Supplementary Table S1. Study inclusion criteria

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| --- |
| 1. Have been clinically diagnosed with chronic abdominal pain (from inguinal crease to T12 ribs), including diagnoses such as abdominal wall pain, chronic pancreatitis, gastroparesis, gastric dysmotility, herniorrhaphy, irritable bowel syndrome (IBS), post-surgical or post-traumatic abdominal pain.
 |
| 1. Have been refractory to conservative therapy for a minimum of 3 months, including assessment of at least 2 different classes of medications and/or an anesthetic block as clinically appropriate.
 |
| 1. Average pain intensity (over the last 7 days) of ≥5 out of 10 cm on the Visual Analog Scale (VAS) in the primary area of pain at enrollment.
 |
| 1. Have stable neurological status measured by motor, sensory and reflex function as determined by the investigator.
 |
| 1. Be on stable pain medications, as determined by the Investigator, for at least 28 days prior to assessing pain intensity as described in inclusion criterion #2, and be willing to stay on those medications with no dose adjustments until activation of the permanently implanted SCS device.
 |
| 1. Be 22 years of age or older at the time of enrollment.
 |
| 1. Be an appropriate candidate for the surgical procedures required in this study based on the clinical judgment of the implanting physician.
 |
| 1. Be capable of subjective evaluation, able to read and understand English-written questionnaires, and are able to read, understand and sign the written inform consent in English.
 |
| 1. Be willing and capable of giving informed consent.
 |
| 1. Be willing and able to comply with study-related requirements, procedures, and visits.
 |
| 1. Have adequate cognitive ability to use a patient programmer and recharger as determined by the Investigator.
 |

Supplementary Table S2. Study exclusion criteria

|  |
| --- |
| 1. Have a medical condition or pain in other area(s), not intended to be treated with SCS, that could interfere with study procedures, accurate pain reporting, and/or confound evaluation of study endpoints, as determined by the Investigator (such as primary headache diagnosis or fibromyalgia).
2. Have a current diagnosis of a progressive neurological disease such a multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, brain or spinal cord tumor, central deafferentation syndrome, Complex regional Pain Syndrome, acute herniating disc, severe spinal stenosis and brachial plexus injury as determined by the Investigator.
3. Have a current diagnosis or condition such as a coagulation disorder, bleeding diathesis, platelet dysfunction, progressive peripheral vascular disease or uncontrolled diabetes mellitus that presents excess risk for performing the procedure as determined clinically by the investigator.
4. Have abdominal pain of spinal origin.
5. Diagnosed with Crohn’s or ulcerous colitis, or any other inflammatory disease with co-existing abdominal pain (ongoing).
6. Significant stenosis, objective evidence of epidural scarring and/or any signs or symptoms of myelopathy as determined by MRI conducted within the past 12 months.
7. Subjects with chronic alcohol abuse or currently in rehabilitation.
8. Have a clinical diagnosis of severe depression (Beck Depression Inventory [BDI]-II score of 20 or more) including suicidal ideation.
9. Be benefitting within from an interventional procedure and/or surgery to treat chronic abdominal pain (Subjects should be enrolled at least 30 days from last benefit).
10. Have an existing drug pump and/or another active implantable device such as a pacemaker.
11. Have a condition currently requiring or likely to require the use of MRI or diathermy.
12. Have metastatic malignant disease or active local malignant disease.
13. Have a life expectancy of less than 1 year.
14. Have an active systemic or local infection at the anticipated needle entry site.
15. Be pregnant (if female and sexually active, subject must be using a reliable form of birth control, be surgically sterile or be at least 2 years post-menopausal).
16. Have been immunocompromised.
17. Are currently nursing (if female).
18. Have been known to be allergic or have shown hypersensitivity to any materials of the neurostimulation system which come in contact with the body.
19. Have within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including opioids, benzodiazepines, alcohol and illicit drugs).
20. Be concomitantly participating in another clinical study.
21. Be involved in an injury claim under current litigation.
22. Have a pending or approved worker’s compensation claim.
23. Presence of abdominal tumor including benign.
 |

Supplementary Table S3. Study safety outcomes

|  |  |  |  |
| --- | --- | --- | --- |
|  | Total number of AEs | Number (% of) Subjects | Description |
| Study Related Serious AEs | 3 | 2 (8.3) | * IPG revision (n=1)
* Aspiration during device implant (n=1)
* Explant due to infection (n=1)
 |

**Supplementary Figure S1.** Non-pain gastrointestinal symptoms were also improved after treatment with 10 kHz SCS. Each bar represents all patients who reported each symptom at baseline and the proportion that reported improvement, no change, or worsening of the symptom after 12 months of 10 kHz SCS therapy. The total number of patients (N) who reported each symptom at baseline is noted under each bar.

**Supplementary Figure S2.** Subject reported pain (VAS) is shown from baseline to twelve months. The light grey lines show each subject’s individual response (n=22). The black line shows the trend in average VAS (cm) with the error bars presenting ±95%CI.

