



## **Deep TMS Information:**

### **About Brainsway Deep TMS Treatment:**

- Deep TMS stands for “Deep Transcranial Magnetic Stimulation.” Brainsway Deep TMS is a non-invasive medical procedure. A treatment session is conducted using a device called the Brainsway Deep TMS System, which delivers pulsed magnetic fields similar in type and strength as those used in magnetic resonance imaging (MRI) machines.
- The magnetic fields created by Deep TMS allow for the targeting and stimulation of the neurons contained in the pre-frontal cortex of the brain.
- Deep TMS is non-invasive, which means that no surgery or incisions into the body are needed. Deep TMS does not require the use of pharmaceutical products; therefore, patients may be able to avoid many of the physical and biological side effects often associated with drug consumption. Deep TMS does not use any anesthesia.
- The FDA cleared the Brainsway Deep TMS treatment in 2013 for patients suffering from Major Depressive Disorder. The FDA clearance was obtained following Brainsway’s completion of a multicenter study in the US and abroad which was conducted to investigate the safety and effectiveness of Deep TMS.
- See patient manual for certain adverse events associated with Deep TMS.

### **The Treatment Process:**

- The first session will consist of mapping or searching for the motor threshold by giving brief magnetic pulses to the left side of the brain. All magnetic pulses are generated from the Brainsway helmet which is worn for both the mapping session and subsequent treatments. The initial mapping session will stimulate the motor strip on the left side of the brain resulting in twitching in the right hand. The motor threshold will determine the proper dosing and location for the Deep TMS treatments. Your doctor may determine other motor threshold reassessments are necessary for providing the optimum dose for treatment.
- During mapping and subsequent treatment sessions, a clicking sound will be heard and a tapping sensation may be felt on the scalp. The treatment sessions will consist of a series of pulses that last about two seconds with a rest period of 20 seconds. Each treatment session lasts approximately 20 minutes. Patients will receive treatments five days a week with approximately 20-30 initial treatments in total and likely some taper or maintenance schedule.

### **Benefits:**

- Partial response or full remission of major depressive symptoms.
- Non-systemic, localized treatment.
- No anesthesia is used.

- Provides an alternative to medication.
- Safest treatment for major depression.
- Non-addictive treatment for major depression.
- Response time is similar to medications.
- No memory loss is associated with Deep TMS treatments.
- No long-term side-effects are associated with Deep TMS treatments.

### **Contraindications:**

- Deep TMS cannot be used in patients who have ferromagnetic metal implants in the head except for standard amalgam dental fillings. Examples of restricted metal substances include: bullet fragments, stents, aneurism clips/coils, implanted stimulators, brain monitoring electrodes, ear/eye ferromagnetic implants, metal ink in facial/head tattoos and permanent makeup. The patient understands that failure to follow this restriction could result in serious injury or death.
- The patient understands that Deep TMS should be used with caution in the case of implanted electronic devices such as: pacemakers, implantable cardioverter defibrillators, or wearable cardioverter defibrillators.

### **Risks:**

- Seizure: There was one case of a seizure reported in Brainsway's FDA clinical study due to high alcohol consumption the night before. There were three other cases (all on high dose antidepressants) reported in other studies out of 50,000 treatment sessions. None of these cases suffered any lingering effects from the seizures. Risk factors for increasing the likelihood of seizures include: history of stroke, head injury, change in medication, change in electrolyte balance, high intracranial pressure, severe headaches, certain drugs that lower seizure threshold, or the presence of other neurologic disease.
- Headaches: May occur as a result of Deep TMS treatments but may decline as treatments continue.
- Hearing loss: The Brainsway Deep TMS system emits a loud clicking sound. It is recommended that patients wear supplied earplugs.
- The depression may worsen before improving. Suicidal thoughts may occur.
- Deep TMS treatments may not provide the desired benefits or be delayed in their response time. Some patients may not see benefits until three to four weeks into treatments or not at all. Some patients may feel worse with treatments. Close communication with your doctor will be critical during the course of Deep TMS treatments.
- Other side effects include: Jaw, facial, and scalp pain, muscle twitching, back pain, anxiety, and insomnia.

### **Alternative Treatment Options to Deep TMS:**

- Psychotherapy or counseling
- Medication
- Electro-Convulsive Therapy (ECT)