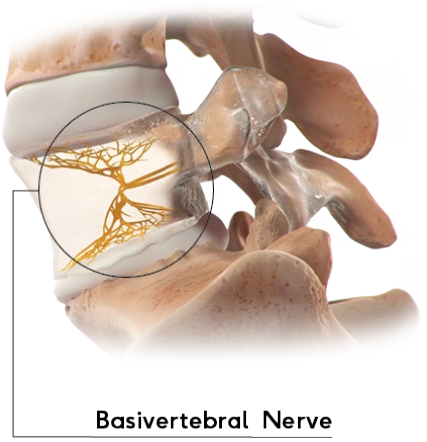
Basivertebral Nerve Ablation (Intracept®) Procedure FAQs

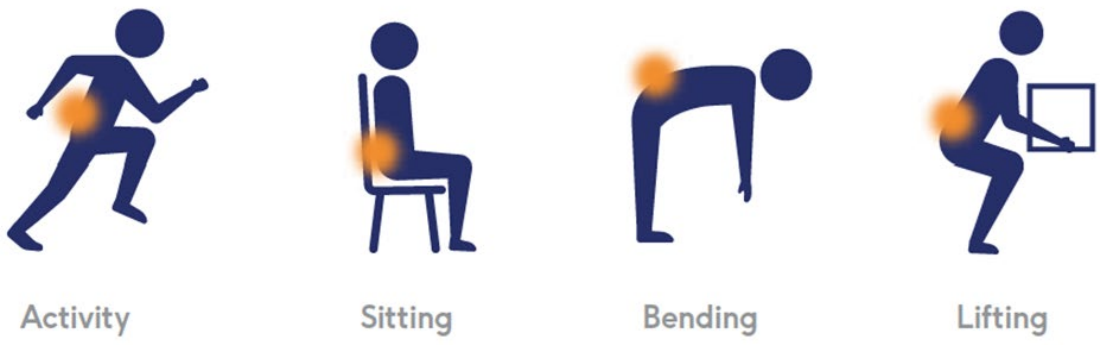
WHAT IS VERTEBROGENIC PAIN?

Vertebrogenic pain is a distinct type of chronic low back pain caused by damage to vertebral endplates, part of the vertebral body that interfaces with the lumbar disc. Disc degeneration, and the wear and tear that occurs with everyday living, produces stresses on the endplates that damage them, leading to inflammation, degeneration and vertebrogenic back pain. This damage leads to distinctive findings on routine MRI. The basivertebral nerve (BVN), found within the vertebrae, carries pain signals from the damaged vertebral endplates.



HOW DO PATIENTS DESCRIBE VERTEBROGENIC PAIN?

The disc and endplate are both part of the anterior spinal column and produce similar low back pain symptoms. Patients who find relief from the Intracept Procedure often describe pain in the middle of their low back that is made worse by physical activity, prolonged sitting, and bending forward or with bending and lifting.[1]



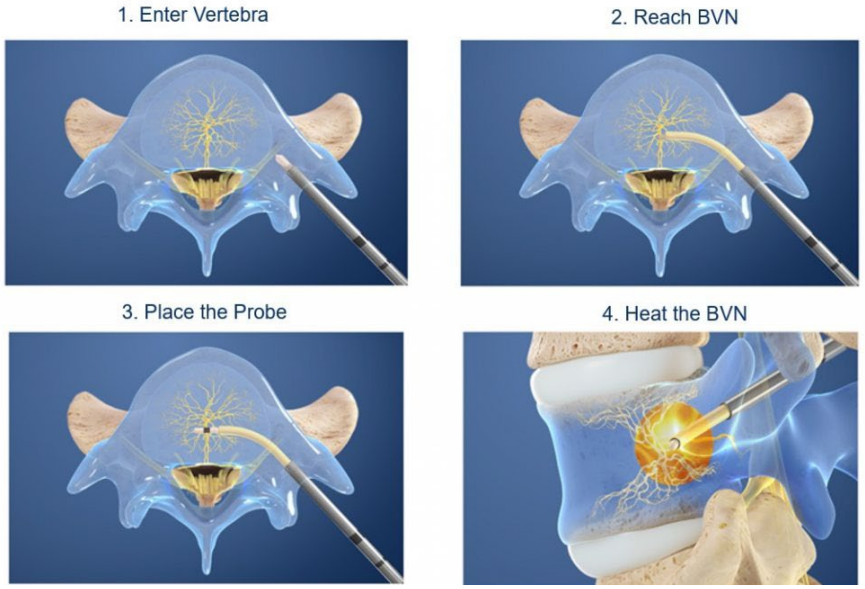
HOW IS VERTEBROGENIC PAIN TREATED?

The basivertebral nerve enters the bone at the back of the vertebral body (the bones in your spine) and “branches” to the endplates (that are located at the top and the bottom of each vertebral body). When endplates are damaged, these nerve endings increase in number and “pick up” pain signals that are then sent to the brain through the basivertebral nerve. The Intracept® Procedure (basivertebral nerve ablation) relieves vertebrogenic low back pain by heating the basivertebral nerve with a radiofrequency probe to stop it from sending pain signals to the brain. The Intracept® Procedure is the only FDA-cleared procedure to treat chronic vertebrogenic low back pain.

HOW IS THE INTRACEPT® PROCEDURE (BASIVERTEBRAL NERVE ABLATION) PERFORMED?

The Intracept Procedure is a minimally invasive, implant free procedure that preserves the overall structure of the spine. The Intracept Procedure is a same-day, outpatient procedure performed at an ambulatory surgery center. Patients are under anesthesia, and the procedure lasts 45 - 60 minutes. The procedure is FDA-cleared and has been proven in multiple studies to be safe, effective, and provide long-lasting results. [2,3]

During the procedure, the patient lies on his/her stomach. The skin of the lower back is cleansed with antiseptic solution and a sterile field is created. Local anesthetic is used to numb the skin and underlying soft tissues. A small incision in the skin is made (<1cm). Under X-ray (fluoroscopy) guidance, an introducer needle is advanced down to the pedicle (bone) of the targeted level. The introducer needle is advanced into the bone and then a curved instrument is inserted further into the vertebral body to the known location of the basivertebral nerve. The radiofrequency probe is then placed through the introducer needle. The radiofrequency ablation is then performed in order to heat the basivertebral nerve and disrupt low back pain signals. The radiofrequency ablation probe and introducer needle are then removed and the incisions closed and covered with a sterile dressing



HOW LONG DOES PAIN RELIEF LAST FOLLOWING THE INTRACEPT® PROCEDURE?

Clinical evidence shows most patients experience significant improvements in function and pain sustained more than 5 years after a single treatment. [2]

HOW DO I KNOW IF I AM A CANDIDATE FOR INTRACEPT® (BASIVERTEBRAL NERVE ABLATION)?

The Intracept® Procedure (basivertebral nerve ablation) is indicated for patients with the following:

- Chronic low back pain for at least six months
- Failure of conservative care (meds, PT, injections, etc.) for at least six months without improvement
- MRI demonstrating Type 1 or Type 2 Modic changes or vertebral endplate changes (defects/disruption/fissuring) indicating damage

WHAT IS THE RECOVERY TIME AFTER INTRACEPT® (BASIVERTEBRAL NERVE ABLATION)?

The Intracept® Procedure is a minimally invasive, outpatient procedure. Recovery time varies from patient to patient, depending on their specific situation, but most patients experience little post-procedure pain and quick recovery times. It is normal to have varying levels of pain after the procedure, but most patients require only minimal narcotic pain medications afterwards as the pain from the procedure can typically be controlled with ibuprofen or acetaminophen. It is recommended to avoid strenuous activity after the procedure for 2-4 weeks. You may perform light activity, such as walking and standing, but should avoid any lifting of more than 25 lbs. and moderate or strenuous exercises for the first 2 weeks. Avoid twisting, bending, pushing, pulling, or any straining movements. After 2 weeks, you may slowly return to normal activities, letting pain be your guide. In most cases you will be off work for several days depending on your job functions.

WHAT ARE THE RISKS ASSOCIATED WITH INTRACEPT® (BASIVERTEBRAL NERVE ABLATION)?

The Intracept® Procedure, as with any procedure, has risks that should be discussed between the patient and medical provider. Potential complications are infection, bleeding, and nerve injury. These complications are minimized by using sterile technique, prophylactic IV antibiotics to prevent surgical site infections, and imaging guidance with X-ray (fluoroscopy) to ensure safety. Overall, the Intracept® Procedure has an excellent safety profile and serious adverse effects/complications are rare.

IS INTRACEPT® (BASIVERTEBRAL NERVE ABLATION) COVERED BY INSURANCE?

There are several plans that currently provide coverage for the procedure, and for those that do not, there are a few steps needed to gain insurance coverage – which is common for a new, advanced procedure like this. The company that offers the Intracept® Procedure, Relievant Medsystems (part of Boston Scientific), has a program that works on behalf of patients and in concert with the physician to navigate prior authorization, communicating directly with the patient's insurance company to explain why the patient will benefit from the procedure. Our team at High Pointe Surgery Center also reviews the financial reimbursement from your insurance company to ensure adequate payment/financial coverage from your insurance company.

REFERENCES

[1] Koreckij T, Kreiner S, Khalil JG, Smuck M, Markman J, Garfin S. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-month treatment arm results. NASSJ. Published online October 26, 2021. DOI: https://doi.org/10.1016/j.xnsj.2021.100089.

[2] Fischgrund J, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020;29(8):1925-34. doi.org/10.1007/s00586-020-06448-x

[3] Relievant data on file as of January 2023.