1. PROTOCOL SYNOPSIS

Investigational Product	DRG stimulator (Model 1000)
Title	A single-arm, open label, single center pilot study to confirm the safety of a dorsal root ganglia (DRG) and high frequency stimulator in patients with lower limb pain
Objectives	Primary: ● To evaluate safety of high frequency DRG stimulation by identifying the incidence rate of adverse events (AEs) and serious adverse events (SAEs) during the trial Secondary: ● To assess the pain reduction of high frequency DRG stimulation ● To determine the presence or absence of paraesthesia. ● To assess the change of pain medication consumption
Indication	Pain control
Design	This study is a prospective, single-arm, open label, single center pilot study to confirm the safety of a DRG stimulator in patients with lower limb pain
Population	**Inclusion criteria** 1. Age ≧20 and ≦75 2. Have a symptom of complex regional pain syndrome (CRPS), failed back surgery syndrome (FBSS), lower limb radicular/neuropathic pain with or without lower back pain with a diagnosis related to spinal lesion and pain history of ≥6 months. 3. Have an average pain score >5 by Visual Analogue Scale (VAS) on inclusion. 4. Has failed to achieve adequate pain relief from prior

	pharmacologic treatments. 5. In the judgement of the investigator, the subject is an appropriate candidate for the trial procedure 6. The subject is willing and able to comply with the procedure and requirements of this trial. 7. The participant is able to understand and provide informed consent, and has signed their written informed consent in accordance with IRB requirements. **Exclusion criteria** 1. Have evidence of a mental or psychological condition that affects pain perception and has difficulty/disability performing objective pain assessment, or have previously failed mental or psychological assessments administered by a psychiatrist that may be deemed to indicate the subject's lack of suitability for participation in this study. 2. Subject has exhibited escalating or changing pain condition within the past 30 days as evidenced by Investigator examination. 3. Be on anticoagulant medication with INR >1.5 or platelet count less than 100,000/μL, peripheral vascular diseases (PVDs), visceral pain or uncontrolled Diabetes mellitus (DM). 4. Has had corticosteroid therapy at an intended site of stimulation within the past 30 days. 5. Pain medication(s) dosages(s) are not stable for at least 30 days. 6. Has previously failed spinal cord stimulation therapy. 7. Currently has an active implantable device including ICD, pacemaker, spinal cord stimulator or intrathecal drug pump or subject requires magnetic resonance imaging (MRIs) or diathermy. 8. Has pain only within a cervical or thoracic distribution. 9. Have a current diagnosis of cancer with active symptoms. 10. Have a known terminal illness with life expectancy less than one year.

	11. Have a systematic or local infection. 12. Currently has an indwelling device that may pose an increased risk of infection. 13. Be pregnant or breast feeding 14. Have a medical history of drug or alcohol addiction within the past 2 years. 15. Participation in any investigational study in the last 30 days or current enrollment in any trial. 16. Be currently involved in an injury claim law suit or medically related litigation, including workers compensation. 17. Be a prisoner.
Sample Size	10 subjects
Study Duration	5 days
Efficacy Data	**Primary efficacy endpoint**: ● Adverse event (AE) and serious AE (SAE) incidence rates during the trial. **Secondary efficacy endpoints**: ● Change in pain reduction of high frequency DRG stimulation (as measured by VAS score compare to baseline) ● Incidence of paresthesia ● Change in pain medication consumption, including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and weak opioids, compared to baseline
Statistical Procedures	All data will be analyzed according to the intention-to-treat (ITT) principle. For the intention-to-treat analysis, all recorded levels were included, without reference to the subjects' degree of compliance during study period. AE, SAE, and paresthesia incidence rates and their 95% confidence interval (CI) will be estimated. Repeated measures analysis of variance (ANOVA) will be adopted to examine whether there are changes in VAS score and pain medication consumption during the trial. Last observation carried forward (LOCF) approach, specific to longitudinal data problems, will be used

	to handle missing data of VAS score and pain medication consumption. Due to small number of subjects, no interim analysis will be undertaken. The statistical significance level will be set at a two-tailed type 1 error of 0.05.