**We are seeking adults with chronic, intractable low back and/or leg pain to participate in a study called MOSAIC.**

This research study is evaluating Spinal Cord Stimulation (SCS) with time variant pulses (TVP) delivered by the Boston Scientific WaveWriter Alpha™ SCS Systems. TVP-SCS is when the electrical stimulation from the SCS is delivered to the spinal cord changes according to a time-varying function. In time varying stimulation, the electrical stimulation can be changed continuously by varying the pulse width, amplitude, or frequency of the stimulation.

**For more information visit ClinicalTrials.gov**

# About the Sponsor.

Boston Scientific is a worldwide developer, manufacturer, and marketer of medical devices with a broad range of interventional medical specialties.

Boston Scientific's Neuromodulation business is one of the innovation leaders in implantable microelectronic technologies used to modulate nerve activity in the treatment of chronic neuropathic pain.

This brochure is for informational purposes only. Any questions related to the MOSAIC should be referred to your study doctor.

The Boston Scientific Spinal Cord Stimulator (SCS) Systems are indicated 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, Complex Regional Pain Syndrome (CRPS) Types I and II, intractable low back pain and leg pain, Diabetic Peripheral Neuropathy of the lower extremities, radicular pain syndrome, radiculopathies resulting in pain secondary to failed degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, multiple back surgeries. The Boston Scientific Spectra WaveWriter™, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems are also indicated as an aid in the management of chronic intractable unilateral or bilateral low back and leg pain without prior back surgery.

The system includes an Implantable Pulse Generator (IPG), External Trial Stimulator (ETS), Remote Control (mySCS Go RC), External Charger, Clinician's Programmer (CP), and a portfolio of lead options. The IPG is rechargeable and is recharged transcutaneously by a charging unit. The System is capable of providing multiple therapies

The Boston Scientific SCS Systems are approved by the Food and Drug Administration (FDA) and will be used per approved Instructions for Use (IFU) in the MOSAIC Study.

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Advancing science for life™
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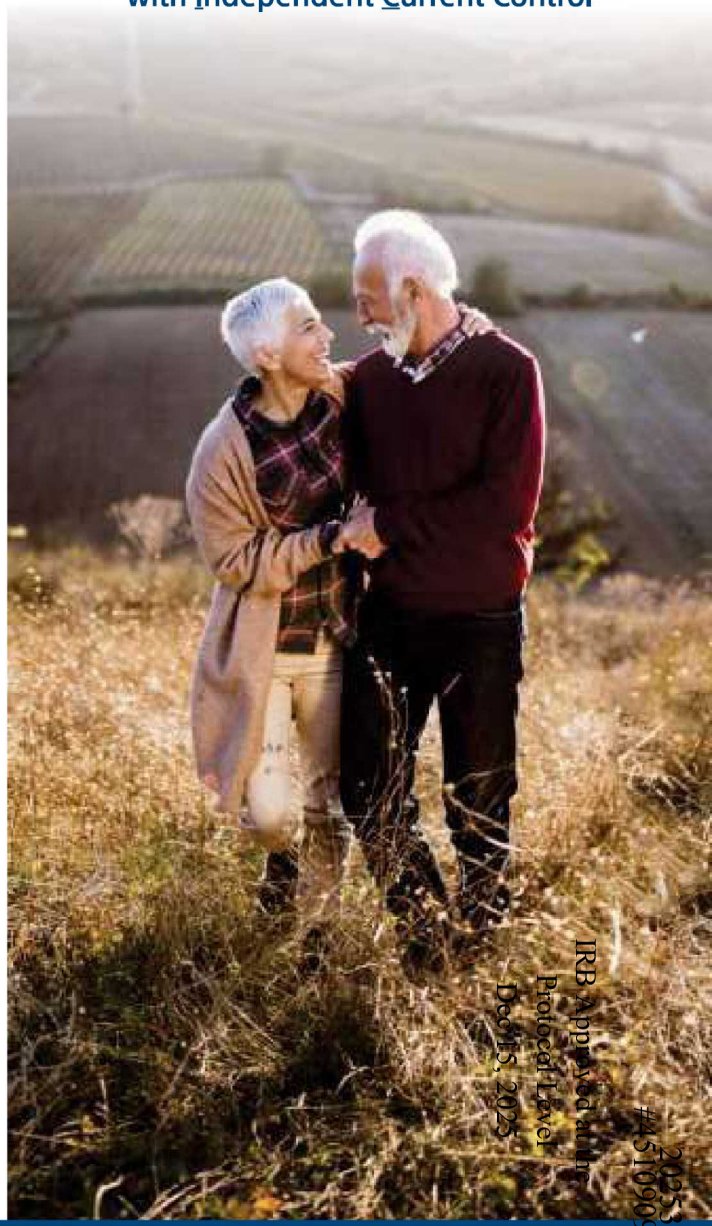
# MOSAIC

## Managing Pain Using Optimized Sequences by Adjusting Parameters with Independent Current Control



**The goal of the MOSAIC Study is to evaluate the effectiveness of time variant pulse (TVP)-SCS in patients with chronic pain using Boston Scientific WaveWriter Alpha™ SCS Systems**

## Who can participate in this study?

Your doctor will review your medical history, perform an examination then ask you to complete assessments to determine your eligibility for the study.

## Eligible study candidates must meet key criteria including but not limited to:

- 18 years of age or older.
- Have a primary complaint of chronic pain of the trunk and/or limbs for at least 6 months.
- Responder to paresthesia-free SCS therapy (based on SCS trial).
- Be able to use a smart phone.

Further information regarding eligibility will be provided by your study doctor.

## What does study participation involve?

If it is determined that you have met all of the study's requirements and you are willing to participate in the study, you will:

- Have a spinal cord stimulation trial procedure and if you prefer paresthesia-free therapy at the end of the trial, you will undergo a permanent implant procedure according to your study doctor's routine practice.
- Have your Boston Scientific SCS system programmed using TVP-SCS therapy options.
- Be asked to complete questionnaires related to your health, well-being and quality of life.
- Following SCS implant, be scheduled for a minimum of 6 study visits to the study doctor's office. Your participation in the study will last approximately 27 months.
- Receive study-related material to be used at home via a mobile app-based pain diary. Subjects will receive continued instruction on using the mobile app throughout the study.
- If you are enrolled in the study, you will receive a stipend for study visits and a monthly payment to reimburse you for your time and effort associated with completing at-home activities and data plan usage for these devices.

## What are the potential benefits of participating?

By joining a clinical study, you will:

- Receive experienced medical care at a health care facility during the study.
- Help others by making a contribution to medical research.
- Experience possible improvement of your pain.

## What are the potential risks of participating?

As with any medical procedure, side effects and complications may be associated with the neurostimulation system surgery, therapy, and device. Your study doctor will review all of the potential risks with you and answer any questions you may have.

## How is your safety protected?

You will receive an Informed Consent form that will provide details about the risks and benefits associated with your participation in the study. Your study doctor will discuss these with you.

Your privacy will be carefully safeguarded. All information collected during the study will be private. Your identity as a participant will remain strictly confidential.

The ethical and legal codes that govern medical practice also apply to clinical studies.