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Revised Statement Regarding SAINT Protocol

Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT), a novel approach to providing Transcranial Magnetic Stimulation (TMS) for treatment resistant depression (TRD), has generated considerable interest in the academic community and in the popular media. Some patients are requesting treatment with this protocol, and some providers are looking for guidance regarding its use.

SAINT is delivered with the Magnus Medical Saint Neuromodulation System, which was cleared by the Food and Drug Administration (FDA) on September 6, 2022 based on results from an open label study (n=21) and a randomized double-blinded sham-controlled trial (active n=14, sham n=15) for TRD. SAINT differs from conventional FDA-cleared intermittent theta-burst stimulation (iTBS) in several ways:

FDA-Cleared 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

The FDA-cleared protocol uses the Magnus Medical SAINT Neuromodulation System. Adherence to the SAINT protocol requires structural and functional MRI, neuronavigation equipment/expertise, and the proprietary algorithm necessary to target treatment based on fMRI connectivity. Whether similar results can be obtained with other systems or with standard heuristic targeting methods is unknown.

In summary, TMS practioners should be aware that the efficacy of off-label SAINT-like protocols without neuronavigation or targeting methodology consistent with the FDA-cleared Magnus Medical Saint Neuromodulation System is unknown.

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