Dr. Sudha Moola
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EXOMIND CONSENT FORM

Patient's name:	Date of birth:
Phone:	Email:
Motor Threshold (%):	Preset:

Preparation for EXOMIND therapy is straightforward and requires no special measures. You may eat, drink, and take your usual medications unless otherwise instructed by your physician. It is recommended that you avoid the consumption of alcohol, tobacco products, caffeinated beverages, or other substances prior to the session. For safety reasons, it is essential to remove all jewelry or metal objects near the treatment area, as the magnetic field may interact with metal. To ensure comfort during the session, it is advisable to wear loose and comfortable clothing.

Initials: _____

EXOMIND therapy utilizes magnetic pulses to stimulate specific areas of the brain. The FDA cleared EXOMIND for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. EXOMIND is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. EXOMIND is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD). EXOMIND is indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21).. During the session, you may experience a light tapping or tingling sensation on your scalp. The therapy is non-invasive and does not require anesthesia.
The therapy is designed to ensure patient comfort and is generally well-tolerated. While some individuals may experience mild discomfort during the initial sessions, this typically diminishes as therapy progresses. It is important to note that the therapy should never be painful. If you experience any discomfort, inform your provider so the settings can be adjusted accordingly.

No recovery time is required following the session, and patients can resume their usual daily activities immediately after the therapy.

Initials: _____

I am aware that I MUST NOT have metallic objects in or near the head during therapy. TMS devices are contraindicated for use in patients who have conductive, ferromagnetic or other magnetically sensitive metals implanted in their head or within 12 inches (30 cm) of the treatment coil (cochlear implants, implanted electrodes or stimulators, aneurysm clips or coils, stents, bullet fragments, jewelry, hair accessories etc.). Exceptions apply to dental materials, such as standard amalgam fillings, single-post dental implants, dental bridgework and braces, which do not contraindicate the therapy.

Additionally, I acknowledge that TMS devices are contraindicated in patients with active or inactive implanted stimulator devices (such as deep brain stimulators, cochlear implants, ocular implants, and vagus nerve stimulators) as well as patients with implanted drug delivery pumps. Failure to follow these restrictions could result in serious injury or death.

Initials: _____

*** Filling this form on your computer or phone?** Fill in the form, sign it, then click Save (not Print) and send us the saved file.

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Have you ever had, or do you currently have, any of the following conditions?

(Consult your treatment provider for the full list of contraindications.)

- Metallic objects in or near the head (Exceptions apply to dental materials, such as standard amalgam fillings, single-post dental implants, dental bridgework and braces.) ☐ YES ☐ NO
- Implanted stimulator devices (such as deep brain stimulators, cochlear implants, ocular implants, vagus nerve stimulators, pacemakers and defibrillators) ☐ YES ☐ NO
- Drug pumps ☐ YES ☐ NO
- Malignant tumor or benign tumor ☐ YES ☐ NO
- Tendency to seizure (e.g., persons suffering from hypotonia and epilepsy) ☐ YES ☐ NO
- Pulmonary insufficiency ☐ YES ☐ NO
- Anticoagulation therapy ☐ YES ☐ NO
- Severe or life-threatening condition ☐ YES ☐ NO
- Decompensated hemorrhagic conditions ☐ YES ☐ NO
- Heart disorders ☐ YES ☐ NO
- Renal insufficiency ☐ YES ☐ NO
- Decompensated blood coagulation disorders ☐ YES ☐ NO
- Decompensated cardiovascular diseases ☐ YES ☐ NO
- Pregnancy ☐ YES ☐ NO
- Fever ☐ YES ☐ NO

If you answer YES to any of these questions, please specify:

_____

_____

I am aware that pregnancy is contraindicated, and pregnant women cannot undergo the therapy.

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THERAPY CONSIDERATIONS

I understand that the side effects that may occur include, but are not limited to the following:

Across 37 published articles of randomized, sham-controlled studies in approximately 1,949 treated patients in the treatment of depression, 17% reported headache without mentioning the severity of the headache (326 events), 1% reported mild headache (26 events), 9% reported pain/discomfort at, or near, the site of application without mentioning of the severity of this adverse event (175 events), while 1% reported mild application site pain/discomfort and only 5 patients reported severe application site pain/discomfort. The most common adverse event being headaches, other sources of discomfort included stimulation site pain, facial/jaw pain, and muscle spasm. 3.5% of the patients reported muscle twitching (68 events), 2.5% of the patients reported insomnia (49 cases), 2.2% of the patients reported lightheadedness or dizziness (43 events), 1.9% of the patients reported fatigue (37 cases), 1.6% of the patients reported nausea (31 events) and only one patient reported vomiting, 1.6% of the patients reported anxiety or agitation (31 events), 1.5% of the patients reported dry mouth (30 events), 0.8% of the patients reported worsening depression (15 events), 0.4% of the patients reported tinnitus (8 events), 0.3% of the patients reported difficulty in concentration (6 events), one patient without any history of epilepsy had a seizure a few hours after the 12th rTMS session. No deaths or suicides have been reported in reviewed clinical articles. An increase in suicidality was reported by 4 patients.

Initials: _____

Seizures are a rare but serious side effect. I understand that I must discuss with my doctor if I have consumed or intend to consume alcohol/drugs prior to treatment, or if I have a history or family history of seizure/epilepsy or potential alteration in seizure threshold.

Initials: _____

I understand that the safety and effectiveness of this therapy have not been established in:

- Individuals younger than 22 years, except when the device is used with EXOMIND Dual applicator as an adjunct treatment for Major Depressive Disorder (MDD) in adolescents aged 15 to 21 years
- Individuals with a suicide plan or a recent suicide attempt.
- Individuals who are unable to discontinue concurrent antidepressant medication.
- Individuals with a history of or concurrent use of electroconvulsive therapy or vagus nerve stimulation.
- Individuals with substance-induced depression or depression secondary to a general medical condition.
- Individuals with seasonal affective disorder.
- Individuals with a history of substance abuse, or post-traumatic stress disorder.
- Individuals with psychotic disorders, including schizoaffective disorder, bipolar disorder, or major depression with psychotic features.
- Individuals with neurological disorders, including a history of seizures, cerebrovascular disease, primary or secondary CNS tumors, cerebral aneurysm, dementia, or movement disorders.
- Individuals with a history of increased intracranial pressure or head trauma.
- Individuals who are nursing.

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During treatment a loud clicking sound is emitted. Therefore, patients should always use earplugs with a rating of at least 30 dB of noise reduction.

Initials: _____

Monitoring and Follow-Up: Your provider will closely monitor your progress and adjust treatment settings as necessary to maximize effectiveness and minimize discomfort. Patients are encouraged to involve caregivers or family members to monitor their symptoms and report any significant changes.

Initials: _____

Withdrawal and Alternative Treatments: You may withdraw your consent and discontinue therapy at any time without penalty. Alternative treatments for neurological and psychiatric conditions include psychotherapy, medications, and other therapies. Your provider will discuss these options with you if EXOMIND therapy is deemed unsuitable.

Initials: _____

My signature below indicates that the above information is accurate and current.

Patient's signature: _____ Date: _____

Witness (in print): _____ Signature: _____ Date: _____

Practice Name: Dr. Sudha Moola MD INC _____

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