Boston Scientific
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SCOPE Study

A 5-year Superion® IDS Clinical Outcomes Post-Approval Evaluation

Study of the Superion® Indirect Decompression System (IDS) in Patients with Moderate Lumbar Spinal Stenosis

CHRONIC PAIN CLINICAL RESEARCH STUDY

A clinical research study is underway to better understand real-world outcomes of the Vertiflex® Procedure in routine clinical practice. The Vertiflex® Procedure uses the Superion® Indirect Decompression System (IDS), a medical device approved for commercial use by the Food and Drug Administration (FDA) in the United States for treatment of moderate lumbar spinal stenosis.

MAIN ELIGIBILITY CRITERIA:

- 45 years of age or older
- Have a primary pain complaint of leg/buttock/groin pain, with or without back pain that is relieved by flexion activities (example: sitting or bending over a shopping cart)
- Diagnosis of degenerative spinal stenosis of the lumbar spine
- Provide written informed consent prior to enrollment

FOR MORE INFORMATION, PLEASE CONTACT:

NWSH Research Department
NWSH.Research@NWSH.com 208-664-0291

FAQs
SCOPE Study

Boston Scientific

Here are some Frequently Asked Questions (FAQs) about the SCOPE Study

1. **What is the SCOPE 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 real-world outcomes of the Vertiflex® Procedure in routine clinical practice. The Vertiflex® Procedure uses a medical device called the Superion® Indirect Decompression System (IDS), approved for commercial use by the Food and Drug Administration (FDA) in the United States for the treatment of moderate lumbar spinal stenosis. A detailed summary of the SCOPE Study can be found at www.ClinicalTrials.gov.

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 45 years of age or older
   - leg/buttock/groin pain, with or without back pain that is relieved by flexion activities (example: sitting or bending over a shopping cart)
   - diagnosis of degenerative spinal stenosis with radiographic confirmation
   - signing an Informed Consent Form

   The study doctor will review your medical history and then ask you to complete assessments and imaging, as needed, 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 a 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?**
   If you decide to participate in the study, you will be asked to read and review the SCOPE Study Informed Consent Form (ICF). After reading the ICF, you will be given time to ask the study doctor/staff any questions you may have. If you'd like, you can also take the ICF home to read and to review with your family. 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 a candidate and decide to participate, you will be expected to:
   - Have surgery to insert (implant) 1-or-2 Superion® IDS devices to treat your lumbar spinal stenosis into the space between the spinous processes in your lower back
   - Complete all of the study visits and study activities throughout the study. This study has the below follow-up visits after your Superion® IDS Implant:
     - 6-Week
     - 6-Month
     - 1,2,3,4 and 5 Year
   - Have radiographic imaging
   - 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 standard care will not change.

For more information please contact: