



Provided by Stephen J. D'Amato, MD, FACEP

"Scrambler Therapy" Specialist

## FACT SHEET: 2023

Calmar Pain Relief, LLC (Calmar) is entirely devoted to the treatment of severe, chronic, neuropathic, and oncologic pain resistant to morphine and other drugs using the MC-5A medical device. The application of the MC-5A is called Scrambler Therapy (ST), an electroanalgesic procedure utilizing the tenets of the information and cybernetic theories. Stephen J. D'Amato, M.D., P.C. was organized in 2009 as the medical provider and billing agent for Calmar. Calmar opened the country's first treatment center utilizing the MC-5A on 11/15/2009 in North Providence, R.I. and opened a treatment center in Bonita Springs, FL. on 3/7/2016.

Dr. D'Amato, Calmar's Medical Director, and Calmar's medical staff use the MC-5A device to provide rapid, **non-narcotic, non-invasive, pain free treatment, without known side effects** and clinically proven effective by scientific research. In a typical treatment cycle, pain, and the need for pain medication is progressively reduced until an 80% reduction occurs (in many cases there is a complete resolution of pain). Scrambler Therapy (neuromodulation) usually consists of 10-12 daily treatment sessions (over two weeks), which are typically 45-60 minutes in length. Pain relief is usually three months to well over a year. Booster sessions (generally 1-3) are administered if the pain returns.

The initial patient encounter includes (i) a medical examination by a licensed medical doctor, physician's assistant, or nurse practitioner to ascertain the nature of the illness and determine if the patient is a candidate for ST, (ii) an explanation of the ST process, and (iii) a development plan and outline of the patient's treatment regimen.

The MC-5A which received broad FDA 510(k) clearance in February 2009 is a computerized medical device that applies a low amperage electric signal which transmits synthetic non-pain information through disposable surface electrodes on the skin (like an EKG) to surface nerve receptors. Scrambler Therapy synthesizes 16 diverse types of nerve action potentials like endogenous ones, assembles them into sequences, and uses algorithms to provide patient-specific cutaneous electrostimulation to reduce and eliminate pain. ST replaces the "pain" information with artificial "non-pain" information. By providing corrective information (bioelectrical codes) through the periphery (dermatomes) to the dorsal horn of the spinal cord and central nervous system, the new code "tricks" the brain to read a discernable non-pain code as real and generated from self. When this occurs, there is an immediate "zeroing out" of the pain. Through neuroplasticity the brain will expect and prefer the non-pain code.

Dr. D'Amato and Calmar's medical staff have successfully treated over 2,000 patients with severe chronic neuropathic and oncologic pain. Dr. D'Amato has trained doctors and nurses from Mayo Clinic, Johns Hopkins, MD Anderson, Walter Reed Army Hospital, Massey Cancer Center, University of Miami Medical Center and Harvard Medical Center in the effective use and administration of Scrambler Therapy. Sixty-six insurance companies including forty-six workers compensation insurance carriers and TPA's have approved and reimbursed Calmar's patients for ST.

The Mayo Clinic, Johns Hopkins and MD Anderson now treat patients with ST in their own clinical practices after years of research confirming the validity and effectiveness of ST from world renowned medical institutions.

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Neuropathic pain from various underlying medical conditions have been successfully treated with ST including: Complex Regional Pain Syndrome (CRPS) formally (RSD); Sciatica and Failed Neck and Back Surgery Syndrome (FBSS); Chemo and Diabetes Induced Peripheral Neuropathy (CIPN) (DPN); Phantom Limb Pain; Trigeminal Neuralgia; Temporomandibular Joint Disorder (TMJ); Fibromyalgia; Post-Surgery Nerve Lesion Neuropathy; Brachial Plexus Neuropathy; Post Herpetic Neuropathy; Pudendal Neuropathy; Vulvodynia; and Oncologic Pain Resistant to Drug Treatment.

Dr. D'Amato and Dr. Frank Sparadeo, Calmar's Director of Clinical Research, collaborated with doctors from Johns Hopkins, Mayo Clinic, MD Anderson and others on a March 11, 2016, Scrambler Therapy Review Study published in Support Care Cancer. That study analyzed 20 successful scientific research studies and favorably examined Calmar's clinical practice. In 2017, Drs D'Amato and Sparadeo contributed a chapter explaining ST for a book published in 2017 by Dr. Alexios Carayannopoulos, Clinical Assistant Professor, Department of Neurology, Brown University, Medical School, Medical Director, Comprehensive Spine Center, Rhode Island Hospital, Providence, RI, entitled Comprehensive Pain Management in the Rehabilitation Patient.

In March 2014, Drs. Sparadeo and D'Amato published: Scrambler Therapy: Effective use of artificial neurons for the treatment of chronic neuropathic pain in the Journal of Life Care Planning Vol. XIV No. 4. In October 2012, Drs. Sparadeo and D'Amato published: Scrambler Therapy: Innovative, Effective Treatment for Chronic Neuropathic Pain in Journal of Life Care Planning, Vol.11, No. 3.

Calmar's website (www.cprcenters.com) includes many video testimonials, information, and news reports re: Calmar, ST and Dr. D'Amato including Calmar's medical staff from NBC News Channel 10, ABC News Channel 6, and an updated list and link to Research Studies and Abstracts regarding ST Technology. In 2010, Calmar received a highly competitive \$250,000 Therapeutic Discovery Project Federal Grant sponsored by The Department of Health and Human Services and the IRS less than one year after it began operation.

In 2007, Competitive Technologies, Inc. (CTT) discovered the MC-5A device at a trade show in Europe. CTT, a small public Connecticut company, was a provider of technology transfer and licensing services. CTT was neither a healthcare, medical device nor a distribution company but believed the MC-5A was groundbreaking technology. CTT purchased exclusive rights in 2007 from Professor Giuseppe Marineo (Rome, Italy), the inventor of the MC-5A, to sell, market and distribute devices worldwide. Unfortunately, neither CTT, nor its 2015 successor, Calmare Therapeutics Inc. (CTI) have ever had the resources to conduct an effective national or even a regional advertising, marketing, or PR campaign.

CTT and CTI have sold devices to approximately 45 medical and chiropractic practices, "clinics," and some Military and VA facilities in this country. Most of these "clinics" and military facilities use one or two devices as adjunctive modalities. Dr. D'Amato and his staff have treated more chronic neuropathic pain patients, are significantly more experienced, get the best results and often successfully treat patients who have been treated unsuccessfully at these "clinics".

On January 1, 2012, the AMA issued a Category III CPT Reimbursement Code (0278T) for the use of Scrambler Therapy. On February 19, 2013, The U.S. Patent and Trademark Office issued a patent for "Scrambler Therapy" to Professor Marineo (Italian inventor of ST technology). ST technology was issued an Italian Patent in 2004. The device has CE Mark certification from the European Union. The MC-5A device was manufactured by GEOMC Co., Ltd, Seoul, South Korea.