

RISKS

Infrequent complications that have been reported following the Neuravive treatment are described below.

SHORT TERM RISKS: DAY OF TREATMENT UP TO 3-MONTHS POST-TREATMENT

The most common potential risks associated with the Exablate Neuro device and thalamotomy procedure are transient numbness and tingling. These sensations are typically mild to moderate in intensity and can last as briefly as the length of the sonication or up to several days. Headaches or head pain and nausea/vomiting may occur during sonication.

Imbalance, unsteadiness, and bruising in the area of the IV catheter are also potential risks, but usually end within a week after treatment.

LONG TERM RISKS: LONGER THAN 3-MONTHS POST-TREATMENT

Overall, Exablate MRgFUS has a very favorable safety profile in treating Tremor-Dominant Parkinson's Disease. Infrequent complications that have been reported following Exablate treatment include long-term numbness and tingling. If you experience a blood clot or deep vein thrombosis after the procedure that is not treated urgently, you may experience long term complications, including muscle, heart, brain or lung damage.

Neuravive

www.parkinsons-tremor.com

INSIGHTEC Ltd. © 2020.
All rights reserved.
PUB41003653-NA Rev. 2
Device name: Exablate Neuro

INSIGHTEC®



Neuravive

FOCUSED
ULTRASOUND
FOR TREMOR-
DOMINANT
PARKINSON'S
DISEASE

ABOUT PARKINSON'S DISEASE

Parkinson's disease is a chronic, degenerative disorder which results from the malfunction and/or loss of brain cells responsible for movement and coordination. Key symptoms include tremor, rigidity, slow movement (bradykinesia) and postural instability.

Nearly one million people will be living with Parkinson's disease (PD) in the U.S. by 2020.¹ In an estimated 26% of PD patients, the primary symptom is tremor.² These patients initially have tremor and as the disease progresses, they may experience onset of other symptoms like bradykinesia and rigidity. But, tremor remains the symptom with the most severe impact on their daily activities.

FOCUSED ULTRASOUND TREATMENT

The Neurovive focused ultrasound treatment may be an option for patients with medication-refractory tremor-dominant PD. Using advanced technology from INSIGHTEC, neurosurgeons are able to treat deep in the brain with no surgical incisions. Sound waves pass safely through a patient's skull to heat and precisely ablate (destroy) the target cells in the thalamus, thereby providing a therapeutic effect.

During the procedure, a patient lies in an MRI scanner with his/her head in the focused ultrasound helmet. Low energy is first applied allowing the patient to provide feedback of tremor improvement as well as any potential side effects. This feedback allows the treating neurosurgeon to adjust the treatment before high energy is applied to make a final ablation. Many patients show immediate improvement in their tremor. The treatment is continuously guided and monitored using MR imaging.

Focused ultrasound procedures are usually performed on an outpatient basis. Patients must be at least 30 years of age.

CLINICAL EVIDENCE

A randomized, double-blinded study² was done to assess the safety and efficacy of focused

ultrasound for patients with disabling tremor-dominant PD.

The study resulted in significant improvement in tremor that was maintained through a 12-month follow up. The trend in improvement for the focused ultrasound group was also shown in functional outcome and quality of life measures. Overall, this study showed a very favorable safety profile with 95% of adverse events reported as mild or moderate and a majority transient. The most common treatment-related complications included numbness/tingling (7%), Imbalance (4%), gait disturbance (2%) and unsteady (1%). There were two serious adverse events (hemiparesis - weakness on one side of the body) reported, one which resolved within one month.

¹ <https://www.parkinson.org/Understanding-Parkinsons/Statistics>

² Pre-Market Approval (PMA) P150038

BENEFITS

- Incisionless Treatment - No implanted hardware
- Immediate results in a single treatment³
- Minimal Hospitalization³
- CE Marked³ - safe and effective with minimal side effects.

