

INTRACEPT

*A minimally-invasive,
outpatient procedure for patients
with vertebrogenic pain.*

Patient Information Guide

CANTOR SPINE CENTER

AT THE PALEY ORTHOPEDIC & SPINE INSTITUTE

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ANTHONY GIUFFRIDA, MD

Interventional Spine & Pain Management

Anthony Giuffrida, MD, Cantor Spine's board-certified Physiatrist, is the first and only physician in South Florida to offer breakthrough treatment for patients with chronic low back pain. The Intracept Procedure is a new minimally invasive approach that is **clinically proven to provide long term relief for chronic low back pain.**

Low back pain is the most expensive occupational disorder in the United States and a leading cause of disability worldwide. CLBP impacts approximately 30 million people in the United States with nearly 900,000 new occurrences each year. The majority of CLBP sufferers do not get adequate relief from conservative treatments and are not surgical candidates. Today, nearly 80 percent of CLBP sufferers fail to find pain relief with available treatments.

One cause of CLBP is microfractures of the vertebral body endplates. Back injury, genetic makeup, and other factors can cause degeneration of the spine, placing stress on the vertebral body endplates. The stress on the endplates can lead to microfractures. The basivertebral nerve is located within the vertebral body and transmits pain from the vertebral body endplates causing CLBP.

Intracept is a **minimally invasive procedure that integrates two decades of scientific research** on the basivertebral nerve and its role in CLBP. Following a small incision, instruments and Xray guidance is used to reach the basivertebral nerve. Once the correct position is verified radiofrequency energy, or heat, ablates the basivertebral nerve which in turn will stop the transmission of pain signals. Intracept is an outpatient procedure, which does not involve an implant or change the structure of the spine. A 225-patient clinical trial demonstrated the safety and effectiveness of the Intracept Procedure, proving long-term relief of chronic low back pain.

“Other than surgery, we’ve never had anything to offer patients suffering from debilitating chronic low back pain that have failed conservative therapy. With the Intracept Procedure, we are embarking on a paradigm shift in how we treat chronic low back pain. The significant improvement in pain and function demonstrated by the Intracept Procedure provides clear proof of the effectiveness of this treatment.”

~ Anthony Giuffrida, MD.

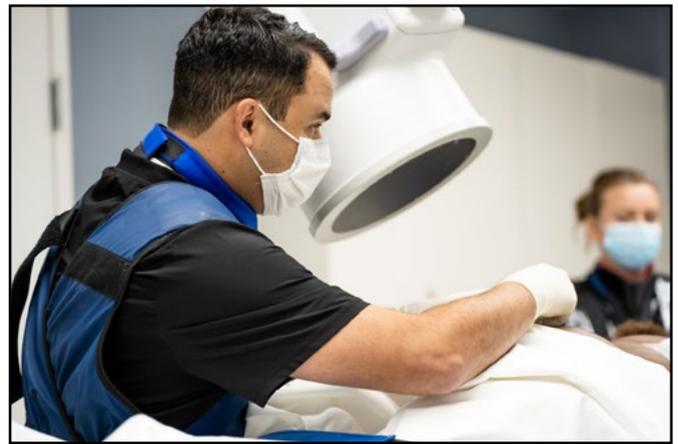
ABOUT THE INTRACEPT PROCEDURE

Relievant Medsystem's Intracept System is based on ground breaking anatomic research that identified and demonstrated the role of the basivertebral nerve (BVN) in generating low back pain from the vertebral body endplates. The procedure uses a trans-pedicular, minimally invasive approach to reach the BVN near the center of the vertebral body, and uses radiofrequency energy to ablate the nerve; once ablated, **these nerves no longer transmit pain signals**. Dr. Giuffrida performs the Intracept Procedure under image guidance in the outpatient setting, with the entire procedure taking approximately 80 minutes. Treated patients report nearly immediate relief of their back pain. The Intracept 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 either Type 1 or Type 2 Modic changes on an MRI.

At Cantor Spine Institute, we specialize in a holistic approach to spinal care through minimally-invasive surgery, cutting-edge technology, methodical research and analysis, and exceptional patient experiences. Our practice is anchored by a comprehensive, whole-body approach to spinal care, and patient-specific perioperative risk mitigation program.

Our first goal is always to avoid surgery. If a patient does not respond to a well-managed, non-surgical treatment path, then we identify the **ideal minimally-invasive procedure to pursue**. In chronic lower back pain, the Intracept procedure has clinically shown to provide long term relief.

Our nationally-recognized team takes the time to connect with, listen to, and really hear a patient and caregiver's needs and concerns. We thoroughly review, assess, and identify the best treatment plan for a given individual. Every



case is different, but all patients are the same in receiving the most thoughtful, personalized plan for treatment and recovery. If you or a loved one are suffering with chronic back pain, please call our office at **(985) 567-1332** to schedule your appointment with **Dr. Giuffrida**.

HOW INTRACEPT WORKS

MINIMALLY INVASIVE. LASTING RELIEF.

Many patients with CLBP are told their pain is discogenic – pain originating from the discs located between the spinal vertebrae. But research over the past 30 years has shown that for many of these patients, their pain actually comes from their vertebral endplates – the bone on either side of the disc. This type of pain is known as vertebrogenic pain.

Intracept is a minimally-invasive, outpatient procedure for patients with vertebrogenic pain. The Procedure targets a specific nerve within the vertebra called the basivertebral nerve, and has been shown to improve function and decrease pain – allowing many patients to return to a level of activity they enjoy.

VERTEBRAL ENDPLATE PAIN

Historically, intervertebral discs have been the presumed source of most chronic low back pain.

Dr. Giuffrida performs the Intracept Procedure under image guidance in the outpatient setting, with the entire procedure taking approximately 80 minutes.

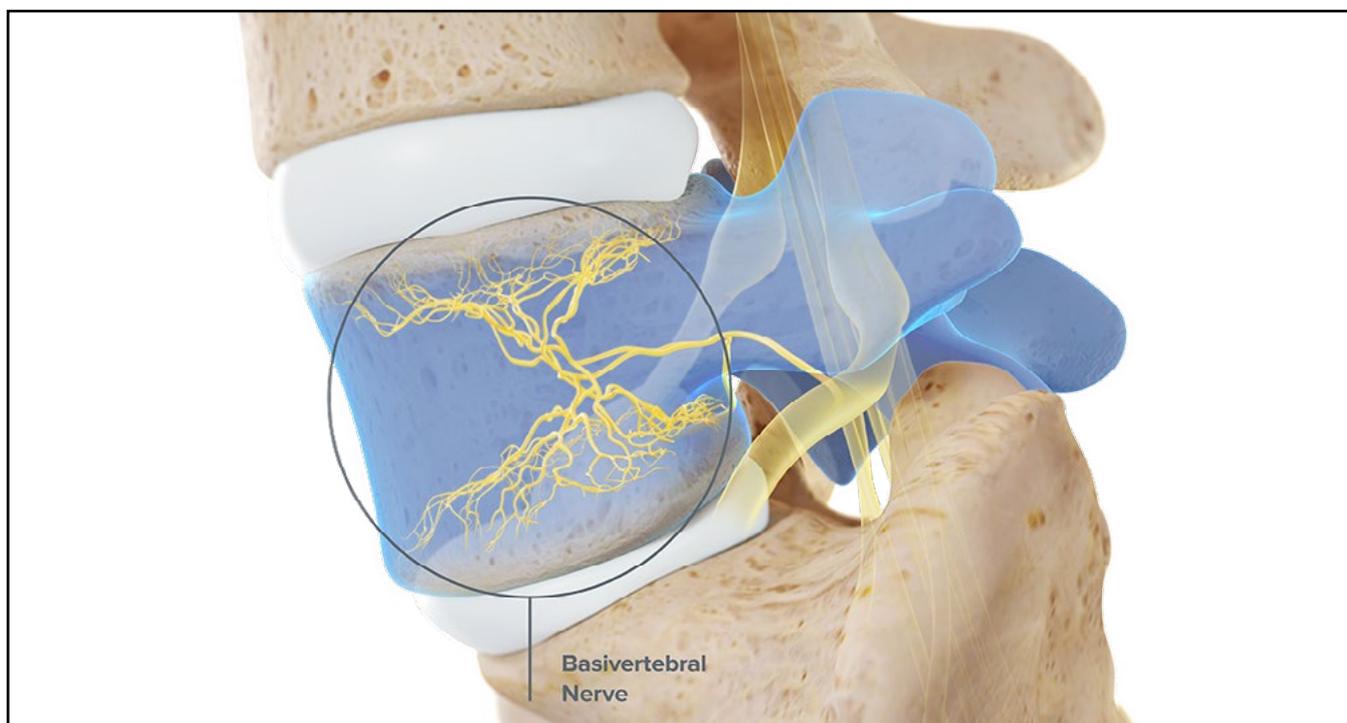
However, treatments focused on the disc have not produced the desired success rates and did not correlate with disc degeneration on MR imaging or on discography results. Recent research has concluded that vertebral body endplates are a significant source of chronic low back pain.

THE ROLE OF THE BASIVERTEBRAL NERVE

Intraosseous nerves within the vertebral body were described in 1998 by Antonacci et al.¹. The existence and distribution of these intraosseous nerves within the vertebral body were subsequently further detailed by Frasca et al.² in 2003 and Bailey et al.³ in 2011, who also described the source of the intraosseous nerves

as the basivertebral nerve (BVN). The BVN enters the posterior vertebral body via the basivertebral foramen (Figure 1) and arborizes near the center of the vertebral body, sending branches to innervate the superior and inferior endplates. These nerve endings have been shown to proliferate in damaged and degenerated endplates⁴ and are more innervated than the intervertebral discs⁵.

In 2003, Frasca et al.² reported on the presence of Substance P within the BVN, concluding that these nerves have the potential for transmitting pain signals. Subsequently in 2011, Bailey et al.³ showed that the basivertebral nerves are PGP 9.5-positive, establishing their role in pain transmission.



ARE YOU A CANDIDATE

- Chronic Low Back Pain of at least 6 months
- Not responded to at least 6 months of conservative care
- Type 1 or Type 2 Modic changes on an MRI (Figure 1)

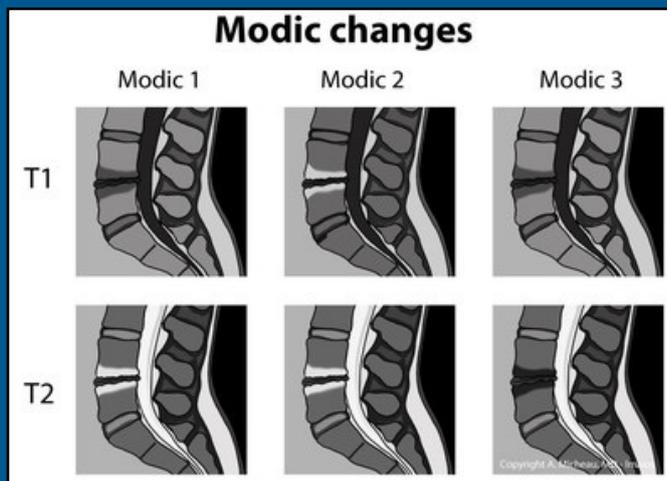
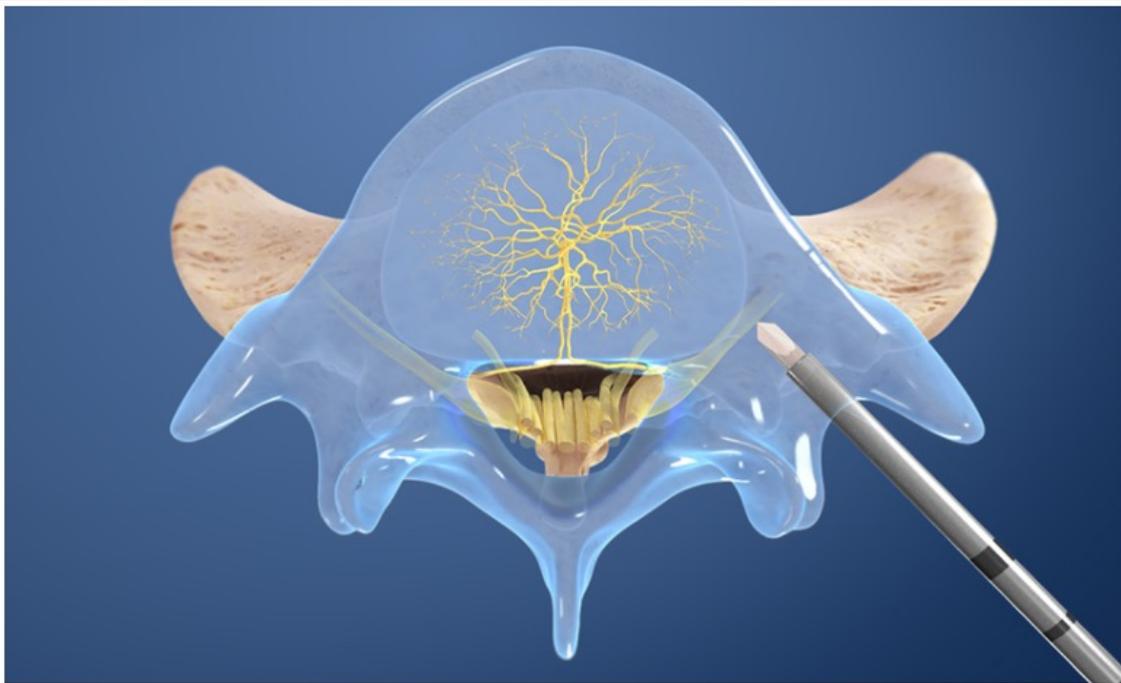


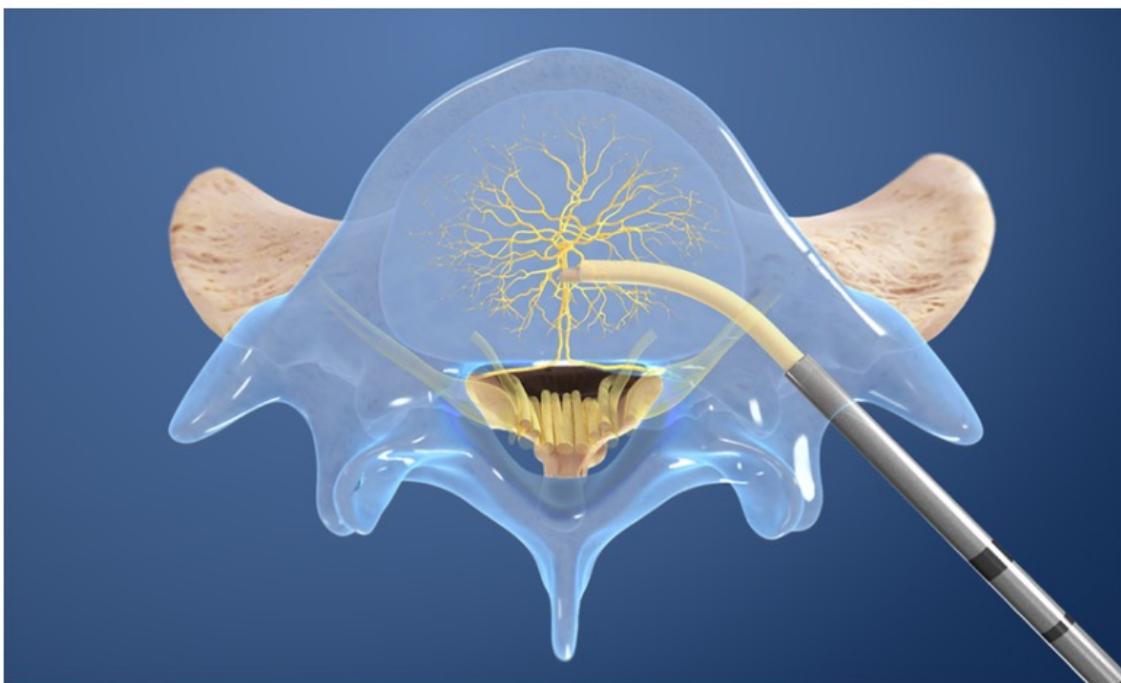
Figure 1

INTRACEPT PROCEDURE STEPS



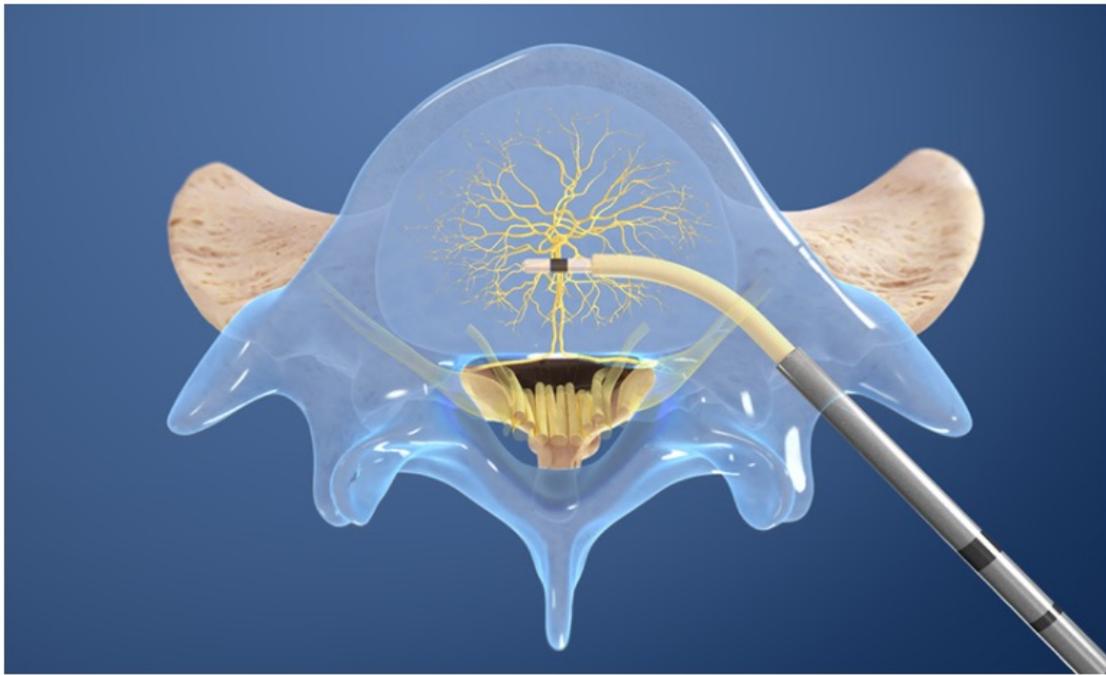
1 Access the pedicle

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



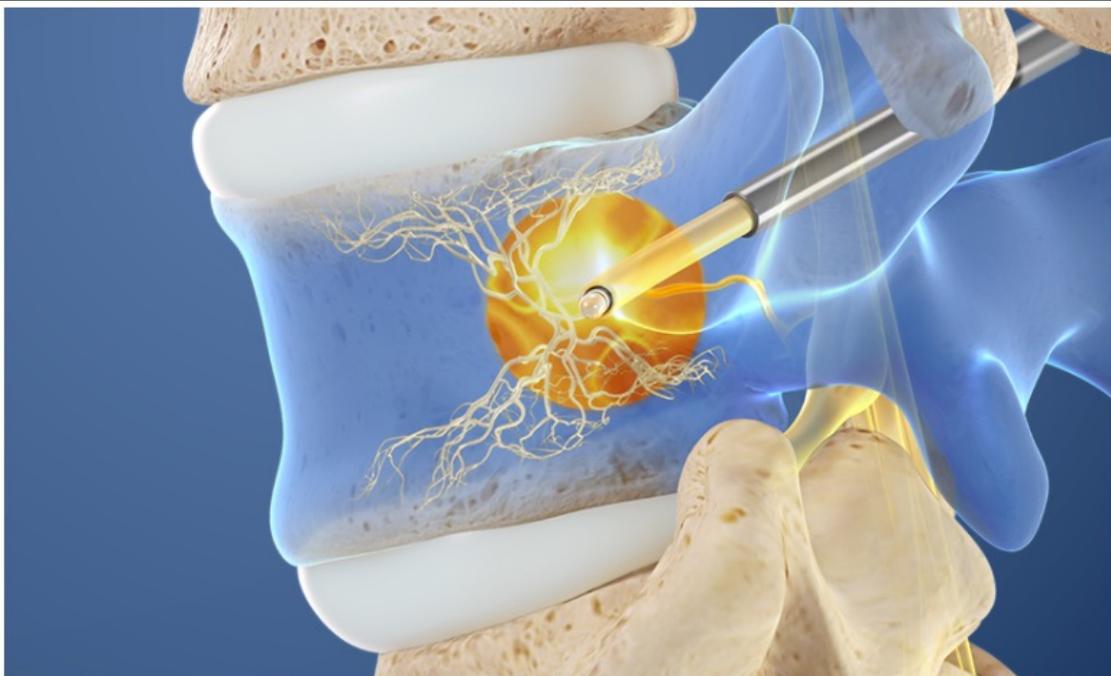
2 Create the channel

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



Intrasept is a minimally-invasive, outpatient procedure for patients with vertebrogenic pain. The Procedure targets a specific nerve within the vertebra called the basivertebral nerve, and has been shown to improve function and decrease pain – allowing many patients to return to a level of activity they enjoy.

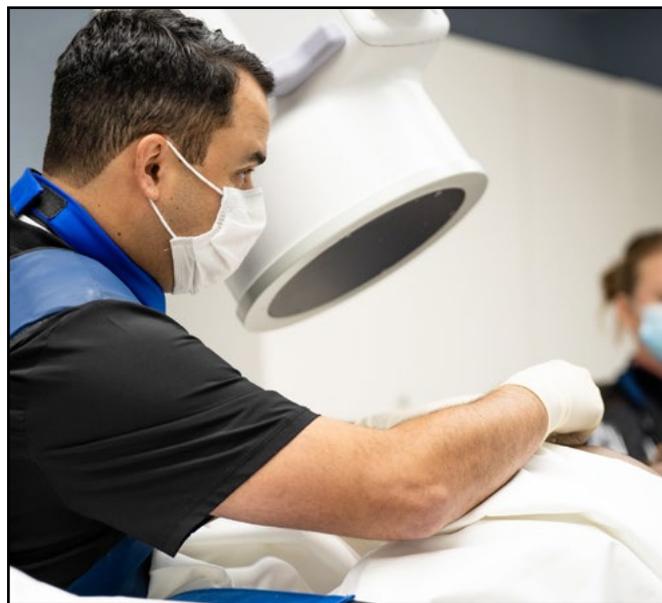
INDICATIONS & RISKS

The Intrasept® Procedure is indicated for patients who have had chronic low back pain for at least six months, who have tried conservative care for at least six months, and whose MRI shows features consistent with Modic changes – indicating damage at the vertebral endplates has led to inflammation.

Not every patient who meets these criteria is a candidate for Intrasept, however – in fact, there are specific characteristics indicating a patient should not be considered for the procedure. These contraindications include being pregnant, having weakened cardiac or pulmonary function, having an implanted electronic medical device in the body (such as a pacemaker or defibrillator), being diagnosed with a systemic or local infection, or having an anatomy that could be damaged unintentionally while ablating the basivertebral nerve (based on your physicians' clinical review). Intrasept is also contraindicated in patients who are skeletally immature – which generally means individuals under the age of 18 are not candidates.

There are also certain risks and precautions regarding the procedure which you should be aware of before proceeding.

Talk with your doctor about what indicates, and contraindicates, certain patients for the Intrasept procedure – as well as the risks and precautions for the procedure.



PATIENT TESTIMONIAL



James Seymour, Chronic Low Back Pain

"I have been suffering with chronic low back pain for more than 20 years. I have sought out massage therapy, chiropractic care, and epidural steroid injections to relieve my pain. Some of it worked for a while, but I after a few months the pain would always return. Eventually, I just started thinking I'd have to learn to live with chronic pain. That was until I found **Dr. Anthony Giuffrida** at **Cantor Spine Institute**. My first treatment was on the conservative side. I had an intradiscal injection that helped me for about two months. Dr. Giuffrida told me about the modic changes occurring in my spine and recommended that I try the new FDA approved procedure called Intrasept. I agreed because, based on the research, individuals have been pain-free for years after the procedure. Dr. Giuffrida performed the procedure on me in early January 2019. I had immediate relief! I would wholeheartedly recommend anyone with modic changes in their lower back to see Dr. Giuffrida."

CANTOR SPINE CENTER

AT THE PALEY ORTHOPEDIC & SPINE INSTITUTE

3000 BAYVIEW DRIVE, SUITE 100
FORT LAUDERDALE, FL 33306

P: 954-567-1332

www.CantorSpineCenter.com

www.PaleyInstitute.org

