

Patient Consent for a Medical Procedure

dTMS Treatment

Name of Attending Physician: _____

Name of Patient: _____

My doctor has recommended that I receive treatment with Brainsway Deep TMS. The nature of this treatment, including the benefits and risks that I may experience, has been fully described to me and I give my consent to be treated with Brainsway Deep TMS.

I will receive Deep TMS therapy to treat my psychiatric condition. I understand that there may be other alternative treatments for my condition. Information regarding Deep TMS is also described in the “Patient Manual” provided by my doctor, which I have had an opportunity to review.

My doctor has explained the following information to me:

I. About Brainsway Deep TMS Technology

- 1) 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 Brainsway’s unique, patented technology allow for the targeting and stimulation of the neurons contained in the pre-frontal cortex region of the brain.
- 2) Brainsway 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 also avoids the need for anesthesia, thereby eliminating certain side effects associated with Electro-Convulsive Therapy (ECT). Nevertheless Brainsway Deep TMS treatment is associated with certain adverse events that are detailed in the Patient Manual.

- 3) The FDA cleared the Brainsway Deep TMS treatment for patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode. 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 efficacy of the Deep TMS treatment.

II. The Treatment Process

- 1) During a treatment session, I will be comfortably seated on a chair, and a cushioned helmet will be gently placed over my head. The helmet generates brief magnetic fields, similar to those used in magnetic resonance imaging (MRI) systems. These magnetic fields briefly stimulate a targeted brain area and improve depressive symptoms.
- 2) During the course of the treatment, I will hear a clicking sound and feel a tapping sensation on my scalp. The operator will ask me to use standard earplugs during the treatment. The operator will then adjust the Brainsway Deep TMS system so that the device will give just enough energy to send electromagnetic pulses into the brain so that my right hand twitches. The amount of energy required to make my hand twitch is called the "motor threshold." Everyone has a different motor threshold and the treatments are given at an energy level that is just above my individual motor threshold. This threshold could fluctuate depending on a variety of factors. My doctor will determine how often my motor threshold will be re-evaluated.
- 3) Once motor threshold is determined, the helmet will be moved, and I will receive the treatment as a series of "pulses" that last about 2 seconds, with a "rest" period of about 20 seconds between each series. This treatment does not involve any anesthesia or sedation and I will remain awake and alert during the entire course of the treatment.
- 4) I will likely receive these treatments daily for four weeks, and sometimes it involves additional treatments once every 2 weeks for a 12-week period. My treatment will be closely medically supervised.
- 5) I understand that most patients who benefit from Brainsway Deep TMS experience results by the third or fourth week of treatment. Some patients may experience results in less time while others may take longer. My doctor has informed me about any applicable fees and/or insurance coverage involved in receiving Brainsway Deep TMS treatment.

- 6) I understand that information obtained within the context of treatment is confidential and can ordinarily be released only with my written permission. I further understand that there are some special circumstances that can limit confidentiality including: a) a statement of harm to others or myself and/or b) issuance of a subpoena from a court of law. I further understand that it is foreseeable although not likely that Brainsway might in the future request certain basic patient information from my doctor, and that any such requests will, to the extent possible, take into consideration my rights with respect to confidentiality.

III. Safety & Risk Information

- 1) The safety of the Brainsway Deep TMS System was demonstrated in a clinical study involving 233 patients with moderate to severe Major Depressive Disorder. However, like other medical procedures and forms of treatment, Brainsway Deep TMS involves some risks and adverse events.
- 2) Seizures (sometimes called convulsions or fits) have been reported with the use of TMS devices. There was one case of seizure reported in Brainsway's FDA clinical study due to high alcohol consumption the night before, and three other cases of seizure were reported in other studies (out of approximately 50,000 treatments sessions) in cases of subjects who were on high doses of antidepressants. None of the subjects who have experienced seizure during the Deep TMS treatment have suffered lasting physical sequel. I understand that I must discuss with my doctor if I have consumed or intend to consume alcohol/drugs prior to treatment. I understand that I must discuss with my doctor if I have a history or family history of seizure/epilepsy or potential alteration in seizure threshold. This includes stroke, head/brain injury, change in medication, change in electrolyte balance, high intracranial pressure, severe headaches or presence of other neurologic disease that may be associated with an altered seizure threshold, or concurrent medication or other drugs that are known to lower the seizure threshold, secondary conditions that may significantly alter electrolyte balance or lower seizure threshold, or where a quantifiable motor threshold cannot be accurately determined.
- 3) Headaches were reported in 47% of the subjects participating in the clinical study. However, 36% of patients who had received a placebo treatment instead of Deep TMS also reported headaches, indicating that the headaches reported by Deep TMS patients were not necessarily caused by the Deep TMS treatment. Headaches usually get better or go away completely with successive treatments. Additionally, headaches may be relieved by over-the-counter medicine such as acetaminophen or Ibuprofen. I understand that I should inform my doctor if this occurs.

- 4) Application site pain and discomfort was reported in 25% and 20%, respectively, of those participating of the subjects participating in the clinical study. I understand that I should inform the treatment administrator if I feel pain or discomfort during the treatment. The Deep TMS helmet may be slightly adjusted on the head to relieve the pain or discomfort. Pain and discomfort associated with treatment usually gets better or goes away altogether with successive treatments.
- 5) Other side effects, which may occur, include pain in jaw, muscle twitching, back pain, anxiety and insomnia. I understand that I should inform my doctor if I experience any of these adverse events.
- 6) If I am currently on antidepressant medications, my doctor may taper down my dosage prior to and during the course of Deep TMS treatment. Because Brainsway Deep TMS may take a few weeks before symptom improvement occurs, in the meantime my depression may worsen and increased mood instability and thoughts of suicide could occur. I understand that if I experience these symptoms, my doctor should be notified immediately.
- 7) I understand that patients with metal implants and other metal substances in or around their heads, except for standard amalgam dental fillings, should not use Deep TMS. 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. I understand that failure to follow this restriction could result in serious injury or death.
- 8) I understand that Deep TMS should be used with caution and only upon close consultation with a doctor by patients who have implanted electronic devices (such as pacemakers, implantable cardioverter defibrillators [ICDs] or wearable cardioverter defibrillators [WCDs]) in their body. I understand that failure to follow this restriction could result in serious injury or death.
- 9) During treatment with the Brainsway Deep TMS System a loud clicking sound is emitted. Therefore, patients must use earplugs with a rating of at least 30 dB of noise reduction. There have been no reports of hearing loss with the Deep TMS Treatment in the clinical study when earplugs were used.
- 10) There were no deaths in patients who took part in the clinical trial for Brainsway Deep TMS, systematic side effects such as weight gain, dry mouth and sexual problems were not observed, and no changes to memory function were shown.

IV. Alternate Treatment Options

- 1) While my doctor has recommended Brainsway Deep TMS for me, I understand that a variety of other treatment options for depression exist which may be suitable for me. Which treatment option is right for me depends on a variety of factors including but not limited to previous experience, severity of my disorder, potential side effects and other factors and risks. Other treatment options might include: Psychotherapy Medication Electro-Convulsive Therapy (ECT) Surface/Ordinary Transcranial Magnetic Stimulation (TMS).

- 2) I understand that Brainsway Deep TMS is not effective for all patients with depression. I will report any signs or symptoms of worsening depression immediately to my doctor. I understand that it is advisable to have a family member or caregiver monitor any symptoms and to assist in spotting any signs of worsening depression.

Additional Information:

PATIENT VERIFICATION:

I have read the information contained in this Medical Procedure Consent Form about Brainsway Deep TMS treatment, the process involved in the treatment and its potential risks. I understand there are other treatment options for my depression available to me and this has also been discussed with me. I have discussed it with my doctor who has answered all of my questions. I understand that I should feel free to ask questions about Deep TMS at any time before during or after the course of treatment and that I may discontinue treatment at any time. I give permission to the above named doctor and his or her staff to administer this treatment to me. I have been given a copy of this consent form to keep.

Consent signed on _____, 20__ at _____ AM/PM

Signature of Patient/or Guardian

Printed Name

Signature of Witness

Printed Name