

# PROVEN, DURABLE RELIEF

The Intracept<sup>®</sup> Procedure

FOR CHRONIC VERTEBROGENIC LOW BACK PAIN

  
medsystems

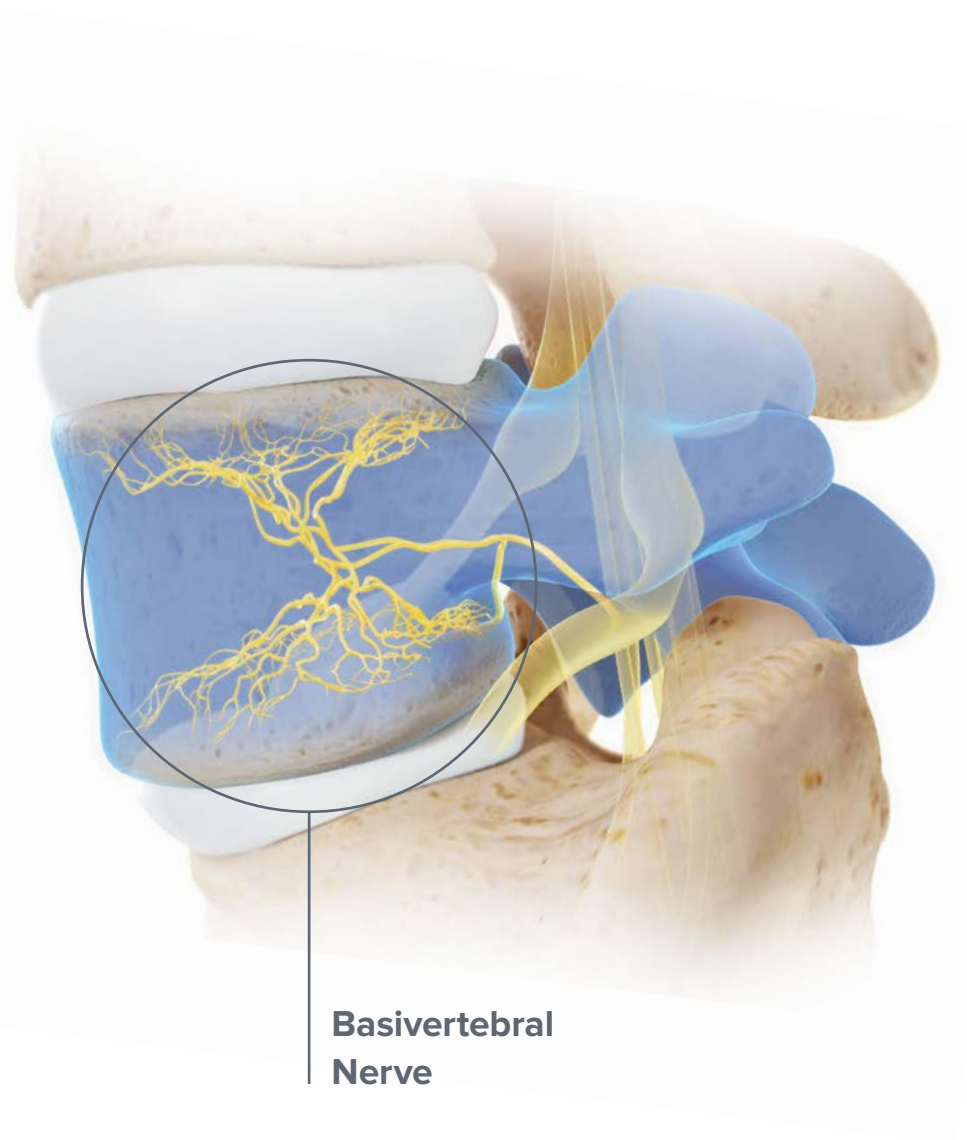
# Vertebral Endplates

are a Significant Source of Chronic Low Back Pain

## Research Findings:

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

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

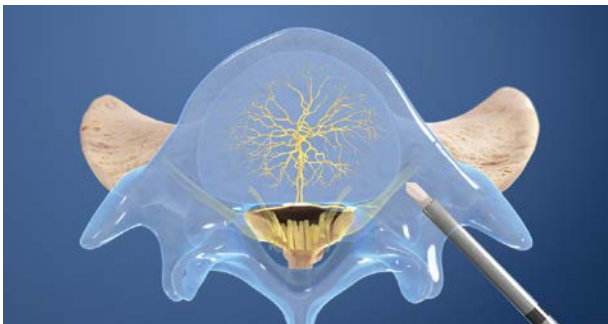
## for the Relief of Chronic Vertebrogenic Low Back Pain

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

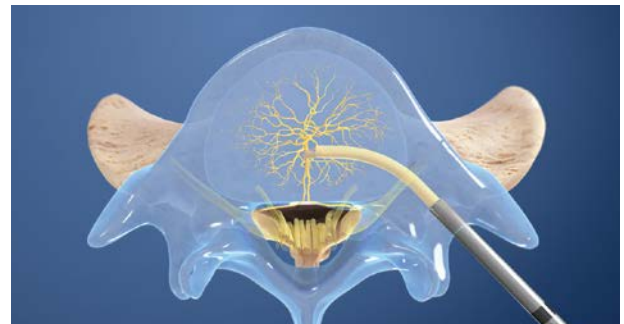
- Provides a treatment option for patients who have not responded to conservative therapy
- Minimally invasive, outpatient procedure
- Implant-free and preserves the structure of the spine
- Provides durable relief of chronic vertebrogenic low back pain<sup>9</sup>

### Intracept Procedure Steps



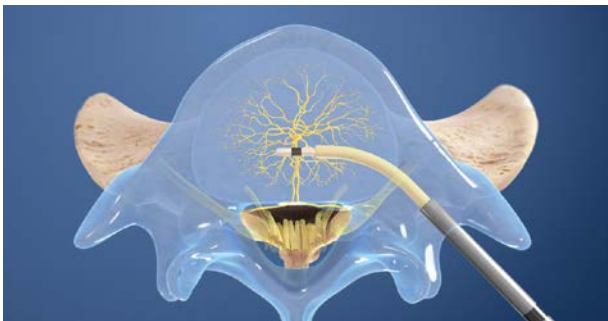
#### 1 Access the pedicle

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

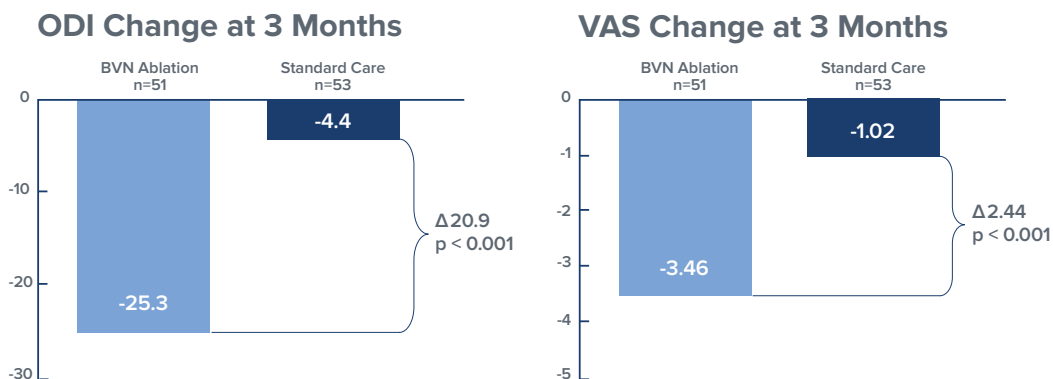


#### 4 Ablate the BVN

The Relevant Radiofrequency Generator is utilized to ablate the basivertebral nerve

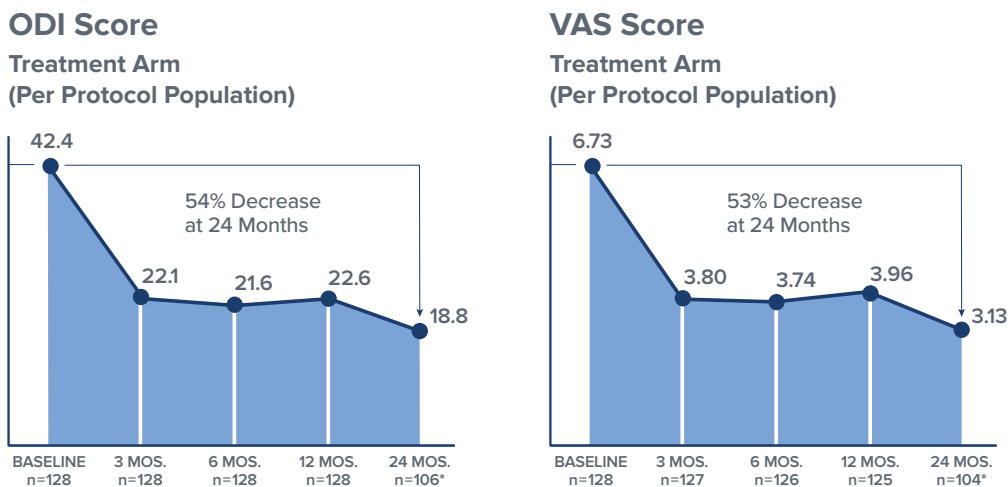
# UNPARALLELED Level I Evidence

Level I  
INTRACEPT Study  
Demonstrated  
Clinical  
Significance<sup>10</sup>



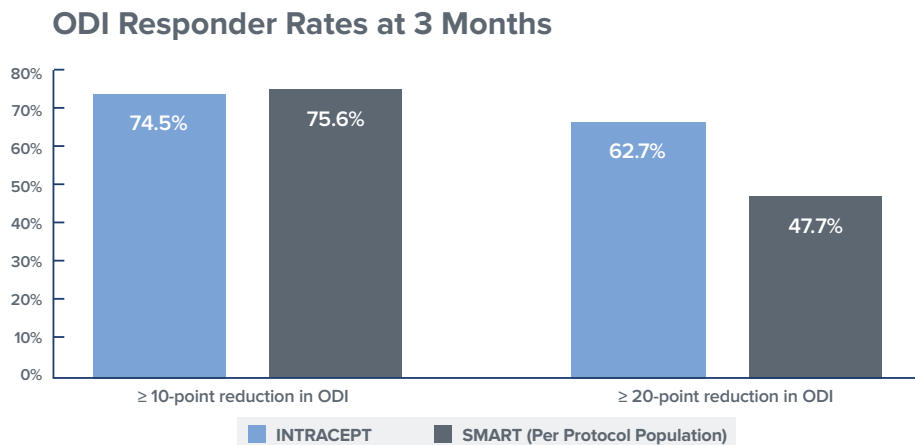
LS Mean difference (p < 0.001 per ANCOVA) in ODI and VAS between the BVN ablation and SC arms, adjusted for baseline ODI and VAS

Level I  
SMART Trial  
Demonstrated  
Durable  
Relief<sup>9</sup>



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

Consistent  
Outcomes in  
Two Level I  
Trials



# The Intracept System



## 1 Access the pedicle

- Trocar Tip Introducer and Cannula
- Bevel Tip Introducer and Cannula

## 2 Create the channel

- J-Stylet and Curved Cannula
- Straight Stylet

## 3 Ablate the BVN

- Radiofrequency Probe
- Radiofrequency Generator

# 510(k) Clearances

## Radiofrequency Probe

510(k) Number: K180369

Decision Date: 09/14/2018

Decision: Substantially Equivalent (SESE)

## Access Instruments

510(k) Number: K170827

Decision Date: 08/09/2017

Decision: Substantially Equivalent (SESE)

## Radiofrequency Generator

510(k) Number: K171143

Decision Date: 08/18/2017

Decision: Substantially Equivalent (SESE)

## Indications

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).

## Risks

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.

# Product Information

CATALOG NUMBER	DESCRIPTION
RLV PK	<b>PROCEDURE KIT</b> <ul style="list-style-type: none"><li>• Access Instruments (1)</li><li>• Radiofrequency Probe (1)</li></ul>
RLV RFP05	<b>RADIOFREQUENCY PROBE</b>
RLV AK05	<b>ACCESS INSTRUMENTS</b> <ul style="list-style-type: none"><li>• Trocar Tip Introducer (1)</li><li>• Bevel Tip Introducer (1)</li><li>• Introducer Cannulas (2)</li><li>• J-Stylet (1)</li><li>• Curved Cannulas (2)</li><li>• Straight Stylet (1)</li></ul>
RLV AKA05	<b>ADDITIONAL LEVEL ACCESS INSTRUMENTS</b> <ul style="list-style-type: none"><li>• Introducer Cannula (1)</li><li>• Curved Cannula (1)</li></ul>
RLV RFG01	<b>RADIOFREQUENCY GENERATOR</b>

## REFERENCES

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### **Relievaant Medsystems, Inc.**

8500 Normandale Lake Blvd, Suite 2150  
Minneapolis, MN 55437  
P 650-368-1000  
[relievaant.com](http://relievaant.com)