1. PROTOCOL SYNOPSIS

Investigational Product	SCS trial stimulator (Model 1000)
Title	A single-arm, open label, single center, prospective study of **an** ultra-high frequency spinal cord stimulation for treatment of chronic back pain or lower limb pain
Objectives	**Primary:** ● To assess the analgesic effectiveness of ultra-high frequency spinal cord stimulation (as measured by VAS score compared to baseline) ● To evaluate safety of ultra-high frequency spinal cord stimulation by identifying the incidence rate of adverse events (AEs) and serious adverse events (SAEs) during the trial **Secondary:** ● The change from baseline in functionality using the BPI/ODI evaluations ● To determine the presence or absence of stimulation-induced paresthesia. ● To assess the change of pain medication consumption
Indication	Pain control
Design	This study is a prospective, single-arm, open label, single center to confirm the effectiveness and safety of an ultra-high frequency spinal cord stimulation in patients with chronic back pain or lower limb pain.
Population	**Inclusion criteria** 1. Age ≧20 and ≦75 2. Have a symptom of back or lower limb pain with a diagnosis related to spinal lesion, herniatic disc, nerve injury, stenosis, failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) or ischemic lower limb pain and have 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 unstable pain condition within the past 30 days as interviewed by Investigator. 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 at investigator's discretion. 6. 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. 7. Have a current diagnosis of cancer with active symptoms. 8. Have a known terminal illness with life expectancy less than one year. 9. Have a systematic or local infection, which may increase study risk.

	10. Currently has an indwelling device that may pose an increased risk of infection. 11. Be pregnant or breast feeding. 12. Have a medical history of drug or alcohol addiction within the past 2 years. 13. Participation in any investigational study in the last 30 days or current enrollment in any trial. 14. Be currently involved in an injury claim law suit or medically related litigation, including workers compensation. 15. Be a prisoner.
Sample Size	10 evaluated subjects
Study Duration	14 (+1) days
Efficacy Data	**Primary endpoint**: ● Analgesic effectiveness of ultra-high frequency spinal cord stimulation (as measured by VAS score compare to baseline) ● Adverse event (AE) and serious AE (SAE) incidence rates during the trial **Secondary endpoints**: ● Change in BPI/ODI compared to baseline ● Incidence of stimulation-induced 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 full analysis set principle, including patients who received at least one dose of study treatment and had at least one follow-up evaluation regardless of their compliance with the protocol. Repeated measures analysis of variance (ANOVA) will be adopted to examine whether there are changes in VAS/BPI/ODI scores and pain medication consumption during the trail. The frequent endpoints in this study include AE, SAE and incidence of paresthesia of stimulation-induced. The incidence rates and their 95% confidence interval (CI) will be estimated. A Last Observation Carried Forward (LOCF)

	method will be used to define endpoints if data is unavailable at the analysis time point; the last available measurement prior to the visit will be used to fill in the missing data. Interim analysis with Pocock-type group sequential plan will be undertaken for the likelihood of no merging trends and no reasonable chance of demonstrating benefit after 5 subjects are enrolled. The statistical significant level will be set at a two-tailed type 1 error of 0.05.