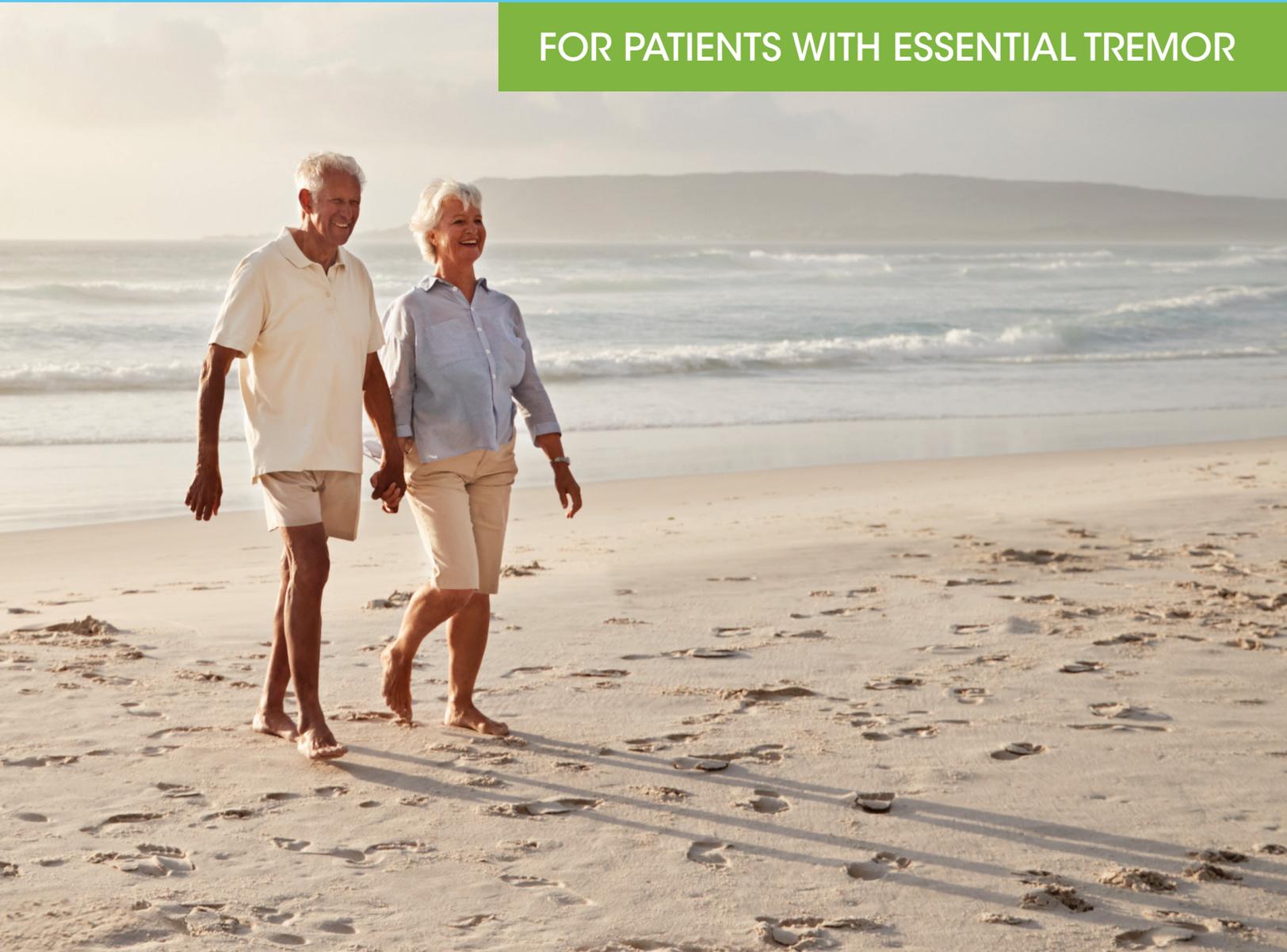


# Neuravive

FREQUENTLY ASKED QUESTIONS

FOR PATIENTS WITH ESSENTIAL TREMOR



## ABOUT NEURAVIVE

### 1. What is Neuravive?

Neuravive 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 using sound waves at the end of 2016.

### 3. Where is this procedure done in the USA?

There are Treatment Centers across the USA. For a complete list visit: <https://usa.essential-tremor.com/neuravive-treatment-centers/>

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

Yes, treatments are being performed in centers across Canada, as well as in the UK, Germany, Spain, Switzerland, Italy, Australia as well as in Japan, Taiwan and Korea. For a complete list of treatment centers visit: [www.insightec.com/us/treatment-centers/neurosurgery/usa](http://www.insightec.com/us/treatment-centers/neurosurgery/usa)

### 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.

## NEURAVIVE TREATMENT

### 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 unilateral treatment - treating one side, usually the dominant hand.

### 8. In the future will it be possible to treat my other side?

A clinical trial would need to be done first to show safety and effectiveness of treating both sides (bi-lateral treatment) and then the results would need to be submitted to the FDA in order to get an approval for treating the other side. To stay up to date on the Neuravive treatment, you can subscribe to our newsletter here: <https://usa.essential-tremor.com/contact/>

### 9. 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.

### 10. Is there a possibility of missing the target?

The possibility is very rare, because MR imaging allows the treating physician to continuously see the treatment area and monitor the temperatures. For information about risks, see <https://usa.essential-tremor.com/safety-information/>

## CANDIDACY PROCESS

### 1. Do I have to visit a doctor before visiting the Neuravive treatment center?

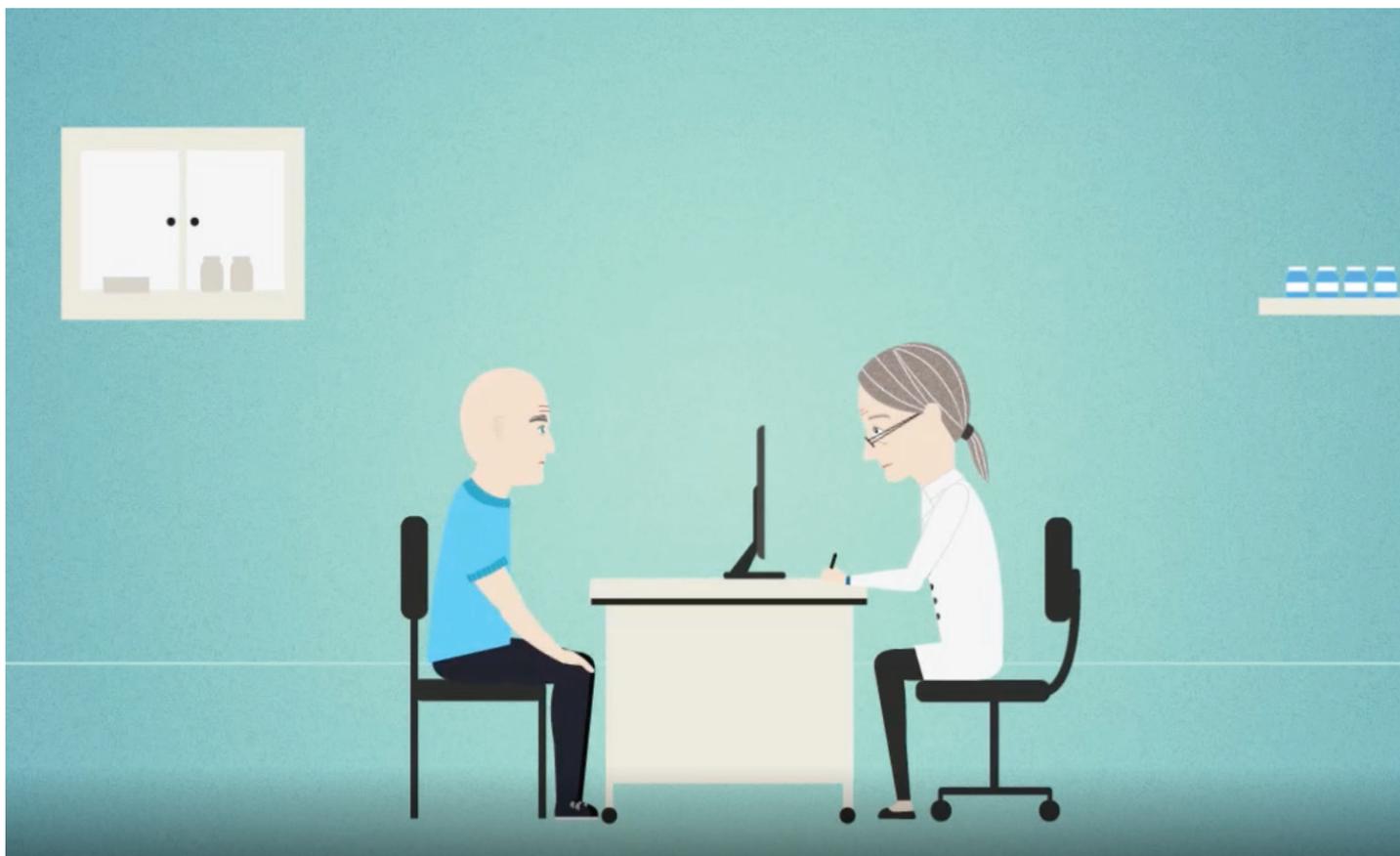
Yes, you need to have a definitive diagnosis of essential tremor, often done by a neurologist or a movement disorder specialist. Other criteria are described below and should be discussed with your physician.

### 2. Should I try medications first?

In order to be a candidate for the Incisionless Neuravive treatment, you must have a confirmed diagnosis of essential tremor that does not respond to medication (such as Propranolol or Primidone). If you do not get tremor relief from medication, then Neuravive may be an option. Please discuss 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 Neuravive treatment.



## ABOUT INSURANCE COVERAGE

### 1. In which states is there Medicare coverage for the Neuravive treatment for essential tremor?

Effective July 12 2020 Neuravive, the MR-guided focused ultrasound treatment for medication-refractory essential tremor, is a Medicare covered benefit in all 50 states. For more details visit: <https://usa.essential-tremor.com/blog/2019/07/14/medicare-coverage-continues-to-expand-across-the-u-s/>

### 2. Can I travel to other states to receive the Neuravive treatment if my state is not covered by Medicare?

It is our understanding that per Medicare Rules and Regulations, Medicare beneficiaries traveling outside of their home state for treatment at a facility providing MRgFUS would be subject to the Medicare contractor coverage decision based on where the treatment is performed. We recommend confirming with your local Medicare contractor and the treating treatment center prior to treatment.

### 3. Is Neuravive covered under Medicare Part A, Medicare Part B, or a supplemental Medicare plan?

Where covered, the Neuravive treatment (also known as Magnetic Resonance guided Focused Ultrasound (MRgFUS), for treatment of essential tremor) is covered under Medicare Part B.

### 4. Do private health insurance plans cover the Neuravive treatment?

Many Blue Cross Blue Shield Association plans cover MR-guided focused ultrasound treatment for medication-refractory Essential Tremor. For a complete list of Blue Cross Blue Shield plans visit: <https://usa.essential-tremor.com/blog/2020/03/01/now-covered-by-blue-cross-blue-shield/>

### 5. Can I travel to other states to receive the Neuravive 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.

### 6. What about private insurance companies, any progress there?

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. For further assistance, visit our site: <https://usa.essential-tremor.com/insurance-coverage-2/>

### 7. 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 CT scan, and some treatment centers may ask you to get an MRI scan as well.

### 2. Why do I need a CT scan?

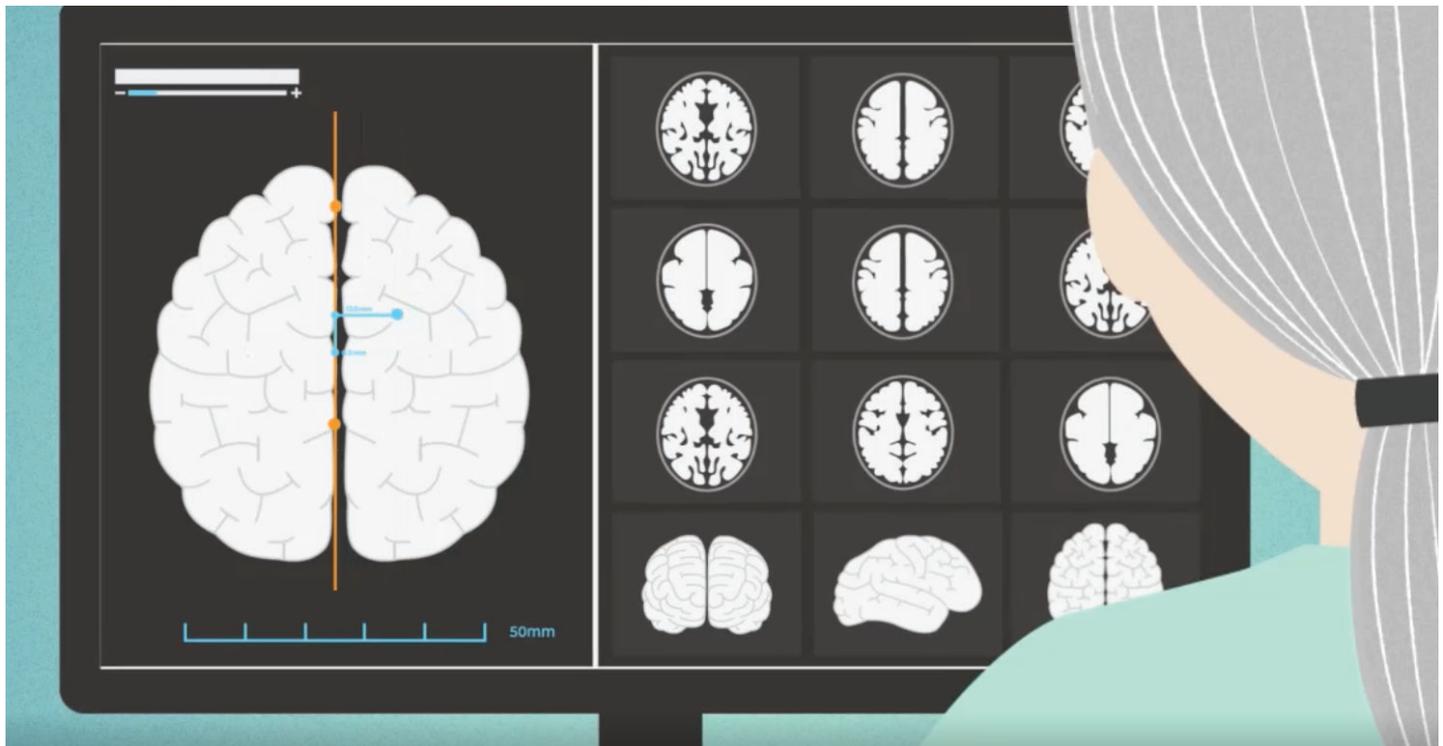
Everyone's skull is different, and a CT scan is done to determine if the shape and thickness of your skull are suitable for the Incisionless Neuravive treatment. Certain skull shapes and thickness may make it impossible for ultrasound beams to reach the temperature at the target required for treatment.

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

Most often, a patient will meet with the treating physician 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.

### 4. Why do I need to have my head shaved?

This is necessary for two reasons: 1) 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. 2) 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?

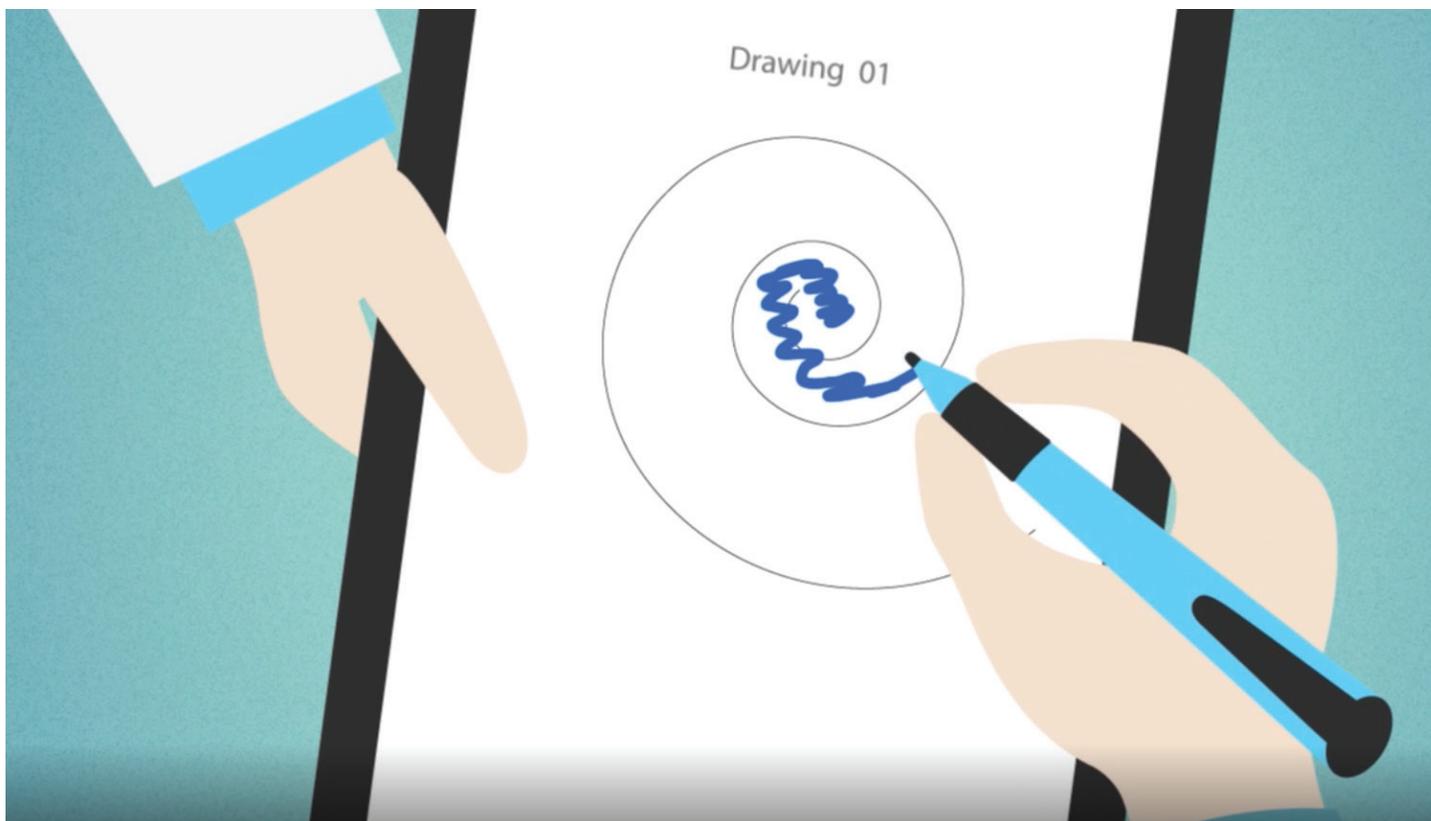
No, the treatment bed will move in and out of the MRI scanner. After each application of energy, your tremor will be assessed by doing tasks such as drawing a spiral.

### 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 approximately 3-4 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.<sup>1</sup> There is the possibility that your tremor may return months or even years after the Neuravive 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.

## 7. What side effects can I expect during and after the treatment?

Overall, focused ultrasound has a very favorable safety profile with infrequent complications reported during and following the Neuravive treatment. During the treatment, you may feel a headache or head pain and nausea and vomiting have been reported during application of the focused ultrasound energy.

The most common potential short-term complications, defined as occurring on the day of treatment and up to 3 months following treatment, are transient numbness or tingling. This is typically mild to moderate in intensity and can last as briefly as the length of the sonication or up to several days. Imbalance, unsteadiness, and bruising in the area of the IV catheter may occur, but usually resolve within a week after treatment. Potential long-term complications, defined as lasting longer than 3-months following treatment, include numbness or tingling, imbalance, unsteadiness, gait disturbance, and muscle weakness. If a blood clot or deep vein thrombosis (DVT) occurs after the procedure and is not treated emergently, it may lead to long term muscle, heart, brain, or lung damage.

There is also the possibility that the 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.

Please visit our site for more details: <https://usa.essential-tremor.com/safety-information/>

<sup>1</sup><https://www.insightec.com/media/11107/exablateneuroinformationforprescribers0usa.pdf>

## 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.

#### **What side effects can I expect after the treatment?**

There is a small risk that you could develop temporary or permanent muscle weakness, unsteadiness when walking, sensory loss, or numbness or tingling in your fingers or elsewhere in your body. Please visit our site for more details: <https://usa.essential-tremor.com/safety-information/>

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PUB41005102-NA Rev. 1 | Device name: Exablate Neuro

Neuravive

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