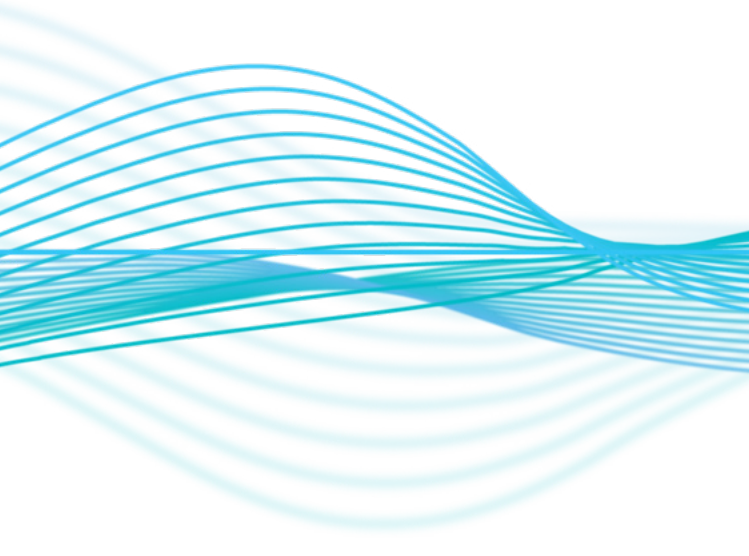


INSIGHTEC

INCISIONLESS
TREATMENT FOR
PARKINSON'S
**TO GET YOU
BACK TO LIFE.**



INVISIBLE THERAPY. VISIBLE RESULTS.

What is Parkinson's Disease?

Parkinson's disease (PD) is a progressive neurological disorder that primarily affects movement. It occurs when nerve cells in the brain that produce dopamine, a chemical crucial for movement control, begin to degenerate.



**1 million
Americans**

**are affected by PD, and
millions more worldwide.¹**

Symptoms²

The main symptoms of Parkinson's disease include tremor (shaking), slowness of movement (bradykinesia), muscle stiffness (rigidity), and impaired balance or posture, which can lead to falls. These are the primary motor symptoms, but Parkinson's also includes non-motor symptoms like sleep disturbances, mood changes, and cognitive difficulties.

MR-guided focused ultrasound may help with some of the motor symptoms of Parkinson's.

1. Dorsey ER, Sherer T, Okun MS, Bloem BR. The Emerging Evidence of the Parkinson Pandemic. *J Parkinsons Dis.* 2018;8(s1):S3-S8.
2. Kouli A, Torsney KM, Kuan WL. Parkinson's Disease: Etiology, Neuropathology, and Pathogenesis. In: Stoker TB, Greenland JC, editors. *Parkinson's Disease: Pathogenesis and Clinical Aspects* [Internet]. Brisbane (AU): Codon Publications; 2018 Dec 21. Chapter 1

Invisible Therapy. Visible Results.³



Improvement in motor symptoms and motor complications

Focused ultrasound treatment results in clinically meaningful improvement in motor symptoms and motor complications. Results are sustained at 12 months. The treatment is approved for bilateral use, with a minimum of six months between the first and second procedures.



Incisionless

Focused ultrasound 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 most patients resume normal activities soon after treatment.



Safe and Effective

FDA-approved treatment with favorable safety profile.

What is focused ultrasound?

Focused ultrasound is an incisionless staged, bilateral treatment for patients with advanced, medication-refractory idiopathic Parkinson's disease. It uses sound waves guided by MRI to treat deep in the brain with no incisions or permanent implants.

With pinpoint accuracy, focused ultrasound works a bit like using a magnifying glass to focus sunlight on one small spot. Instead of light, it uses sound waves that are carefully aimed to treat a very specific area inside the brain without affecting the surrounding tissue. Focused sound energy generates heat, resulting in a small ablation that disrupts the electrical activity contributing to abnormal movements in Parkinson's disease.

During focused ultrasound treatment, the MRI provides a detailed view of the brain, which the care team uses to plan, guide, and precisely target the treatment area.

The MRI also allows for real-time temperature mapping, which the physician uses to monitor and control treatment.







“

**From the minute
I walked in the door,
the lady behind
the counter said
to me, your life is
about to change.**

And she was so right.

Marie Baker, focused ultrasound patient

Patient testimonials may not be representative
of all treatment outcomes.

Why consider focused ultrasound?

It is important to consult with the patient's physician or a focused ultrasound treatment center to determine if focused ultrasound treatment is right for them.

As part of the evaluation process, the severity of the patients Parkinson's symptoms and their overall health will be evaluated.

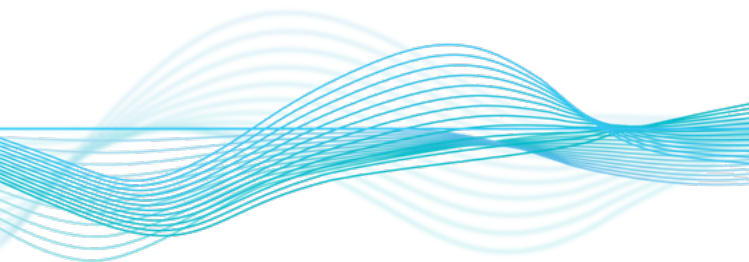
Patients will need to undergo a CT scan in order to determine if they are candidates for focused ultrasound treatment.

If patients have metallic implants such as pacemakers, neuro-stimulators, spine or bone fixation devices, total joints, metal clips, screws, etc. they will need to consult with a physician to determine if focused ultrasound is an option for them. Any metallic implants must be MR-conditional to prevent injury from the MRI's strong magnetic field.

Also, if the patient is not generally healthy enough to withstand the treatment and lie still in the same position for on average 2.5 hours, they may not be a good candidate for this treatment. There are additional limitations and a physician will do an assessment to verify if the patient is a candidate for the treatment.

For safety information, please visit:

<https://insightec.com/safety-information>





What happens before, during, and after the treatment?

Preparation

Focused ultrasound treatment requires a cleanly shaven head, to ensure efficient transmission of sound waves. A local numbing medication will be applied and a frame will be secured to the patient's head so that their head does not move during treatment.

The patient's heart rate, blood pressure, and blood oxygen levels will be monitored throughout the treatment. They will be awake, communicating with the treatment team throughout the treatment. They may be given additional medication to keep them comfortable.

Cool water will circulate in the helmet around the top of the patient's head, and they will be given a blanket if they are cold. The patient will also be given a "stop" button to indicate to the physician that they want to stop or pause the treatment for any reason.

Planning

A series of MRI images will be taken for planning the treatment according to the patient's specific anatomy. The treating physician will first apply light doses of ultrasound energy. This helps to identify the precise spot in the brain for treatment by assessing temporary improvement and any potential side effects.

Between some applications of energy, called a sonication, the patient's physician may evaluate improvements of their symptoms. Tasks may include testing their strength, muscle tone, and vision.

Treatment

The treating physician will then gradually increase the energy to create a small ablation, usually resulting in a therapeutic effect. Although individual results may vary, the patient may notice immediate improvement during the treatment itself. The treatment lasts on average 2.5 hours.

After Treatment

After treatment, the frame will be removed, and the patient will go to the recovery room. The physician will let the patient know when they can go home and when they may need to return for a follow-up visit. Most patients return to normal activities within a few days. The treatment team will provide the patient with instructions related to the patient's post-treatment recovery.

What results can I expect?

In a clinical trial sponsored by Insightec, patients with Parkinson's disease experienced meaningful improvements after staged, bilateral* focused ultrasound treatment:

68% Average improvement in medication-related motor fluctuations and complications such as involuntary movements (dyskinesia).

32% Average improvement in motor symptoms.

These benefits were observed one month after treatment, and they lasted for at least 12 months¹.

*Second side treatments are staged at least 6 months after successful first treatment.

“

That peace I felt was unbelievable.

Marie Baker, focused ultrasound patient

Patient testimonials may not be representative of all treatment outcomes.

Safety Information

From the Insightec Sponsored Study

The Insightec-sponsored study included 54 patients treated at 9 centers. The majority (74%) of the participants (40) went on to receive staged, bilateral treatments. Second-side treatments were staged at least 6 months from the first side. The majority of adverse events were not clinically significant. The most common adverse events were hypertension, imbalance, and falling.

For unilateral procedures the majority of adverse events resolved in 12 months.

Bilateral adverse events—70% were mild (30), 28% moderate (12), and 2% severe (1). At the 12-month mark, 40% of these events had resolved, while 60% remained ongoing, including 10 of the 12 moderate events and the single severe case of anarthria.

No life-threatening events related to device or procedure occurred.

Additional safety considerations

Overall, MR-guided focused ultrasound has a favorable safety profile in treating Parkinson's disease. The majority of side effects were not clinically significant and resolved in 3 months or less. The patient should have a detailed conversation with their physician regarding the risks and benefits of treatment options. If the patient experiences significant difficulties in swallowing food or liquids, abnormal speech function, or an unusual walking pattern that are moderate to severe after having one side of their brain treated with focused ultrasound, they will not be a good candidate for the procedure on the other side of their brain.

If the patient experiences a blood clot after the procedure that is not treated quickly, they may have long-term related complications.

You should have a detailed conversation with your physician regarding the risks and benefits prior to treatment.

For full safety information please visit website. All data and claims are based on an Insightec sponsored clinical study.

For complete safety and indication information, please refer to PMA150038/S037.



INSIGHTEC

INSIGHTEC Ltd. © 2025. All rights reserved.

PUB41012186 | US only Rev 1.0

Device name: Exablate Neuro

Visit our website for more information about focused ultrasound treatment for Parkinson's Disease:

www.insightec.com/parkinsons-disease/