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CTMSS Press Release: Regarding FDA Clearance of SAINT Neuromodulation System -

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Fresno, CA. September 16, 2022 – Last week, Magnus Medical Inc, announced that the U.S. Food & Drug Administration (FDA) has cleared the SAINTTM (Stanford Accelerated Intelligent Neuromodulation Therapy) Neuromodulation System for the treatment of major depressive disorder (MDD) in adults who have failed to achieve adequate improvement from antidepressant medications.

The Clinical TMS Society is encouraged by the new FDA clearance and SAINT's rapid and excellent results found in its clinical trials. Our society would like to highlight the components of Magnus Medical's SAINT Neuromodulation System, as well as how it differs from other FDA cleared Transcranial Magnetic Stimulation (TMS) protocols for depression. The SAINT approach uses structural magnetic resonance imaging (MRI), as well as a special type of brain MRI called a functional connectivity MRI to identify an individualized treatment target. It also delivers 50 treatments over the course of five days (10 treatments per day). Clinics offering SAINT Neuromodulation treatment would require patients to undergo both structural and functional connectivity MRIs, would upload those scans to specialized cloud-based software which identifies the treatment targets, and would use special equipment (neuronavigational equipment) to navigate the TMS coil over the individualized treatment target within each patient's brain for each treatment.

The Clinical TMS Society's Clinical Standards Committee is currently updating a more comprehensive statement about the SAINT Neuromodulation System, which will be released shortly. The table below highlights the differences between the newly FDA-cleared SAINT Neuromodulation System and the 2019 FDA-cleared intermittent theta burst stimulation (iTBS) protocol.

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SAINT Protocol	FDA-Cleared iTBS Protocol
10 sessions per day with 50-minute intersession interval for 5 days	One session per day for 36 days
1,800 pulses iTBS per session	600 pulses iTBS per session
Treatment at 90% motor threshold (MT) adjusted for cortical distance difference from motor cortex to dorsolateral prefrontal cortex based on the individual's MRI image	120% MT with no adjustment for depth
Location of stimulation based on individualized functional MRI with neuronavigational targeting equipment	Probabilistic location based on measurements on the scalp

While the SAINT Neuromodulation System has received FDA clearance, it should be noted that most insurance companies (if any) do not yet offer coverage for this type of TMS treatment, we hope that insurance coverage will soon be offered. It is worth mentioning that the equipment and software for the MRI scans are not widely accessible at this time.