

CRPS AND Neuropathic Pain Center of America
CONSENT AND RELEASE FOR
CALMARE[®] SCRAMBLER PAIN THERAPY TREATMENT

By executing this CONSENT AND RELEASE, the undersigned is voluntarily agreeing to use, or have used upon him/her, the Calmare[®] Scrambler Pain Therapy Treatment Medical Device (“Calmare[®]” or “Medical Device”), a treatment that, through the use of disposable surface electrodes imparts electrical impulses, referred to as artificial neurons, to the body for the purpose of the stimulation of, and communication through, the C-fiber of the nerves to affect how the body detects, interprets or feels pain or painful sensations. The Calmare[®] has Federal Food and Drug Administration (“FDA”) clearance for use within the United States. In addition, Calmare[®] has received European Commission (EC) approval for use in Europe.

CONTRAINDICATIONS: You should not have the treatment if you suffer from and/or have any of the following contraindications including symptoms, conditions, or devices:

- *you have a pacemaker or automatic defibrillator;*
 - *you have a aneurysm clip, vena cava clips, or skull plates (metal implants for orthopedic repair, e.g. pins, plates, joint replacements are allowed);*
 - *you have any implanted device such as a spinal nerve stimulator or implanted drug delivery system;*
 - *you are, or could be pregnant and/or breast feeding;*
- *you have a history of epilepsy, brain damage, use of anticonvulsant medications for purposes other than pain control;*
- *you have a history of, or have been treated for myocardial infarction or ischemic heart disease within the past six months;*
- *you have, or believe that you may have, severe heart arrhythmia or any form of equivalent heart disease;*
- *you have a condition that would require electrode placement on front of the neck (carotid sinus region) or head;*
 - *you are in active withdrawal from drugs and/or alcohol;*
- *you have wounds or skin irritation in areas where the electrodes are required to be placed;*
- *you are allergic to latex;*

- *you have a history of a previous intolerance to transcutaneous electronic nerve stimulation.*

The use of the medical device could lead to injury or even death due to the presence of any of the above listed contraindications. You hereby represent and warrant that you do not suffer from or have any of the above identifying contraindications including symptoms, conditions or devices.

PRECAUTIONS: The primary care provider should review and consider the risk vs. benefit ratio for patients considering treatment with this medical device under the following situations, conditions, or devices:

- *you have pain originating in the central nervous system;*
- *because this device is capable of delivering a charge per pulse of 25 micro coulombs or greater, you should not place electrodes in a trans-thoracic position (may cause cardiac arrhythmia);*
- *you are prone to skin irritation (isolated cases have occurred);*
- *you have not had a clear diagnosis of neuropathic pain;*
- *you are connected to other electronic monitoring equipment (ECG monitor) – may not operate properly with the medical device is in use;*
- *you are on neuroleptic medications (examples: carbamazepine, pregabalin, gabapentin) which appear to “interfere with treatment efficacy” and “decrease longevity” of no-pain post treatment protocol.*

YOUR VOLUNTARY USE OF THIS MEDICAL DEVICE IS DONE AT YOUR OWN RISK AND WITH FULL KNOWLEDGE OF THE ABOVE, AS WELL AS THE RISKS INCUMBENT WITH ANY MEDICAL DEVICE. YOU HEREBY RELEASE CRPS and Neuropathic Pain Center of America AND THEIR RESPECTIVE AFFILIATES, EMPLOYEES, DIRECTORS, OFFICERS, AGENTS AND REPRESENTATIVES, INCLUDING, AND WITHOUT LIMITATION, ANY PERSON ASSISTING YOU WITH YOUR VOLUNTARY USE OF THE MEDICAL DEVICE (THE “RELEASED PARTIES”), FROM ANY AND ALL DAMAGES, PAIN, CONDITIONS, DISEASES AND ANY OTHER HARM THAT YOU MAY SUFFER OR COME TO SUFFER AS A RESULT OF YOUR USE OF THE MEDICAL DEVICE. IN ADDITION, YOU HEREBY WAIVE ANY AND ALL CLAIMS THAT YOU MAY HAVE AGAINST THE RELEASED PARTIES, AND COVENANT NOT TO SUE THE RELEASED PARTIES, IN CONNECTION WITH, ARISING FROM OR RELATING TO YOUR USE OF THE MEDICAL DEVICE.

By executing this document below, in addition to agreeing to all of the above, you represent and warrant that you are of legal age to enter into a legally binding agreement.

PATIENT

I have read and understand this form and I voluntarily authorize and consent to the treatment. My signature below acknowledges that I have been provided with the information necessary to make an informed decision and wish to proceed with the proposed treatment/procedure. I further acknowledge that I have had the opportunity to discuss the proposed treatment, concerns or questions with my referring physician or medical practitioner including risks, benefits and alternative treatments

PRINTED Patient Name

Patient Signature

Date

Provider:

I verify that I have explained the information contained in this document to the patient. It is my opinion that the person granting consent fully understands all subjects discussed and medically meets the criteria for treatment.

PRINTED Provider Name

Provider Signature

Date

Revised 7.30.2023