

Press Release: FDA clears 3-minute, non-pharmaceutical depression treatment



For people suffering from severe depression, the road to remission just became a lot shorter: The treatment is known as Transcranial Magnetic Stimulation (TMS), and MagVenture has now, as the only TMS provider in the US, received FDA clearance for a newer and much faster treatment protocol which will cut down treatment time to just 3 minutes per session. Before that, the required treatment time per session was up to 37 minutes.*

TMS has been FDA cleared for treatment-resistant major depressive disorder since 2008. Since then, over 1,000 psychiatric clinics have emerged in the US. Most private health insurance companies also cover the treatment. The relatively long treatment sessions have, however, not only limited the treatment capacity for TMS practices but also hindered a more widespread dissemination. Until now, each session has been up to 37 minutes long, with 20-30 sessions needed in total. The new treatment form, which is known as Theta Burst Stimulation (TBS), offers one significant advantage: Time. A TBS treatment session lasts only 3 minutes and thus has the potential to revolutionize the clinical field of TMS.

“We have named it “Express TMS®” because that’s what it is: a treatment which is just as safe and effective for the treatment of depression as conventional TMS, only much, much faster. We are happy and proud to be the first in the US to receive an FDA clearance for this revolutionary treatment which is backed up by substantial scientific evidence. Our current treatment system, MagVenture TMS Therapy, can easily be upgraded with the new Express TMS option. This will enable our many customers to treat far more patients per day without having to invest in another TMS device. For people needing treatment, this will also be a huge benefit, as treatment will now take up less of their time,” says Kerry Rome, Vice President of Sales, MagVenture Inc.

The new FDA cleared treatment protocol, currently only offered by MagVenture, is based on a new clinical study, named the THREE-D trial, and led by a partnership of three leading research hospitals in Canada (CAMH, UHN, and UBC).

It is the largest, double-blinded, randomized TMS trial to date, with 414 participants suffering from major depressive disorder. Response/remission rates were 32% for those receiving the TBS protocol, whereas 49% had an improvement in their depressive symptoms. These rates are similar to the standard, longer TMS protocol. The article was published in The Lancet in 2018.

*Indications for use

MagVita TMS Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

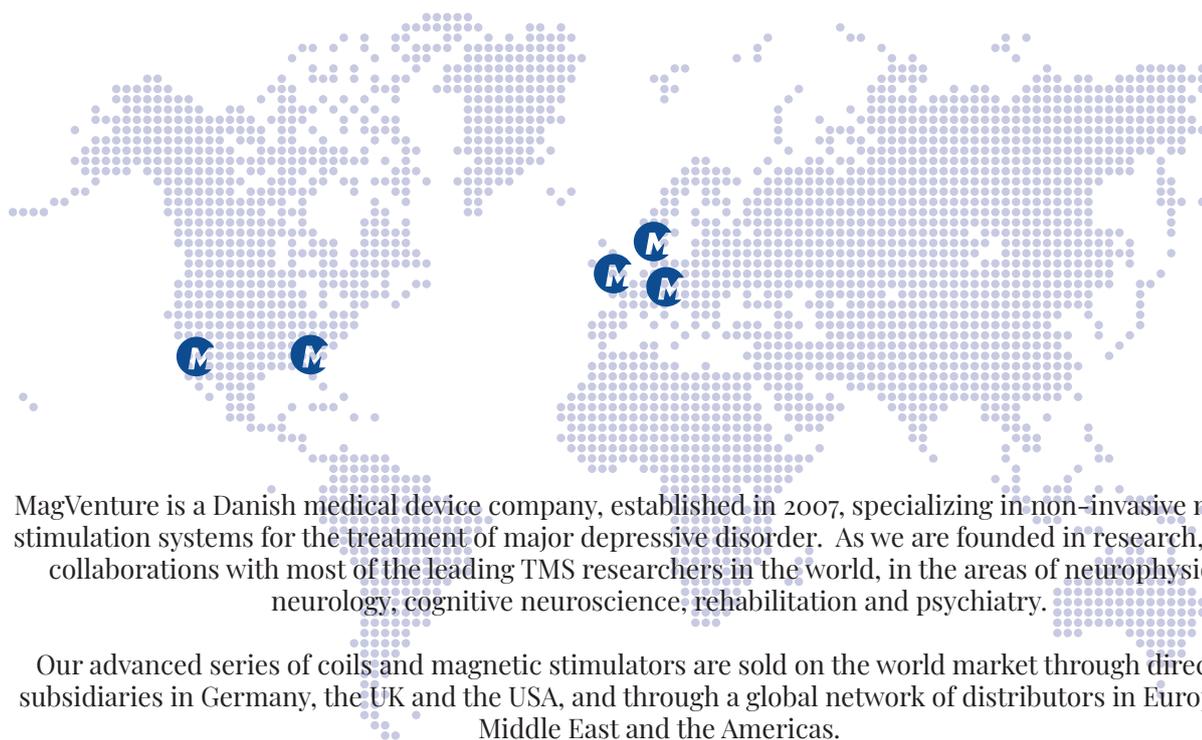
What is TMS?

Transcranial Magnetic Stimulation, or TMS, is an effective, non-invasive alternative for the large number of patients not responding to medication. It does not require anesthesia – and is not to be confused with ECT (Electro Convulsive Therapy).

MagVenture TMS Therapy delivers magnetic pulses to stimulate nerve cells in the part of the brain controlling the mood. The rapid change in the magnetic field induces a current, and if the current induced is of sufficient amplitude and duration, it will excite neurons.

Both TMS and TBS are based on these principles. The difference lies in the way the magnetic pulses are delivered.

MagVenture is the only company with an FDA cleared Theta Burst solution for the treatment of depression; Express TMS®.



MagVenture is a Danish medical device company, established in 2007, specializing in non-invasive magnetic stimulation systems for the treatment of major depressive disorder. As we are founded in research, we have collaborations with most of the leading TMS researchers in the world, in the areas of neurophysiology, neurology, cognitive neuroscience, rehabilitation and psychiatry.

Our advanced series of coils and magnetic stimulators are sold on the world market through direct sales subsidiaries in Germany, the UK and the USA, and through a global network of distributors in Europe, Asia, Middle East and the Americas.

MagVenture, Inc.
2300 Lakeview Parkway, Suite 700
Alpharetta, GA 30009
USA
Phone: 888-624-7764
Email: infousa@magventure.com

MagVenture A/S
Lucernemarken 15
3520 Farum
Denmark
Phone: +45 4499 8444
info@magventure.com

www.magventure.com