

**CONSENT AND RELEASE**  
**CALMARE® PAIN THERAPY TREATMENT**

By executing this CONSENT AND RELEASE, the undersigned is voluntarily agreeing to use, or have used upon him/her, the Calmare 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 CE approval for use in Europe.

***Because of the manner in which the Ca/mare ® Pain Therapy Treatment operates, 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 heart stent, aneurysm clip, vena cava clip, or any other coronary or vascular stent;*
- *you have a skull plate, (Metal implants for orthopedic repair, e.g. pins, plates, joint replacements are allowed)*
- *you are, or could be, pregnant;*
- *you are nursing;*
- *you have a history of epilepsy, brain damage, use of anti-convulsants 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 any implanted device such as a spinal nerve stimulator or implanted drug delivery system;*
- *you have wounds or skin irritation in areas where the electrodes are required to be placed;*
- *you are allergic to latex; or*
- *you have a history of an allergic reaction or 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.

**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 COMPETITIVE TECHNOLOGIES, INC. (AKA "CTTC" OR "CTT") 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 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

\_\_\_\_\_  
Patient Name (Print)

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

**PHYSICIAN**

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.

\_\_\_\_\_  
Physician Name (Print)

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date