



MR-Guided Focused Ultrasound: Frequently Asked Questions

For people with essential tremor

About MR-guided focused ultrasound

What is MR-guided focused ultrasound?

MR-guided focused ultrasound is an incisionless treatment for people with essential tremor 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.

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.

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

Yes, treatments are being performed in centers across Canada, UK, Germany, Spain, Switzerland, Italy, Australia as well as in Japan, Taiwan and Korea.

Why is the treatment limited to age 22 and older?

The limitation is based on the FDA approval.

MR-guided focused ultrasound treatment

Is this effective with hand tremors?

The treatment is FDA-approved to treat hand tremor.

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.

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 (bilateral treatment) and then the results would need to be submitted to the FDA in order to get an approval for treating the other side. Contact our program coordinator for the latest updates at (714) 378-5022.

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, creating a lesion that helps disrupt what is causing the tremor.

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 usa.essential-tremor.com/Safety-Information





Candidacy process

Do I have to visit a doctor before having the MR-guided focused ultrasound treatment?

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.

Should I try medications first?

In order to be a candidate for the incisionless MR-guided focused ultrasound treatment, you must have a confirmed diagnosis of essential tremor that does not respond to medication (such as Propranolol or Primidone). If medication does not relieve your tremor, then MR-guided focused ultrasound may be an option. Please discuss with your physician.

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

Orange Coast Medical Center is available to start you on this journey immediately. It will typically require two to four weeks to prepare you for the procedure.

Insurance coverage

In which states is there Medicare coverage for the MR-guided focused ultrasound treatment for essential tremor?

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

Can I travel from another state to Orange Coast Medical Center to receive the MR-guided focused ultrasound treatment?

Yes, 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 treatment center prior to treatment.

Is MR-guided focused ultrasound covered under Medicare Part A, Medicare Part B, or a supplemental Medicare plan?

The procedure (magnetic resonance-guided focused ultrasound) is currently covered by Medicare Part B and Medicare Advantage Plans, as well as many Blue Cross Blue Shield plans, including Blue Shield of California for the treatment of essential tremor. Medicare Supplemental Plans offer support to their beneficiaries where coverage applies.

Do private health insurance plans cover the MR-guided focused ultrasound treatment?

Many Blue Cross Blue Shield Association plans cover MR-guided focused ultrasound treatment for medication-refractory essential tremor. 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.

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

Orange Coast Medical Center can provide you with information on a cash rate for the MR-guided focused ultrasound treatment. Please call us for more information.

Before the treatment

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

Yes, you will need to have a CT scan.

Why do I need a CT scan?

Everyone's skull is different, and a CT scan determines if the shape and thickness of your skull are suitable for the incisionless MR-guided focused ultrasound treatment. Certain skull shapes and thickness may make it impossible for ultrasound beams to reach the required temperature for treatment.

How many times will I meet with my treating physician?

Most often, you will meet with the treating physician two to three times. At the first consultation, the physician will evaluate your CT scans to determine whether you are a candidate for the treatment. The second visit is on treatment day. In some instances, you may meet a third time for follow-up imaging, the day after treatment.

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

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.

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.

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 and touching your nose.

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.

How long is the procedure?

The treatment time can take up to three to four hours. The treatment is usually performed on an outpatient basis.

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 MR-guided focused ultrasound 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.



What side effects can I expect during the treatment?

Overall, focused ultrasound has a very favorable safety profile with infrequent complications reported during and following the MR-guided focused ultrasound 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 three 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 may occur, but usually resolve within a week after treatment.

Please visit our site for more details:

usa.essential-tremor.com/Safety-Information

insightec.com/media/1107/ExablateNeuroInformationforPrescribers0USA.pdf

After the treatment

How soon can I return to work after the treatment?

It 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: usa.essential-tremor.com/Safety-Information



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please call us at **(800) 758-5817**
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