

Contact your health plan's Member Service department by calling the phone number listed on the back of your insurance ID card. Ask whether or not MR-guided Focused Ultrasound for treating essential tremor (CPT code 0398T) is a covered benefit in an outpatient setting based on your health plan.

6

What is the cost of the procedure if it's not covered by my insurance?

The cost for cash paying patients is set by the treatment center.





BEFORE THE TREATMENT

1 Do I need to get any imaging scans done before the treatment?

Yes, you will need to get a specialized CT scan, and some treatment centers may ask you to get an MRI scan as well.

2 Why do I need a CT scan?

Everyone's skull is different, and a CT scan is done to determine if the shape and thickness of your skull are suitable for the incisionless treatment. Certain skull shapes and thickness may make it impossible for ultrasound waves to reach the temperature at the target required for treatment.

3 How many times will I meet with my treating physician?

Most often, a patient will meet with the treating physician at least two times. At the first consultation, the physician will evaluate your CT scans to determine whether you are a candidate for the treatment. The second is on treatment day. In some instances, you may meet a third time for follow-up imaging on the day after treatment. The treating team will also discuss any additional follow up visits needed as well as information that will be relayed back to your referring physician.

4 Why do I need to have my head shaved?

This is necessary for two reasons:

- Ultrasound waves do not travel well through air. In this treatment, water is used (like a gel used when having an abdominal ultrasound) as a conductive medium. The smooth-shaven scalp and a silicone cap enable a tight interface with the ultrasound transducer.
- Air bubbles could get trapped in the hair, blocking the ultrasound waves and absorbing energy which could potentially lead to skin burns.





DURING THE TREATMENT

1 Why do I need to have a frame put on?

The frame is a standard stereotactic frame that helps ensure your head does not move during the treatment.

2 Does my entire body need to be put inside the MRI scanner?

No, from about your mid-torso up will be placed inside the scanner.

3 Will I be in the MRI scanner for the entire treatment?

No, the treatment bed will move in and out of the MRI scanner. After each application of energy, your tremor will be assessed by doing various tasks such as drawing a spiral.

4 Why do I have to be awake?

Your feedback during the treatment is necessary as you will be asked to do different neurological tasks such as drawing spirals. This is so the physician can evaluate the improvement of your tremor and identify and address any potential side effects that you may be experiencing during the treatment.

5 How long do I need to stay for the treatment during and after?

The treatment time is on average 2.5 hours. The treatment is usually performed on an outpatient basis. However, the treating physician will decide when you can return home.

6 How long is the effect of the treatment expected to last?

The most recent data shows hand tremor improvement of the study subjects was mostly maintained at three years.¹ There is the possibility that your tremor may return months or even years after the treatment, or that the tremor may not improve at all. And while the treatment may improve your tremor, it is important to understand that it does not treat the underlying disease nor prevent its progression.

¹ Pre-Market Approval (PMA) P150038

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P150038>



DURING THE TREATMENT

7

What side effects can I expect during and after the first side treatment?*

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 experienced after treatment of the first side included:

- 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 adverse events resolved on their own within 30 days.

Complications 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)

8

What side effects can I expect during and after the second side treatment?*

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 patients at seven leading academic medical centers in the US, 85% of the safety events reported were mild and 98% of the adverse events were mild or moderate.

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 of the second side 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)

Additional infrequent events include dizziness, taste disturbance, slurred speech, fatigue and vomiting. For additional safety information, please refer to [Pre-Market Approval \(PMA\) P150038-S022](#)

Please visit our site for more details:
insightec.com/essential-tremor-treatment



AFTER THE TREATMENT

1

How soon can I return to work after the treatment?

That depends on the type of work that you do and how you feel. Please consult with your physician.

2

What do I need to do once I am home?

The treatment team will provide you with instructions related to your post-treatment recovery.

3

How long after the first side treatment do I need to wait before getting the second side treated?

If your first treatment was at least 9 months ago, you may be eligible to have the second side treated. Contraindications for treating the second side include: clinically significant dysphagia (difficult swallowing), abnormal speech function, or gait abnormalities that are moderate to severe, following the index MRgFUS unilateral thalamotomy procedure.

