

High Intensity Focused Ultrasound (HIFU)

A non-invasive treatment for
Parkinson's and essential tremor



About HIFU

1. What is HIFU?

High Intensity Focused Ultrasound (HIFU) is an incisionless treatment for patients with essential tremor (ET) and tremor-dominant Parkinson's disease (PD) that has not been effectively managed with medications. It uses beams of focused ultrasound delivered in a magnetic resonance imaging (MRI) machine to precisely treat areas deep in the brain that are causing tremor.

2. Is this procedure FDA approved?

The FDA approved it for treating ET in 2016 and for treating an ET patient's second side in 2022. It was approved for treating tremor-dominant PD in 2018, and for PD-associated rigidity/dyskinesia in 2021, and for second side treatment in 2025.

3. Where is this procedure done at Henry Ford Health?

The procedure is performed at a specially equipped MRI suite at Henry Ford Hospital in Detroit.

4. Who performs the procedure?

Specially trained neurosurgeons from Henry Ford perform the procedure, assisted by support staff including nurses and others who care for a variety of movement disorder patients, including those with PD and ET.

5. Are there age limits regarding who can receive the treatment?

The procedure is FDA approved for patients age 22 and older, based on the clinical study that was performed and its criteria.

6. What type of tremor is this effective in treating?

The treatment is FDA approved to treat tremor of the hands and may also treat head and voice tremor.

7. If I have tremor in both hands, will I need two separate treatments to address the tremor on each side?

The treatment is FDA approved for staged unilateral treatment - treating one side at a time with at least 9 months between treatments for eligible patients and without significant clinical events from the first treatment.

8. Can the treatment affect other parts of my 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 permanent change to the tissue/brain that results in tremor improvement.



Requesting a consult

1. How can find out if I am a candidate for HIFU?

To be considered for HIFU, you need to have a diagnosis of ET , or tremor-dominant PD from your primary care physician or a neurologist. Other criteria are described below and should be discussed with your physician.

2. Do I have to have tried medications first to treat my tremor?

To be a candidate for HIFU, you must have a confirmed diagnosis of ET or tremor-dominant PD that does not respond to or are ineligible for at least two standards of care. Please discuss with your physician.

**For questions or more information, please contact
Julie Loomis, R.N., Nurse Navigator, at 313.916.2241**

**To learn more about HIFU treatment
<http://www.henryford.com/HIFUfortremor>**



About insurance coverage

1. Does insurance cover HIFU treatment?

Once you are scheduled for a HIFU procedure, Henry Ford Health will get authorization from your insurance company. It may be helpful to talk to your insurance provider about what you would be financially responsible to pay. The CPT code for the procedure is 61715.

2. Does Medicare cover HIFU treatment for tremor?

As of 2020, HIFU treatment for patients whose tremor medications are ineffective or give them undesirable side effects is a Medicare covered benefit in all 50 states.

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

HIFU treatment for ET and tremor-dominant PD is covered under Medicare Part B.

4. Do private health insurance plans cover the treatment?

Aetna and many Blue Cross/Blue Shield Association plans cover HIFU treatment for medication-refractory ET and tremor-dominant PD. For specific information, contact your health plan's Member Services department

5. 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. You can get more specific information by contacting our nurse navigator.

Before the treatment

1. Do I need to get any imaging scans done before the treatment?

Yes, you will need to get specialized CT and MRI scans of your brain for treatment planning.

2. Why do I need a CT scan?

Everyone's skull is different, and a CT scan is done to measure what is known as skull density ratio to determine if you are a candidate for the procedure. Certain skull shapes and thickness may make it impossible for ultrasound waves to reach the temperature at the target required for treatment.

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

In general, a patient will meet with the neurosurgeon at least twice. 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. Following your procedure and discharge from the hospital, the physician will follow up to see how you are doing through a phone call or virtual visit. The treating team will also discuss any additional follow up visits needed as well as information that will be relayed back to your referring physician.

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

This is necessary for two reasons. First, ultrasound waves do not travel well through hair. 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. Secondly, 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. How will I be prepared for the treatment?

In the pre-op area, the patient will have a frame placed on their head. This is used for guidance of the ultrasound beams. Once inside the specially equipped MRI suite where the procedure is performed, a dome or helmet-like device that is filled with cold water is placed over the top of the head and attached to the frame. This is the mechanism that the ultrasound will be conducted through for the treatment.

2. Will my entire body go inside the MRI machine?

No, only the top half of your body, from about mid-torso up, will go inside the MRI scanner.

3. Will I be in the MRI 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 various tasks such as drawing a spiral or writing your name.

4. Will I be awake for the procedure?

Yes your feedback during the treatment is necessary as you will be asked to do simple motor tasks, like writing your name or 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 does the procedure take?

Treatment time is, on average, 2.5 hours. It is generally performed on an outpatient basis, so most patients go home the same day.

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.

2. What do I need to do once I am home?

The treatment team will provide you with instructions related to your post-treatment recovery.

3. How long after the first side treatment do I need to wait before getting the second side treated?

If your first treatment was at least 9 months ago, you may be eligible to have the second side treated. Conditions that may affect the ability to have treatment for the second side include: clinically significant dysphagia (difficult swallowing), abnormal speech function, or gait abnormalities that are moderate to severe, following the first side procedure.

4. 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 treatment, or that the tremor may not improve at all. It's important to note that the procedure can be repeated, as long as there are 9 months in between the time of the previous treatment. 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.

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¹ Pre-Market Approval (PMA) [P150038](#)

After the treatment (continued)

5. Are there any possible side effects to HIFU treatment?*

You should have a detailed conversation with your physician regarding complications that you may experience. Clinical studies have shown that the most common side effects experienced after treatment of the first side included:

- Headache/head pain (51% of subjects)
- Numbness/tingling (33% of subjects)
- Imbalance/gait disturbance (26% of subjects)

Most of these side effects were classified as mild or moderate, and 48% of the effects resolved on their own within 30 days.

Complications that persisted at 3 years were all mild or moderate and included:

- Numbness/tingling (9%)
- Imbalance (4%)
- Unsteadiness (4%)
- Gait disturbance (2%)
- Musculoskeletal weakness (2%)

6. Are there any side effects associated with treatment of the second side?*

The safety profile of the second side treatment is similar to the safety profile of the treatment of the first side.

The most common adverse events experienced during and after treatment of the second side were:

- Numbness/tingling (31%)
- Slurred speech (29%)
- Lack of coordination (24%)
- Imbalance (10%)
- Unsteadiness (10%)
- Walking difficulties (10%)
- Difficulty swallowing (10%)
- Fatigue (4%)

Additional infrequent events include dizziness, taste disturbance, slurred speech, fatigue and vomiting. For additional safety information, please refer to Pre-Market Approval (PMA) P150038-S022

Please visit our site for more details www.henryford.com/HIFUfortremor