

A photograph of a person playing tennis on a court. The person is wearing a white shirt, white socks, and white sneakers. They are holding a tennis racket in their right hand and a yellow tennis ball in their left hand. The background shows a tennis court with a net and a building in the distance. The sun is shining brightly, creating a lens flare effect.

LIVING
WITH
ESSENTIAL
TREMOR?

GET BACK TO LIFE!

USING SOUND
WAVES TO TREAT
ESSENTIAL TREMOR
WITH NO INCISIONS



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 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 millions worldwide.¹

The cause of essential tremor is not fully understood, but clinical research has identified the Vim nucleus of the thalamus as the spot in the brain which can be treated to alleviate the tremor. The thalamus is a structure deep in the brain that coordinates and controls motor activity as well as other functions.

<https://www.essentialtremor.org/wp-content/uploads/2019/06/FactSheet062019.pdf>



SYMPTOMS

The primary symptoms associated with essential tremor include:

- Uncontrollable shaking that occurs while performing an action
- 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

WHAT IS FOCUSED ULTRASOUND TREATMENT?



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

Ultrasound is a form of energy that passes through skin, muscle, fat and bone. Ultrasound energy is non-ionizing, meaning there is no radiation exposure during the procedure.

During the procedure, ultrasound waves safely pass through the skull without a need for an incision. The ultrasound waves are focused on a small point in the brain (Vim of the thalamus). The temperature at the target rises high enough to create a small ablation or burn, providing a therapeutic effect. The whole procedure is conducted inside an 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.

CE INDICATIONS FOR USE: Intended for thermal ablation of targets in thalamus, subthalamus and pallidum regions of the brain. Exablate 4000 transcranial MR guided focused ultrasound can be used for the treatment of neurological disorders (Essential Tremors, Tremor Dominant idiopathic Parkinson's Disease-Unilateral) and neuropathic pain in the brain by heat induced focusing using ultrasound energy under full MR planning and thermal imaging control.

TREATMENT BENEFITS



TREMOR IMPROVEMENT

In an INSIGHTEC-sponsored clinical study, patients reported an immediate improvement in tremor which was mostly maintained at three years.²

INCISIONLESS

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

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.

²Pre-Market Approval (PMA) P150038



“
BECAUSE
I WANT
TO BE
INDEPENDENT
”

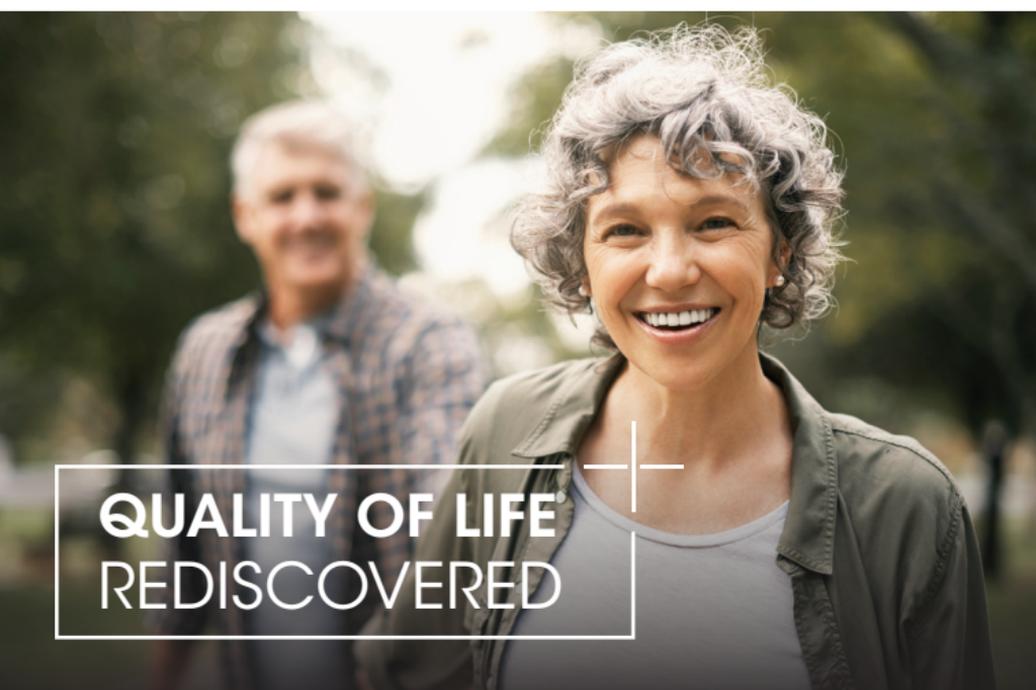
IS FOCUSED ULTRASOUND AN OPTION FOR ME?

It is important to consult with your physician or a Treatment Center to determine if the focused ultrasound 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 Neuravive treatment.

During the treatment, the patient will lie down on the treatment bed which will move in and out of the MRI scanner. The patient is awake in order to provide feedback about tremor improvement and potential side effects during the treatment.



**QUALITY OF LIFE
REDISCOVERED**



**BECAUSE
I WANT TO
LIVE MY LIFE
TO ITS FULLEST.**



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.

Also, if you are not generally healthy enough to withstand the treatment and lie still in the same position for 3-4 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 complete safety information:

<https://essential-tremor.com/safety-information>

WHAT HAPPENS BEFORE, DURING AND AFTER THE TREATMENT?

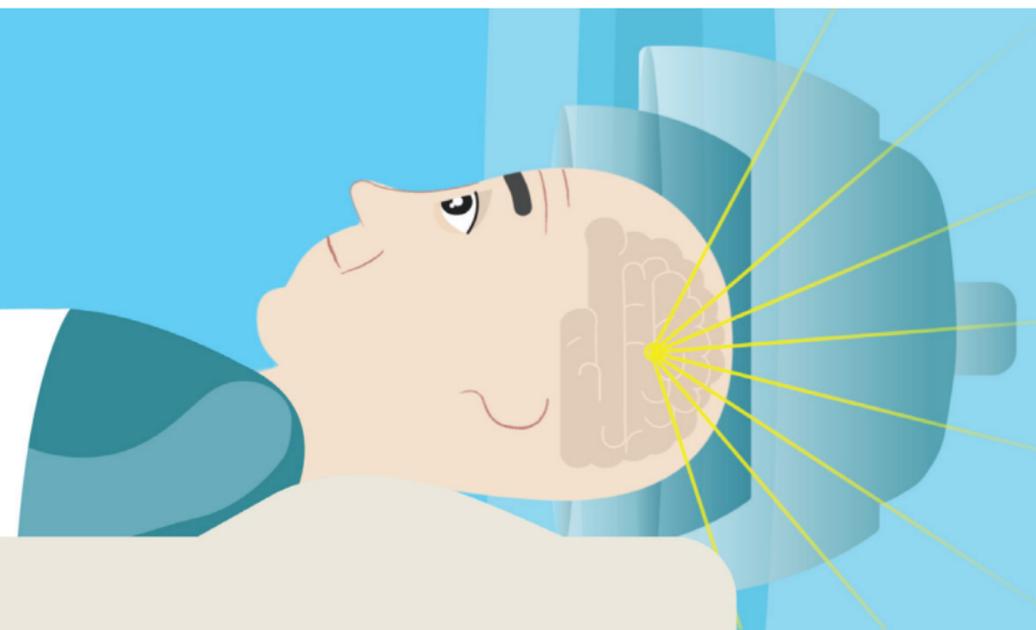


PREPARATION

The focused ultrasound treatment requires that a patient have a cleanly shaven head. This is in order to ensure no obstruction of the sound waves. A local numbing medication will be applied and a standard 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 will 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 spot in the brain for treatment by assessing temporary tremor improvement and any potential side effects before treatment.

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 on a board.



TREATMENT

The treating physician will then apply higher energy to create the permanent lesion. Although individual results may vary, you should notice improvement during the treatment itself. At the end of the procedure a final MRI scan will be done to assess the treatment. The treatment will last approximately 3-4 hours.



POST TREATMENT

After treatment, you will move to the recovery room where the frame will be removed. The physician will let you know when you can go home and when you will need to return for a follow-up visit. Within days you should be able to return to normal activities.

WHAT RESULTS CAN I EXPECT?



The outcomes of the INSIGHTEC sponsored clinical trial demonstrated an average 76.5% improvement in tremor severity at 3-year follow up in 54 subjects.²

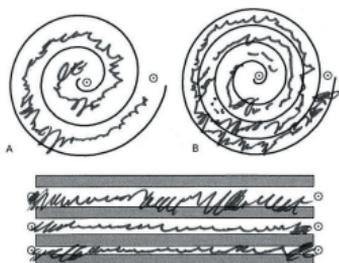
Adverse events (AEs) that persisted at 3 years were mild or moderate and included gait disturbance (2%), imbalance (4%), musculoskeletal weakness (2%), unsteadiness (4%) and numbness (9%). The number in parenthesis is the percentage of active subjects experiencing these adverse events.

At three-year follow-up, 56% of the adverse events still ongoing were mild and the remaining were moderate. The majority of all adverse events began within 30 days of the procedure and nearly all resolved.²

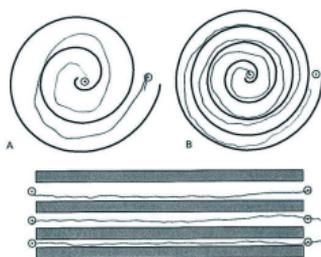


DRAWING TEST

Before



After



Individual results may vary.

RISKS & SIDE EFFECTS

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 associated with this treatment are 1) imbalance/gait disturbance (26% of study patients), 2) numbness/tingling (33%), and 3) 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.

For additional safety information, please refer to: [Pre-Market Approval \(PMA\) P150038](#)

Again, you should discuss in detail the risks, benefits and treatment options with your physician prior to treatment.

SHORT TERM RISKS – DAY OF TREATMENT UP TO 3-MONTHS POST-TREATMENT

The most common potential risks associated with the Exablate Neuro device and thalamotomy procedure are transient numbness and tingling. These sensations are typically mild to moderate in intensity and can last as briefly as the length of the sonication or up to several days.

You may experience bruising in the area of the IV catheter following the procedure similar to that experienced after blood draws. Any bruising should resolve on its own within a week.

LONG TERM RISKS – LONGER THAN 3-MONTHS POST-TREATMENT

Overall, Exablate Neuro is a reasonably safe procedure for treating essential tremor with minimal risk. Infrequent complications that have been reported following Exablate Neuro treatment include long-term numbness and tingling. Additionally, if (unintended) brain tissue is damaged, there may be muscle weakness, numbness, or sensory loss that may resolve after several months, or it may be non-reversible. There is the possibility that your tremor may return some months or years after treatment. This procedure does not treat the underlying disease nor prevent the exacerbation or progression of the disease. If you experience a blood clot after the procedure that is not treated quickly, you may have long term related complications.



I always loved baking, so I decided to open my own a 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,
Neuravive Patient

Patient testimonials may not be representative of all treatment outcomes.

INSIGHT-TEC®

INSIGHTTEC Ltd. © 2020. All rights reserved.

PUB41005797-EU Rev. 1

Device name: Exablate Neuro

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

www.essential-tremor.com