

Living with Tremor?

Get back to life!

Essential tremor (ET) and tremor-dominant Parkinson's disease (TDPD) are neurological conditions that cause shaking of the hands, head and voice. Some people even have a feeling of internal tremor. ET and TDPD affect millions of Americans and people worldwide.

Symptoms:

The primary symptoms treated by MR-guided Focused Ultrasound for essential tremor and TDPD include:

- Uncontrollable shaking of the hands that occurs with purposeful movement, which is defined clinically as an "action tremor"
- Tremors that worsen during periods of emotional stress



What is the MR-guided Focused Ultrasound (MRgFUS) treatment?

MRgFUS is an incisionless, implant-free treatment which uses MRI-guided sound waves to target a region deep in the brain of those with essential tremor for whom medication has not brought noticeable benefit or relief.

The MRI helps the neurosurgeon plan, guide and target ultrasound waves into a small spot in the brain – the Vim of the thalamus, the area considered responsible for tremor – continuously monitoring the temperature to a point high enough to create a small ablation or burn to therapeutically impact the intended area and provide at minimum 70% tremor control.

For essential tremor, MRgFUS was previously approved only for the dominant hand, the FDA has recently expanded eligibility to treatment of the second, non-dominant hand – provided 9 months have elapsed since the first-side procedure.

FDA Labeling:

Exablate® Neuro is intended for use in the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication-refractory tremor. Patients must be at least age 22.



Focused Ultrasound Benefits:



Tremor Improvement

In an Insightec-sponsored clinical study, subjects reported an immediate improvement in tremor which was sustained for at least five years for treatment of the first hand¹ and at least six months for treatment of the second hand.²



Incisionless

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



FDA Approved

MRgFUS treatment has been FDA approved for treating hand tremor associated with ET and TDPD.



Quick Recovery

With no surgical incisions, there is minimal to no risk of infection. The treatment is performed on an outpatient basis and you can expect to resume normal activities within days.

¹Pre-Market Approval (PMA) P150038

²(PMA) P150038-S022

Is focused ultrasound treatment an option for me?

It is important to consult with your physician or a Focused Ultrasound Treatment Center to determine if the treatment is right for you. If you are generally healthy enough to withstand the treatment and can lie still in the same position for one to two hours, you are considered a good candidate for this MR-Guided Focused Ultrasound treatment.

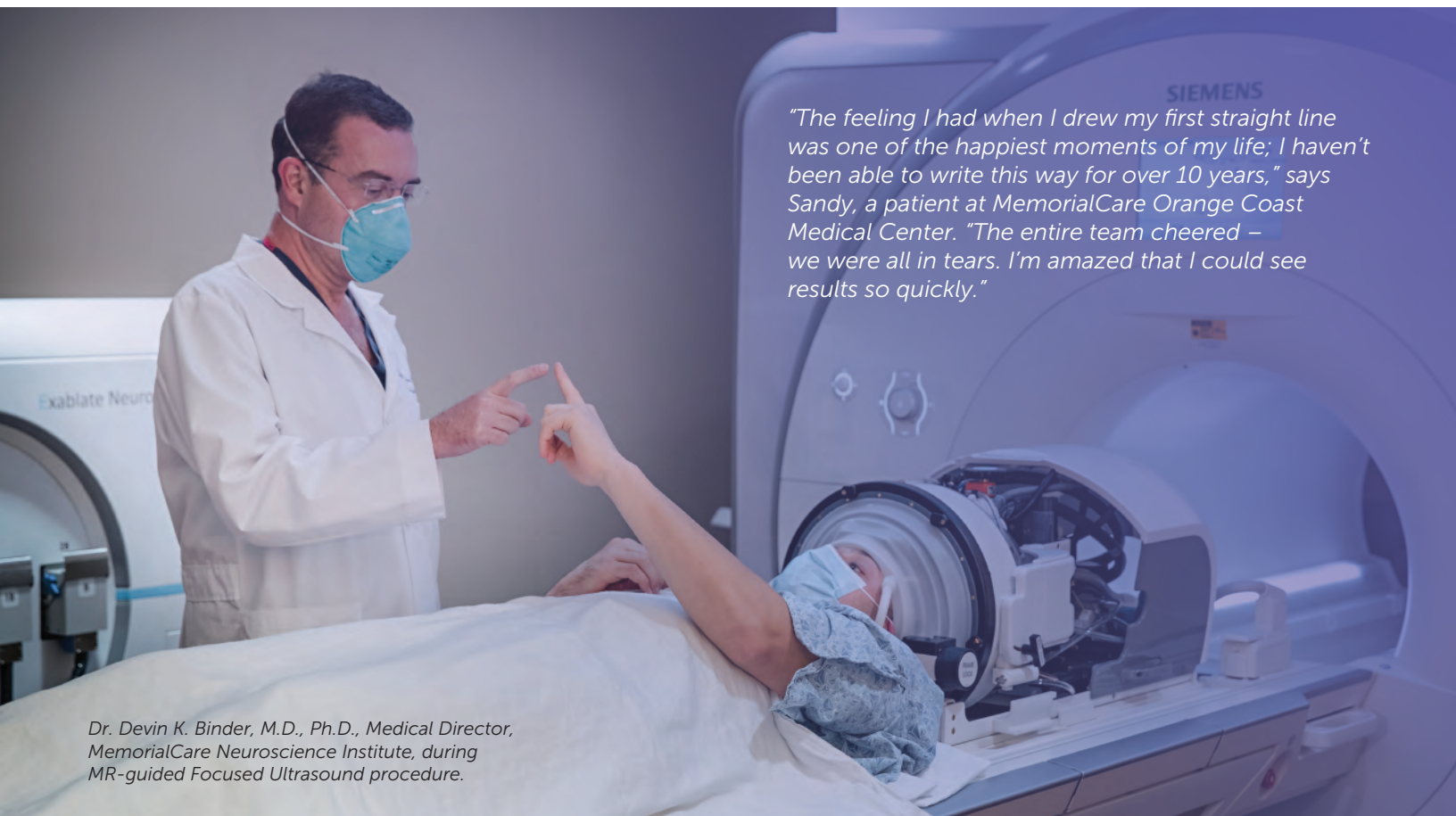
As part of the evaluation process, the severity of your tremor and your overall health will be evaluated.

A CT scan will be ordered to determine if you are a candidate for focused ultrasound treatment. During the treatment, you will lie down on the treatment bed, which will move in and out of the MRI scanner, and you will be awake during the procedure in order to provide feedback about tremor improvement and any potential symptoms you may be experiencing.

If you have metallic implants such as pacemakers, neurostimulators, 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's strong magnetic field.

If this treatment is not an option, we offer other treatments, such as Deep Brain Stimulation, to alleviate tremor symptoms.

For complete safety information: [insightec.com/safety-information](https://www.insightec.com/safety-information)



"The feeling I had when I drew my first straight line was one of the happiest moments of my life; I haven't been able to write this way for over 10 years," says Sandy, a patient at MemorialCare Orange Coast Medical Center. "The entire team cheered – we were all in tears. I'm amazed that I could see results so quickly."

Dr. Devin K. Binder, M.D., Ph.D., Medical Director,
MemorialCare Neuroscience Institute, during
MR-guided Focused Ultrasound procedure.