Northeast TMS
16 Fifth St
Dover NH 03820
603-617-4799

Consent Form for Treatment with the Deep TMS System On and Off-Label Consent

This is the patient consent form for Deep Transcranial Magnetic Stimulation (dTMS) Therapy. This consent form outlines the treatment that your doctor has prescribed for you, the risks, potential benefits, and any alternative treatments if you decide not to be treated with dTMS.

What is dTMS?
Deep Transcranial Magnetic Stimulation (dTMS) is a noninvasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative to the brains' neuronal pathways, the neurons in the relevant brain structure are activated.

Is it approved?
The Brainsway Deep TMS System is cleared by the Food and Drug Administration (FDA) for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder.

How does it work?
dTMS will be administered by a trained Technician. During a dTMS treatment session, the technician will place the magnetic coil cover over your head. To calibrate the intensity of dTMS you need, we will stimulate the region of your brain that makes the thumb move. You will hear a click and sound and feel a tapping sensation on your scalp. The device will be adjusted to give just enough energy to send electromagnetic pulses into the brain so that your thumb twitches. The intensity of stimulation that barely produces a movement is called the motor threshold (MT). Once your MT is determined, the magnetic coil will be moved to the location of the brain that scientists think may be responsible for causing depression. The stimulation will be set to 120% of your MT. How often your MT will be re-evaluated will be determined by your doctor.

The treatment session is delivered as a series of pulses that last 2 seconds, with a rest period of 20 seconds between each pulse sequence for a total of 1,980 pulses. Treatment is targeted to the region of your brain called the dorsolateral prefrontal cortex (DLPFC). Each treatment session lasts approximately 20 minutes.

This treatment does not involve any anesthesia or sedation and you will remain awake and alert during the treatment. You may be evaluated by a healthcare provider during this treatment course.

Is the treatment effective?
The effectiveness of the Brainsway Deep TMS System has only been tested in patients receiving 5 daily sessions over a four-week course, and optional maintenance treatments with bi-weekly sessions for an additional 12 weeks, with the stimulation parameters outlined above. Any change in this treatment course, intensity, or location has not been tested, and efficacy results are not

available.

Brainsway Deep TMS System is not effective for all patients with depression. Any signs or symptoms of worsening depression or signs of suicidality should be reported immediately to your doctor. You may want to ask a family member or caregiver to monitor your symptoms to help you spot any signs of worsening depression.

Are there any risks?
The most common adverse events reported are application site pain or discomfort and headache. If you experience these, we may be able to modify the location or intensity of the treatment, or you can use over-the-counter analgesics for relief.
Brainsway Deep TMS System is contraindicated for use in patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or are non-removable. Failure to follow this restriction could result in serious injury or death. An object that may have this kind of metal includes, but is not necessarily limited to:

Aneurysm clips or stents
Implanted electrodes/stimulators
Ferromagnetic implants in ears or eyes
Cochlear implants

Brainsway Deep TMS System should be used with caution in patients who have pacemakers or implantable cardioverter defibrillators.

If you have a removable device or object that may be affected by the magnetic field, the device should be removed from the patient area before treatment to prevent possible injury to the wearer or damage to the device. Examples include wearable monitors, bone growth stimulators, earrings, hearing aids, eyeglasses, jewelry, hair barrettes, cell phones, MP3 players, etc.
One seizure has been reported with the use of the dTMS device in the clinical study leading to Food and Drug Administration (FDA) approval. The seizure was reported in a patient who drank a significant amount of alcohol the day before treatment. Therefore, we advise that you refrain from alcohol consumption during the course of the treatment. Some patients may be at potential increased risk of seizure, including those with a history or family history of seizure or epilepsy, a history of stroke, head injury or trauma, presence of other neurological disease (CVA, cerebral aneurysm, dementia, increased ICP, or movement disorder), concurrent use of tricyclic antidepressants, neuroleptic medications, or other drugs known to lower the seizure threshold.

Long term effects of exposure to magnetic fields are not known. Due to the loud sound, earplugs or similar hearing protection devices with a rating of 30dB or higher of noise reduction must be used during treatment. Your hearing will be assessed before we begin treatments, and again once they are completed. Your insurance may be charged for this. Brainsway Deep TMS System has not been studied in patients who have had no prior antidepressant medication.

I understand that my treatment may be considered off-label for the following reasons:
(please initial where applicable):

_____ More or less than 5 treatments per week for 4 weeks
_____ More or less than 1,980 pulses per treatment session
_____ dTMS prescribed for a diagnosis other than Major Depressive Disorder
_____ Insufficient antidepressant medication trial
_____ I am younger than 22 years old
_____ I am older than 70 years old

I have read the information contained in this Consent Form about Brainsway Deep TMS System and its potential risks and possible benefits. I understand that my course of dTMS treatment may be considered off-label for the reasons stated above. I have discussed this treatment with Drs. Schmidt or Naimark and/or their designee, and all of my questions have been answered.

I understand that there are other treatment options that are considered safe and efficacious (medications, therapy, ECT, etc.). I further understand that no guarantee of any results has been made. I understand that if during the course of treatment, in the best judgment of the neuromodulation or medical staff, I require emergency treatment, I authorize and request that the said treatment be performed.

I understand that I can change my mind any time, and choose a different option. I voluntarily choose to receive dTMS Therapy with the Brainsway Deep TMS System and authorize Northeast TMS, Dr. Schmidt, Dr. Naimark, and his staff to administer dTMS treatments to me.

_____
PRINTED NAME OF PATIENT

_____ _____
PATIENT SIGNATURE DATE

_____ _____
Dr. Schmidt or Dr. Naimark, M.D. DATE

_____ _____
GUARDIAN OR PARENT (if applicable) DATE

_____ _____
DESIGNEE (if applicable) DATE