Boston Scientific
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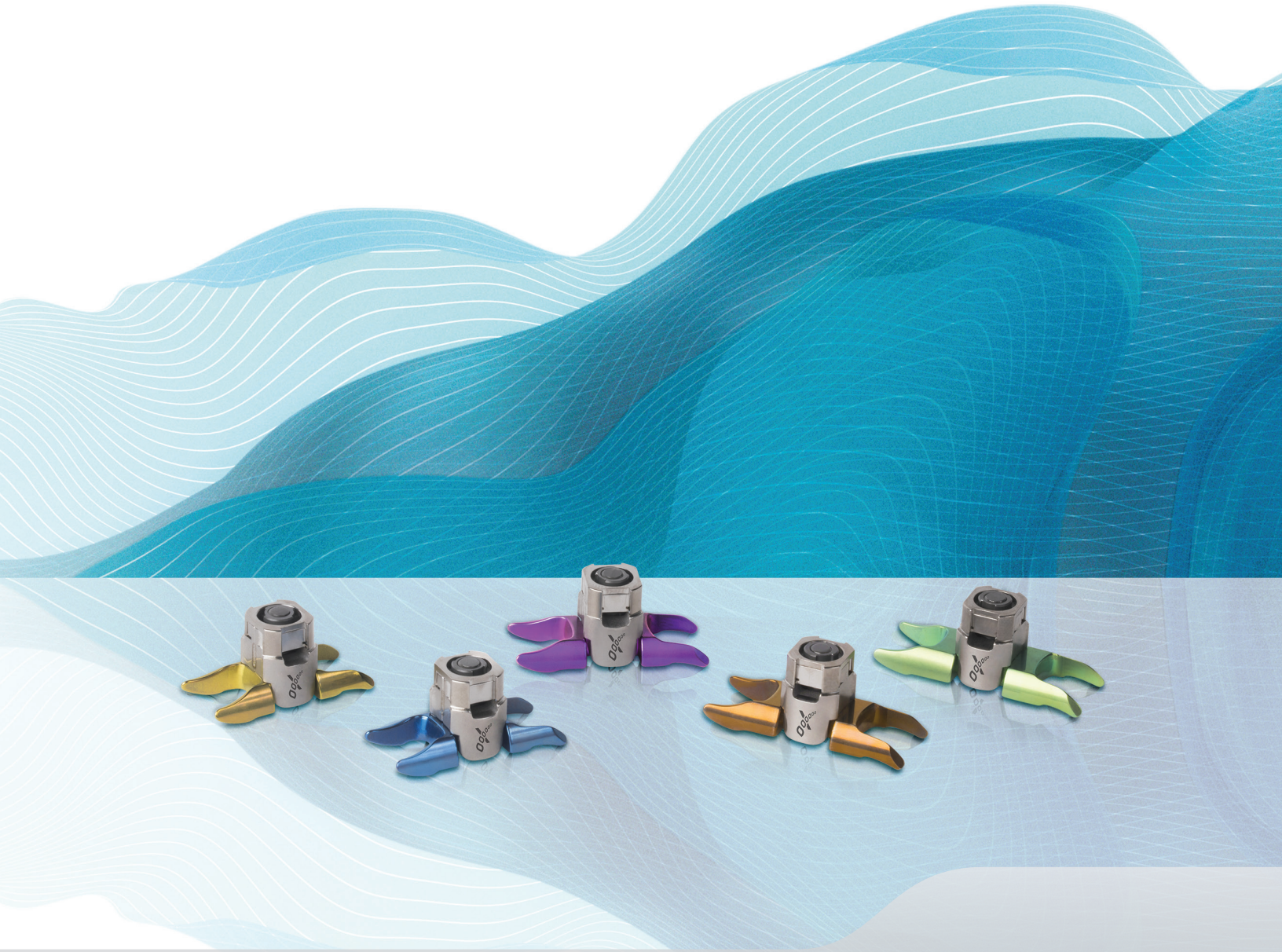
VERTIFLEX™
PROCEDURE
Superion™ Indirect Decompression System

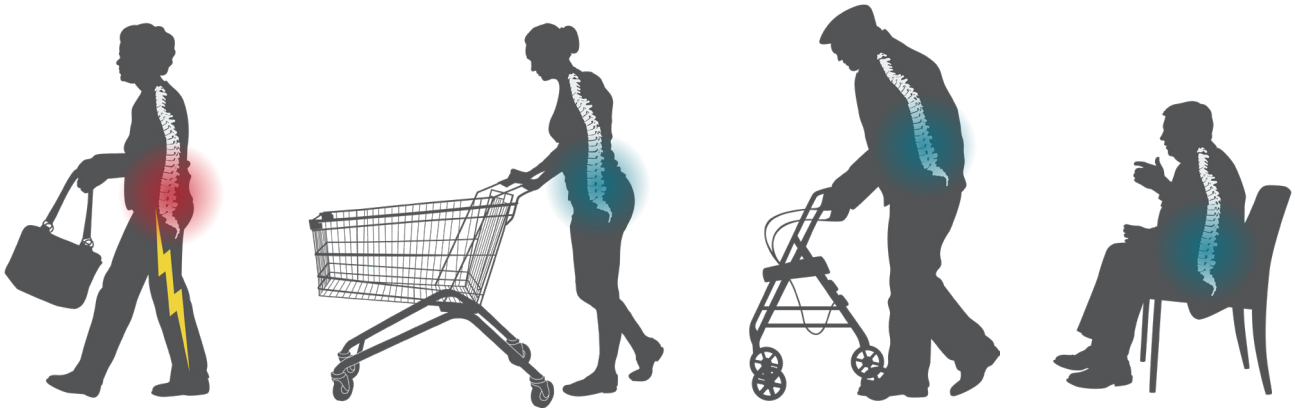
# DEFINING THE TREATMENT FOR LUMBAR SPINAL STENOSIS

## PROVEN. PUBLISHED. PREFERRED.



# LSS PATIENTS ARE EVERYWHERE

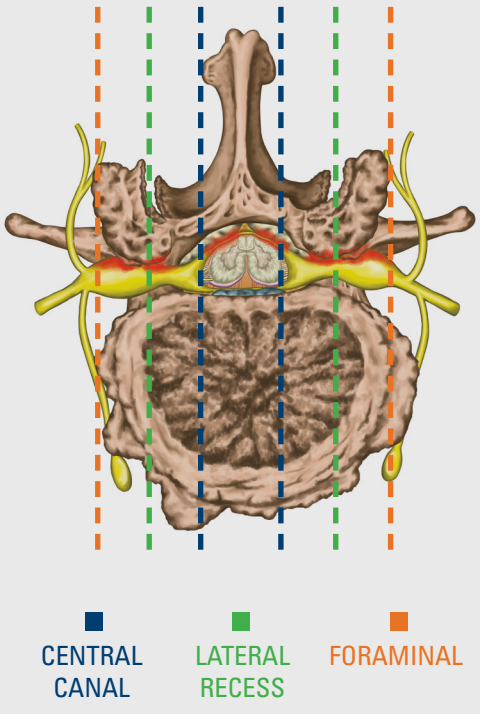
One of the most common degenerative diseases is Lumbar Spinal Stenosis (LSS). Patients with LSS experience pain while walking, weakness or loss of balance, or numbness or tingling in legs, calves, or buttocks, and find relief in a flexed position. These patients are in pain. **The Vertiflex™ Procedure† provides clinically proven[1,2] long-term relief.**



| EXTENSION | "SHOPPING CART" SIGN | FLEXION |
|---|---|---|
| Extension provokes symptoms, pain/ weakness in legs | Leaning forward while walking to ambulate more comfortably | Sitting relieves symptoms |

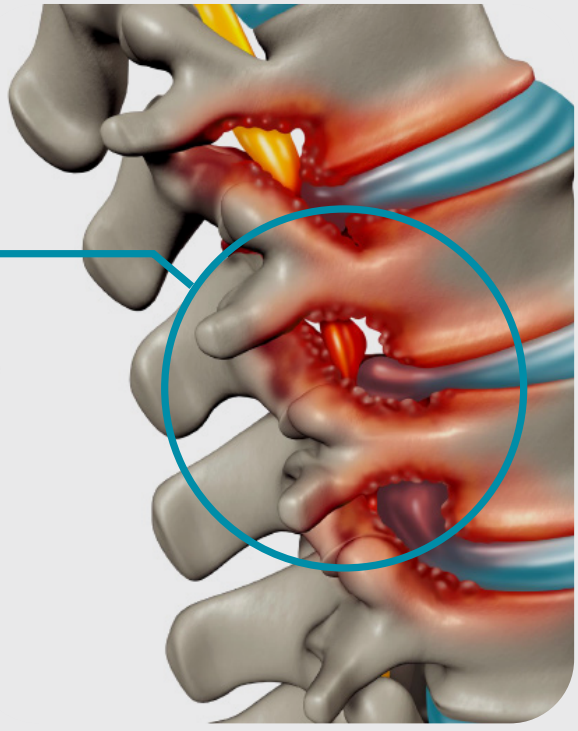
# THE ANSWER TO A MECHANICAL PROBLEM

THE VERTIFLEX PROCEDURE IS CLINICALLY PROVEN TO TREAT ALL FORMS OF MODERATE LSS.




## TREAT THE ROOT CAUSE

The Vertiflex Procedure uses **indirect decompression** to treat the root cause of pain by lifting pressure from the nerve roots at the affected segment.



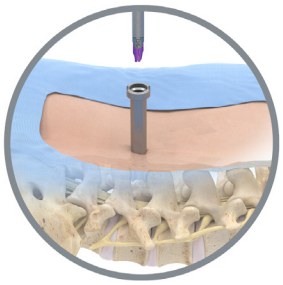
# VERTIFLEX PROCEDURE: ADVANCED TECHNOLOGY, MINIMALLY INVASIVE TREATMENT FOR LSS

The Vertiflex Procedure treats the root cause of LSS symptoms without further destabilization of the spine and is minimally disruptive to tissue, preserving the patients anatomy *(no bone or tissue removal)* leaving future treatment options on the table.

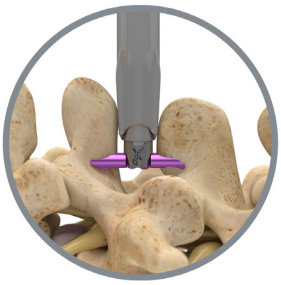
CLINICAL DATA

**5-YEAR** CLINICAL DATA

TISSUE-SPARING MIDLINE APPROACH

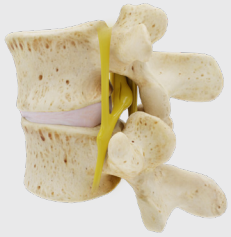


SINGLE-STEP IMPLANT DEPLOYMENT

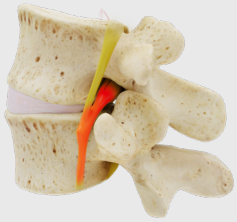


PATIENT-FOCUSED OUTCOMES

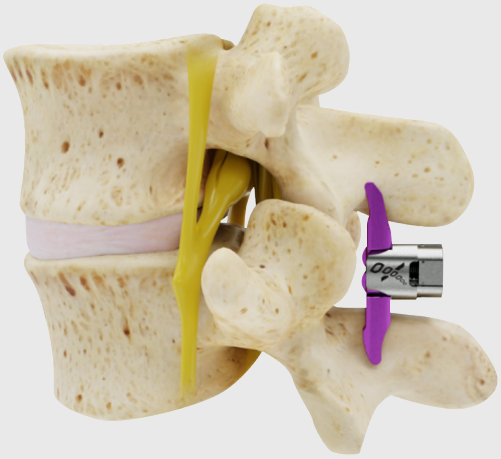
## HOW INDIRECT DECOMPRESSION WORKS



Canal and foraminal space for nerves increase in **FLEXION**



Canal and foraminal space for nerves decrease in **EXTENSION**



### EXTENSION BLOCKER

The Vertiflex Procedure blocks spinal extension which reduces or eliminates the compression of nerves at the implanted level(s)

| | IN FLEXION (NO IMPLANT) | IN EXTENSION (NO IMPLANT) | IN EXTENSION WITH VERTIFLEX |
|---|---|---|---|
| **Canal Area** | Area increases | Area decreases | Area increases 13% |
| **Foraminal Area** | Area increases | Area decreases | Area increases 15% |
| **Ligamentum Flavum** | Thickness decreases | Thickness increases | Thickness decreases 9% |

# PROVEN. PUBLISHED. PREFERRED.

The Vertiflex™ Procedure† is a broadly indicated, clinically proven, minimally invasive solution. The Vertiflex Procedure uses the Superion™ Indirect Decompression System—a small interspinous spacer designed to lift pressure off the nerves in the lower back, helping to minimize or eliminate the symptoms of leg and back pain due to LSS.

## **PROVEN** CLINICAL OUTCOMES

In a 5-year clinical trial, the Vertiflex Procedure demonstrated significant decreases in back and leg pain, a marked decrease in the need for opioid medication, and high patient satisfaction.

**66%** **BACK PAIN** improvement[1*]

**75%** **LEG PAIN** improvement[1*]

**85%** **OPIOID** reduction[2*]

**90%** **PATIENT** satisfaction[1*]

* Study completers at 5 years when compared to baseline scores

## **PUBLISHED** CLINICAL DATA

The Vertiflex Procedure is **approved** by the FDA and backed by science: 28 peer reviewed publications, including Level 1 data—an in-depth, randomized, multiple site investigational device exemption (IDE) clinical study with five year follow-up.

## PREFERRED BY PATIENTS

"My leg doesn't bother me anymore, that's what I'm really happy about."

**–Shirley,**
**VF Patient Ambassador**

## TAKE THE QUIZ!

Pain.com/LSSQuiz

† Superion™ Indirect Decompression System


1. Nunley, PD, et al. Clinical Interventions in Aging 2017. (N=88)
2. Nunley, PD, et al. Journal Pain Research 2018. (N=107)


Indications for Use: The Superion™ Indirect Decompression System (IDS) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, having radiographic evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing . The Superion™ Interspinous Spacer is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, who have undergone at least 6 months of non-operative treatment. The Superion™ Interspinous Spacer may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5. Contraindications, warnings, precautions, side effects. The Superion™ Indirect Decompression System (IDS) is contraindicated for patients who: have spinal anatomy that prevent implantation of the device or cause the device to be unstable in situ (i.e., degenerative spondylolisthesis greater than grade 1), Cauda equina syndrome, or prior decompression or fusion at the index level. Refer to the Instructions for Use provided on www.vertiflex.com for additional Indications for Use, contraindications information and potential adverse effects, warnings, and precautions prior to using this product. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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