

## **Patient and Relatives Manual**

**Neuro-MSX Repetitive Magnetic Stimulator for major depressive disorder (MDD) treatment**



**Major Depressive Disorder (MDD) is characterized by a persistent feeling of sadness or a lack of interest in outside stimuli.**

**More than just a bout of the blues, depression isn't a weakness and you can't simply "snap out" of it. Depression may require long-term treatment. But don't get discouraged. Most people with depression feel better with medication, psychotherapy or both. If you feel depressed, make an appointment to see your doctor or mental health professional as soon as you can.**

**A treatment option for major depressive disorder includes medication and therapy, but unfortunately roughly 40% of people with depression are resistant to medication while many others experience unbearable side effects.**

**TMS is a noninvasive treatment with no systemic side effects, with clinically proven results.**

## What You Should Know about TMS Treatment

### What is Transcranial Magnetic Stimulation (TMS)?

The principle of therapeutic magnetic stimulation is based on the use of short-duration magnetic pulses. The induced high-intensity electromagnetic field easily penetrates through clothes, cranium bones and soft tissues. It impacts the brain.

If compared to electrical stimulation, magnetic stimulation does not cause painful sensations that usually occur due to the activation of skin receptors under the electrode, and does not require additional preparation time.

#### Quick facts about TMS

- TMS is for patients who failed to receive improvement (so-called, treatment-resistant)
- TMS should be provided alongside medication or ERP as an add-on therapy
- TMS can be used to treat several mental health disorders, but effective MDD treatment involves TMS “recipes” that combine specific techniques that studies have found to be helpful

### What’s It Like to Receive TMS Therapy?

TMS is intended to be an add-on therapy that patients receive alongside other MDD treatments like, for example, medication.

TMS treatment is typically provided in an office setting on an outpatient basis. During each treatment, the patient will sit in a chair and wear ear plugs. The patient is awake during the treatment. The machine will turn on, and during the treatment the patient will hear loud clicking sound and feel a “tapping” sensation on the scalp.

Some patients have reported feeling some mild discomfort during and shortly after the treatment, including scalp pain. Once the treatment is completed, the patient is free to continue with daily activities.

### **Is TMS Right for You?**

To find out if an MDD patient qualifies for TMS, one must consult a doctor. A qualified physician conducts an in-depth survey of the patient's MDD symptoms and medical history. Then personalized MDD treatment recommendations are offered to the patient.

TMS is generally considered to be a safe and well-tolerated treatment for MDD, but there are instances in which an MDD patient might not qualify for this treatment.

### **What Are the Side Effects?**

The knowledge of side effects allows informing patients about what can happen and how to deal with these effects. Seizure is a rare but most severe adverse effect of rTMS. In some publications the following possible side effects are mentioned: epileptiform abnormalities on EEG, transient acute hypomania induction, syncope, headache, neck pain, discomfort at the stimulation site, transient hearing changes, transient cognitive/neurophysiological changes and other biological effects.

### **Who Should not Receive TMS?**

Neuro-MSX is a safe and effective device when it is used as intended.

Every patient must be screened for contraindications prior to perform magnetic stimulation.

When deciding on rTMS treatment, the respective contraindications described in safety recommendations shall be considered.

There are two contraindications for rTMS therapy:

- 1. Metallic objects in or near the head**

Patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or within 30 cm of the treatment coil. Examples include cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents, bullet fragments, jewelry and hair barrettes. Failure to follow this restriction could result in serious injury or death.

- 2. Implanted stimulator devices in or near the head**

Active or inactive implants (including device leads), including deep brain stimulators, cochlear implants and vagus nerve stimulators. Contraindicated use could result in serious injury or death.

**To identify if TMS therapy is right for you, your physician will ask you questions like:**

yes  no Do you have epilepsy or have you ever had a convulsion or a seizure?

yes  no Have you ever had a fainting spell or syncope? If yes, please describe on which occasion(s).

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yes  no Have you ever had a head trauma that was diagnosed as a concussion or was associated with loss of consciousness?

yes  no Do you have any hearing problems or ringing in your ears?

yes  no Do you have cochlear implants?

yes  no Are you pregnant or is there any chance that you might be?

yes  no Do you have metal in the brain, skull or elsewhere in your body (e.g., splinters, fragments, clips, etc.)? If so, specify the type of metal.

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yes  no Do you have an implanted neurostimulator (e.g., DBS, epidural/subdural, VNS)?

yes  no Do you have a cardiac pacemaker or intracardiac lines?

yes  no Do you have a medication infusion device?

yes  no Are you taking any medications? (please list)

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yes  no Did you ever undergo TMS in the past? If so, were there any problems?

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yes  no Did you ever undergo MRI in the past? If so, were there any problems?

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**Affirmative answers to one or more of these questions do not represent absolute contraindications to TMS, but the risk/benefit ratio should be carefully balanced by the operator.**