

## FOCUSED ULTRASOUND TO TREAT ESSENTIAL TREMOR

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### 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 an estimated 10 million Americans and millions more worldwide.<sup>1</sup>

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.

### FOCUSED ULTRASOUND TREATMENT

The Sentara Comprehensive Movement Disorders program provides expert treatment for those living with movement disorders, including essential tremor. MRI Guided Focused Ultrasound is an incisionless treatment for essential tremor patients who have not responded to medication. It uses focused sound waves guided by MRI 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.

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.

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## TREATMENT BENEFITS

**TREMOR IMPROVEMENT:** In a clinical study, patients reported an immediate improvement in tremor which was mostly maintained at three years.<sup>2</sup>

**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.

**FDA APPROVED:** Safe and effective with minimal side effects.<sup>2</sup>

**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.

## PREPARATION

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

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.

Patients must be at least age 22.

## CLINICAL EVIDENCE

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

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.<sup>2</sup>

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## RISKS & SIDE EFFECTS

Be sure to discuss with your physician all the risks involved with the focused ultrasound treatment.

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

The most common potential risks associated with the treatment device (Exablate) and thalamotomy procedure are transient numbness and tingling. Headaches or head pain during sonication and imbalance or unsteady were other potential risks, but most often ended shortly after treatment. Nausea/vomiting were also reported in some instances. It is unclear if this is related to medications used during the treatment or the procedure itself. 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 – LONGER THAN 3-MONTHS POST-TREATMENT

Infrequent complications that have been reported following Exablate 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 — seek emergency care.

To schedule a consult with a neurologist call 1-877-310-8713.

If you have a current ET diagnosis and would like to schedule a consult with the neurosurgeon call 757-395-8720.

<sup>1</sup> <https://www.essentialtremor.org/about-et/>

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