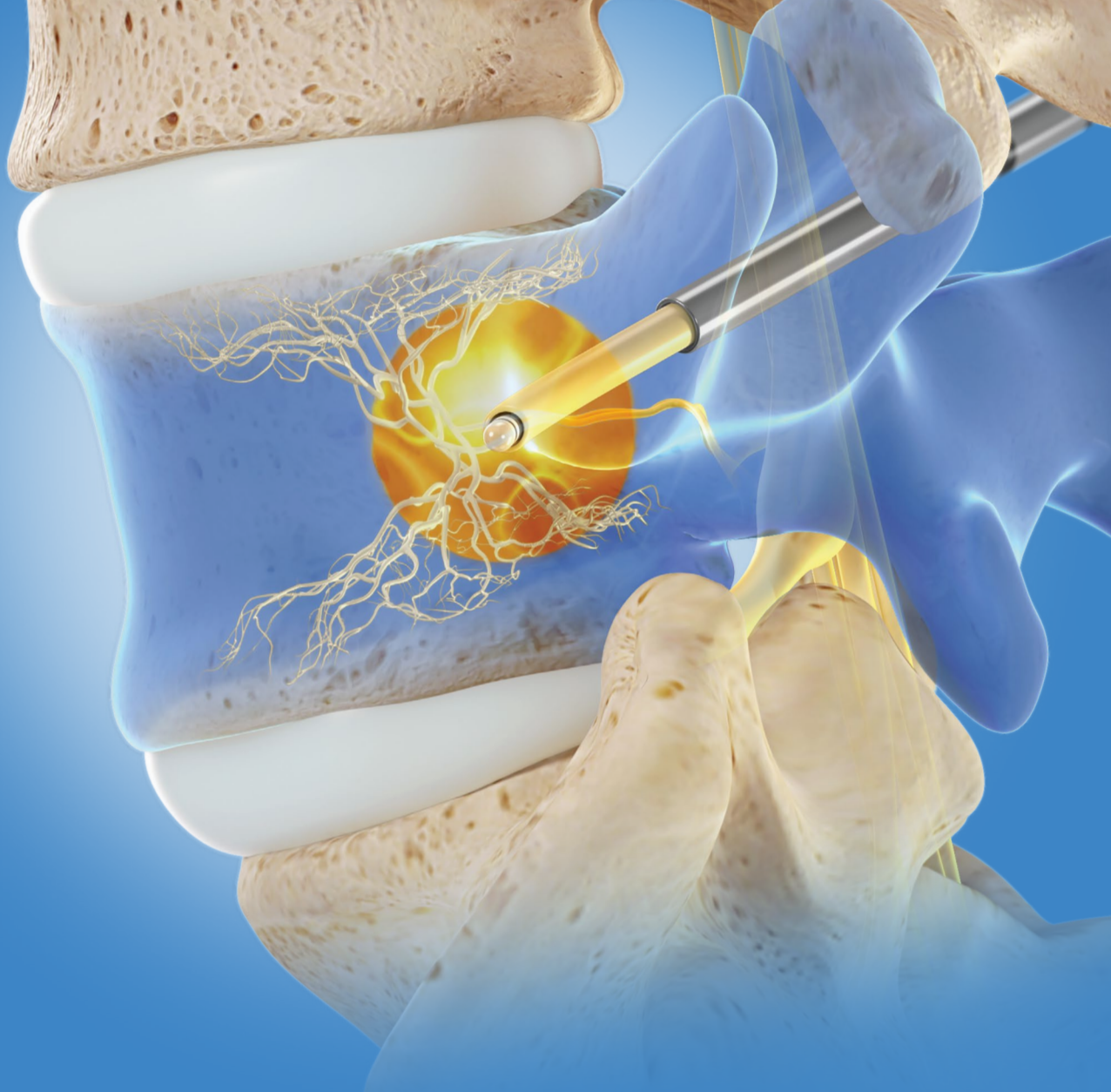


PROVEN, DURABLE RELIEF

The Intracept® Procedure

FOR CHRONIC VERTEBROGENIC LOW BACK PAIN

relievant medsystems

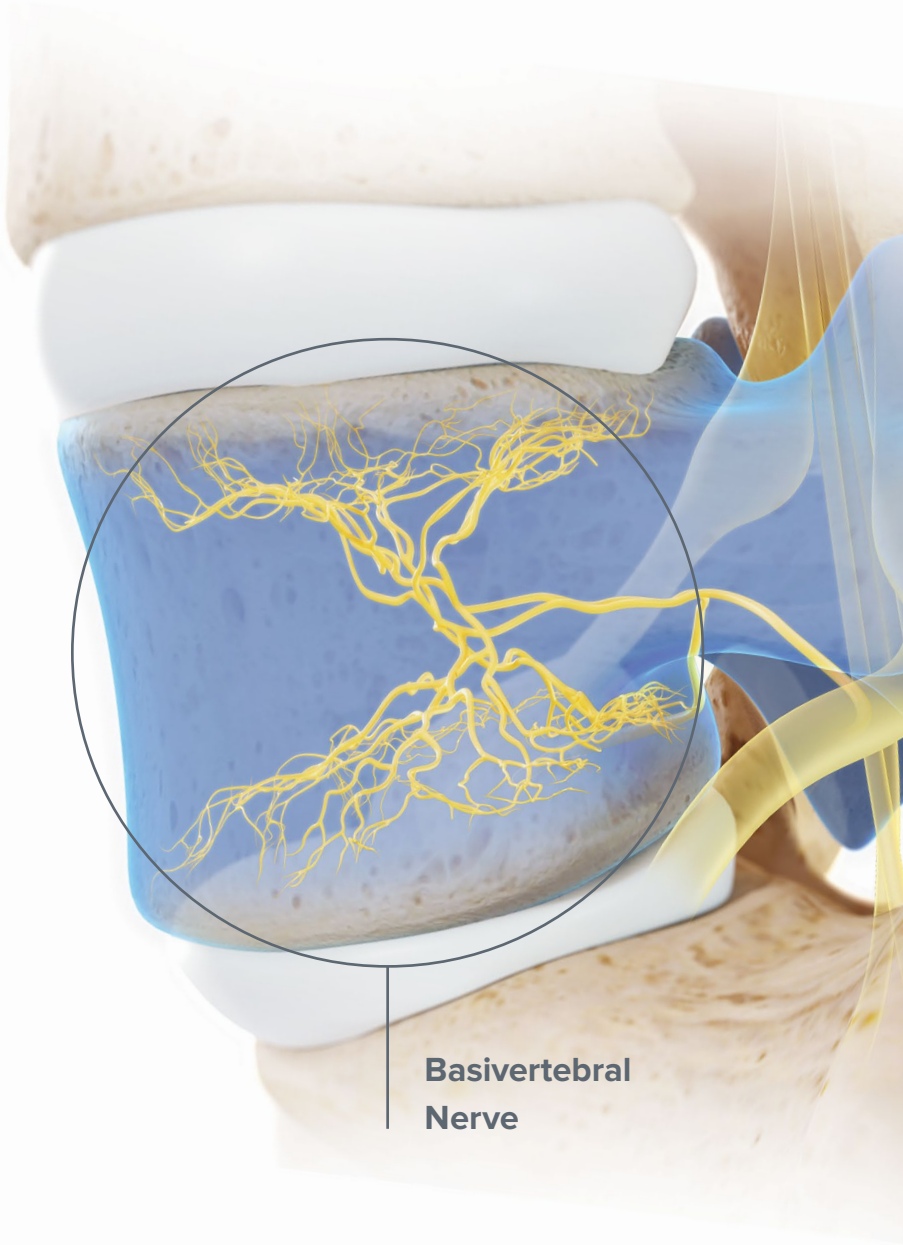
Vertebral Endplates

are a Significant Source of Chronic Low Back Pain

Research Findings:

1. Vertebral endplates are more innervated than intervertebral discs[1]
2. The basivertebral nerve innervates the endplates and proliferates in damaged and degenerated endplates[2,3]
3. Modic changes and associated endplate damage strongly correlate with chronic low back pain[4,5,6,7,8]

Collectively, these findings validate vertebral endplates as a significant source of chronic low back pain in patients with Type 1 or Type 2 modic changes, also referred to as vertebrogenic pain, and this pain is transmitted via the basivertebral nerve.



The Intracept Procedure

for the Relief of Chronic Vertebrogenic Low Back Pain

The **Intracept Procedure** is a minimally invasive procedure that targets the basivertebral nerve for the relief of chronic vertebrogenic low back pain.

Key Benefits of Intracept

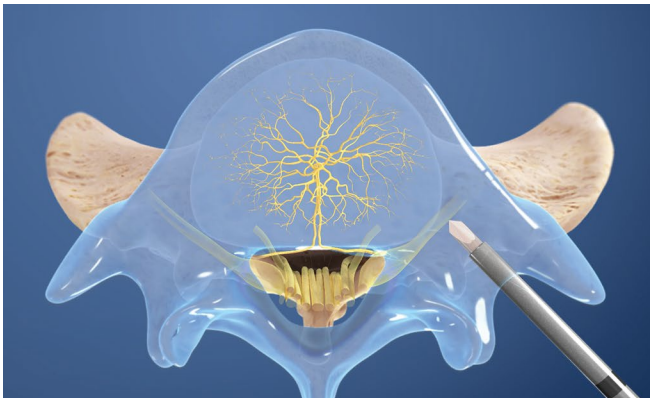
- **Provides a treatment option for patients who have not responded to conservative therapy**
- **Minimally invasive, outpatient procedure**
- **Implant-free and preserves the structure of the spine**
- **Provides durable relief of chronic vertebrogenic low back pain[9]**

Indications and Risks

The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

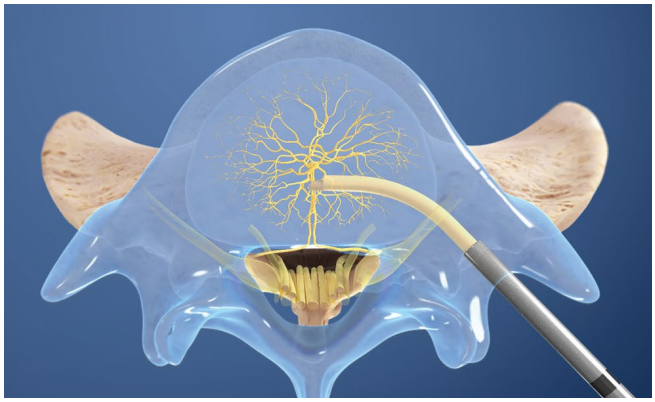
As with any surgical procedure, there are risks and considerations associated with the Intracept Procedure. Please see the device labeling for a discussion of the risks, contraindications, warnings and precautions.

Intracept Procedure Steps



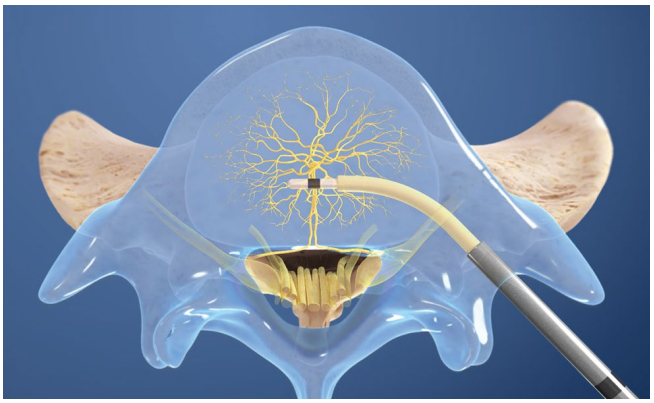
1 Access the pedicle

Under fluoroscopic guidance, the Intracept Introducer Cannula is advanced through the pedicle



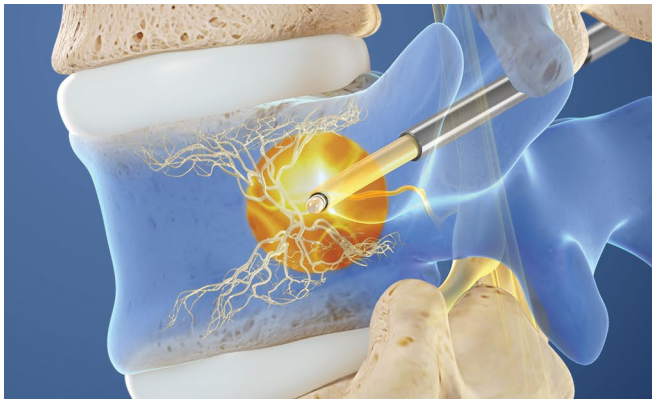
2 Create the channel

The Intracept Curved Cannula is utilized to create a channel to the trunk of the basivertebral nerve



3 Place the RF Probe

The Intracept Radiofrequency Probe is inserted into the curved path and placed at the basivertebral nerve



4 Ablate the BVN

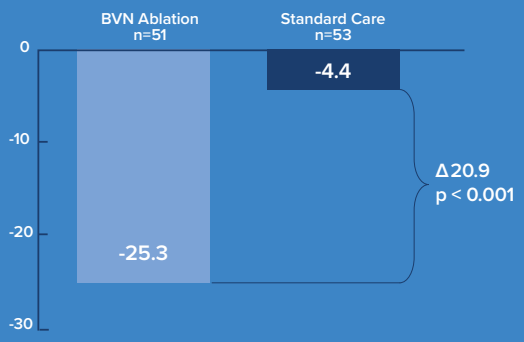
The Relievant Radiofrequency Generator is utilized to ablate the basivertebral nerve

UNPARALLELED Level I Evidence

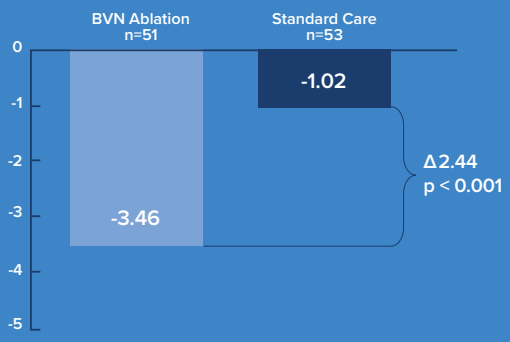
Level I
INTRACEPT Study

Demonstrated Clinical Significance[10]

ODI Change at 3 Months



VAS Change at 3 Months



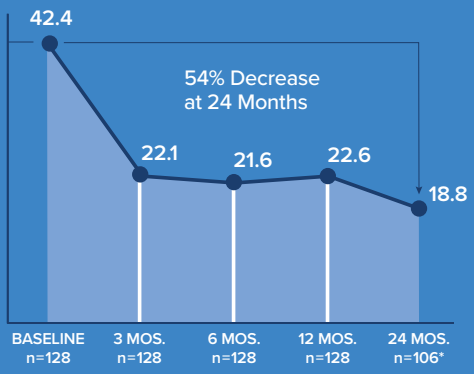
LS Mean difference ($p < 0.001$ per ANCOVA) in ODI and VAS between the BVN ablation and SC arms, adjusted for baseline ODI and VAS

Level I
SMART Trial

Demonstrated Durable Relief[9]

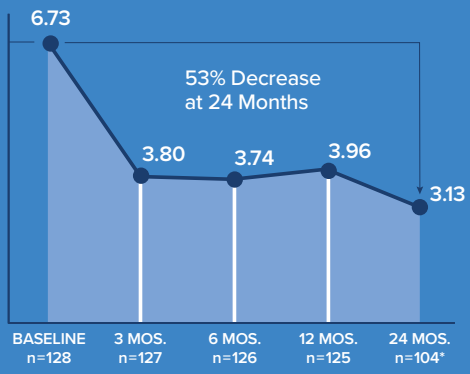
ODI Score

Treatment Arm
(Per Protocol Population)



VAS Score

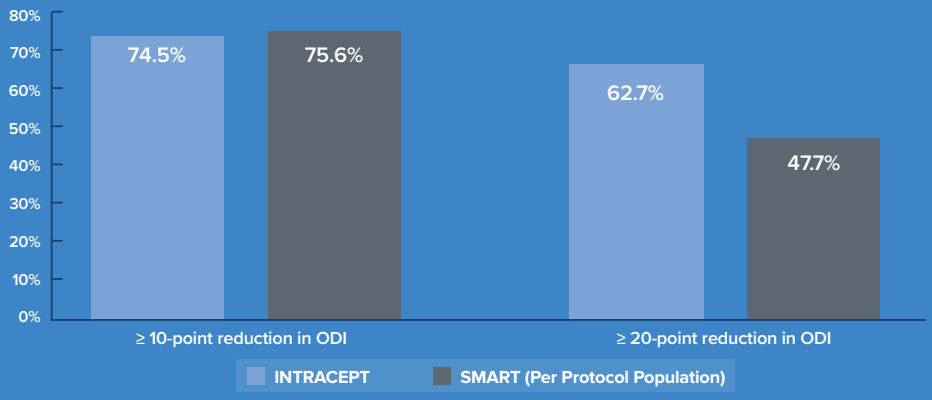
Treatment Arm
(Per Protocol Population)



*LOCF imputation used at all time points except 24 months where all observed data without imputation used

Consistent Outcomes in Two Level I Trials

ODI Responder Rates at 3 Months



REFERENCES

1. Fields AJ, Liebenberg EC, Lotz JC. Innervation of pathologies in the lumbar vertebral endplate and intervertebral disc. *The Spine Journal: Official Journal of the North American Spine Society* 2014;14(3):513-521.
2. Bailey JF, Liebenberg E, Degmetich S, Lotz JC. Innervation patterns of PGP 9.5-positive nerve fibers within the human lumbar vertebra. *Journal of Anatomy* 2011;218(3):263-70.
3. Lotz JC, Fields AJ, Liebenberg EC. The Role of the Vertebral End Plate in Low Back Pain. *Global Spine J* 2013;03:153-64.
4. Modic MT, Steinberg PM, Ross JS, Masaryk TJ, Carter JR. Degenerative disk disease: assessment of changes in vertebral body marrow with MR imaging. *Radiology* 1988;166:193-9.
5. Carragee EJ, Alamin TF, Miller JL, Carragee JM. Discographic, MRI and psychosocial determinants of low back pain disability and remission: a prospective study in subjects with benign persistent back pain. *The Spine Journal: Official Journal of the North American Spine Society* 2005;5(1):24-35.
6. Weishaupt D, Zanetti M, Hodler J, et al. Painful Lumbar Disk Derangement: Relevance of Endplate Abnormalities at MR Imaging. *Radiology* 2001;218(2):420-7.
7. Kuisma M, Karppinen J, Niinimaki J, et al. Modic changes in endplates of lumbar vertebral bodies: prevalence and association with low back and sciatic pain among middle-aged male workers. *Spine* 2007;32(10):1116-22.
8. Mok K, Samartzis D, Karppinen J, et al. Modic changes of the lumbar spine: prevalence, risk factors, and association with disc degeneration and low back pain in a large-scale population-based cohort. *The Spine Journal: Official Journal of the North American Spine Society* 2016;16(1):32-41.
9. Fischgrund J, Sasso R, Bae H, Rhyne A. Two-year outcomes of patients treated with BVN ablation for the relief of chronic low back pain: results of the SMART trial. *The Spine Journal: Official Journal of the North American Spine Society* 2018;18(8):S15.
10. Khalil J, Smuck M, Koreckij T, et al. A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain. *The Spine Journal* 2019; doi: https://doi.org/10.1016/j.spinee.2019.05.598

relievant medsystems

Relievant Medsystems, Inc.
8500 Normandale Lake Blvd, Suite 2150
Minneapolis, MN 55437
P 650-368-1000
relievant.com

MKT 0037, Rev E