

FAQ's MOSAIC Study

Here are some Frequently Asked Questions (FAQs) about the Boston Scientific MOSAIC Study.

1. What is the MOSAIC Study and why is it being done?

Boston Scientific is sponsoring (funding) a clinical trial (also known as a clinical study or clinical investigation) to better understand the effectiveness of time variant pulse-spinal cord stimulation (TVP-SCS) in patients with chronic pain using commercially approved Boston Scientific SCS Systems per local Instructions for Use (IFU).

The study involves the FDA-approved and commercially available WaveWriter Alpha™ SCS Systems device manufactured by Boston Scientific. A detailed summary of the MOSAIC study can be found at www.ClinicalTrials.gov (NCT07190807).

2. Who can participate in this study?

The decision of whether a patient is eligible for the study is based on the study requirements, of which some include: being 18 years of age or older; having a primary pain complaint of chronic pain of the trunk and/or limbs for at least six months, with back pain greater or equal to leg pain; and signing an Informed Consent Form.

The study doctor will review your medical history and then ask you to complete assessments to determine if you are an appropriate candidate.

3. What should I do if I am interested in finding out more about the study?

Tell the study doctor or your treating physician that you are interested in learning more about the study. The study doctor or their study staff (such as Clinical Research Coordinator) can provide you more information including the Informed Consent Form and answer any questions you may have.

4. What happens if I want to participate in the study?

You will be asked to read and review the MOSAIC Study Informed Consent Form (ICF). After reading the ICF, you will be given time to ask the study doctor/staff any study questions you may have. If you'd like, you can also take the ICF home to read and to review with your family.

If you decide to participate in the study, you will be asked to sign the ICF. Keep in mind, however, that further screening tests may be required to determine if you can participate. Based on further screening, it may be determined that you are not a candidate even after the ICF is signed. 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 (e.g. Mobile App activities, sharing device data) and for data plan usage for these devices.

If you are a candidate and decide to participate, you will be expected to:

- Be trialed with a commercially approved Boston Scientific neurostimulator.
During the trial period, respond to paresthesia-free therapy
- Have the study permanent SCS implant procedures.
- Receive instructions for downloading an e-Diary mobile app for completing questionnaires at home, and for sharing your neurostimulator data with the study team
- Complete all of the study visits and study activities including questionnaires/assessments.
- Tell your study doctor if you experience any abnormal health conditions, hospitalizations, visits to the emergency room, visits to other doctors, or side effects, or if you start any new medications or treatments.

5. What happens if I decide not to participate in this study or if I withdraw from the study?

Your participation is voluntary. You may choose not to be in the study, and you may withdraw from the study at any time. There will be no penalty or loss of benefit to you if you decide not to be in the study. If you decide not to participate, your care will not be affected. In other words, the care you would normally receive as part of routine care will not change.

For more information please contact: