TAMPA NEUROPSYCHIATRY

CONSENT FORM

This is a patient consent for a medical procedure called Transcranial Magnetic Stimulation (TMS), and/or Theta Burst Stimulation (TBS). This consent form outlines the treatment your doctor has prescribed, potential benefits associated with the treatment, any risks associated with the treatment and any alternative treatments that are available to you should you decide not to be treated with TMS or TBS.

The information contained in this consent form is also provided in the MagVenture patient manual, available at www.magventuretms.com. Please read the manual online and refer any questions you may have regarding TMS Therapy back to your doctor.

WHAT IS TRANSCRANIAL MAGNETIC STIMULATION (TMS)

Transcranial Magnetic Stimulation or TMS is a medical procedure. A TMS treatment session is conducted using a device called the MagVenture TMS Therapy System, which provides electrical energy to a "treatment coil" or magnet that delivers pulsed magnetic fields. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines 1.5 tesla, but the energy is much more focused in TMS to allow for the stimulation of neurons 2 cm deep into the brain.

APPROVED FOR

MagVenture TMS Therapy received FDA-cleared in 2008 for treatment resistant depression found in patients whose symptoms are non-responsive to antidepressant medications. It was also FDA-cleared for thre treatment of Obsessive Compulsive Disorder in 2020. It is also reported to be a safe and effective treatment for patients with some pain syndromes, anxiety, bipolar disorders, ADHD, TBI, post-stroke complications, autism, brain enhancement, etc. For those conditions, the treatment is considered ‘off-label,’ meaning not FDA-cleared.

MagVenture TMS Therapy has been shown to effectively relieve depression symptoms in adult patients who have historically not had relief from antidepressant medications.

PROCEDURE

During a TMS treatment session, the doctor, or a member of their certified staff, will place the magnetic coil gently against the scalp, focusing on the left front region of the head, or other relevant regions of the brain. The magnetic fields produced by the magnetic coil are concentrated on a region of the brain that scientists have found to be responsible for causing or adding to the severity of the illness, ie. the prefrontal cortex.

Prior to initial treatment, the doctor or a member of his staff, will position the patient's head in the head support system to obtain a snapshot or map of the patient's brain. During the mapping procedure, measurements are drawn out onto the cranial cap that will be worn throughout each of the patient's treatments. These measurements are tailored to each individual patient and are used as a guideline to locate specific treatment areas. The magnetic coil will then be placed onto the left side of the head, on an area known as the "motor strip". As the treatment location and power level are calibrated, the patient will hear clicking sounds accompanied by a tapping sensation on the scalp. The technician then adjusts the MagVenture TMS Therapy system so that the device will provide just enough energy to send electromagnetic pulses into the patient's brain, causing the right-hand to twitch. The amount of energy required to initiate the hand twitch is called the "motor threshold" (MT). Every individual has a different MT, so treatments are specifically calibrated at an appropriate energy level that is just above or below a patient's individual MT. As treatment progresses, the doctor will determine how often a MT will be re-evaluated.

The following visit will be the first day of TMS treatment. While wearing the previously mapped cranial cap, the patient's measurements will be taken to ensure proper location of the cap, and the magnetic coil will be placed on the head. The treatment consists of a series of 10 Hz "pulses," for a duration of 20 minutes or more. This treatment does not involve anesthesia or sedation, and patients are to remain awake and alert during the treatment. Treatments are scheduled five times a week for a duration of seven weeks, for a total of about 35 treatment days. During the treatment course, the patient will be scheduled for a TMS follow up visit with their Doctor and/or the Nurse Practitioner/Physician Assistant every 2 weeks or so. TMS is designed to provide relief from presenting symptoms.

THETA BURST STIMULATION (TBS)

Theta Burst Stimulation (TBS) is an alternative process recently approved by the FDA, but not yet covered by health insurance. Rather than the 10 Hz pulses used in

traditional TMS treatment, TBS uses a different wavelength of three pulses at 50 Hz, at the rate of 5 Hz for two seconds. The TBS treatment coil is placed on the same location indicated on the patient's cranial cap, and is run from 3 to 12 minutes on the left side of the brain, and/or 39 seconds to 5 minutes on the right side of the brain.

METAL IMPLANTS

The MagVenture TMS system should not be used by anyone who has magnetic-sensitive metal cranial implants, and any magnetic metal within 12 inches of the treatment coil must be removed. Failure to follow this restriction could result in serious injury, or death. Objects that may contain magnetic metals include:

- Neck or brain stents
- Implanted stimulators
- Cardiac pacemakers or implantable cardioverter defibrillator (ICD)
- Cardiac stents
- Electrodes to monitor brain activity
- Metallic implants in the ears or eyes
- Shrapnel or bullet fragments
- Facial tattoos with metallic or magnetic- sensitive ink
- Other metal devices or objects implanted in or near your head

The MagVenture TMS System should be used with caution in those patients who have pacemakers, implantable cardioverter defibrillators (ICDs), or are using wearable cardioverter defibrillators (WCD). Failure to follow these restrictions could result in serious injury or death.

SIDE EFFECTS

The MagVenture TMS System is not effective for all patients. Any signs or symptoms of worsening presenting symptoms should be reported immediately to your doctor.

Patients should ask a family member or caregiver to monitor symptoms to assist with identifying any signs of worsening symptoms. The patient should provide a release of information for any family member they would like to speak on their behalf.

In addition, some patients treated with TMS experience headaches. Any associated discomfort and headaches tend to lessen over time, and headaches can be effectively managed with over-the-counter pain medications.

RISK

As with all antidepressant treatments, there is a small risk for the emergence of mania with TMS therapy. The doctor will monitor the patient throughout treatment for the development of these symptoms. If symptoms should arise, the patient should alert the doctor immediately.

The most serious known risk of TMS is the possibility of causing a seizure. Although there have been a few reports of patients affected by seizures from the use of TMS devices, the risk is extremely low. Patients are responsible for reporting any known history of seizure disorders to their doctor, as it may influence the patient's risk of developing a seizure during a TMS procedure. The TMS team is committed to following all up-to-date safety guidelines for the TMS treatment system, including those designed to minimize the risk of seizures.

PREGNANCY

Effects of exposure to TMS during pregnancy are currently unknown. To mitigate possible risks, women of childbearing capacity may be asked to take a pregnancy test before starting treatment.

HEARING PROTECTION

Because the TMS device can produce a loud click with each pulse, patients may be required to wear earplugs during treatment to minimize the risk of hearing loss.

There have been no reported cases of permanent hearing loss with properly functioning hearing protection. If the patient's earplugs become loose or fall out, the patient should notify treatment staff immediately.

BENEFITS

Results vary with each individual patient. Some patients report experiencing beneficial results from TMS by the fourth week of treatment. Some patients treated with TBS report beneficial results in just two weeks. Some patients may experience beneficial results in less time, while others may take longer.

ALTERNATIVES TO TMS

The patient should understand that there are alternative treatment options for their condition, including medications, psychotherapy, esketamine (spravato), and electroconvulsive therapy (ECT). The doctor has explained all risks and benefits of these other treatment options. The doctor has also explained why TMS has been recommended for the patient's specific case.

CONSENT

I have read (or have had read to me) the information contained in this consent form regarding TMS therapy and its potential risks and benefits for the treatment of my current diagnosis of Major Depressive Disorder (MDD), severe, single/recurrent episode. I acknowledge that Faizi Ahmed, MD has explained the purpose of the procedure, the potential risks and benefits of the procedure, and the alternatives to TMS. All my questions regarding the procedure have been answered to my satisfaction. I understand there are other treatment options for my condition available to me, and I have discussed my options with my doctor.

I therefore permit Faizi Ahmed, MD and his staff to administer this treatment to me.

Patient Name (PRINT): _____ Date: _____

(SIGNATURE): _____ DOB_____

TMS 10 MINUTE/RESCHEDULING/NO CALL NO SHOW POLICY

TAMPA NEUROPSYCHIATRY

TMS appointments are designated a 30 minute window within our daily schedule. Because of our very busy and compact schedule, it is important that our patients arrive on time. Patients who arrive 10 minutes AFTER their appointment time will not be seen. The appointment will be canceled and will resume the next business day. If you are unable to make your appointment time, and would like to reschedule for a different time on the same day; calls must be made at least one day prior to your appointment. Calls made at the time of your appointment to reschedule will not be granted. Appointment will be canceled and resumed the next business day. NO CALL NO SHOWS will result in a $100 fee.

(Please initial) _____ I have read and understand the 10 minute, rescheduling, and no call no show policy.

PRINT NAME: _____
DATE:_____
DOB:_____

SIGNATURE: _____

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