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 Therapeutic Goods Administration (TGA) clearance for use within Australia. In addition, Calmare has clearance for use in the United States and 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 symptom, conditions or devices:

- You have a pacemaker or automatic defibrillator;
- You have an aneurysm clip, vena cava clips, or skull plates (metal implants for orthopaedic repair, e.g. pins, plates, joint replacements are allowed);
- You have an implanted device such as a spinal nerve stimulator or implanted drug delivery system;
- You are, or could be pregnant and / or breastfeeding;
- 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 ischaemic heart disease within the past 6 months;
- You have, or believe you may have, severe heart arrhythmia or any form of equivalent heart disease;
- You have a condition that would require the placement of electrodes on the 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 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 COMPLEX PAIN SOLUTIONS, INC (AKA 'CPS') AND THEIR RESPECTIVE AFFILIATES, EMPLOYEES, DIRECTORS, OFFICERS, SHAREHOLDERS, 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 PERTAINING 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 authorise 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 medical Practioner including risks, benefits and alternative treatments.

_____	_____	_____
PRINTED Patient Name	Patient Signature	Date

MEDICAL PRACTIONER

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 Medical Practioner's Name	Medical Practioner's Signature	Date