NeuroStar TMS Therapy indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode. NeuroStar TMS Therapy has not been studied in patients with post-partum depression.

The safety and efficacy of NeuroStar TMS Therapy in Major Depressive Disorder (MDD) was studied in a randomized controlled trial of patients who had failed to receive benefit from one to four prior antidepressant medications. A retrospective subgroup analysis of the overall study population demonstrated that the device was safe and effective for patients who had failed to benefit from one prior antidepressant medication of adequate dose and duration in the current episode. In this study population, patients had received a median of 4 total prior antidepressant medication attempts in the current episode, one of which achieved treatment adequacy at or above the minimal effective dose and duration.

In a controlled trial, patients treated with active NeuroStar TMS Therapy received greater than 3x the improvement in depressive symptoms compared to placebo at four weeks (-7.1 vs -2.1, P=0.0006, change in MADRS score from baseline). An open-label, uncontrolled clinical study showed approximately half of the patients treated with NeuroStar TMS Therapy experienced significant improvement in their depression symptoms. About a third of the patients treated with NeuroStar TMS Therapy experienced complete symptom relief at the end of 6 weeks.<sup>2</sup>

NeuroStar TMS Therapy is contraindicated in patients with non-removable conductive metal in or near the head. NeuroStar TMS Therapy is not associated with systemic side effects reported for antidepressant medications. The most frequently reported side effect with NeuroStar TMS Therapy is scalp pain or discomfort at the treatment location. There is a rare risk of seizure with NeuroStar TMS Therapy; in post-market experience, the risk is approximately 0.1% (1 in 1000 patients). Patients undergoing treatment for Major Depressive Disorder, including NeuroStar TMS Therapy should be monitored closely for worsening symptoms and signs of suicidal behavior and/or unusual behavior.

The safety of NeuroStar TMS Therapy in the presence of concomitant antidepressant medication was evaluated in a 6-month follow-up open-label clinical trial in patients who had previously responded to acute NeuroStar TMS Therapy. The safety outcomes did not differ from those observed during acute TMS monotherapy.<sup>3</sup>

The safety and effectiveness of NeuroStar TMS Therapy has not been established in the following patient populations or clinical conditions through a controlled clinical trial: Patients who have failed to receive benefit from 2 or more antidepressant medications given at or above minimal effective dose and duration in the current episode or who have had no prior antidepressant medication failure; Patients who cannot tolerate withdrawal of antidepressant medications; Patients who have a suicide plan or have recently attempted suicide; Patients younger than 22 years of age or older than 70 years of age; Patients with history of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder: Patients with a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features; Patients with neurological conditions that include history of seizures, cerebrovascular disease, dementia, movement disorders, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the CNS; Patients with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents; Patients with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators; Patients with major depressive disorder who have failed to receive clinical benefit from ECT\* or VNS; Patients who are pregnant or nursing. NeuroStar TMS Therapy has not been demonstrated to be equivalent in efficacy to ECT for the treatment of major depressive disorder. Efficacy was not studied in patients using concomitant antidepressant medications or receiving psychotherapy during TMS Therapy treatments. Safety and efficacy have not been established for NeuroStar TMS Therapy beyond a 4-6 week acute course, use of treatment parameters outside the labeled protocol or for maintenance therapy.

NeuroStar TMS Therapy is available by prescription only. Patients should talk to their doctor when considering NeuroStar TMS Therapy as a treatment option. For questions regarding this article, please contact Customer Service at 1-877-600-7555. Full safety and prescribing information is available at www.NeuroStar.com.

3. Janicak PG, et al. (2008). Transcranial Magnetic Stimulation in the treatment of major depression: A comprehensive summary of safety experience from acute exposure, extended exposure, and during reintroduction treatment. J Clin Psychiat 69(2):222-232.

<sup>1.</sup> Data on file at Neuronetics, Inc.

Demitrack MA, Thase ME (2009). Clinical Significance of Transcranial Magnetic Stimulation (TMS) in the Treatment of Pharmacoresistant Depression: Synthesis of Recent Data. Psychopharmacol Bull 42(2):5-38.





# \* "Because of my baby, I decided to try a new treatment. In a little over a week, I was astonished: For the first time in 20 years, I felt normal." -CARMEN BURTON



### ► I EXPERIENCED MY

first symptoms of depression when I was 16. I was on the cheerleading team at my high school in Memphis and about to head to the national championships when I tore a ligament in my knee and had to undergo surgery. Quitting the activity I loved—the one that really defined me-was tough. I stopped seeing my friends and started skipping classes and drinking. I made it to college, but flunked out in my freshman year. That summer, I spiraled deeply into depression. I felt like I wasn't part of anything, that my life had no purpose. I saw a therapist, who put me on Prozac, but it didn't really help.

## ON A ROLLER COASTER

For the next 20 years, I swung between a shaky contentment and despair. I had a baby boy, Austin, when I was 21, and I felt well enough to return to college and finish nursing school. Then I married, divorced, and entered a bleak period, just lying on the couch and avoiding everyone, including Austin. During those years, I saw many therapists and probably took every medication on the market-Zoloft, Paxil, Effexor, and others-but nothing worked. I met my

current husband, Rob, in 2009, and I was happy when we married and moved to a suburb just outside Nashville. But I had a miscarriage soon after, and that plunged me back into the depths.

FEEL GOOD

#### THE LOWEST MOMENT

My life truly fell apart when I got pregnant in December 2010. I developed gestational diabetes and preeclampsia and was ordered to bed. For six months, I just lay there, curtains drawn, blankly watching the Casey Anthony trial, which was depressing in itself. After my son Bowen was born in August 2011, a full-blown postpartum depression leveled me. I wanted nothing to do with the

# CARMEN'S TIPS

- "How can you help a depressed friend? Remind yourself it's not her fault. Encourage her to do small things, like take a walk."
- "Your family may need to be insistent with you: When I didn't want to go for treatment, my husband took me in my pajamas."



Good

baby and handed him off to the nanny or to Rob. Austin, then 17, was furious with me. "You sleep all day and don't care about me!" he'd scream. And Rob, who was busy running a medical-device company, had to lift me out of bed to wash my hair or get me to the table to eat. He even threatened to leave, but I didn't care. I was just numb.

The following April I was holding 8-month-old Bowen, and he reached out to the nanny with a whimper. It broke my heart and, right then, I decided to try a new treatment my psychiatrist had recommended-transcranial magnetic stimulation (TMS). It uses electric currents to stimulate cells in the part of the brain that regulates mood. Rob and I had been reluctant: It seemed so extreme, and it was expensive-\$12,600—and not covered by our insurance (though some companies do pay for it). But after that devastating moment, I was ready.

#### **BREAKING THROUGH THE FOG**

Still, I was trembling as the technician at the TMS center placed the magnetic coil against my scalp for the first time last May. Although I'd been assured that "If I had one message, it would be, 'Don't wait to get help for depression." Also, **keep trying till you find something that works.** I wish I hadn't suffered for so many years"

the risk of serious side effects was very low, I worried about what the treatment might do to my brain. And would it hurt? But all I felt was a *ding, ding, ding* vibration, like a woodpecker, for 45 minutes.

In all, I had 30 daily treatments, but by the second week, I could feel my depression lifting. It was really powerful. I started getting up in the morning and showering, even playing with the baby. I felt hopeful for the first time in a very long time.

Since I finished treatment last July, my depression has been in remission. I cook, I clean, I take yoga—regular stuff I could never do before. I've even helped Austin with his college applications. It's funny the other day, a new friend asked me why I was so happy all the time. I thought about it for a minute and realized, I am happy now. For me, that's an amazing new feeling.

–CARMEN BURTON, AS TOLD TO GRETCHEN VOSS

# Readers' Tips Our Facebook fans on how they get out of a funk

"I walk, bike, do yoga, or lift weights. They each help."

> —Jacquie Whitt, Virginia Beach, VA

"I write a 'woe is me' list. Seeing why I'm upset justifies my bad mood and makes me feel better."

> –CARRIE FINN, ALPHARETTA, GA



Photograph by Getty Images

–JEN BLUMENTHAL, CAVE CREEK, AZ

