

vertiflex[®]

The new standard for
lumbar spinal stenosis



CLINICAL PRESENTATION



EXTENSION

Extension provokes symptoms, pain / weakness in legs

"SHOPPING CART" SIGN/FLEXION

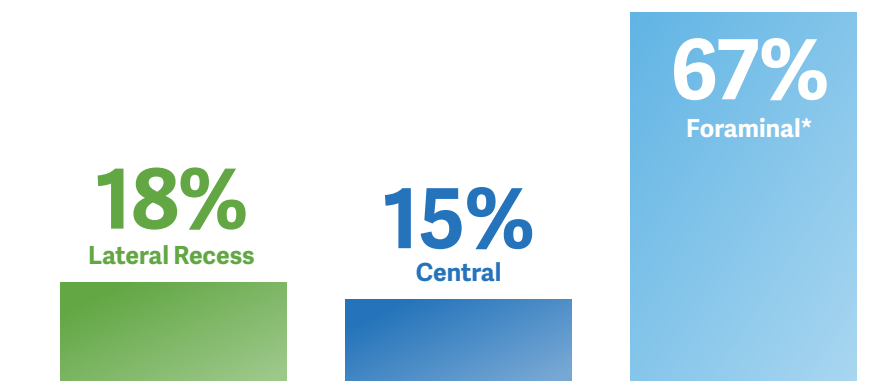
Leaning forward while walking to ambulate more comfortably/
Sitting relieves symptoms*

INDICATIONS FOR USE

- 1 Neurogenic Intermittent Claudication (NIC) secondary to diagnosis of moderate LSS
- 2 Relief in flexion from back, buttock, leg pain / cramping, weakness, tingling
- 3 ≥ 6 months of conservative care without relief
- 4 1 or 2 adjacent levels from L1 to L5

THE VERTIFLEX® PROCEDURE TREATS SYMPTOMS FROM VARIOUS TYPES OF LSS

- Biomechanically addresses all three types of posterior column stenosis
- Foraminal stenosis was the most prevalent subtype in the IDE trial, often in combination with others

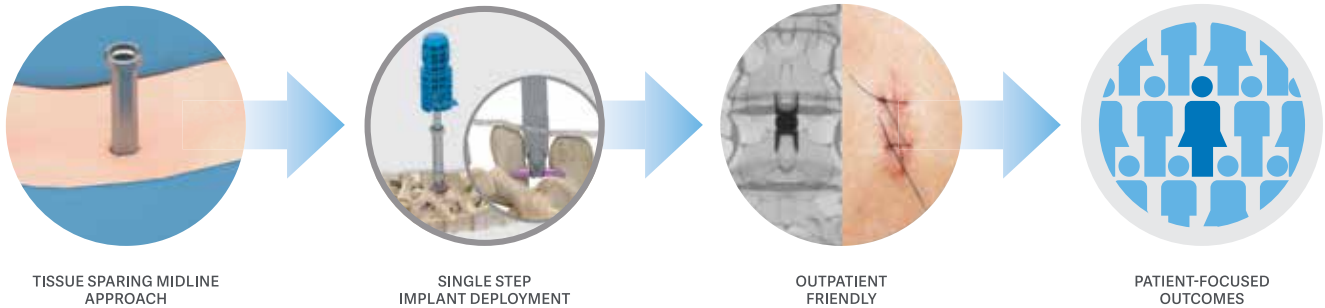


*Foraminal stenosis only/or in combination with central and/or lateral recess.

SAME PAIN, NEW TREATMENT OPTION

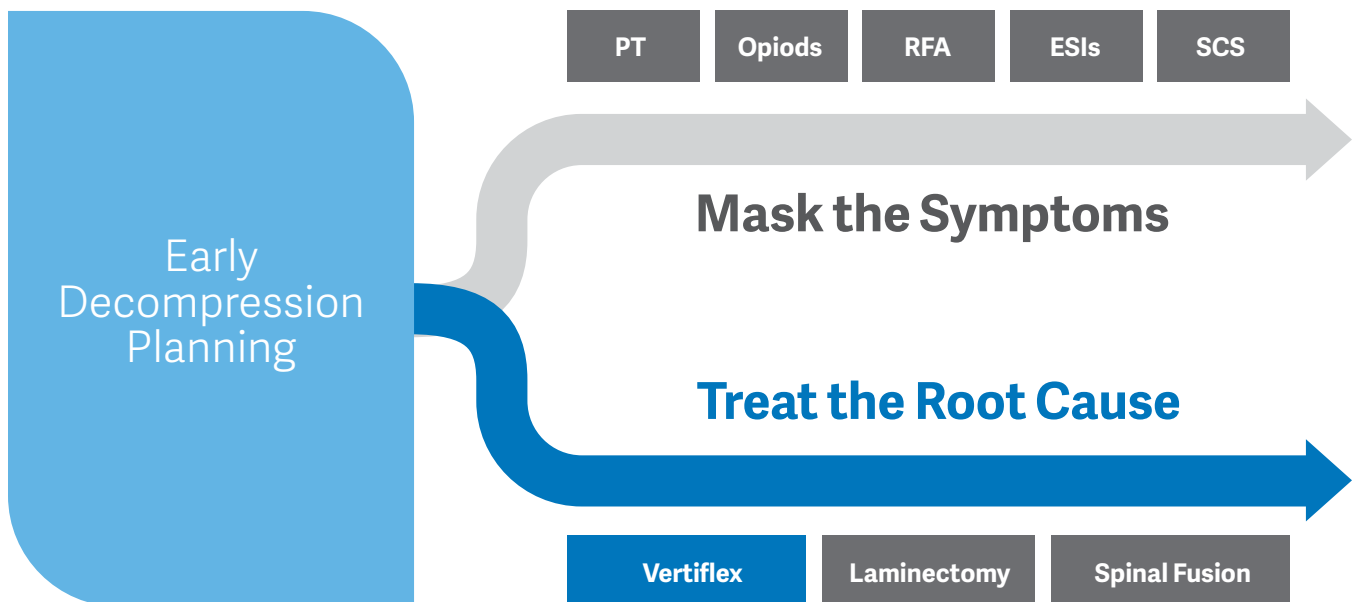
Designed with patient safety and comfort in mind.

The Vertiflex® Procedure is a broadly indicated, clinically proven, minimally invasive solution designed to deliver long-term relief from the pain associated with lumbar spinal stenosis (LSS). The Vertiflex Procedure uses the Superior Indirect Decompression System, which is 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.



THE QUEST FOR CARE ENDS WITH DURABLE RELIEF

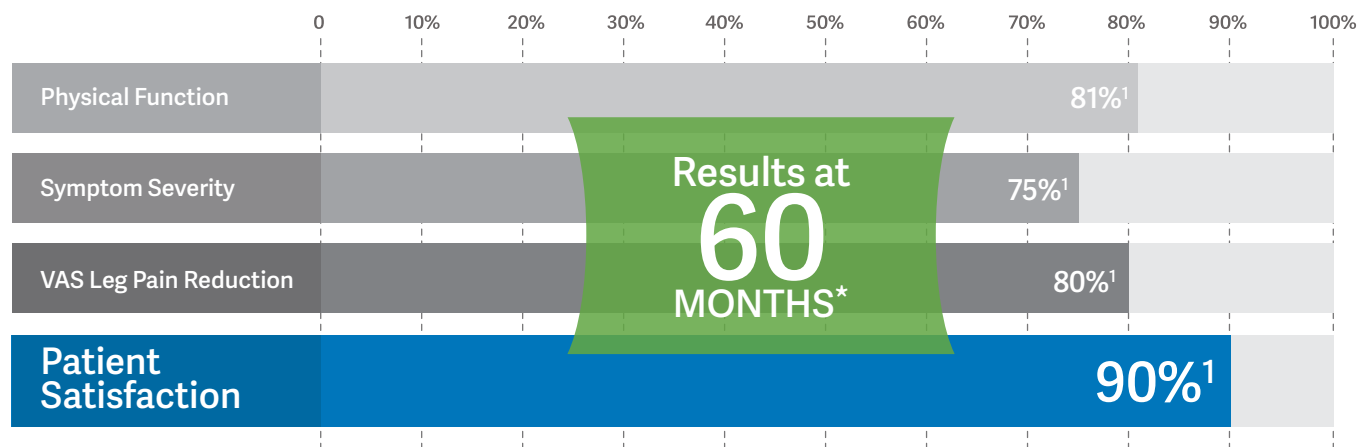
The first choice for treating the underlying condition when conservative care fails.



THE RESULTS ARE CLEAR

The most extensive device clinical trial on lumbar spinal stenosis.

The Vertiflex Procedure is supported by a rigorous body of clinical and real-world evidence demonstrating its safety and efficacy: prospective, randomized, controlled, multicenter trial with 470 patients at 29 sites; plus, a 24-month follow-up and annually thereafter through 60 months.



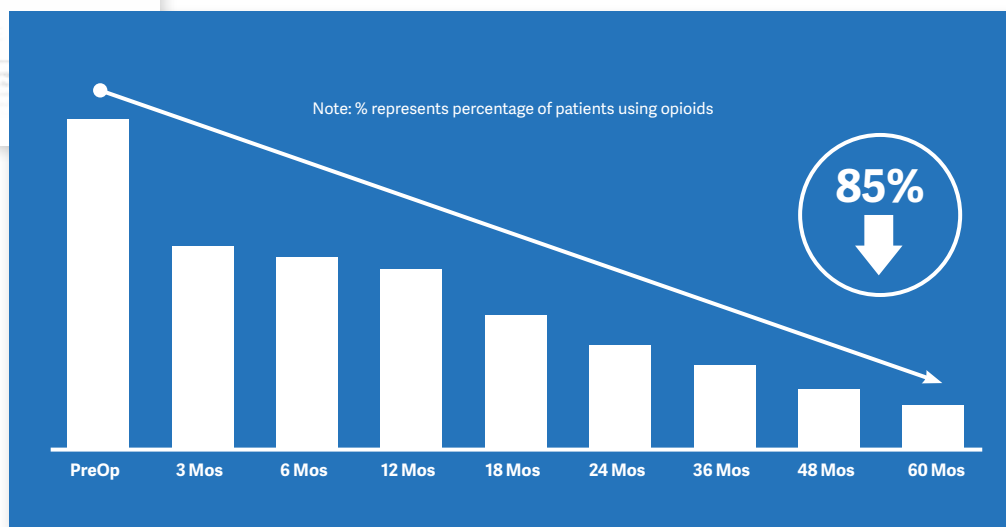
*Among Responders

THE IMPACT ON OPIOID REDUCTION

In a clinical trial the Vertiflex Procedure demonstrated a marked decrease in the need for opioid medications, showing long-term sustained clinical improvements.



85% of Opioid Users in Superior IDE Trial Ceased Using at 5 Years²



OUTCOMES FROM A COMMERCIAL REGISTRY

Commercial success greater than or equal to the FDA Trial Data
~3,900 Patients Tracked in 2 Registries

	1 Year IDE	1 Year Registries ³
VAS – Back Pain	63%	67%
VAS – Leg Pain	71%	74%
Functional Objective	N/A	76%
Patient Satisfaction	81%	82%

MEDICARE COVERED



Superion® received FDA approval for commercialization in 2015 and Category 1 CPT Code in 2017.

The Vertiflex Procedure is covered by Medicare in all 50 states. The following CPT® codes should be used to report the insertion of Superior® at one or two contiguous levels.

CPT® Code	Description
22869	Insertion of interlaminar/interspinous process stabilization/distraction device without open decompression or fusion, including image guidance when performed, lumbar; single level
+22870	Second level (list separately in addition to code for primary procedure, 22869)

1 Nunley PD, et al (Clinical Interventions in Aging 2017 12 1409-1417)

2 Nunley PD, et al (Journal of Pain Research, published Nov 20, 2018)

3 One Year Registry data compiled from PRESS, Direct Patient Consent Registry through Feb 2019

ABOUT VERTIFLEX®

At Vertiflex®, we are relentlessly focused on providing the most advanced, least invasive treatments for LSS. Vertiflex® fills this gap in the treatment algorithm, allowing patients to take back their lives with a solution that is simple, safe, and clinically proven to be effective. The Vertiflex Procedure may lift the burden of pain for both physicians and their patients by offering a durable and effective solution for LSS.



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