

Who can participate?

In general, patients who have experienced specific pain symptoms may be eligible when other methods, such as medications and non-surgical treatments, have failed to alleviate their pain.

Inclusion Criteria:

Participants in the clinical research study must meet the following criteria:

- Experience moderate to unbearable pain that is more acute in the legs than the back
- Have pain that causes moderate to severe walking impairment
- Experience symptoms when walking, standing or exercising in an upright position
- Be unable to get adequate pain relief after six months of non-surgical management
- Men and women over 21

Exclusion Criteria:

Some people who meet the inclusion criteria may still be ineligible to participate in the clinical study. This includes the following:

- Those with prior lower back surgery with the exception of Lamino-Foraminotomy, Microdiscectomy, IDET or Percutaenous Discectomy (and no more than one such surgery)
- Those with a primary diagnosis of back pain caused by conditions other than spinal stenosis, such as those related to a disk disorder
- Patients with peripheral vascular disease requiring intervention
- Patients with insulin-dependent diabetes
- Patients who are receiving immunosuppressive or long-term steroid therapy
- Those receiving Worker's Compensation or who are involved in active litigation relating to his/her spinal condition

Other criteria

The criteria listed above are not the only eligibility criteria. Only a clinical research study staff member can determine if you are eligible for this clinical research study.

Is there any cost for participation?

Participants enrolled in this clinical research study will not be responsible for covering any costs other than their current insurance policy deductibles; that portion for which they would be responsible for paying if they were seeking treatment that was not part of a research study (such as co-payments). Participants will be required to seek preauthorization and submit insurance claims to their insurance providers. If, after sufficient appeal, an insurance company does not provide coverage, the cost of the procedure and the cost of the follow-up visits will be covered by the Sponsor in accordance with the contract between the participant's physician and the Sponsor, and between the hospital and the sponsor.

Where is the clinical research study being conducted?

There are clinical research study sites located nationwide. Please call 1-866-256-4447 for more details about where this clinical research study is being conducted and to determine your eligibility for participation.

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.

Call 1-866-256-4447

for more details about this clinical research study and to determine your eligibility for participation.

www.legandbackpainstudy.com



Medications. Physical Therapy.
Exercise. Steroids. Chiropractic.

You've tried it all and the pain is still there.

If this sounds familiar, you're not alone. Millions of Americans have tried all those methods with the same result: *leg and back pain* that just won't go away.



Perhaps it's time to explore new options.

The Stabilimax NZ® Dynamic Spine Stabilization System, a device designed to provide stabilization while allowing for motion (ROM), is now being clinically evaluated.

The Stabilimax NZ is approved for investigational use only. The Food and Drug Administration has granted approval for Applied Spine to conduct a clinical research study to assess its safety and effectiveness when compared against other methods used in the treatment of spinal stenosis. *You or someone you know may be eligible to explore this exciting investigational spine stabilization system for the relief of chronic pain.*



What is spinal stenosis?

With aging (or as a result of injury or damage to the lower back), some degeneration of the skeletal and muscular structures of the lumbar area of the spine occurs. This degenerative process creates instability in the spine and a narrowing of the spinal canal, or spinal stenosis. As the narrowing occurs, and as the body tries to compensate, there is compression of the nerve roots, which causes the pain associated with spinal stenosis.

- More often than not, the pain is felt most acutely in the legs, but can also be felt in the buttocks and lower back
- The pain may come and go, as opposed to continuous pain
- Pain occurs during certain activities (like walking) or while standing for longer periods
- Temporary pain relief can be attained by resting or assuming a forward-leaning position

What is the purpose of the study?

The purpose of the clinical research study is to assess the safety and effectiveness of Stabilimax NZ when compared against spinal fusion surgery, which is the current standard of care.

Why the Stabilimax NZ investigational device might be right for you.

Stabilimax NZ is designed to offer a unique treatment for spinal stenosis called “dynamic stabilization.” This means that while Stabilimax NZ works to stabilize the affected area of the spine, it does so in a manner which preserves both bending and twisting motion.

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for more details about this clinical research study.