

### Safety Information

Clinical trials with Deep TMS have not demonstrated the presence of systemic side effects. Some subjects have reported experiencing headaches, application site pain or discomfort and other non-systemic side effects. There is also a very rare risk of seizure associated with the treatment. Subjects with metal in or around the head, such as in metal plates, implants and stents, should not undergo Deep TMS.

### Indication:

Brainsway Deep TMS is indicated by the FDA for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder, who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode. FDA 510(k) No. K122288. Brainsway is also certified by the CE for the following indications: Major Depression, Bipolar Depression, Schizophrenia - Negative Symptoms, Parkinson's Disease (with antiparkinsonian medications), Post-Traumatic Stress Disorder (PTSD), Smoking Cessation, Autism and Asperger's Disorder, Alzheimer's Disease, Chronic Diabetic Pain, Obsessive Compulsive Disorder (OCD), Multiple Sclerosis (MS), Stroke. Certificate No. 6106GB410141202



# BrainsWay Deep TMS Exploring the Depths of Possibility

[Brainsway.com](http://Brainsway.com) | [info@brainsway.com](mailto:info@brainsway.com)

BRO-D110-00 V.1



[info@brainsway.com](mailto:info@brainsway.com)  
[Brainsway.com](http://Brainsway.com)



BrainsWay is a medical device company dedicated to developing and providing highly innovative solutions across a variety of brain disorders.

Deep transcranial magnetic stimulation (Deep TMS) using BrainsWay's patented H-coils is a novel development in TMS technology, which enables stimulation of significantly deeper and broader cortical brain regions, inaccessible with other non-invasive technologies.

The deeper and more widespread field distribution of the H-coils is suitable for reliable targeting of brain networks, whose anatomical and functional architecture is known to vary greatly between individuals.

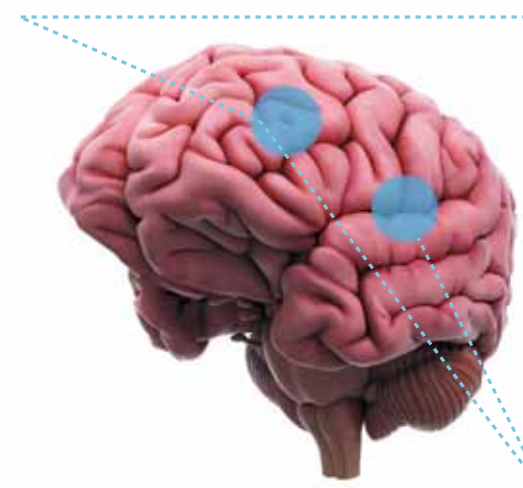
### Key Technological & Research Features

- ▶ A variety of patented Deep TMS H-coils for clinical and pre-clinical research
- ▶ Supports a broad range of TMS protocols
  - + LF-rTMS, HF-rTMS, TBS
- ▶ Multiple clinical and research applications
  - + Psychiatric disorders
  - + Neurological disorders
  - + Addictions and substance abuse
- ▶ Unique blinding system for randomized studies
  - + Incorporation of active and sham coils into a single helmet affords high integrity of blinding in clinical trials
- ▶ EEG-compatible
  - + Online TMS-EEG can be used to record brain activity concurrently with TMS
  - + Enables detection of biomarkers that serve as predictors of clinical response

## Novel Stimulation Targets

### Prefrontal cortex (PFC)

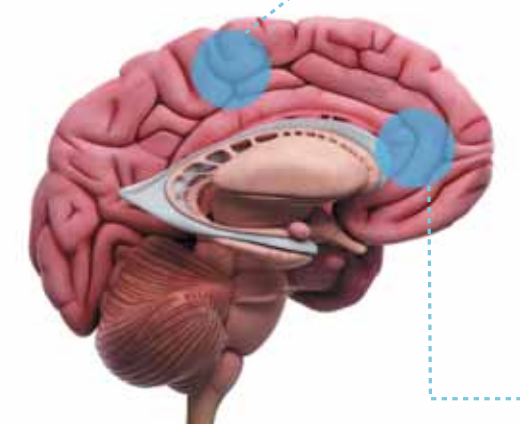
Deep TMS using the H1-coil to stimulate the left dorsolateral PFC has shown therapeutic efficacy in treatment-resistant major depression<sup>1</sup>, and in bipolar depression.<sup>2</sup> The H1-coil can also be used to modify highly salient traumatic memories, thereby alleviating the symptoms of PTSD.<sup>3</sup> Combined bilateral Deep TMS over the prefrontal and motor cortices using the H5-coil can address both motor and depressive symptoms of Parkinson's disease.<sup>4</sup>



### Primary motor cortex (M1)

The H10-coil can target the representation of the lower limbs in the primary motor cortex, located deep within the inter-hemispheric fissure.

This stimulation improves chronic lower limb motor dysfunction in stroke victims,<sup>6</sup> and produces analgesic effects in patients with painful diabetic neuropathy.<sup>7</sup>



### Bilateral insular cortex and PFC

Combined evidence suggests a crucial role for the insular cortex (IC) in cravings for food, cocaine, and cigarettes. Indeed, a recent study, which used the H4-coil to target the PFC and IC in heavy smokers, demonstrated a significant reduction in tobacco consumption.<sup>5</sup>

### Anterior cingulate cortex (ACC)

The ACC, which implicated in the pathology of obsessive-compulsive disorder (OCD), is beyond the reach of conventional TMS coils. A recent study indicates that stimulation of the ACC with the H7-coil is an effective treatment for this disorder.<sup>8</sup>

1. Levkovitz Y et al. World Psychiatry 2015, 14:64-73.

2. Harel EV et al. World J Biol Psychiatry 2011, 12:119-26.

3. Isserles M et al. Brain Stimul 2013, 6:377-83.

4. Spagnolo F et al. Brain Stimul 2014;7:297-300.

5. Dinur-Klein L et al. Biol Psychiatry 2014, 76:742-9.

6. Chieffo R et al. Arch Phys Med Rehabil 2014, 95:1141-7.

7. Onesti E et al. Eur J Pain 2013, 17:1347-56.

8. Carmi et al, in preparation.