PROVEN, DURABLE RELIEF
The Intrasept® Procedure
FOR CHRONIC VERTEBROGENIC LOW BACK PAIN
Vertebral Endplates are a Significant Source of Chronic Low Back Pain

Research Findings:

1. Vertebral endplates are more innervated than intervertebral discs.

2. The basivertebral nerve innervates the endplates and proliferates in damaged and degenerated endplates.

3. Modic changes and associated endplate damage strongly correlate with chronic low back pain.

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 Intratect Procedure
for the Relief of Chronic Vertebrogenic Low Back Pain

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

**Key Benefits of Intratect**
- 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

**Intratect Procedure Steps**

1. **Access the pedicle**
   Under fluoroscopic guidance, the Intratect Introducer Cannula is advanced through the pedicle

2. **Create the channel**
   The Intratect Curved Cannula is utilized to create a channel to the trunk of the basivertebral nerve

3. **Place the RF Probe**
   The Intratect Radiofrequency Probe is inserted into the curved path and placed at the basivertebral nerve

4. **Ablate the BVN**
   The Relevent Radiofrequency Generator is utilized to ablate the basivertebral nerve
UNPARALLELED Level I Evidence

Level I INTRACEPT Study
Demonstrated Clinical Significance

**ODI Change at 3 Months**

- BVN Ablation: 42.4
- Standard Care: 18.8
- Δ20.9 p < 0.001

**VAS Change at 3 Months**

- BVN Ablation: -3.46
- Standard Care: -1.02
- Δ2.44 p < 0.001

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

**ODI Score**

- Treatment Arm (Per Protocol Population)
- Baseline: 42.4
- 3 MOS: 22.1
- 6 MOS: 21.6
- 12 MOS: 22.6
- 24 MOS: 18.8
- 54% Decrease at 24 Months

**VAS Score**

- Treatment Arm (Per Protocol Population)
- Baseline: 6.73
- 3 MOS: 3.80
- 6 MOS: 3.74
- 12 MOS: 3.96
- 24 MOS: 3.13
- 53% Decrease at 24 Months

*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**

- INTRACEPT: 74.5%
- SMART (Per Protocol Population): 75.6%
- 62.7%
- 47.7%

≥ 10-point reduction in ODI
≥ 20-point reduction in ODI
The Intracpect 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 Intracpect Procedure. Please see the device labeling for a discussion of the risks, contraindications, warnings and precautions.
# Product Information

<table>
<thead>
<tr>
<th>CATALOG NUMBER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RLV PK</strong></td>
<td>PROCEDURE KIT</td>
</tr>
<tr>
<td></td>
<td>• Access Instruments (1)</td>
</tr>
<tr>
<td></td>
<td>• Radiofrequency Probe (1)</td>
</tr>
<tr>
<td><strong>RLV RFP05</strong></td>
<td>RADIOFREQUENCY PROBE</td>
</tr>
<tr>
<td><strong>RLV AK05</strong></td>
<td>ACCESS INSTRUMENTS</td>
</tr>
<tr>
<td></td>
<td>• Trocar Tip Introducer (1)</td>
</tr>
<tr>
<td></td>
<td>• Bevel Tip Introducer (1)</td>
</tr>
<tr>
<td></td>
<td>• Introducer Cannulas (2)</td>
</tr>
<tr>
<td></td>
<td>• J-Stylet (1)</td>
</tr>
<tr>
<td></td>
<td>• Curved Cannulas (2)</td>
</tr>
<tr>
<td></td>
<td>• Straight Stylet (1)</td>
</tr>
<tr>
<td><strong>RLV AKA05</strong></td>
<td>ADDITIONAL LEVEL ACCESS INSTRUMENTS</td>
</tr>
<tr>
<td></td>
<td>• Introducer Cannula (1)</td>
</tr>
<tr>
<td></td>
<td>• Curved Cannula (1)</td>
</tr>
<tr>
<td><strong>RLV RFG01</strong></td>
<td>RADIOFREQUENCY GENERATOR</td>
</tr>
</tbody>
</table>
REFERENCES


