A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation

ACCELERATE

CLINICAL PROTOCOL

IDE # G130044

Sponsored By

Boston Scientific Neuromodulation Corporation 25155 Rye Canyon Loop

Valencia, CA 91355

United States of America

Contact Information

Role	Contact

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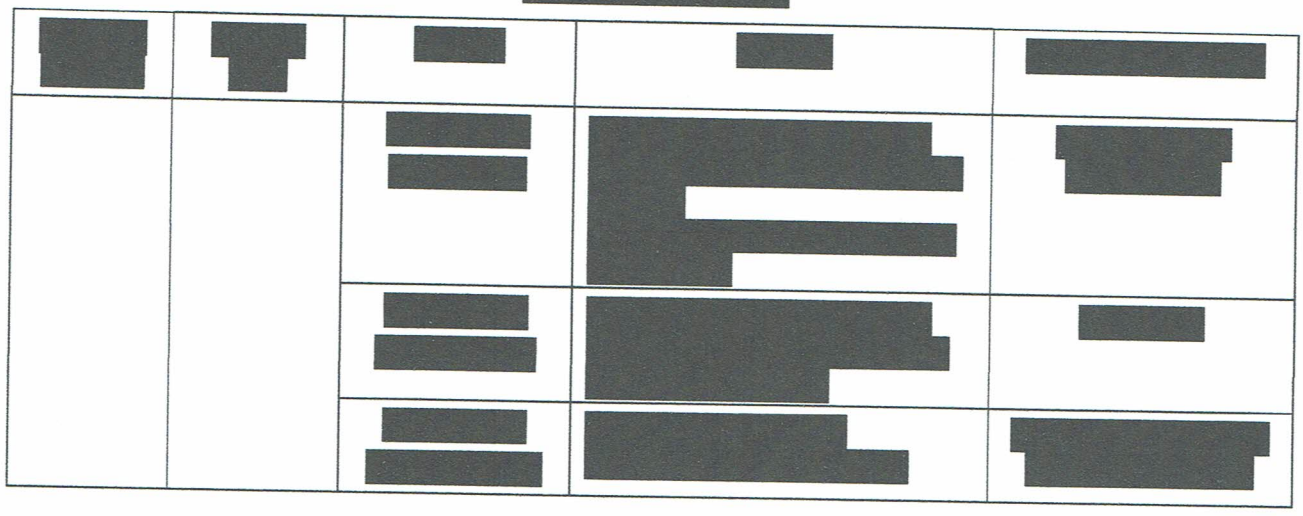

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Coordinating Principal Investigator	Mark S. Wallace, M.D. University of California San Diego Medical Center 9500 Gilman Drive San Diego, CA 92093 United States

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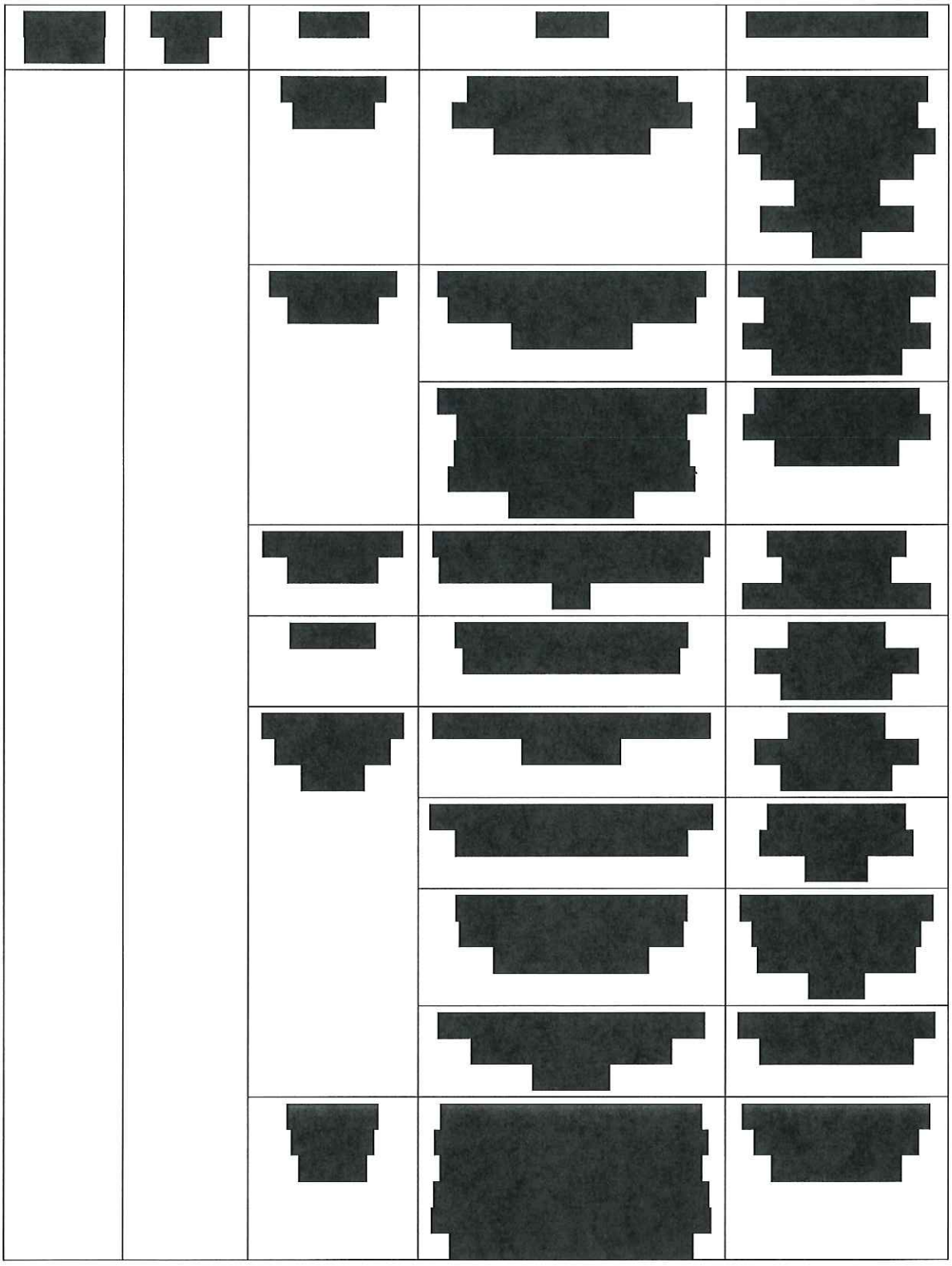

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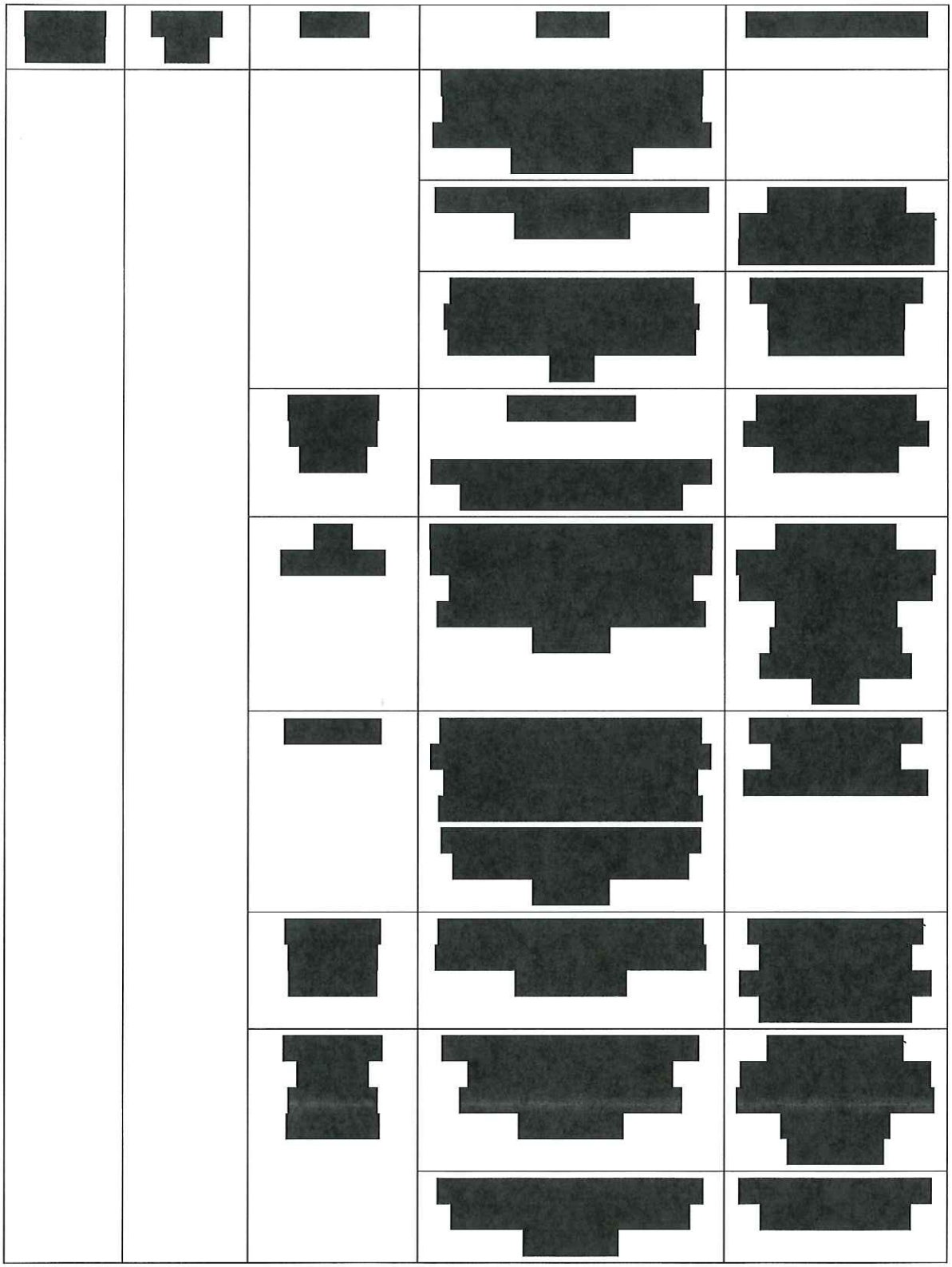

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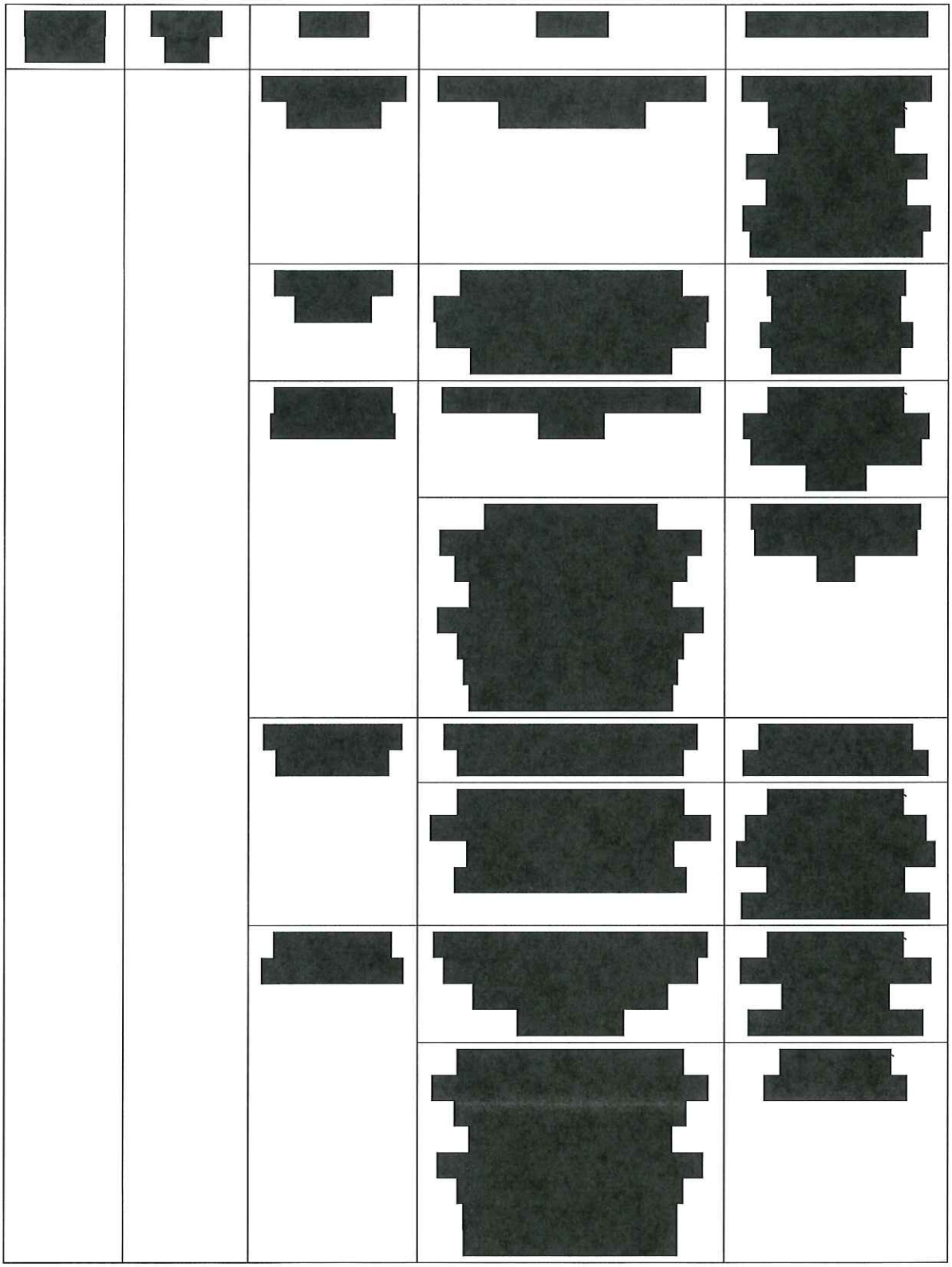

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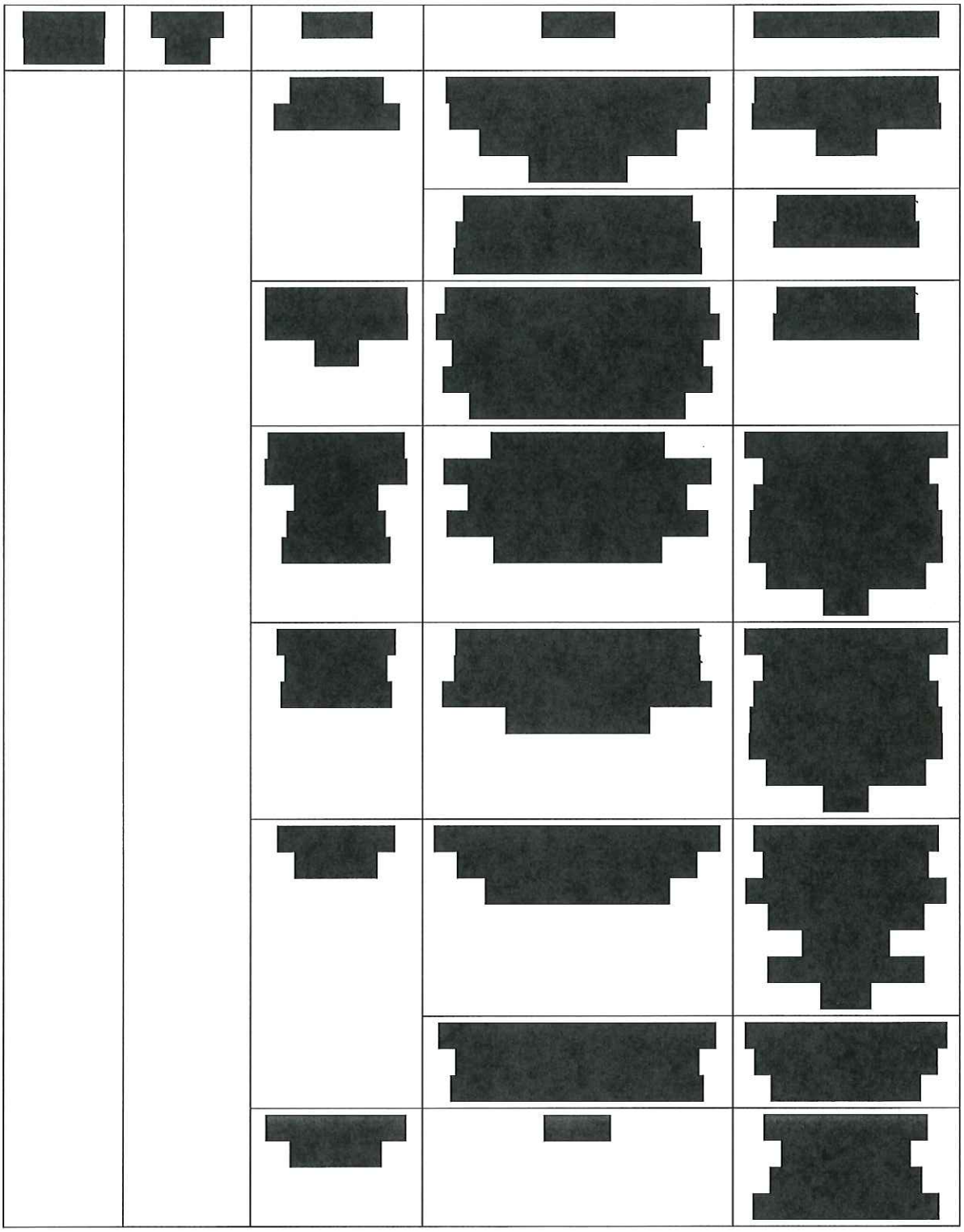

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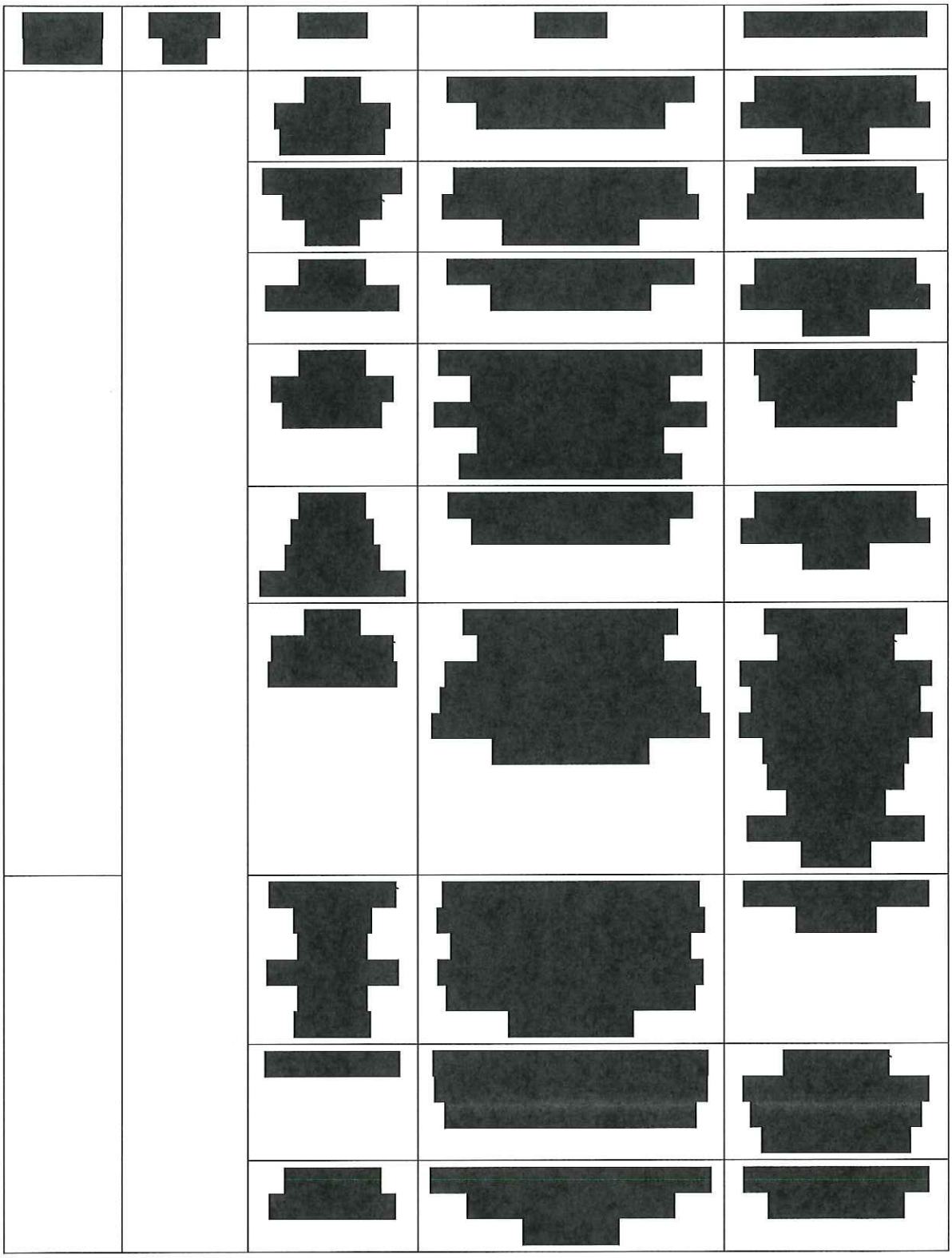

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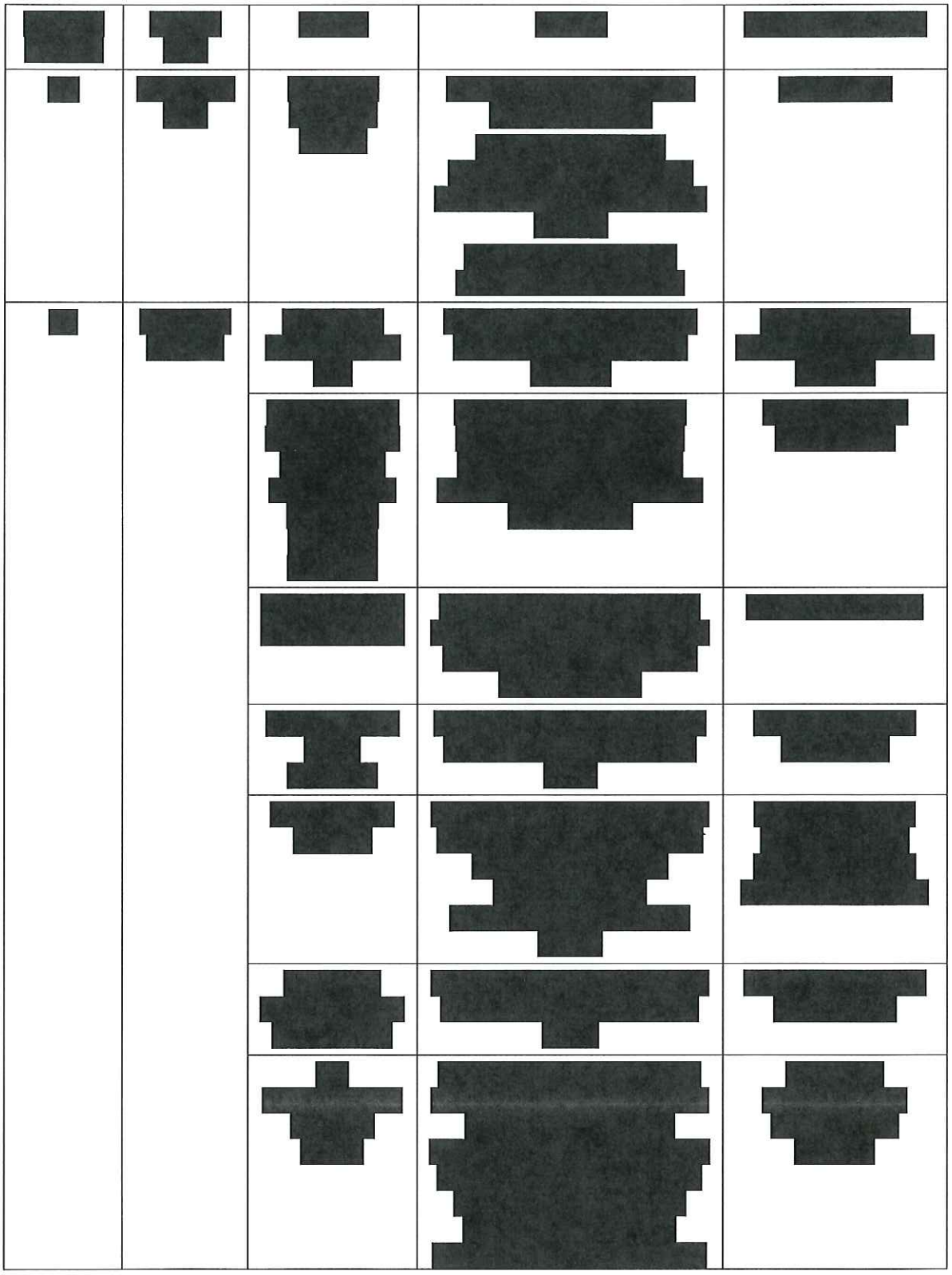

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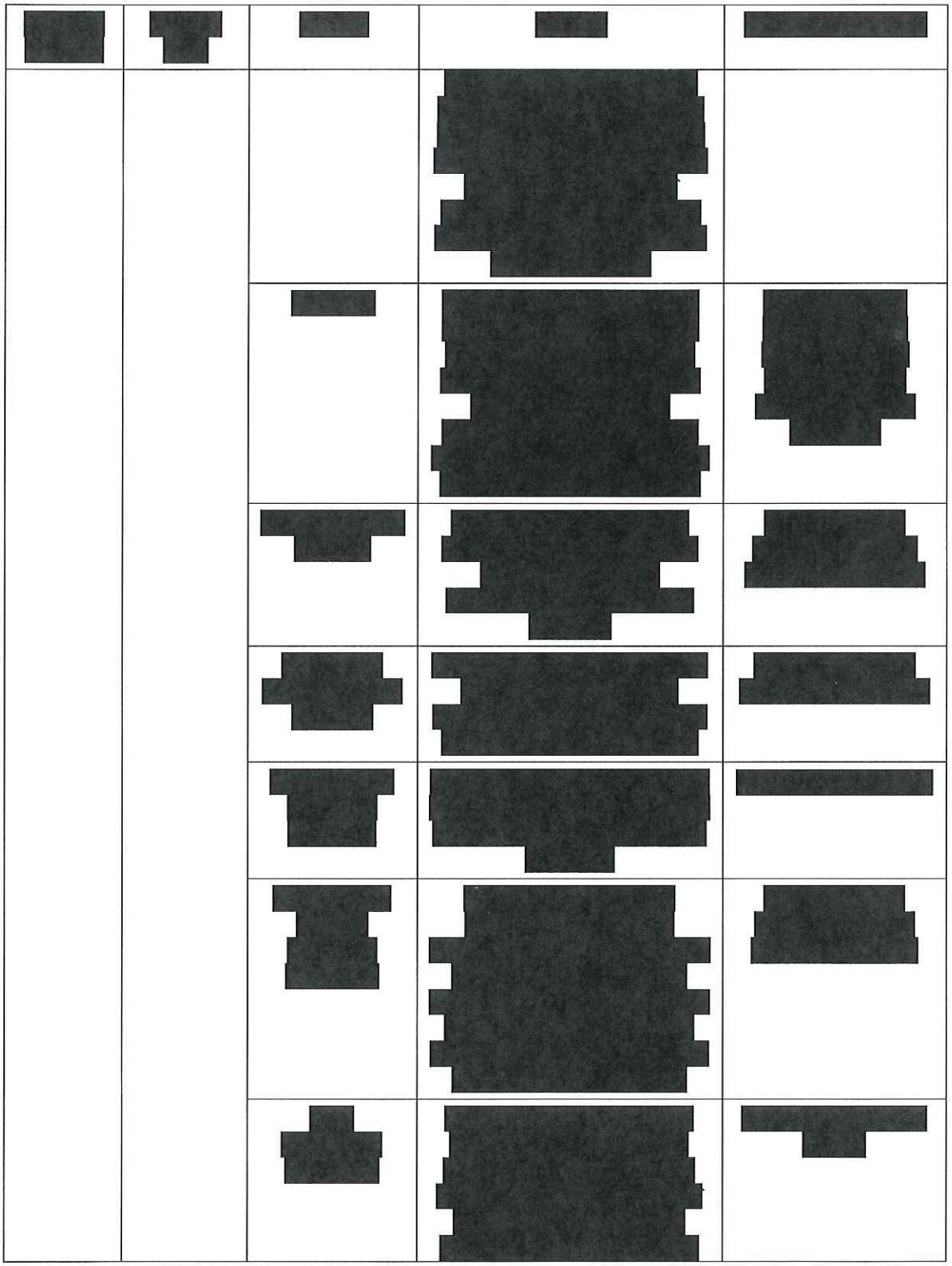

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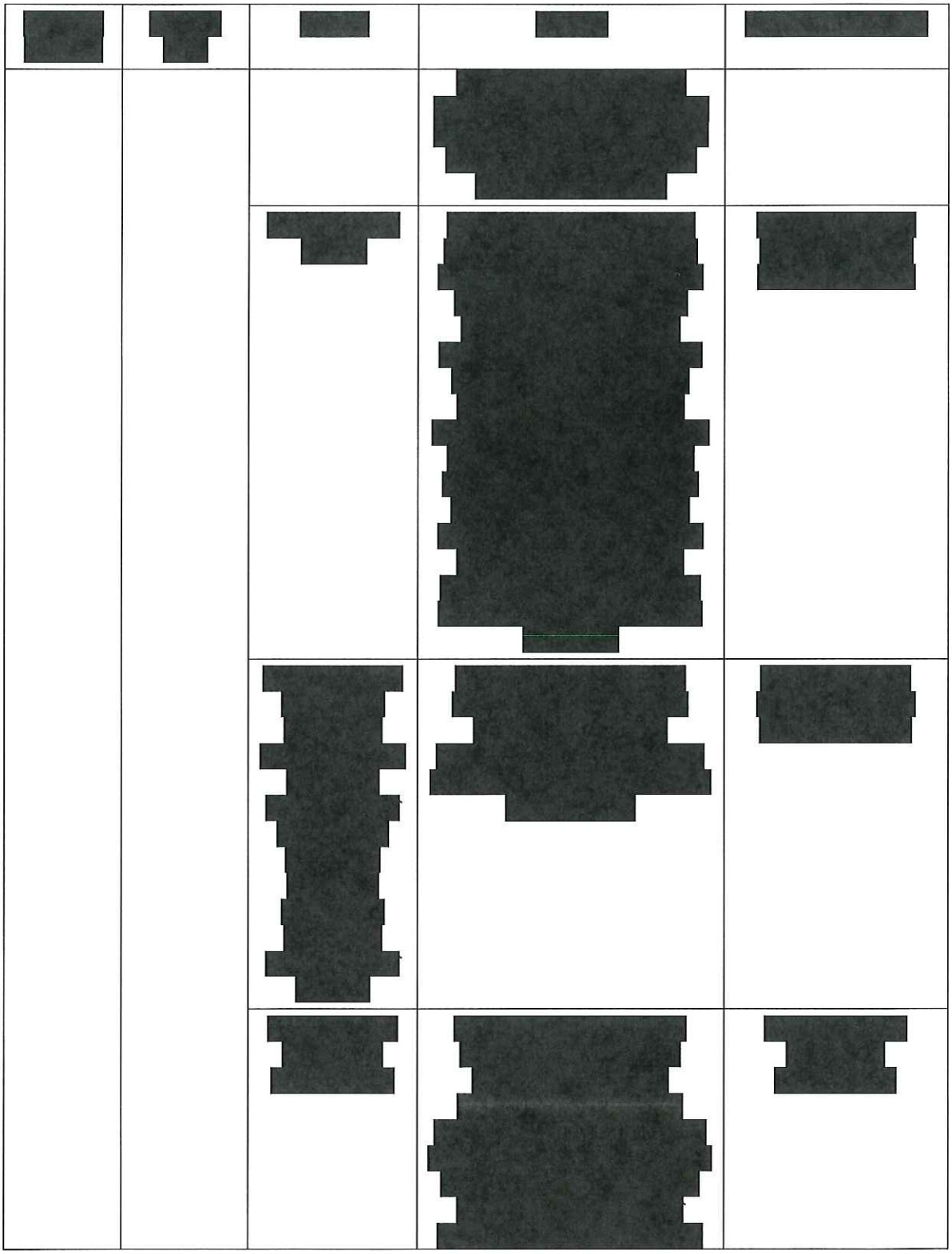

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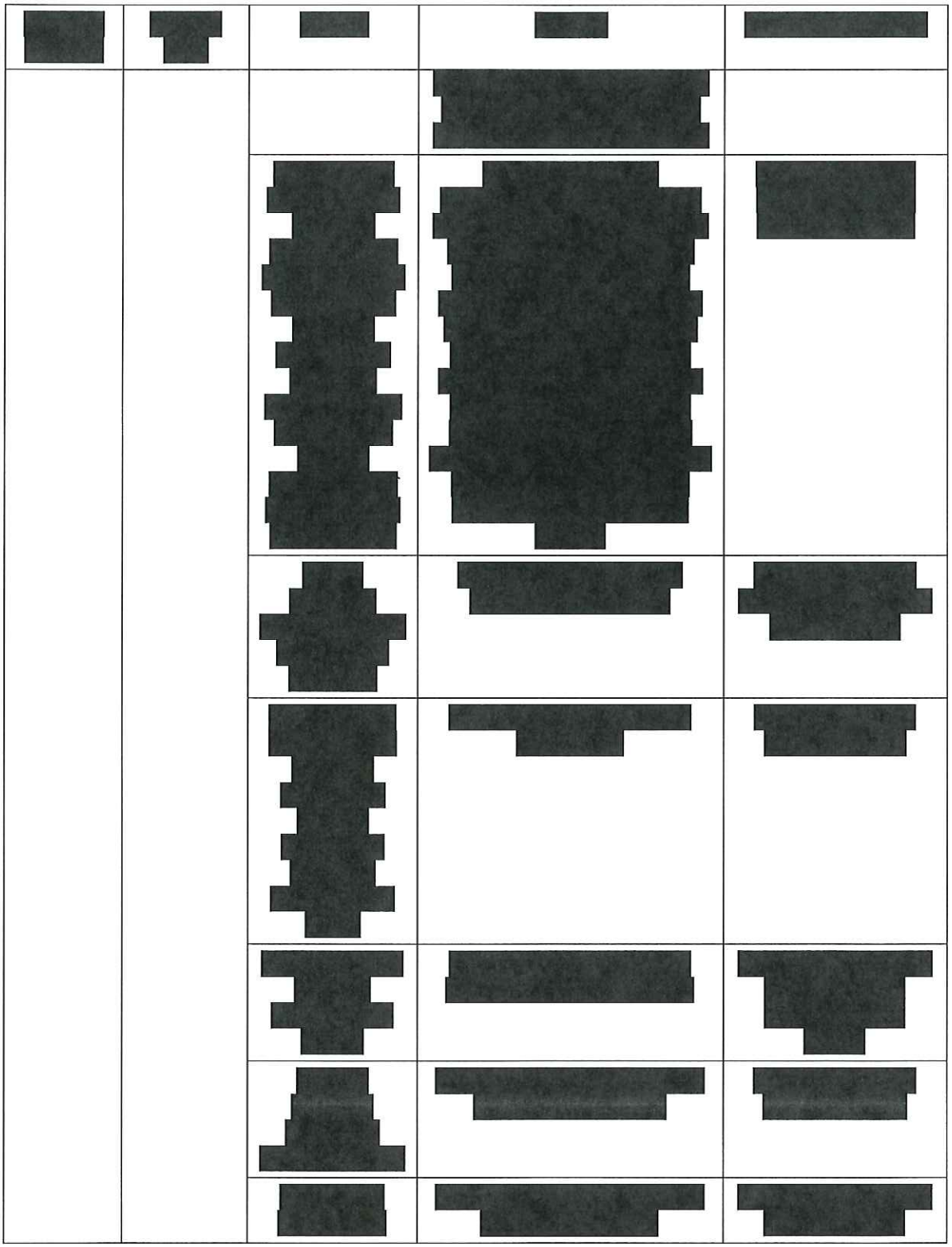

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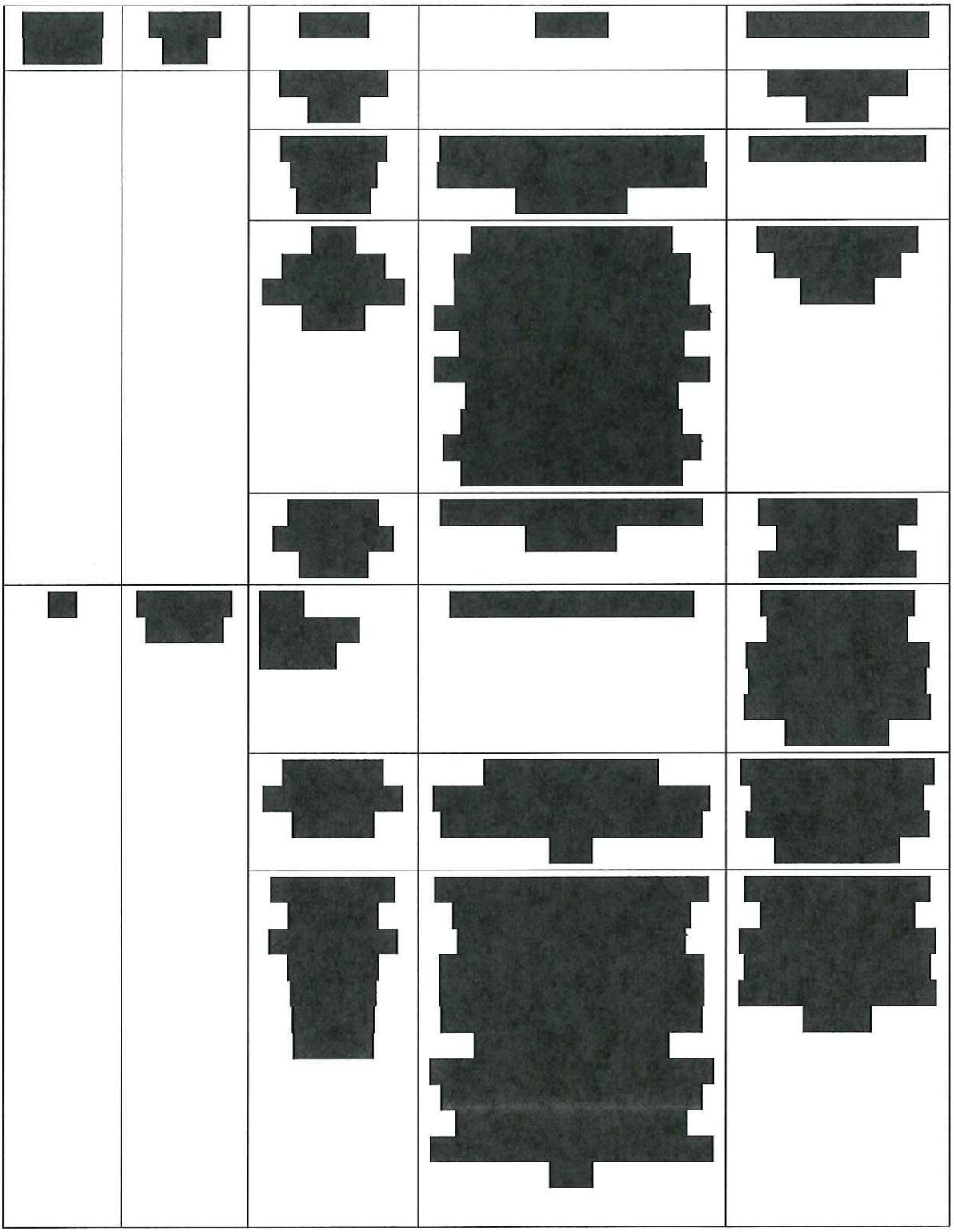

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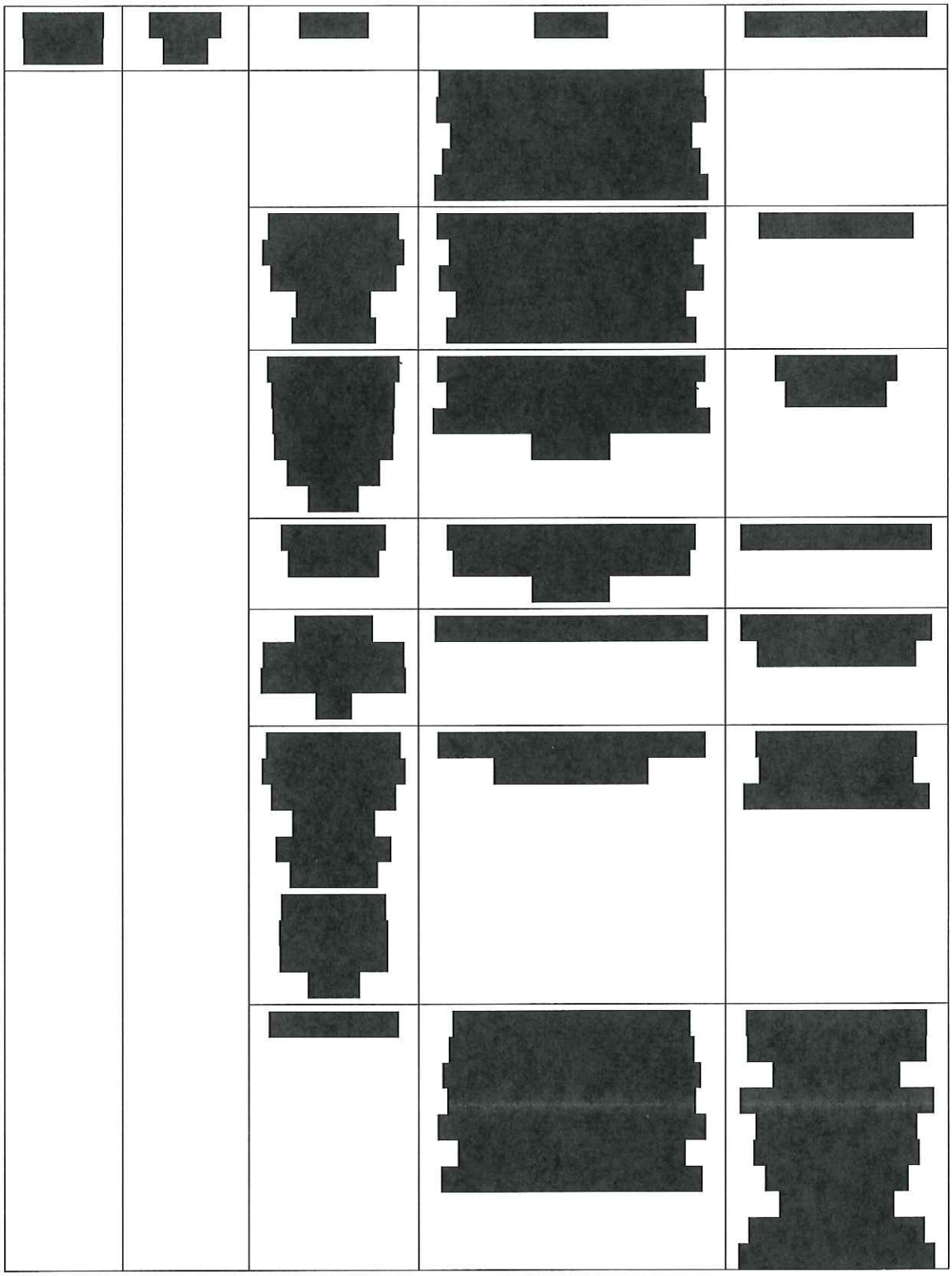

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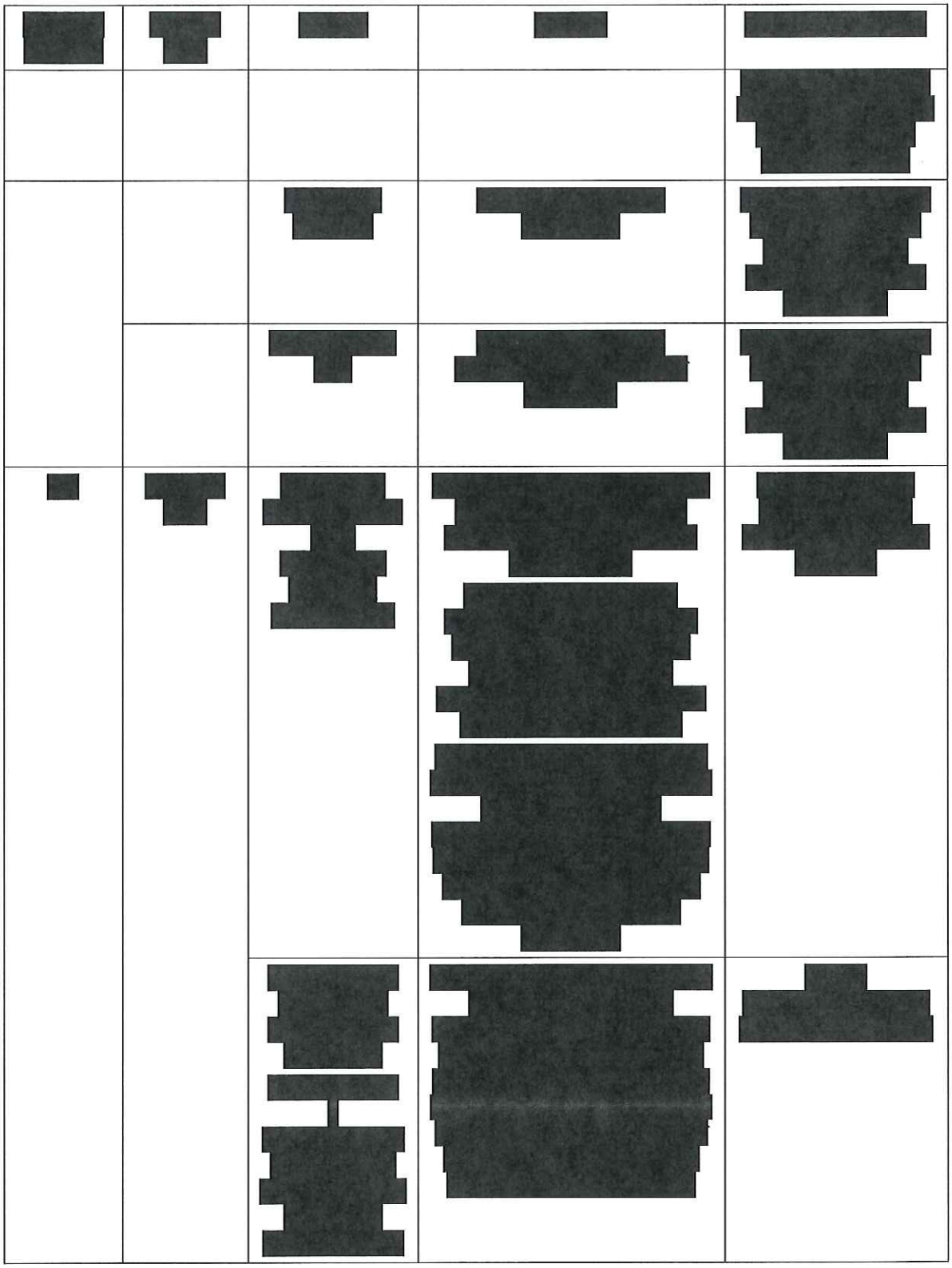

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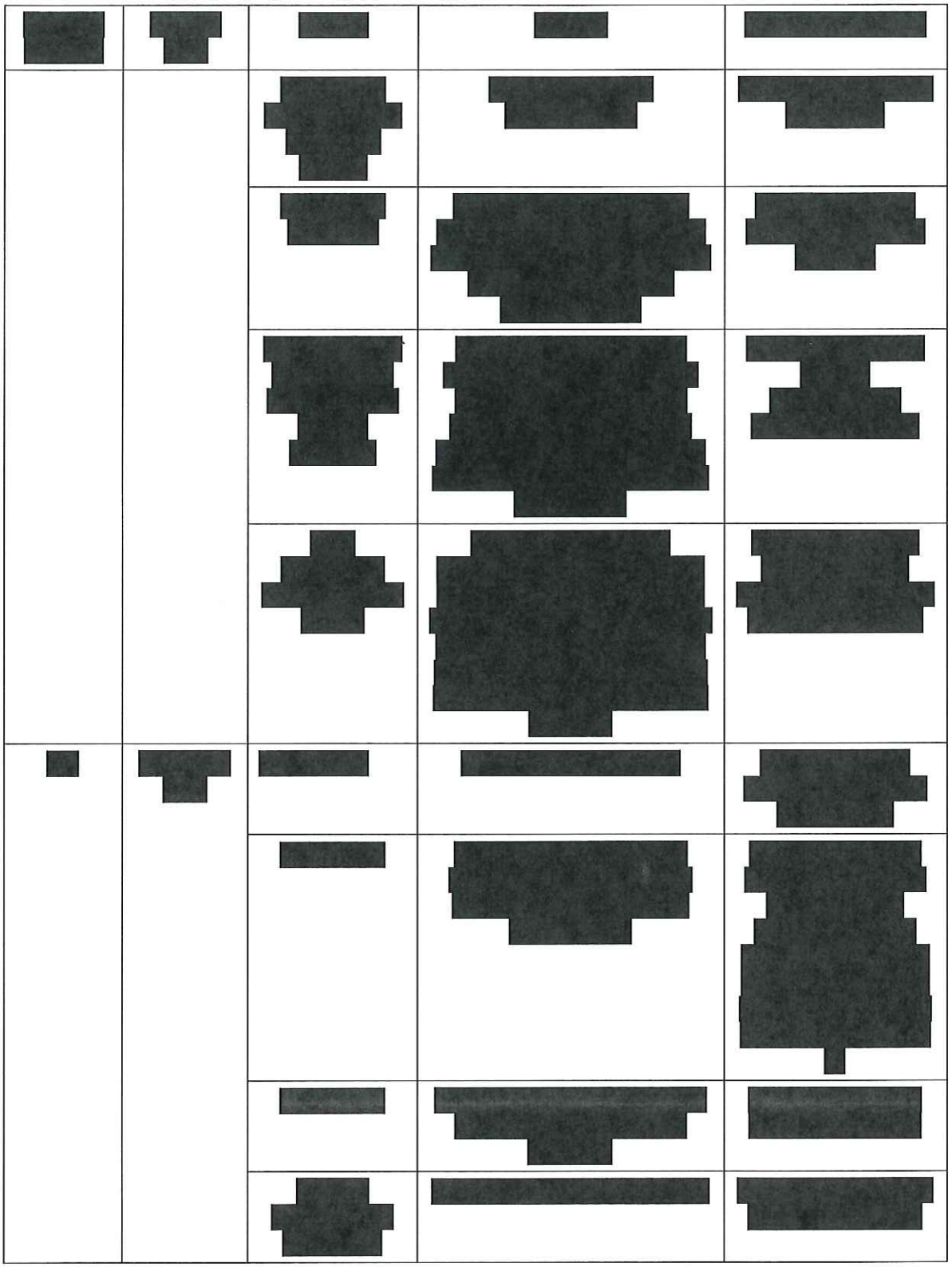

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2. Primary Protocol Synopsis*

***For subjects enrolled during protocol AA-AG. All new subjects will be enrolled under the extension (sub-study) protocol in Appendix A.**

ACCELERATE **A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation**	
Primary Objective	To evaluate the safety and effectiveness of high rate spinal cord stimulation (HR-SCS) therapy as compared to commercial rate spinal cord stimulation (CR-SCS) therapy as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain using the Boston Scientific (BSC) PRECISION Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation (PRECISION SCS System for HR)
Secondary Objective	To determine the impact of HR-SCS therapy on global patient outcomes as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain using the Boston Scientific (BSC) PRECISION SCS System for HR
Planned Indication(s) for Use	The BSC PRECISION SCS System for HR is indicated as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back pain.
Test Parameters	BSC PRECISION SCS System for HR: Stimulation rate: locked at 10kHz during crossover period, 2-1200 Hz or 2KHz – 10KHz during long-term follow-up period
Control Parameters	BSC PRECISION™ SCS System: Stimulation rate: Commercially Approved range (2-1200 Hz)
Study Design	Multi-center, randomized, controlled, non-inferiority, crossover, adaptive, open label
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ACCELERATE **A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation**	
Primary Endpoint	Low back pain responder rate at 3 months post-activation, based on reduction from Baseline in average low back pain intensity with no change from Baseline in average daily opioid intake, compared between HR-SCS and CR-SCS (*eDiary*)
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A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation

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ACCELERATE A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation	
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Additional Safety Parameters	• Rate of occurrence of all adverse events (AEs) through End of Period 2 • Rate of occurrence of all device or procedure related adverse events (AEs), SAEs including serious adverse device events (SADEs), unanticipated adverse device events (UADEs) through end of study.
Method of Assigning Patients to Treatment	Eligible subjects will be randomized in a 1:1 ratio to receive one of the following sequences: • CR-SCS followed by HR-SCS • HR-SCS followed by CR-SCS Randomization will be implemented in the Electronic Data Capture (EDC) system using a pre-generated randomization table. Random permuted blocks stratified by site will be employed to ensure approximate balance of treatment allocation.
Study Schedule	Study events occur at the following time points: • Screening (Up to 60 days following Informed Consent) • Medication Lock Visit • Period 1 Baseline (30 days)

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	• Period 1 Baseline Visit (0-7 days post Period 1 Baseline) • Permanent Implantation (0-14 days post Period 1Baseline Visit) • Healing Period (7-14 days) • Period 1 Activation Visit (Period 1 Day 0) • Period 1 Interim Programming Visit (21 ± 7 days post-Period 1 Activation Visit) • Mid Period 1 Visit (45 ± 7 days post-Period 1 Activation Visit) • End of Period 1 Visit (90 ± 14 days post-Period 1 Activation Visit) • Washout Period (7 days) • Period 2 Baseline (15 days) • Period 2 Baseline/Activation Visit (0-7 days post Period 2 Baseline) • Period 2 Interim Programming Visit (21 ± 7 days post-Period 2 Baseline/Activation Visit) • Mid Period 2 Visit (45 ± 7 days post-Period 2 Baseline/Activation Visit) • End of Period 2 Visit (90 ± 14 days post-Period 2 Baseline/Activation Visit) • End of Study Visit (365 ± 30 days post-Period 1 Activation Visit) [redacted]
[redacted]	[redacted]
Key Inclusion Criteria	IC1. Complaint of persistent or recurrent low back pain, with or without equal or lesser leg pain, for at least 180 days prior to Screening [redacted] IC5. Average low back pain intensity, during the position/activity which routinely causes worst pain, of 5 or greater on a 0-10 numerical rating

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	scale during the 7-day period prior to Screening based on study candidate recall [redacted] IC10. Willing and able to comply with all protocol-required procedures and assessments/evaluations (e.g. willing to comply with opioid prescription lock from the Medication Lock Visit through End of Period 2 and protocol required stimulation parameter locks, complete daily diary) [redacted] IC13. 22 years of age or older when written informed consent is obtained IC14. Able to independently read and complete all questionnaires and assessments provided in English IC15. If female of childbearing potential: not pregnant, as evidenced by a negative pregnancy test at Screening IC16. Subject signed a valid, IRB-approved informed consent form (ICF) provided in English
Key Exclusion Criteria	[redacted]

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[redacted]

EC9. Any pain-related diagnosis or medical/psychological condition that, in the clinician's best judgment, might confound reporting of study outcomes (e.g. pelvic pain, anginal pain, chronic migraine)

[redacted]

EC12. Current systemic infection, or local infection in close proximity to anticipated surgical field, at Screening

[redacted]

EC17. Current condition associated with risk of immunocompromise that might increase risk of infection during study duration

[redacted]

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[redacted]

EC20. Significant cognitive impairment at Screening that, in the opinion of the Investigator, would reasonably be expected to impair the study candidate's ability to assess pain intensity and/or complete an electronic pain diary

EC21. Participating (or intends to participate) in another drug or device clinical trial that may influence the data that will be collected for this study

EC22. Previous spinal cord stimulation trial or is already implanted with an active implantable device(s) (e.g. pacemaker, drug pump, implantable pulse generator)

EC23. A female who is breastfeeding

EC24. A female of childbearing potential planning to get pregnant during the course of the study or not using adequate contraception

[redacted]

EC27. Any injury or medical/psychological condition that might be significantly exacerbated by the implant surgery or the presence of an implantable stimulator or otherwise compromise subject safety

[redacted]

Statistical Methods

ACCELERATE A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation	
Primary Statistical Hypothesis	H_0: A(CR-SCS) - A(HR-SCS) > 0.10 H_1: A(CR-SCS) - A(HR-SCS) ≤ 0.10 where A(CR-SCS) and A(HR-SCS) are the cumulative distribution functions of the Responder Rates for CR-SCS and HR-SCS, respectively, and 0.10 is the non-inferiority margin.
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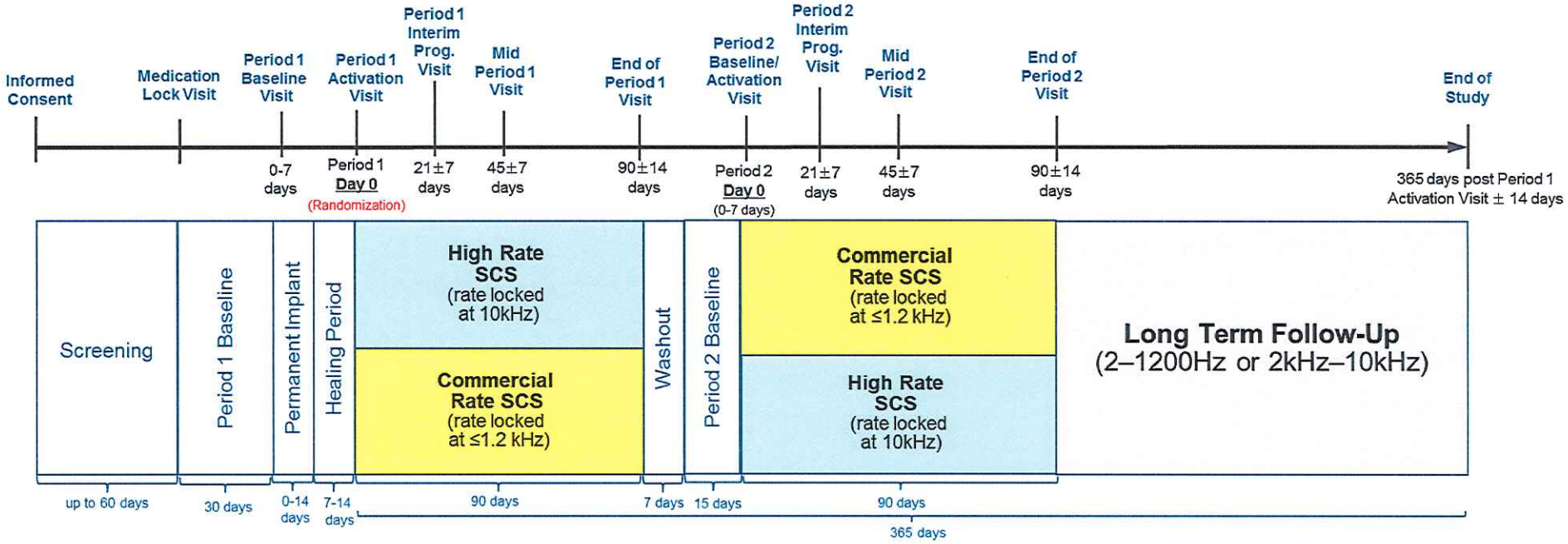
Informed Consent
Medication Lock Visit
Period 1 Baseline Visit
Period 1 Activation Visit
Period 1 Interim Prog. Visit
Mid Period 1 Visit
End of Period 1 Visit
Period 2 Baseline/ Activation Visit
Period 2 Interim Prog. Visit
Mid Period 2 Visit
End of Period 2 Visit
End of Study
0-7 days
Period 1 Day 0 (Randomization)
21±7 days
45±7 days
90±14 days
Period 2 Day 0 (0-7 days)
21±7 days
45±7 days
90±14 days
365 days post Period 1 Activation Visit ± 14 days
Screening
Period 1 Baseline
Permanent Implant
Healing Period
High Rate SCS (rate locked at 10kHz)
Commercial Rate SCS (rate locked at ≤1.2 kHz)
Washout
Period 2 Baseline
Commercial Rate SCS (rate locked at ≤1.2 kHz)
High Rate SCS (rate locked at 10kHz)
Long Term Follow-Up (2–1200Hz or 2kHz–10kHz)
up to 60 days
30 days
0-14 days
7-14 days
90 days
7 days
15 days
90 days
365 days

See below primary protocol. The primary protocol reflects requirements for subjects enrolled during protocol Versions AA-AG. All new subjects will be enrolled under the extension (sub-study) protocol in Appendix A. The extension protocol only contains information that is unique to the sub-study. Information that is common to both is not repeated.

3. Introduction

3.1. *Chronic Intractable Pain*

Chronic intractable pain is often defined as pain persisting for at least 6 months which has not responded to conservative treatment(s). The pain may be due to current or past nerve injury and causes significant disability, reduced work productivity, reduced quality of life, and significant cost burden. Early treatments for chronic pain typically include over the counter and prescription medications. Later treatments like physical therapy and interventional pain procedures (e.g. intraspinal injections, vertebroplasty, pulsed RF) are attempted, sometimes followed by chronic high dose opioids and back surgery, if indicated. If back surgery is unsuccessful in relieving the chronic pain, the patient can be labeled as having failed back surgery syndrome (FBSS). Spinal cord stimulation is an option in the well-selected patient with chronic low back and/or leg pain. Such pain can lead to a number of co-morbidities, including reduced health-related quality of life, reduced ability to engage in activities of daily living, increased disability, increased emotional depression, and weight gain due to the adoption of a sedentary lifestyle. Chronic low back and/or leg pain is typically categorized as either neuropathic, which involves pathological nerve activity and is commonly characterized by patients as 'shooting' or 'burning'; nociceptive, which involves nerve signals indicating actual or impending tissue damage or inflammation (Grabois *et al.*, 2005); or a varying mixture of neuropathic and nociceptive pain.

3.2. *Conventional Spinal Cord Stimulation*

SCS is effective for chronic intractable pain associated with a variety of conditions, including, but not limited to, FBSS (Carter et al., 2004, Taylor et al., 2004), complex regional pain syndrome (Sears et al., 2011), and low back pain and leg pain (Cameron et al., 2004). Spinal cord stimulation (SCS) is a less invasive treatment option for FBSS but has generally been reserved for patients who have failed multiple, and indeed all possible, repeat operations. With SCS, an implanted pulse generator (IPG) delivers electrical current to electrode(s) implanted in the epidural space. This current stimulates nerves and can be programmed to direct stimulation to the nerves innervating the painful location, resulting in a reduction of the intensity of that pain (Kumar et al., 2006). Before an SCS system is implanted, a patient often undergoes a screening trial with an electrode that is connected to an external stimulator that the patient wears outside of the body. The results of the screening trial can predict the patient's outcome with an implanted system (Kumar et al., 2006).

In SCS pain relief is realized when the nerves that innervate the painful region(s) are electrically stimulated (North et al., 1990). To increase the chance of success, the electrode contacts are programmed based on the patient feedback to various combinations of contact

polarities (anodes and cathodes), pulse rate (or frequency), pulse amplitude (or current), and pulse width.

In an international multi-center RCT, Kumar *et al* (2007) randomized 100 patients: 48 to conventional medical management alone (CMM group) and 52 to SCS plus CMM (SCS group). At 6 months, patients randomized to SCS achieved significantly greater pain relief and improved functional capacity and health-related quality of life compared with patients randomized to CMM. Specifically, twenty four patients in the SCS group (48%) and four patients in the CMM group (9%) achieved the primary outcome of 50% leg pain relief ($p < 0.001$) at 6 months. This trend continued over the duration of 12 months as reported in Kumar 2007 with the SCS group experiencing improved pain relief, quality of life and functional capacity, as well as greater treatment satisfaction ($p \leq 0.05$). At 24 months (Kumar 2008), 37% of patients in SCS group continued to achieve at least 50% pain relief versus 2% of patients in the CMM group ($p = 0.003$). The results from the PROCESS study provide evidence that SCS is effective and cost effective in relieving chronic neuropathic pain associated with FBSS.

In 2004, the FDA approved the Boston Scientific Corporation (BSC) PRECISION™ Spinal Cord Stimulator (SCS) System as the first rechargeable system for treatment of chronic intractable pain of the trunk and limbs. The results of a multi-center, non-randomized study conducted with this system demonstrated more than 50% pain relief through a maximum follow-up of 18 months, but the single-arm design and small number of subjects enrolled limit the strength of the conclusions (Oakley et al., 2007). To-date, over 60,000 patients have been implanted with the PRECISION™ SCS System worldwide.

3.3. *High Frequency Electrical Stimulation*

Spinal cord stimulation as a treatment for chronic pain has been utilized since the 1960s. Stimulation is delivered on a pulsatile basis, with frequencies of pulse delivery typically programmed between 2 and 1200 Hz (1Hz = 1 pulse per second). High frequency (HF) electrical neurostimulation (generally referring to stimulation using >1200 Hz) has been studied by physiologists since the late 20th century (Geddes, 1984). Neurostimulation frequencies in those ranges have been employed in various biomedical applications, including muscle strengthening (Ward et al., 2001; Ward 2009), bladder dysfunction (Jezernik et al., 2002), cochlear stimulation (House and Berliner, 1986; Zhang et al., 2005; Mueller et al., 2011), obesity (Camilleri et al., 2008), and chronic pain (Smet et al., 2011 a&b; Van Buyten et al., 2011). Stimulation of first order sensory nerves may exhibit a similar mechanism of action to spinal cord stimulation and therefore may provide an insight into the safety of spinal cord stimulation.

3.3.1. *HF Stimulation for Muscle Strengthening*

Transcutaneous electrical stimulation using kilohertz frequencies became popular in the 1950's for producing depth-efficient stimulation of nerve and muscle as a means for muscle

strengthening (Ward *et al.,* 2009). To this end, frequencies have been evaluated from 1 kHz up to 25 kHz (Ward et al., 2001; Ward et al. 2009).

3.3.2. *HF Stimulation for Bladder Dysfunction*

High frequency neurostimulation has been utilized in spinal cord injury (SCI) patients for the treatment of bladder dysfunction. Over 2000 patients have been implanted with sacral ventral root stimulators such as the Finetech-Brindley Bladder System. This is the only commercialized and FDA-approved solution for micturition in SCI patients (Jezernik et al., 2002).

The mechanism by which the urethral sphincter inhibition is obtained is not well understood; high-frequency stimulation may stop the propagation of nerve action potentials, and maintain the neuromuscular junction in a refractory status. Frequencies from 300 Hz to 30 kHz can be used to achieve a complete and reversible nerve conduction block depending on the stimulation amplitude (Mounaim et al., 2011). However, below 1 kHz, a sinusoidal stimulation can generate action potentials at the same or a submultiple rate. Increasing the frequency has the advantage of lowering the amount of injected charge per-phase needed for a complete blockade.

3.3.3. *Cochlear Implants and High Frequency Stimulation*

Cochlear implants (CIs) have also utilized high frequency neurostimulation. As of December 2010, approximately 219,000 people worldwide have received CIs; in the U.S., roughly 42,600 adults and 28,400 children are recipients (NIH publication No. 11-4798). In the 1970's House et al, commenced work on a single-channel device with a five-wire electrode, in this case, the speech was modulated onto a carrier of 16 kHz. The device, manufactured by 3M, was ultimately implanted in nearly a thousand patients and this paved the way for future clinical development of multichannel CIs. The House/3M unit was the first approved by the FDA for implantation in adults in 1984. In 1990 the FDA lowered the approved age for CI implantation to two years of age, then lowered the age to 18 months in 1998, and finally to 12 months of age in 2000. Currently most commercially available CIs stimulate with pulse rates ranging from 250 Hz to 5 kHz (Zhang et al., 2007).

Clinical data on cochlear implant patients with variable follow up durations (from 3 months to 1 year) has also shown safe use of these devices (House and Berliner, 1986; Mueller et al., 2011). Safety analyses in cohorts of >450 patients have shown no unexpected adverse effects as a result of the implant surgery, and minimal adverse events as a result of electrical stimulation on the auditory system. House and Berlinger (1986) provided a review of efficacy data in 250 patients and safety data in 369 patients over a period of 1 year follow up. Mueller et al., 2011 performed a multicenter-study in 50 cochlear implant patients (30 adults and 20 children). Although both these articles discussed surgical harms in implanted patients, none were related to the stimulation therapy or to the implant.

3.3.4. *HF Stimulation for Obesity*

High frequency neurostimulation (5 kHz) has been used to treat obesity and metabolic diseases (Camilleri et al., 2008). EnteroMedics Maestro® VBLOC® (St. Paul, MN) stimulates and blocks the vagus nerve. Two small electrodes are laparoscopically implanted and placed in contact with the trunks of the vagus nerve just above the junction between the esophagus and the stomach. The Maestro RC System has received CE Mark and has been listed on the Australian Register of Therapeutic Goods. Camilleri et al, 2008 conducted an open-label, 3-center study in 31 obese subjects, in whom electrodes were implanted laparoscopically on both vagi near the esophagogastric junction to provide electrical block. The therapeutic rate selected to block neural impulses on the vagal trunks was 5000 Hz, amplitudes utilized ranged from 1–6 mA. The device was activated in the morning, and turned off before sleep. Patients were followed for 6 months to assess safety and eating habits. Although adverse events were reported in this study, none were related to the device or therapy.

3.3.5. *HF Stimulation for Pain*

Neuros Medical, Inc., (Cleveland OH), a US medical device company, announced IDE approval from the U.S. Food and Drug Administration to commence a pilot clinical trial to evaluate the company's high frequency (5 – 30 kHz) Electrical Nerve Block™ technology for use in acute treatment of pain in the residual limb of amputees. The IDE approval builds off of the company's first human feasibility study on patients with chronic amputation pain. The pilot study reported that four out of five study patients reported significant pain reduction and some reported zero pain post-treatment.

High-Frequency (up to 10 kHz) spinal cord stimulation has also been evaluated in chronic pain patients. Nevro Corporation's Senza™ System (Menlo Park, CA) delivers electrical stimulation at higher rates than conventional SCS devices (Smet et al., 2011 a&b; Van Buyten et al., 2011). Data from previous European clinical studies suggest that Nevro's therapy may be effective in treating leg and back pain and other challenging types of chronic pain that often do not respond to conventional spinal cord stimulation (Smet et al., 2011 a&b; Van Buyten et al., 2011).

These data also indicate significant and sustained pain reduction in patients with chronic back and leg pain. This study reported that 87% of their patients had predominant back pain, and 80% had pain following prior one or more back surgeries. Study results showed that, following treatment with the Senza™ System, average back pain VAS scores dropped from 8.4 at baseline to 1.9 at twelve month follow-up. Average VAS leg pain scores were reduced from 5.4 at baseline to 1.6 at twelve months. The Senza™ high-frequency spinal cord stimulation system is authorized for sale in Europe and Australia. In May 2012, Nevro received FDA approval to initiate a randomized pivotal trial evaluating the safety and effectiveness of the Senza™ system.

Boston Scientific has undergone development to expand the range of stimulation rates that the commercially available PRECISION™ SCS System (approved in 2004 under PMA #

P030017) can deliver (See Section 5). The purpose of this study is to evaluate the safety and effectiveness of high rate spinal cord stimulation (HR-SCS) therapy as compared to commercial rate spinal cord stimulation (CR-SCS) therapy as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain using the Boston Scientific (BSC) PRECISION SCS System for HR)

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[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

4.1. *Device Labeling*

Directions for use (DFU) will be provided to each Investigator. The study devices and packaging are physically identified and labeled as applicable. The device labeling contains the following information:

- Device description
- Model number
- Serial number / Lot number as applicable
- Device dimension (i.e. Length), as applicable
- Manufacturing location
- Expiration date ("use before date"), as applicable
- Labeled for investigational use

5. Objectives

5.1. *Primary Objective*

The primary objective of this study is to evaluate the safety and effectiveness of high-rate spinal cord stimulation (HR-SCS) therapy as compared to commercial rate spinal cord stimulation (CR-SCS) therapy as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain using the Boston Scientific (BSC) PRECISION Spinal Cord Stimulator System Adapted for High Rate Spinal Cord Stimulation (PRECISION SCS System for HR).

5.2. *Secondary Objective*

The secondary objective of this study is to determine the impact of HR-SCS therapy on global patient outcomes as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain using the Boston Scientific (BSC) PRECISION SCS System for HR.

6. Endpoints

6.1. *Primary Endpoint*

The primary endpoint is the comparison of low back pain responder rate in the HR-SCS group to that of the CR-SCS group at 3 months post-activation, based on reduction from Baseline in average low back pain intensity with no change from Baseline in average daily opioid intake as assessed by the eDiary.

[redacted]

[redacted]

[redacted]

6.6. *Additional Safety Parameter*

Additional safety parameters include the following:

- Rate of occurrence of all adverse events (AEs) through End of Period 2
- Rate of occurrence of all device or procedure related adverse events (AEs), SAEs including serious adverse device events (SADEs), unanticipated adverse device events (UADEs) through end of study.

7. Design

The study is a multi-center, randomized, controlled, non-inferiority, crossover, adaptive, open label design. In this crossover design, eligible subjects will be randomized in a 1:1 ratio to receive one of the following sequences:

- CR-SCS followed by HR-SCS
- HR-SCS followed by CR-SCS

using the Boston Scientific PRECISION™ SCS System and the Boston Scientific PRECISION SCS System for HR. The study is open label, thus the study participants, investigative site personnel, and the sponsor will not be blinded. All subjects will undergo permanent system implantation. The study design is shown in Figure 7-1.

[redacted]

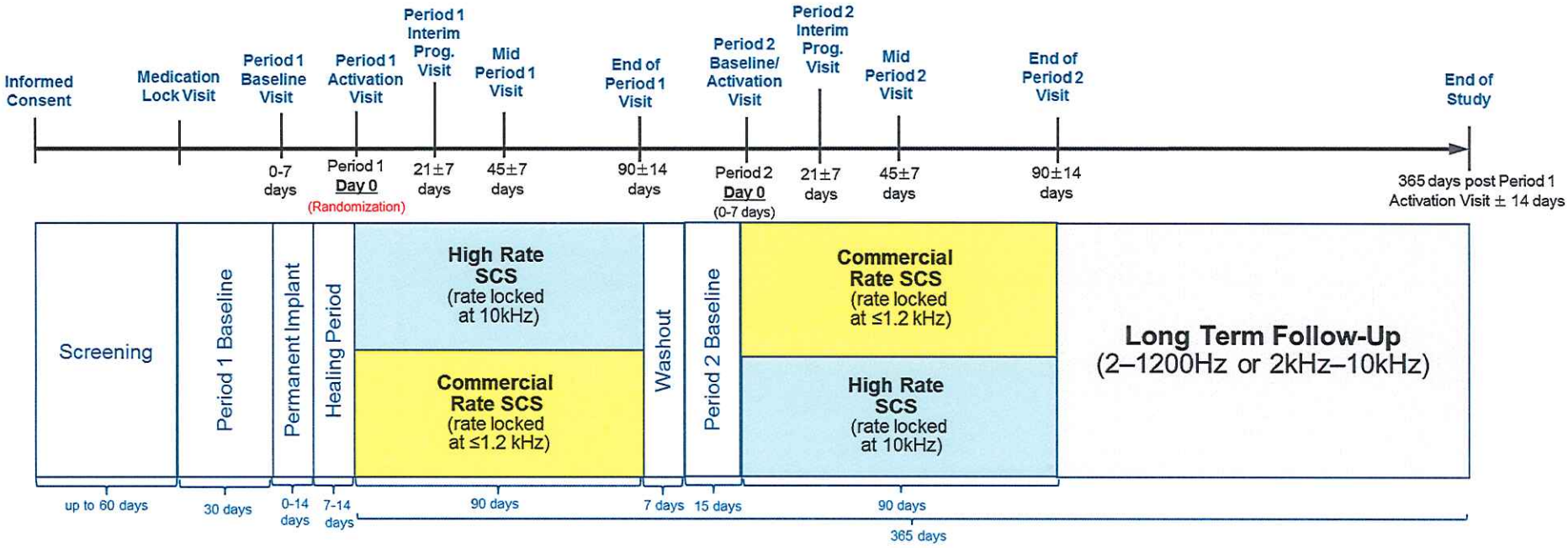


Figure 7-1. ACCELERATE Study Design

7.2. *Treatment Assignment*

Eligible subjects will be randomized in a 1:1 ratio to receive one of the following sequences:

- CR-SCS followed by HR-SCS
- HR-SCS followed by CR-SCS

Randomization will be implemented in the Electronic Data Capture (EDC) system using a pre-generated randomization table. Random permuted blocks stratified by site will be employed to ensure approximate balance of treatment allocation.

7.3. *Treatment and Control*

The treatment device is the Boston Scientific PRECISION SCS System with high-rate stimulation parameters. The control device is the Boston Scientific PRECISION™ SCS System with commercially approved stimulation parameters. See Section 4 for details regarding HR-SCS and CR-SCS therapies.

7.4. *Justification for the Study Design*

The study is a randomized controlled crossover, non-inferiority, adaptive, open label study of spinal cord stimulation using high rate stimulation parameters for the treatment of chronic intractable pain as compared to commercial rate stimulation parameters. The study will evaluate if high rate stimulation parameters are non-inferior to commercially approved stimulation parameters in the reduction of low back pain intensity in the population with chronic pain (See Section 8 for study inclusion and exclusion criteria). Chronic low back pain is historically more difficult to treat than other pain regions (e.g. lower extremity) and thus high rate SCS therapy may allow for expanded treatment options for these patients.

A multi-center design will minimize the impact on treatment outcome that may potentially result from differences in patient selection, regional differences in the patient demographic, and differences in investigator technique and patient management.

A prospective study design will eliminate the bias associated with case selection in a retrospective review and will ensure that identical procedures are followed for data capture and review.

The study design includes two groups (arms) – a treatment group (HR-SCS) and a control group (CR-SCS). The treatment group will receive stimulation using high rate SCS system, while the control group will receive stimulation using a commercially-approved SCS system. The control group will serve as a comparator to the standard-of-care in spinal cord stimulation therapy using currently-approved stimulation rates.

Randomization will be used to minimize selection bias and the impact of demographic variables.

The primary efficacy endpoint will be measured at 90 days post-activation of the SCS system because this represents a duration sufficient for a subject to have their programming parameters optimized as well as to allow for therapy to become stable.

The responder rate, as measured by reduction in baseline low back pain intensity as measured daily using the numerical rating scale during the 15 day period prior to Baseline Visit and 3-months post-activation, was chosen as the primary endpoint as it provides a clinically-relevant metric to assess the pain-relieving impact of the therapy.

The electronic diary will be administered daily under real-life conditions as subjects continue to use their device and medication. The analysis window of 15 consecutive days of electronic diary completion was chosen to adequately capture the normal fluctuations in pain intensity that is typical with chronic pain. Additionally, the numerical rating scale for measuring pain intensity is a validated measure and has been used in other randomized controlled trials to measure the outcomes of SCS.

8. Subject Selection

8.1. *Study Population and Eligibility*

Study candidates will be drawn from the population of patients resident in pain management or surgical medical practices. The study eligibility criteria are listed in Sections 8.2 and 8.3.

8.2. *Inclusion Criteria*

Subjects who meet all of the following criteria (see Table 9-1) will be considered for inclusion in this clinical investigation, provided no exclusion criterion (see Table 9-2) is met.

Table 8-1. Inclusion Criteria

Clinical Inclusion Criteria	IC1. Complaint of persistent or recurrent low back pain, with or without equal or lesser leg pain, for at least 180 days prior to Screening [redacted] IC5. Average low back pain intensity, during the position/activity which routinely causes worst pain, of 5 or greater on a 0-10 numerical rating scale during the 7-day period prior to Screening based on study candidate recall [redacted] IC10. Willing and able to comply with all protocol-required procedures and assessments/evaluations (e.g. willing to comply with opioid prescription lock from the Medication Lock Visit through End of Period 2 and protocol required stimulation parameter locks, complete daily diary) [redacted] IC13. 22 years of age or older when written informed consent is obtained IC14. Able to independently read and complete all questionnaires and assessments provided in English IC15. If female of childbearing potential: not pregnant, as evidenced by a negative pregnancy test at Screening IC16. Subject signed a valid, IRB-approved informed consent form (ICF) provided in English

8.3. *Exclusion Criteria*

Subjects who meet any one of the following criteria (Table 9-2) will be excluded from this clinical study.

Table 8-2. Exclusion Criteria

Clinical Exclusion Criteria	[redacted] EC9. Any pain-related diagnosis or medical/psychological condition that, in the clinician's best judgment, might confound reporting of study outcomes (e.g. pelvic pain, anginal pain, chronic migraine) [redacted] EC12. Current systemic infection, or local infection in close proximity to anticipated surgical field, at Screening [redacted] EC17. Current condition associated with risk of immunocompromise that might increase risk of infection during study duration [redacted]

[redacted]

EC20. Significant cognitive impairment at Screening that, in the opinion of the Investigator, would reasonably be expected to impair the study candidate's ability to assess pain intensity and/or complete an electronic pain diary

EC21. Participating (or intends to participate) in another drug or device clinical trial that may influence the data that will be collected for this study

EC22. Previous spinal cord stimulation trial or is already implanted with an active implantable device(s) (e.g. pacemaker, drug pump, implantable pulse generator)

EC23. A female who is breastfeeding

EC24. A female of childbearing potential planning to get pregnant during the course of the study or not using adequate contraception

[redacted]

	EC27. Any injury or medical/psychological condition that might be significantly exacerbated by the implant surgery or the presence of an implantable stimulator or otherwise compromise subject safety [redacted]

9. Subject Accountability

9.1. *Point of Enrollment*

A subject will be considered enrolled in the study at the time that the informed consent form is signed. Subjects who are discontinued prior to randomization are considered "enrolled but not randomized." All enrolled and randomized subjects will be included in the study analyses.

If device implantation is unsuccessful, the subject will be followed for 2 weeks post implantation attempt to assess for procedure related adverse events. Implant failures will be withdrawn from the study and will be handled as described in Section 10.2.

9.2. *Withdrawal*

All subjects enrolled in the clinical study (including those withdrawn from the clinical study or lost to follow-up) shall be accounted for and documented. If a subject withdraws from the clinical investigation, the reason(s) shall be reported. If such withdrawal is due to problems related to investigational device safety or performance, the investigator shall ask for the subject's permission to follow his/her status/condition outside of the clinical study.

While study withdrawal is discouraged, subjects may withdraw from the study at any time, with or without reason and without prejudice to further treatment. In all cases of withdrawal or discontinuation, the Investigator will make all reasonable efforts to determine the reason for the subject's withdrawal. Subjects may be discontinued from the study for the various reasons, such as:

- Withdrawal of consent;
- A safety concern defined by the Principal Investigator and/or BSN (e.g., adverse event);
- Study non-compliance;
- Subject did not meet inclusion criteria or met an exclusion criteria after signing informed consent
- Subjects not agreeing to a recommended revision;
- Loss to follow-up;
- Death of the subject.

Withdrawn subjects will be followed per End of Study Action Plan.

9.3. *Subject Status and Classification*

Subjects who provide written informed consent but do not meet all of the study eligibility criteria will not be implanted and randomized. These subjects will be deemed as "enrolled but not randomized" and their reason for ineligibility will be documented in the EDC system. Enrolled subjects who are not randomized will not count towards the enrollment cap. Subjects who sign consent, meet all eligibility criteria, and are randomized cannot be replaced.

[redacted]

9.5. *End-of-Study Action Plan*

The End-of-Study Action Plan (ESAP) defines the actions to be taken when a subject reaches the end of their study participation. At the time of subject withdrawal or during the last study follow-up visit the ESAP will be implemented.

All ESAP decisions made by a subject need to be documented in the subject's source documents.

Device related medical events/deficiencies should be reported to BSN Patient Care at: **866-360-4747** for subjects who choose to retain the device after withdrawal or who have completed participation prior to approval of the device. Such complications should not be captured as adverse events in the EDC system.

If the subject is explanted as part of the ESAP, it is recommended that the subject be evaluated by their study doctor for any complications of the explant procedure and followed for 30 calendar days for adverse events related to the explant procedure or longer until the adverse events have either resolved or stabilized, per investigator discretion. Complications of the explant procedure should be captured as adverse events and/or a device deficiency in the EDC system.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

10. Study Methods

10.1. *Data Collection*

There are a number of different study assessments required at each visit. The data collection schedule is provided in Table 11-1. Full descriptions for all assessments are provided in Section 12.

Table 10-1: Data Collection Schedule

	Screening	Medication Lock Visit	Period 1 Baseline (30 days)	Period 1 Baseline Visit (0-7 days post Period 1 Baseline)	Permanent Implantation (0-14 days post-Period 1 Baseline Visit)	Healing Period (7-14 days)	Period 1 Activation Visit (Day 0)	Period 1 Interim Programming Visit (21 days ± 7)	Mid Period 1 Visit (45 days ±7)	End of Period 1 Visit (90 days ±14)	Washout Period (7 days)	Period 2 Baseline (15 days)	Period 2 Baseline Visit/ Activation Visit (Day 0)	Period 2 Interim Programming Visit (21 days ± 7)	Mid Period 2 Visit (45 days ±7)	End of Period 2 Visit (90 days ±14)	End of Study Visit (365 ± 30 days post-Period 1 Activation)	Unscheduled Visit
Adverse Event (AE)	X	X	X	X	X		X	X	X	X		X	X	X	X	X	X	X
Beck Depression Inventory (BDI-II)				X						X			X			X	X	
Columbia Suicide Severitry Rating Scale (C-SSRS)				X						X			X			X	X	
Concomitant Medications		X		X	X		X		X	X			X		X	X	X	X
Demography				X														
Electronic Diary (eDiary)		Give eDiary →														Collect eDiary		
EQ-5D 5 Level (EQ-5D-5L)				X						X			X			X	X	
Inclusion/Exclusion Criteria Evaluation	→			→														
Informed Consent (ICF)	X																	
Long-Term Therapy Selection (LTTS)																X		
Medical History				X														
Neurological Assessment				X						X			X			X	X	
Oswestry Disability Index version 2.1a (ODI v2.1a)				X						X			X			X	X	
Pain Intensity				X						X			X			X	X	
Patient Global Impression of Change (PGI-C)										X						X	X	
Percent Pain Relief (PPR)										X						X	X	
Physical Exam				X									X					
Pittsburgh Sleep Quality Index (PSQI)				X						X			X			X	X	
Post-Operative Evaluation							X											
Procedure Information					X													X**
Programming Parameters							X	X	X*	X			X	X	X*	X	X	X***
Resource Utilization Inventory (RUI)				X						X			X			X	X	
Short Form Health Survey 36 item (SF-36v2)				X						X			X			X	X	
Short Form McGill Pain Questionnaire (SF-MPQ-2)				X						X			X			X	X	
Stimulation Sesnation Questionnaire (SSQ)										X						X	X	
Treatment Satisfaction Questionnaire (TSQM-9m)										X						X	X	
Work Productivitiy & Impairment (WPAI:SHP V2.0)				X						X			X			X	X	

*Last programming until the End of Period Visit. ← Opioid Medications Locked →

**For unscheduled visits where procedures are performed.

***Only when device programming is performed.

10.2. *Study Candidate Screening (Up to 60 days following Informed Consent)*

Inclusion and Exclusion criteria listed in Sections 9.2 and 9.3, respectively, will be assessed to determine study candidate eligibility. Screening is a process that includes criteria being assessed from the time of informed consent through the Period 1 Baseline Visit. The 60 day window for screening reflects the maximum timeframe from which a patient can be consented and for screening activities to begin prior to completing the medication lock visit. Subjects who have provided informed consent and who have been determined to not meet all eligibility requirements prior to randomization will be withdrawn.

10.3. *Informed Consent*

Written Informed Consent must be obtained for all patients who are potential study candidates. Study candidates will be asked to sign the Informed Consent form before any study-specific tests or procedures are performed. The context of the study must be fully explained to the study candidate in language that is easily understood by the study candidate. Study candidates must also be given the opportunity to ask questions and have those questions answered to their satisfaction. The Informed Consent form is study-specific and must be approved by the site Institutional Review Board (IRB). Study personnel should explain that even if a study candidate agrees to participate in the study and signs an Informed Consent form, certain diagnostic or screening procedures might demonstrate that the study candidate is not eligible to continue participation.

Research study candidates in the State of California will also be provided with the California Experimental Patient's Bill of Rights.

10.3.1. *Post-Consent Eligibility Validation*

After obtaining written informed consent, the following tests may be conducted to evaluate study-specific eligibility criteria. Study candidates not meeting the eligibility criteria will be withdrawn:

[redacted]

[redacted]

Subjects taking prescription opioids for primary chronic pain complaint (low back and/or leg pain) whose pain medications are not stable for 30 days following informed consent will be withdrawn however may be reconsented and rescreened once 30 days have passed.

10.4. *Medication Lock Visit*

The Medication Lock Visit will occur after completion of screening requirements as described in Section 10.2. At this visit, subjects' opioid medications will be locked (no change in type/dose/route) and will remain unchanged until End of Period 2 visit.

- **Visit Type:** In-office
- **Required Attendees:** Subject; Clinical Research Coordinator (CRC) and/or Investigator
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **Medications:** During the screening period or at this visit, the investigator will convert the subject's opioid medication prescriptions from PRN to a fixed dose, as needed. Subjects will be reminded not to make any changes to their opioid medications (type/dose/route) through End of Period 2 Visit and record their opioid medication use daily, as directed by the eDiary. The details regarding protocol medication requirements are summarized in Section 11.22.
- **eDiary:** At the end of this visit subjects will be given an eDiary for daily use during the Baseline period through the End of Period 2 Visit. The eDiary will collect information regarding subjects' pain intensity, medication and device charging compliance (after permanent implantation) and subjects will be instructed on the use of the eDiary. The details regarding the information collected in the eDiary is summarized in Section 13.1.1

10.5. *Period 1 Baseline*

Period 1 baseline will last for 30 consecutive days following the Medication Lock visit. During this period, subjects will be asked to answer all questions on the eDiary daily for 30

consecutive days beginning with the first entry the day following receipt of the eDiary. Subjects will return to the clinic with their eDiary for the Period 1 Baseline Visit.

10.6. *Period 1 Baseline Visit (0-7 days post Period 1 Baseline)*

At the Period 1 Baseline Visit, subjects will return to the office with their eDiary to evaluate their continuing eligibility in the study. Subjects that meet all study criteria will be scheduled for the device implant procedure. If subjects fail to meet all the eligibility criteria, they will be withdrawn from the study.

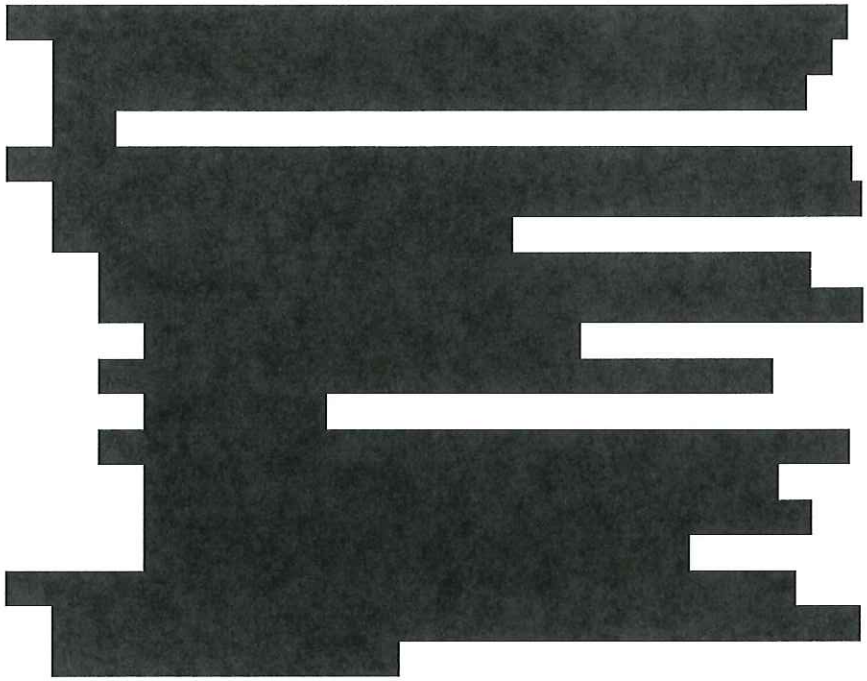
- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed at the beginning of the visit.
- **eDiary:** All eDiary inclusion and exclusion criteria will be evaluated by the investigator. Subject's compliance to the fixed opioid dose will also be assessed. Subjects who do not meet required inclusion/exclusion criteria will be withdrawn. The eDiary will be reviewed during the visit and all eligible subjects will be instructed to continue completing their eDiary daily.
- **End of Visit Information:** Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and record their opioid medication use daily, as directed by the eDiary.

10.7. *Permanent Implantation (0-14 days Post Period 1 Baseline Visit)*

Subjects have up to 14 days to receive their Precision SCS System implant. All subjects in this study will proceed directly to permanent implantation and not undergo a screening trial. Subjects where implant procedure was unsuccessful will be withdrawn from the study as summarized in Section 9.2.

- **Visit Type:** Procedure
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** The eDiary will be reviewed and updated as needed (e.g. addition of new acute opioid medications for procedural discomfort) during the visit and subjects will be instructed to continue completing their eDiary daily.

[redacted]



- **Programming Requirements:** The IPG may be programmed but, following the completion of programming, the device will be OFF until the Period 1 Activation Visit.
- **Acute Opioid Pain Medication:** The use of acute opioid pain medication for procedural discomfort is allowed, per site's routine care.
- **End of Visit Information:** Following the implant procedure, instructions related to follow up care will be provided.
    - Subjects are to contact the site in an event that any additional intervention is warranted, to report a suspected adverse event, etc.
    - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.
    - If device implantation is unsuccessful, subjects will be followed for 2 weeks post implantation in an attempt to assess for procedure related adverse events, if they occur.

10.8. *Healing Period (7-14 days)*

The subject's device will remain inactivated (device OFF) for 7-14 days following the permanent implantation procedure to allow for healing. Acute opioid pain medications may be taken during this period. No additional scheduled assessments will be completed during this period. Subjects will continue to complete their eDiary daily during this period.

10.9. *Period 1 Activation Visit (Period 1 Day 0)*

Subjects' device will be activated at the Period 1 Activation Visit based on their treatment assignment. Subjects will be randomized (1:1) to either receive High Rate or Commercial Rate settings at this visit.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Randomization:** Randomization must occur at the start of visit and prior to device activation at the Period 1 Activation Visit.
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** The eDiary will be reviewed during the visit and subjects will be reminded to continue to complete their eDiary daily.
- **Device Programming**: To aid in programming it is recommended that Anterior/Posterior thoracic and lumbar imaging (e.g. x-ray or fluoroscopy) is obtained at this visit or up to 7 days prior to the visit to show the position(s) of the study device lead(s). The IPG will be activated using one or more programs created strictly in accordance with Section 10.22.1 for the Period 1 assignment based on their treatment assignment. Final program settings must be documented in the study records. In the event of suspected lead migration, imaging may be performed to document lead positions.
- **Acute Opioid Pain Medication:** The continued use of acute opioid pain medication for procedural discomfort is **not** allowed following the Period 1 Activation Visit.
- **End of Visit Information:** Subjects should receive instructions on the use of the device including Remote control and charging system.
    - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
    - Subjects should be instructed to evaluate all programs saved on the remote control prior to their next visit.
    - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps). It is recommended that they check the status of their battery using their remote control.
    - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.

Subjects may have as many unscheduled visits as required for optimization of programming prior to mid period visit, as long as programming is done in accordance with Section 10.22.

10.10. *Period 1 Interim Programming Visit (21 ± 7 days post-Period 1 Activation Visit)*

Subjects' device may be programmed for optimization of therapy in accordance with Section 10.22 based on their treatment assignment.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** Subjects should be reminded to continue to complete their eDiary daily
- **Device Programming:** The device may be reprogrammed but only in strict accordance with Section 11.21.2 for the Period 1 assignment. Final program settings must be documented in the study records. In the event of suspected lead migration and/or for programming, imaging may be performed to document lead positions.
- **End of Visit Information:** Subjects should receive instructions on the use of the device including Remote control and charging system as needed.
    - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
    - Subjects should be instructed to evaluate all programs saved on the remote control prior to their next visit.
    - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps). It is recommended that they check the status of their battery using their remote control.
    - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.

Subjects may have as many clinic visits as required for optimization of programming prior to mid period visit, as long as programming is done in accordance with Section 10.22.

10.11. *Mid Period 1 Visit (45 ± 7 days post Period 1 Activation Visit)*

At the Mid Period 1 visit, subjects' device may be reprogrammed for optimization of therapy. However, their settings (e.g. pulse width and rate) will be locked for the rest of Period 1 at this visit.

- **Visit Type:** In-office

- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** The eDiary will be reviewed during the visit and subjects will be reminded to continue to complete their eDiary daily

- **Device Programming:** The device may be reprogrammed but only in strict accordance with Section 10.22.1 for the Period 1 assignment. In the event of suspected lead migration and/or for programming, imaging may be performed to document lead positions. Final program settings must be documented in the study records. At the end of the visit the device programming (all parameters except for amplitude) is locked and may not be changed except to resolve a device and/or stimulation-related AE. Any such reprogramming between Mid Period 1 Visit and the End of Period 1 visit must be documented.
- **End of Visit Information:** Subjects should receive instructions on the use of the device including Remote control and charging system as needed.
  - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
  - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps). It is recommended that they check the status of their battery using their remote control.
  - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.

10.12. *End of Period 1 Visit (90 ± 14 days post-Period 1 Activation Visit)*

This visit will represent the End of Period 1 and subjects' device will be turned OFF at the end of this visit.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator , Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** The eDiary will be reviewed during the visit and subjects will be reminded to continue to complete their eDiary daily

- **Device Programming:** No device programming is allowed except to disable stimulation. Current program settings must be documented in the study records.
  - The device must be deactivated and the remote control must be retained at the site.
- **End of Visit Information:** Subjects should be reminded that their device will remain OFF for the duration of the washout period (7 days) and Period 2 baseline (15 days).
  - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.
  - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps).

10.13. *Washout Period (7 days)*

The subject's device will remain inactivated (device OFF) for 7 days of washout period. Subjects should continue to complete their eDiary daily during this period.

10.14. *Period 2 Baseline (post-Washout Period, 15 days prior to Period 2 Baseline/Activation Visit)*

Subjects should continue to answer all the questions on the eDiary daily as described in Section 12.1.1 with their device OFF during the Period 2 baseline (15 consecutive days). Subjects will return to the clinic with their eDiary for the Period 2 Baseline Visit at the end of this period.

10.15. *Period 2 Baseline/Activation Visit (0-7 days post Period 2 Baseline, Period 2 Day 0)*

Subjects' baseline data for Period 2 will be collected at the start of this visit. Subjects' device will be programmed based on their treatment assignment for the remainder of Period 2. The device must be activated only after completion of required assessments for this baseline visit. Subjects should continue to complete their eDiary with no changes to their opioid medications.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** The eDiary will be reviewed during the visit and subjects will be reminded to continue to complete their eDiary daily

- **Device Programming:** To aid in programming it is recommended that Anterior/Posterior thoracic and lumbar imaging (e.g. x-ray or fluoroscopy) is obtained at this visit or up to 7 days prior to the visit to show the position(s) of the study device lead(s). The IPG will be activated using one or more programs created strictly in accordance with Section 11.21.2 for the Period 2 assignment. Final program settings must be documented in the study records. In the event of suspected lead migration, imaging may be performed to document lead positions.
- **End of Visit Information:** Subjects should receive instructions on the use of the device including Remote control and charging system.
    - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
    - Subjects should be instructed to evaluate all programs saved on the remote control prior to their next visit.
    - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps). It is recommended that they check the status of their battery using their remote control.
    - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.

Subjects may have as many unscheduled visits as required for optimization of programming prior to mid period visit, as long as programming is done in accordance with Section 10.22.

10.16. *Period 2 Interim Programming Visit (21 ± 7 days post-Period 2 Activation Visit)*

Subjects' device may be programmed for optimization of therapy in accordance with Section 10.22 based on their treatment assignment.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** Subjects will be reminded to continue to complete their eDiary daily
- **Device Programming:** The device may be reprogrammed but only in strict accordance with section 11.21.2 for the Period 2 assignment. In the event of suspected lead migration and/or for programming, imaging

may be performed to document lead positions. Final program settings must be documented in the study records.

- **End of Visit Information:** Subjects should receive instructions on the use of the device including Remote control and charging system as needed.
  - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
  - Subjects should be instructed to evaluate all programs saved on the remote control prior to their next visit.
  - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps). It is recommended that they check the status of their battery using their remote control.
  - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.

Subjects may have as many clinic visits as required for optimization of programming prior to mid period visit, as long as programming is done in accordance with Section 10.22.

10.17. *Mid Period 2 Visit (45 ± 7 days post-Period 2 Baseline/Activation Visit)*

At the Mid Period 2 visit, subjects' device may be reprogrammed for optimization of therapy. However, their settings (e.g. pulse width and rate) will be locked for the rest of Period 2 at this visit.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed.
- **eDiary:** The eDiary will be reviewed during the visit and the subject instructed to continue completing daily. Details regarding eDiary use can be found in Section 13.1.1
- **Device Programming:** The device may be reprogrammed but only in strict accordance with Section 10.22.1 for the Period 2 assignment. In the event of suspected lead migration and/or for programming, imaging may be performed to document lead positions. Final program settings must be documented in the study records. At the end of the visit the device programming (all parameters except for amplitude) is locked and may not be changed except to resolve a device and/or stimulation-related AE. Any such reprogrammings between Mid Period 2 Visit and the End of Period 2 visit must be documented.

- **End of Visit Information:** Subjects should receive instructions on the use of the device including Remote control and charging system as needed.
    - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
    - Subjects should be reminded to charge their Precision SCS system daily until charging is complete (charger double-beeps). It is recommended that they check the status of their battery using their remote control.
    - Subjects should be reminded not to make any changes to their opioid medications (type/dose/route) and to record their opioid medication use daily, as directed by the eDiary.

10.18. *End of Period 2 Visit (90 ± 14 days post-Period 2 Baseline/Activation Visit)*

This visit will represent the End of Period 2 and subjects will begin long term follow up after completion of this visit. Subjects will choose to either receive HR-SCS or CR-SCS therapy for the rest of the study and may not change once chosen. Programming will be done only after all the required assessments are completed.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments:** All required visit assessments, as outlined in Table 11-1, should be performed at the beginning of the visit.
- **Device Programming:** Following the completion of all End of Period 2 Visit assessments and procedures, subjects will choose whether to receive HR-SCS or CR-SCS therapy until the End of Study Visit. The device may be reprogrammed in accordance with Section 11.21.3 and the treatment parameters selected by the subject. Program settings must be documented in the study records.
- **eDiary Collection:** The eDiary must be collected from the subject along with all eDiary peripherals. Subjects no longer need to complete the eDiary.
- **End of Visit Information:** Subjects will receive instructions on the use of the device including Remote control and charging system as needed
    - Subjects are to contact the site in an event that any additional intervention is warranted, to report a complaint and/or a suspected adverse event, reprogramming, etc.
    - Subjects should be reminded to charge their Precision SCS system as needed. It is recommended that they check the status of their battery using their remote control

- Subjects' opioid medications can be changed, if needed for the remainder of the study. .

10.19. *End of Study Visit (365 ± 30 days post-Period 1 Activation Visit)*

This visit will represent the End of Study visit and subjects will be followed in accordance to the End of Study Action Plan as described in Section 9.5. This visit will occur 365 days ± 30 days post Period 1 Activation Visit.

- **Visit Type:** In-office
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee
- **Study Assessments**: All required visit assessments, as outlined in Table 11-1, should be performed.
- **Device Programming:** Following the completion of all End of Study Visit assessments and procedures, subjects will be followed in accordance with the End of Study Action Plan.
- **End of Visit Information:** Subjects will receive instructions in accordance with the End of Study Action Plan as described in Section 9.5.

10.20. *Unscheduled Study Visits*

Subjects may have unscheduled study visits as needed for device related visits (e.g., reprogramming, replacement, revision) or evaluation of adverse events as described below.

- **Visit Type:** In-office or Procedure
- **Required Attendees:** Subject; CRC and/or Investigator; Field Clinical Engineer/Field Clinical Specialist or designee as needed.

10.20.1. *Prior to the End of Period 2 Visit*

Unscheduled visits may occur at any time for evaluation of possible adverse events and re-positioning, replacement or explant of a device component. Reprogramming is also allowed from the Activation visit through the Mid-Period visit of each period. However, the device should be programmed in accordance to Section 10.22. Subjects should be reminded that they are required to remain on a fixed opioid medication regimen until the End of Period 2 Visit. Details regarding protocol-allowable opioid medication requirements are described in Section 10.23.

In the event of suspected lead migration and/or for programming, imaging may be performed to document lead positions.

10.20.2. *Long-term Follow-up Period (After the End of Period 2 Visit)*

Unscheduled visits after the End of Period 2 Visit may occur at any time for any of the following reasons

- Evaluation of possible adverse events
- Re-positioning, replacement or explant of a device component
- Medication adjustments
- Programming adjustments

The device may be programmed in accordance to Section 10.22.

In the event of suspected lead migration, imaging may be performed to document lead positions.

10.21. *Revision or Replacement of Leads, Extensions and/or IPGs*

During the course of the study, it is possible that leads may be placed incorrectly, migrate, or malfunction and require repositioning or replacement. It is also possible that the extensions or splitters or IPG may be uncomfortable or malfunction and may require repositioning or replacement. The decision to reposition or replace any device component will be made by the investigator and only if the subject agrees. Subjects not agreeing to a recommended lead revision will be withdrawn from the study but will be included in the intent-to-treat and safety analyses. Subjects agreeing to revision will continue on study and will be followed according to the original study schedule. Effectiveness data from these subjects will be included in the intent to treat analysis. Any replacements or revisions performed during the course of the study must be recorded on an eCRF specific to the procedure and on the AE eCRF, if applicable. Lead revisions/replacements for the purpose of correcting for migration and/or malfunction must be performed as soon as is reasonably possible following determination of the need for revision/replacement. Acute opioid pain medications may be taken for up to 14 days after these procedures.

The investigator should notify Boston Scientific prior to any study procedures. Any replacements or revisions performed during the course of the study should be recorded in the EDC system, including information about the procedure, device, and/or adverse event if applicable.

Information on assessing revisions or replacements of leads, extensions or IPGs as adverse events is described in Section 19.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

10.23. *Protocol Medication Requirements*

Opioid Medication Lock Period (Medication Lock visit to End of Period 2 visit):

Investigators/Subjects will not be allowed to change opioid medications from the Medication Lock visit until the end of Period 2 Visit. Type/dose/route must remain unchanged.

The use of acute opioid pain medication for procedural discomfort is allowed during the Healing Period and in the event of the revision or replacement of leads, extensions and/or IPG, per site's routine care.

Opioid Medication Open Period (End of Period 2 visit to End of Study visit)

Investigators/Subjects may change opioid medications during the opioid medication open period, from End of Period 2 visit to End of Study visit as needed

10.24. *Interventional Pain Procedure Restriction*

No interventional pain procedures to treat the SCS-targeted pain are allowed during the study. Procedures associated with the SCS device (e.g. IPG Revision, Lead revision, CSF leak interventions and interventions associated with SCS procedure related adverse event

management) are allowed. Excluded procedures include, but are not limited to, the following:

- Epidural steroid injection
- Facet joint injection
- Selective nerve root block
- Radiofrequency ablation
- Spine surgery (e.g., discectomy, vetebroplasty, fusion)

10.25. *Study Completion*

All subjects permanently implanted with an IPG will be followed through completion of the End of Study visit. In the event that approval is received prior to all enrolled subjects completing the End of Study visit, all study sites will be notified and all enrolled subjects who have not yet completed the End of Study Visit will no longer be followed per protocol. The End of Study Action Plan (see Section 10.5) defines the actions to be taken when the subject reaches the end of their study participation.

10.26. *Source Documents*

Table 10-3 Source Document Requirements

Requirement	Disposition
Hospital records and/or clinical and office charts including the evidence of but not limited to inclusion/exclusion criteria, informed consent, procedures, laboratory results, medications, assessment of adverse events, health resource utilization information	Retained at investigational site
Imaging films/prints documenting lead(s) location	Retained at investigational site
Assessments and questionnaires	Retained at investigational site and/or electronic data collection platform / EDC
Clinician programmer printouts for programming information	Retained at investigational site
Device accountability reports	Retained at investigational site and Device management vendor database

11. Statistical Considerations

11.1. *Primary Endpoint*

The primary endpoint for this study is low back responder rate at 3 months post-activation, based on reduction from Baseline in average low back pain intensity with no change from Baseline in average daily opioid intake.

Average low back pain intensity will be based on the *Pain Intensity Diary* questions regarding the average low back pain for the day on a 0-10 numerical rating scale (NRS). Opioid intake will be calculated for each subject based on *Pain Medication Diary*, a daily capture of all pain-related medication intake.

[redacted]

[redacted]

11.1.1. *Hypotheses*

The primary statistical hypothesis in this study is that the proportion of low back pain intensity responders at 3 months post-activation for HR-SCS is non-inferior compared to CR-SCS:

H_0: A(CR-SCS) - A(HR-SCS) > 0.10

H_1: A(CR-SCS) - A(HR-SCS) $\leq$ 0.10

where A(CR-SCS) and A(HR-SCS) are the areas under the CDFs of response for CR-SCS and HR-SCS, respectively. Calculation of the area under the curve must be bounded over a finite range of threshold values, which are specified to be 0% to 100%. The non-inferiority margin is 0.10.

[redacted]

[redacted]

[redacted]

11.1.3. *Statistical Methods*

For the primary endpoint, statistical testing will be performed to determine if the low back pain responder rate with HR-SCS is non-inferior to that with CR-SCS.

In order to provide maximal information, and since no single clinically-relevant responder definition exists for this endpoint, a non-inferiority comparison will be performed between the cumulative distribution functions (CDFs) of the CR-SCS and HR-SCS response rates.

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11.6. *Analysis Sets*

All primary and secondary endpoints will be analyzed on both intent-to-treat and a per-protocol basis. Safety endpoints will be analyzed in the safety analysis set.

11.6.1. *Intent-to-Treat (ITT)*

In the intent-to-treat analysis, all subjects who are randomized will be included in the analysis. Subjects will be analyzed according to their randomization group, regardless of the treatment they receive. Subjects who are implanted with the investigational device, but decided to withdraw from the study prior to randomization will not be included in the ITT analysis.

11.6.2. *Per-Protocol*

In the per-protocol analysis, only subjects with no major protocol deviations will be included in the analysis. [redacted]

11.6.3. *Safety Analysis Set*

In the safety analysis, all subjects who sign the IRB-approved written Informed Consent form will be included.

11.7. *Control of Systematic Error/Bias*

Selection of patients will be made from the Investigator's usual patient load. All patients meeting the inclusion/exclusion criteria and having signed the Informed Consent Form will be eligible for participation in the study. The reasons for exclusion, for subjects who sign an informed consent form but are not randomized, will be indicated in the screening log. Consequently, consecutively eligible subjects will be randomly allocated into the study, minimizing selection bias. Boston Scientific will report to the FDA any evidence of fraud, including deliberate tampering with the selection of subjects.

[redacted]

11.9. *Eligibility of Subjects, Exclusions, and Missing Data*

All subjects who are randomized will be eligible for evaluation. Sensitivity analyses will be conducted to assess the impact of different assumptions on the interpretation of the results. For continuous covariates, the missing/unknown values will be imputed using the mean of the pooled observed data. For categorical covariates, the missing/unknown values will be combined with the category with the most subjects if the missing/unknown rate is ≤2% of the pooled observed data, or they will be classified into a separate category if the missing/unknown rate is >2% of the pooled data. If the covariates are also used as subgroup variables, the imputed values of subgroup variables will not be used for subgroup categorization.

[redacted]

11.10. *Data Analyses*

All statistical analyses will be done using the SAS System software, version 8.2 or later (Copyright © 2000 SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27513, USA. All rights reserved). [redacted]

[redacted]

11.10.3. *Justification of Pooling*

Analyses will be performed using data pooled across various sites/institutions. Multivariate analysis techniques, including contingency tables and logistic regression for binary outcomes

and analysis of variance for continuous measures, will be used to assess differences among study sites to justify pooling data across sites.

[redacted]

11.11. *Changes to Planned Analyses*

[redacted] Changes from the planned statistical methods after performing the analyses will be documented in the clinical study report along with a reason for the deviation.

12. Data Management

12.1. *Data Collection, Processing, and Review*

Subject data will be recorded in a limited access secure electronic data capture (EDC) system.

The clinical database will reside on a production server hosted by Medidata. All changes made to the clinical data will be captured in an electronic audit trail and available for review by Boston Scientific Corporation (BSC) or its representative. The associated RAVE software and database have been designed to meet regulatory compliance for deployment as part of a validated system compliant with laws and regulations applicable to the conduct of clinical studies pertaining to the use of electronic records and signatures. Database backups are performed regularly.

The Investigator provides his/her electronic signature on the appropriate electronic case report forms (eCRFs) in compliance with local regulations. Changes to data previously submitted to the sponsor require a new electronic signature by the Investigator acknowledging and approving the changes.

Visual and/or electronic data review will be performed to identify possible data discrepancies. Manual and/or automatic queries will be created in the EDC system and will be issued to the site for appropriate response. Site staff will be responsible for resolving all queries in the database in a timely manner.

12.1.1. *Electronic Diary (eDiary)*

Subjects who meet the applicable Inclusion and Exclusion criteria will be given an eDiary to capture daily assessments once a day of average low back pain intensity, average leg pain intensity, worst low back pain intensity, worst leg pain intensity, opioid medication intake, and device charging information.

Diary entries will be collected daily for each morning-to-night period. The eDiary will be automatically unlocked for data entry each evening at approximately 7 PM. At this time, an alarm will sound to ask subjects to report information for that day. Once the subject enters the required information, the eDiary will be automatically locked until the following evening. If the subject fails to enter the required information by approximately 3 AM, the eDiary will

be automatically locked until the following evening, and the data for that day will be classified as missing.

The eDiary consists of a small, handheld computer programmed specifically for this study. Data entry is interactive and based on a series of questions and is dated and time stamped. Data will be uploaded to a central computer resource. Specific training materials for the use of the eDiaries will be provided to each study subject.

The eDiary data are critical to endpoint analysis in this study. Thus, subjects who are non-compliant will be counseled by site staff as to the importance of daily entries.

12.1.2. *Paper Questionnaires*

Data from paper forms may be collected from the site using fax and automatic character recognition. Paper forms and questionnaires are completed by the subject or a clinician and then sent via facsimile from the site. When the forms are received, each page is automatically scanned and indexed by intelligent character recognition (ICR) software, and uploaded into the EDC system.

12.1.3. *Electronic Questionnaires*

Questionnaires in electronic form may be collected directly using an electronic data collection platform at the clinical site (e.g. iPad). After completion by the subject or a clinician, data from the electronic questionnaires are transmitted directly into the EDC system.

12.1.4. *Direct Data Upload*

For quality assurance purposes and validation, technical data on the SCS device, stored in the BSC Field Clinical Engineer/Field Clinical Specialist's (FCE) Clinician Programmer, will be collected using direct data upload to a secure BSC server. BSC FCEs, who assist in programming the device settings per routine care, will upload the Clinician Programmer database files to a secure server stored in a restricted location at BSC.

12.2. *Study Assessments*

12.2.1. *Adverse Events*

Adverse event evaluation will conducted to identify adverse events occurring during the study and classify them in regards to seriousness, relationship to the study procedure and/or device, action taken and outcome. Safety events will be reported as specified in Table 20-3.

- Non-serious AEs which are neither device/procedure related will be collected from the time of informed consent through the end of period 2.
- Adverse events which are device/procedure related will be collected from the time of informed consent through 12 months post-Period 1 activation

- SAEs, SADEs, Device Deficiencies and UADEs will be collected from the time of informed consent through 12 months post-Period 1 activation.

12.2.2. *Beck Depression Inventory (BDI-II)*

BDI-II measures the intensity, severity, and depth of depression. It includes a long form of 21 questions, each evaluating a specific depression symptom (e.g., sadness, pessimism, irritability, loss of energy, concentration difficulty, indecisiveness, changes in sleep pattern, fatigue, etc.).

12.2.3. *Columbia Suicide Severity Rating Scale (C-SSRS)*

C-SSRS is a measure of suicidal ideation and behavior. It rates an individual's degree of suicidal ideation on a scale, ranging from "wish to be dead" to "active suicidal ideation with specific plan and intent." The scale identifies behaviors, which may be indicative of an individual's intent to commit suicide.

12.2.4. *Concomitant Medications*

All prescribed pain-related medications will be collected throughout the study in order to obtain a full record of medication-related resource utilization. Information will include medication name, dates of prescription, indication or purpose, dose, frequency, and route of administration.

12.2.5. *Demography*

Demographic information will include birth year, birth day and month (if allowed by local regulations), gender, and race/ethnicity.

12.2.6. *Electronic Diary (eDiary)*

The eDiary is an electronic questionnaire assessing the daily intensity of the subject's average and worst back and leg pain, opioid medication intake, and device charging compliance. Pain intensity is measured daily on a 0 – 10 numerical rating scale (NRS), where 0 indicates "no pain" and 10 indicates "worst pain imaginable".

12.2.7. *EQ-5D 5 Level (EQ-5D-5L)*

EQ-5D-5L is a standardized measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys.

EQ-5D-5L is comprised of a descriptive system and a visual analog scale. The descriptive system measures quality of life along five dimensions, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, with five levels for each dimension from which subjects are asked to select one. The visual analog scale is used to record the subject's self-rated health on a 20cm vertical line with endpoints labeled 'the best health you can imagine' and 'the worst health you can imagine'.

12.2.8. *Long-Term Therapy Selection (LTTS)*

The Long-Term Therapy Selection form records which treatment (High Rate, Commercial Rate, or Neither) was selected by the patient at the end of Period 2.

12.2.9. *Medical History*

Medical history will include medical and procedural history relating to pain management, onset of chronic pain, and all pain-related diagnoses.

12.2.10. *Neurological Assessment*

Standard neurological assessments will be performed by the investigator to examine neurological status. Assessments of a subject's strength, sensation, deep tendon reflexes will be performed, and questions asked regarding bladder, bowel, and sexual function to evaluate thoracolumbar spinal cord function. The investigator will determine whether there is evidence of a clinically significant improvement, worsening, or no-change in neurological function as compared to the patients' baseline neurological assessment. If the investigator concludes that a clinically significant change in neurological function has occurred, then he/she must indicate whether the change: a) affected motor, sensory, deep tendon reflexes, bladder, bowel or sexual function, and whether the change in neurological status is b) related to the physical presence of the device, the effect of device stimulation, and/or the surgical procedure, or if it is related to another condition.

12.2.11. *Oswestry Disability Index version 2.1a (ODI v2.1a)*

ODI v2.1a assesses the degree of subject disability due to pain, measuring the impact of pain on activities of daily living. ODI v2.1a is composed of 10 questions that describe the pain and its impact on daily life on a 0-5 scale, with higher values indicating the more severe impact.

12.2.12. *Pain Intensity*

Pain Intensity is a questionnaire that assesses the intensity of the subject's leg pain and low back pain over the past 7 days. Pain intensity is expressed on a 0 – 10 numerical rating scale (NRS), where 0 indicates "no pain" and 10 indicates "pain as bad as you can imagine". The questionnaire assesses pain intensity separately for the subject's average daily leg pain

intensity, average daily low back pain intensity, worst leg pain intensity, and worst low back pain intensity.

12.2.13. *Patient Global Impression of Change (PGI-C)*

PGI-C is a seven-point scale that requires the subject to assess how much their condition has improved or worsened relative to their baseline. Subjects will rate themselves as: very much improved; much improved; minimally improved; no change; minimally worse; much worse; or very much worse.

12.2.14. *Percent Pain Relief (PPR)*

PPR is a questionnaire assessing how much of the subject's low back pain and leg pain has been relieved by the SCS treatment. Pain relief is expressed as a percentage from 0 – 100%.

12.2.15. *Physical Exam*

A complete physical exam will be performed by the clinician. The physical exam will include height, weight and a neurological evaluation (strength, sensory, and reflexes) demonstrating thoracolumbar spinal cord function.

12.2.16. *Pittsburgh Sleep Quality Index (PSQI)*

PSQI is a self-rated questionnaire assessing sleep quality and disturbances. This questionnaire include 19 individual items grouped into 7 component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of these 7 scores yields a single global score.

12.2.17. *Post-Operative Evaluation*

An assessment of the surgical implant site with an evaluation for adverse events will be performed post-operatively.

12.2.18. *Procedure Information*

General information will be collected regarding the SCS procedures performed during the study, including implant, explant, and revision procedures.

12.2.19. *Programming Parameters*

Standard information regarding the programming parameters used to program the subject's IPG, as well as measurements taken using the device (e.g. contact impedances) will be collected from the Clinician Programmer (CP).