Non-CME Webinar Series
designed with the trainee in mind
first Tuesday of the month

ASRA PAIN MEDICINE
THE ASSOCIATION OF PAIN PROGRAM DIRECTORS
ADVANCING EDUCATION IN MULTIDISCIPLINARY PAIN MEDICINE

Novel Minimally Invasive Interventions: Decompressions, Spacers, and Endoscopic Options

Tuesday, March 1, 2022

7-8:30 pm ET

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Interspinous Spacers

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Chong Kim MD

MetroHealth/Case Western Reserve University School of Medicine

Professor- PM&R and Anesthesiology. Case Western Reserve University School of Medicine
Program Director- Pain Medicine Fellowship. Case Western Reserve University/ MetroHealth

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DISCLOSURES (on label use)

- Research/Industry
  - Abbott Neuromodulation
  - Boston Scientific
  - Jazz Pharma
  - Medtronic
  - Mainstay
  - Nevro
  - Pfizer
  - Renaissance
  - Saluda Medical
  - St. Jude Neuromodulation
  - **Vertiflex**

- Research
  - NIH
  - NIH/NICHD
  - OMHAS/ SAMSA
  - CDC

- Advisory/ Consulting
  - Abbott
  - Medtronic
  - Saluda Medical
  - SPR Therapeutics

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Objectives:

1. Definition (examples)
2. Indication and patient selection
3. Brief overview of technique
4. Evidence review

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Interspinous Spacers- what is it?

…AKA

- minimally invasive interspinous process devices
- interspinous distraction devices
- interspinous stabilizers

Interspinous Spacers- what is it?

- "between the spinous process"
- "spacer"
- Device that….

  Mechanically inhibit extension

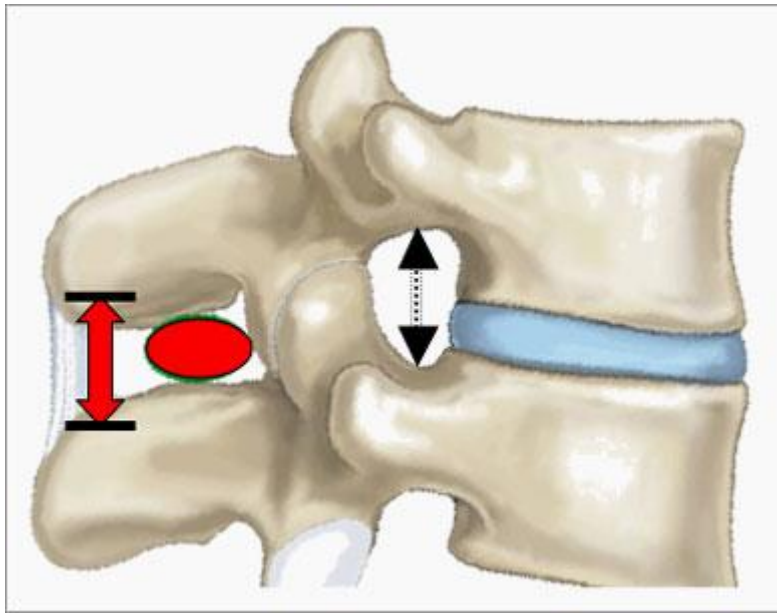


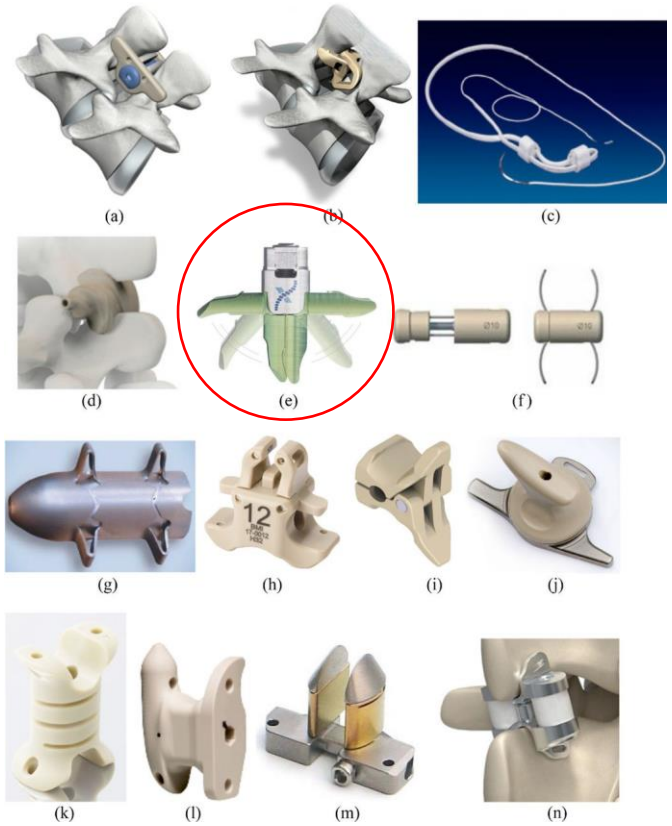
Table 1

Examples of Interspinous Distraction Devices (IDD) and Interspinous Stabilizers (ISS)

Interspinous Distraction Device (IDD)		Interspinous Stabilizers (ISS)	
Brand name	**Manufacturer**	**Brand name**	**Manufacturer**
Aperius (5)	Medtronic, Switzerland	Coflex (6)	Paradigm Spine, USA
In-Space (7)	Synthes, Germany	DIAM (8)	Medtronic Sofamor Danek, USA
Superion (9)	Vertiflex, USA	Wallis (10)	Zimmer, USA
X-Stop (11)	St Francis Medical technologies, USA		

Open in a separate window

DIAM, device for intervertebral assisted motion.



Onggo JR, Nambiar M, Maingard JT, et al. The use of minimally invasive interspinous process devices for the treatment of lumbar canal stenosis: a narrative literature review. *J Spine Surg*. 2021;7(3):394-412. doi:10.21037/jss-21-57

Superion Vertiflex

Boston Scientific
Advancing science for life™

Indications

The Vertiflex™ Procedure† **is** indicated for patients with:

- Neurogenic Intermittent Claudication (NIC) secondary to diagnosis of moderate degenerative Lumbar Spinal Stenosis (LSS)
- Relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain
- >6 months of non-operative treatment
- 1 or 2 adjacent levels from L1 to L5
- Confirmed diagnosis of LSS by X-Ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing

† Superion™ Indirect Decompression System

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, scoliosis or spinous process fractures, osteoporosis, infection, allergy or reaction to any metal or implant or a high Body Mass Index. Avoid strenuous activity for 6 weeks after surgery, contact your physician if there is fluid leaking from your incision, if you have pain, swelling or numbness in your legs or buttocks or if you fall. 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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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**.

Symptomatic Lumbar Spinal Stenosis with Neurogenic Claudication

Clinical Presentation of Symptoms

- Extension provokes symptoms
- Pain while walking
- Numbness or "tingling" feeling in the legs, calves, or buttocks
- Weakness and/or loss of balance
- Decreased endurance during physical activities
- Relief experienced when leaning or bending forward
- Patient uses walker, cane, or shopping cart to help relieve symptoms
- Symptom relief when sitting (flexion)

QUESTIONS TO ASK

1. Do you experience pain, numbness, cramping and/or tingling in the legs, buttocks and/or back?
2. Does the pain get worse when you stand or walk?
3. Do you experience any weakness or loss of balance?
4. Do you frequently need to sit down or lean forward because of your pain?
5. Do you use a walker, cane or shopping cart to move around more comfortably?

If patient answers yes to any of the questions above, they may be a candidate for the Vertiflex™ Procedure. Confirm diagnosis of LSS with X-Ray, MRI and/or CT.

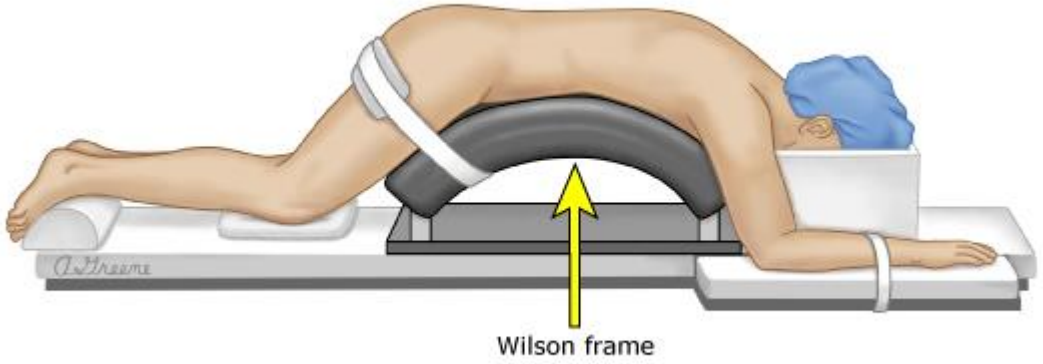
Contraindications

The Vertiflex Procedure **is not** indicated for patients with:

- An allergy to titanium or titanium alloy
- Spinal anatomy or disease that would preclude implantation:
  - Instability of lumbar spine, e.g. isthmic spondylolisthesis or degenerative spondylolisthesis > Grade 1
- Ankylosed segment; spinous process pars interarticularis, or lamina fracture
- Cobb angle > 10 degrees
- Prior fusion or decompression at index level
- Morbid obesity, defined as BMI >40
- Cauda equina syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction
- Diagnosis of severe osteoporosis defined as bone mineral density (DEXA scan or equivalent) in the spine or hip >2.5 S.D. below the mean of adult normals
- Active systemic infection or infection localized to the site of implantation

Technique

Positioning



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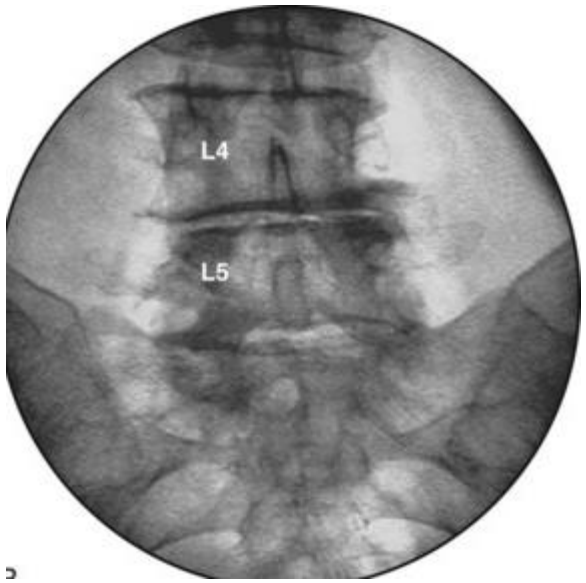

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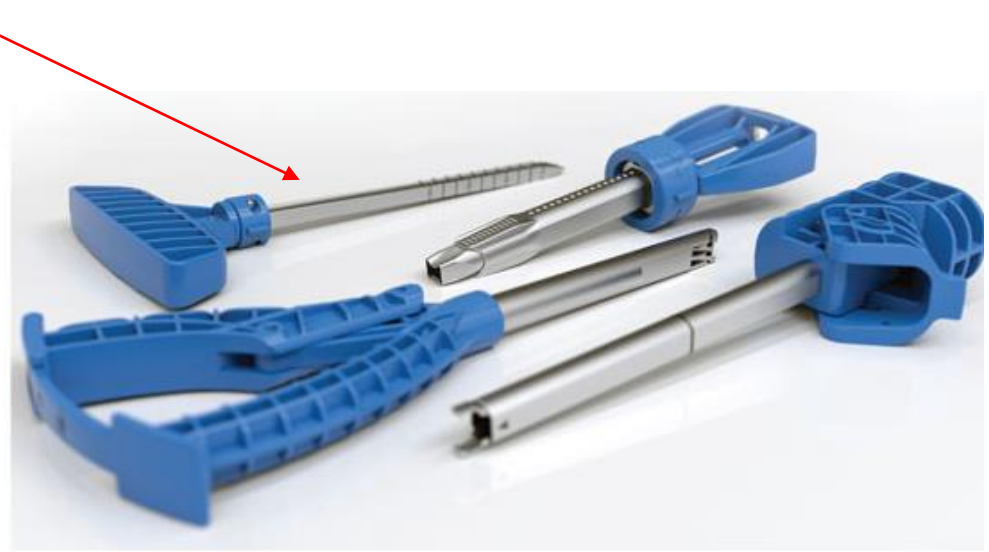

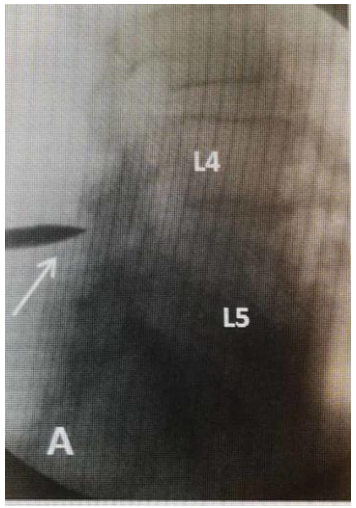

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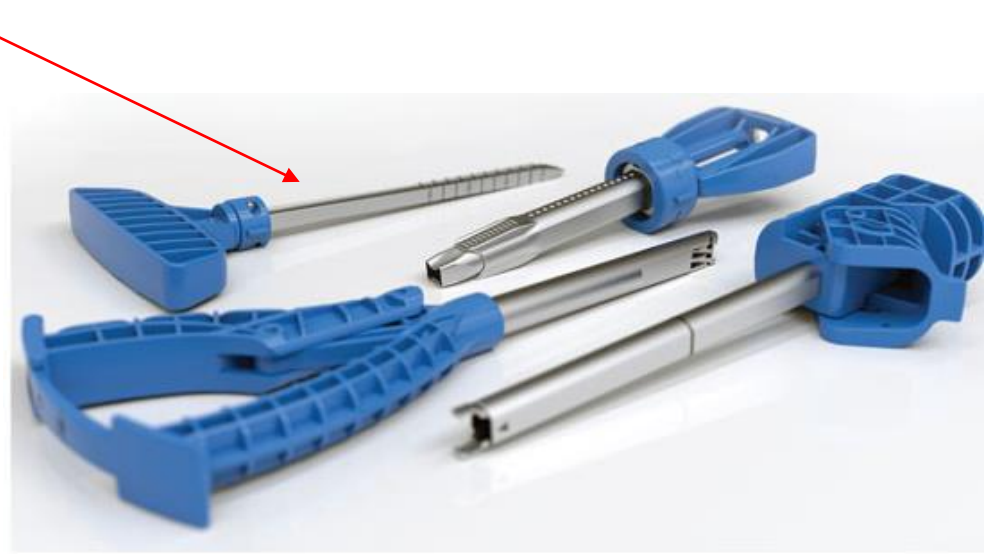

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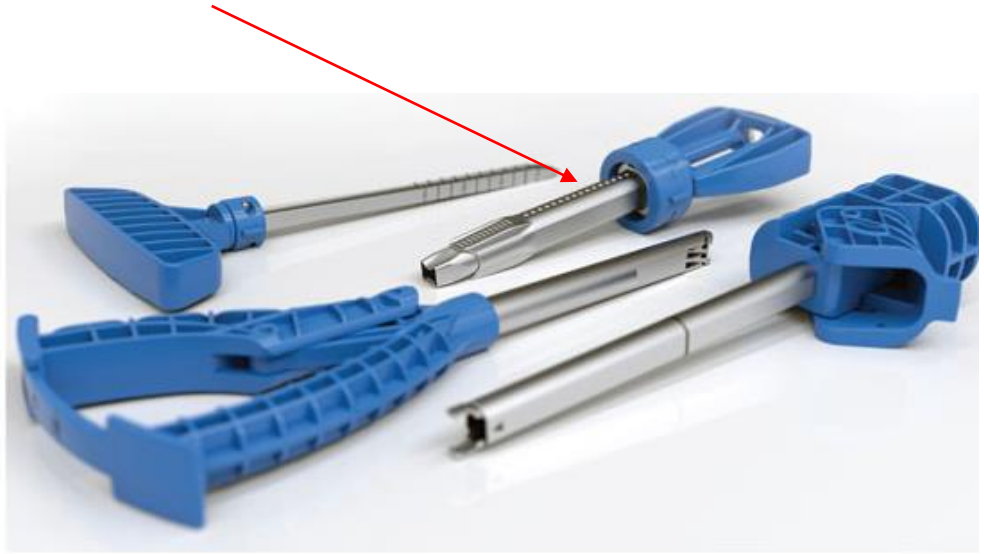

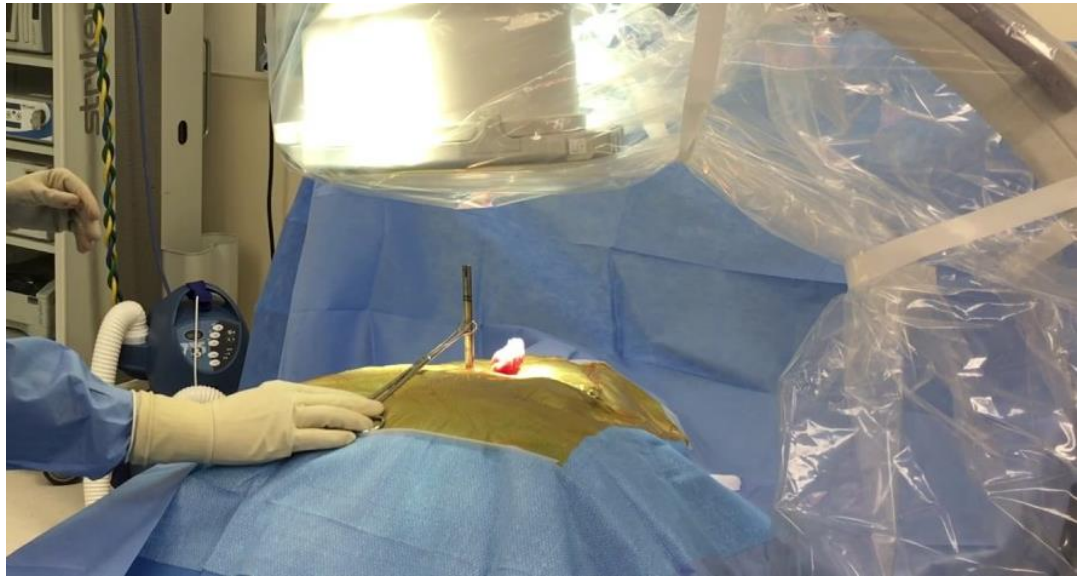

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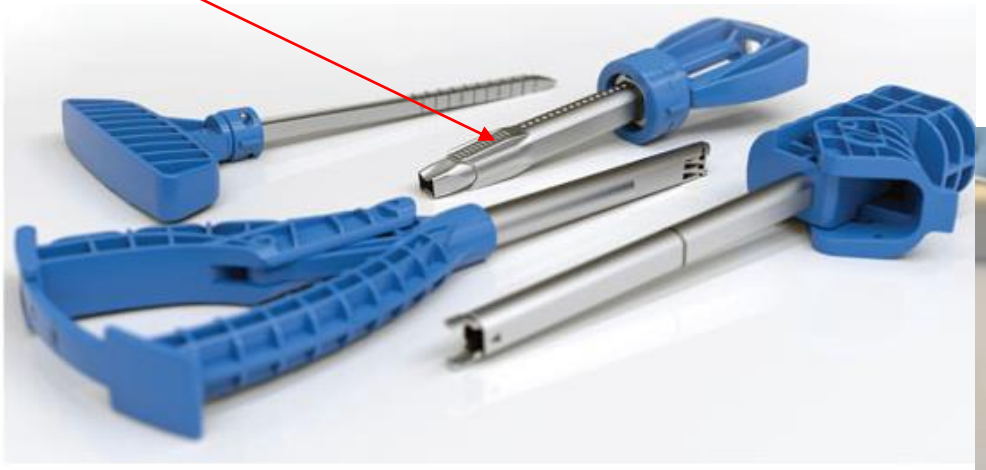
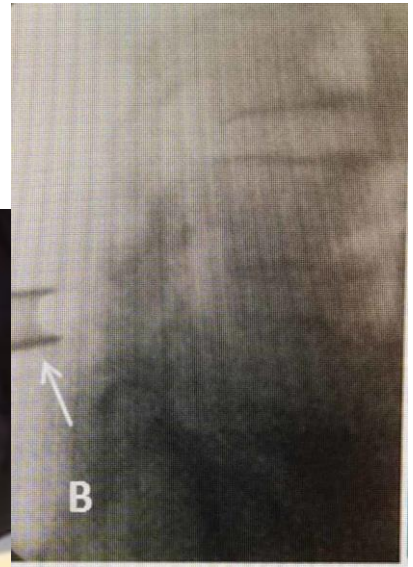
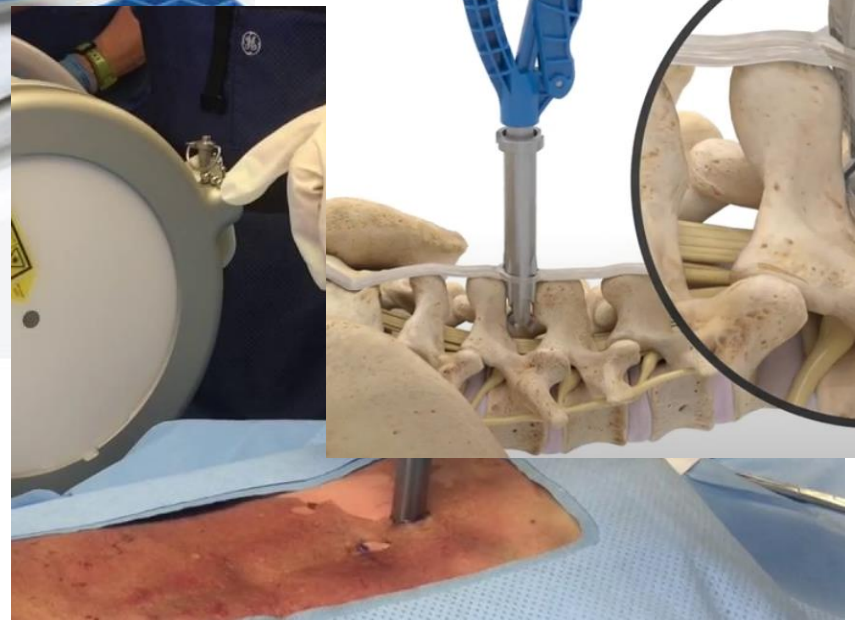
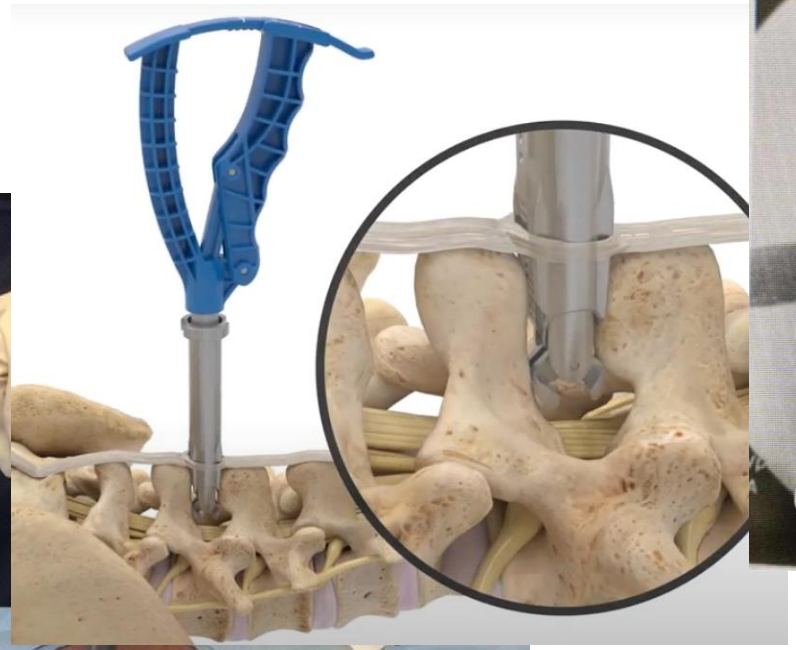
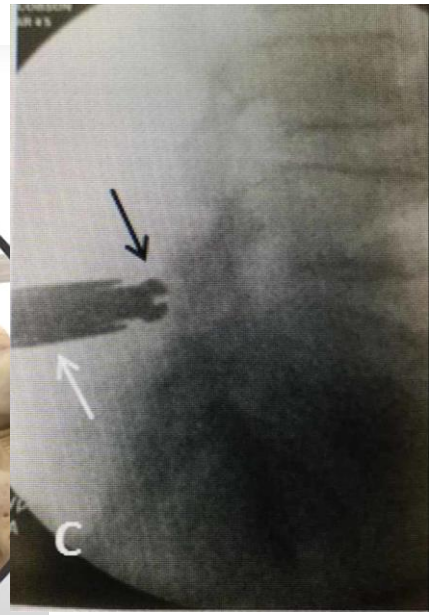




Interspinous Spacers- Technique







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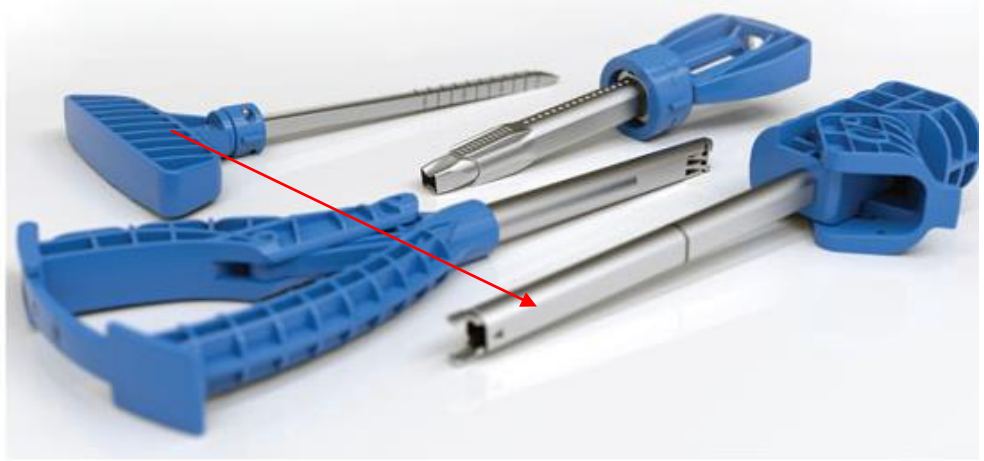

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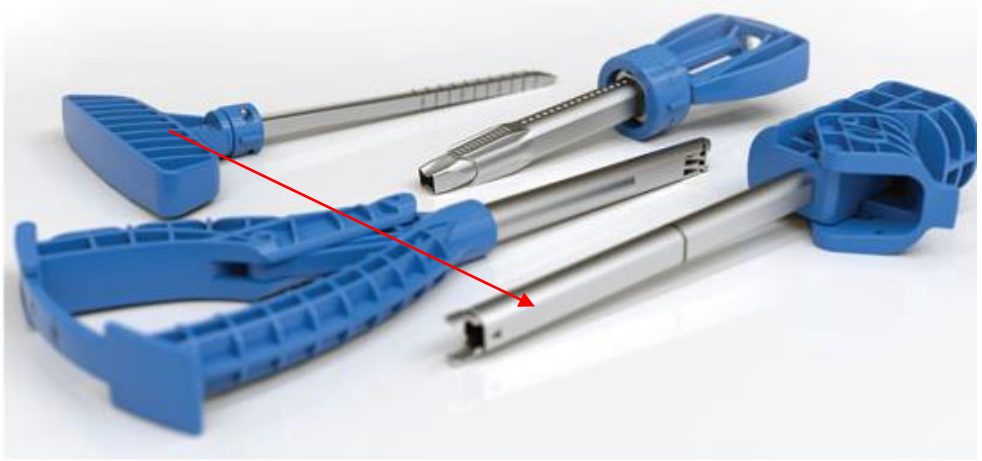

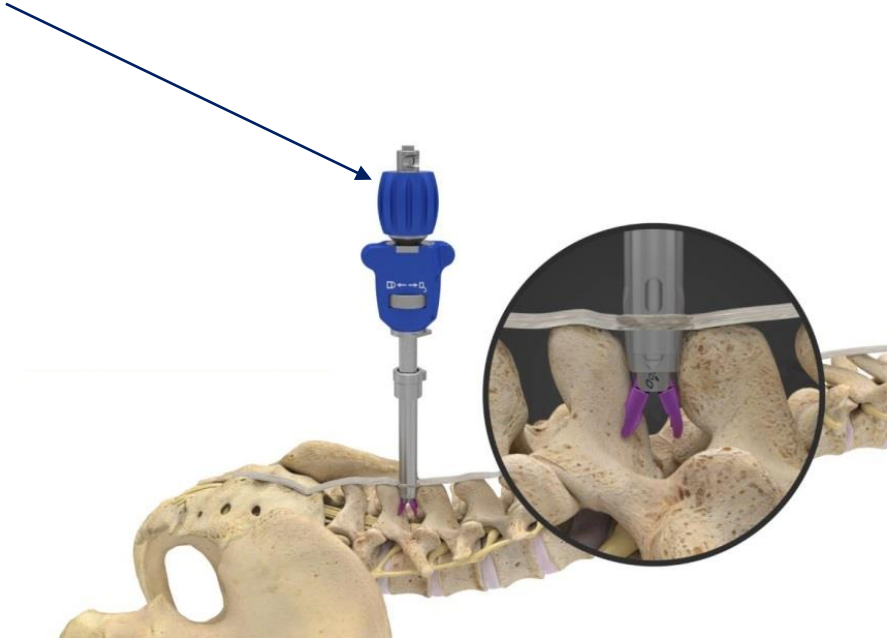

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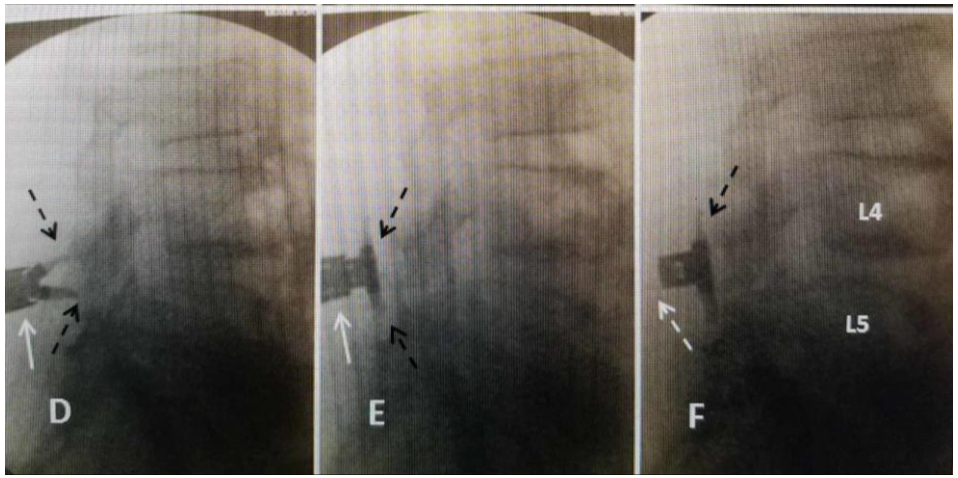

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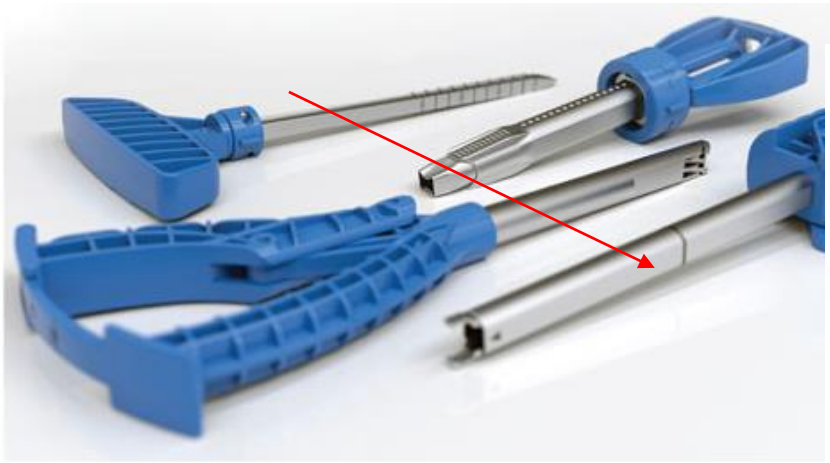

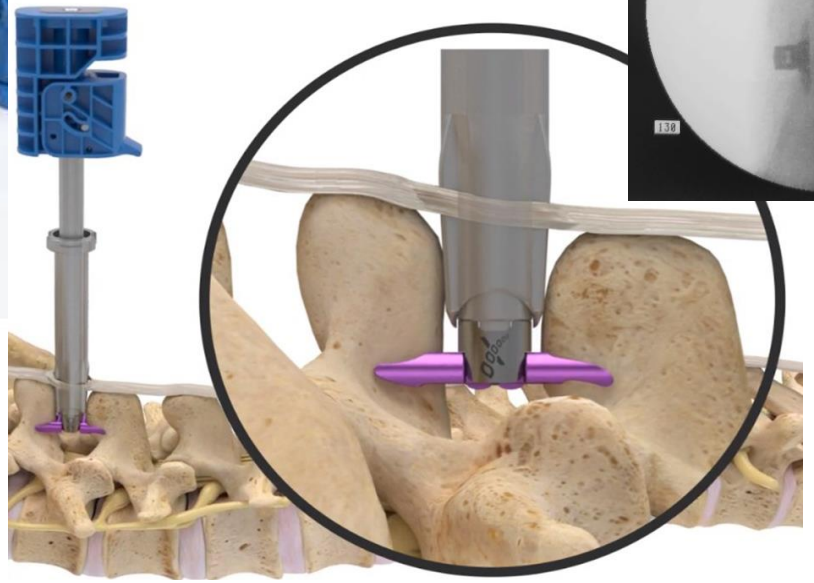

Technique

Evidence (2011)

Clinical Interventions in Aging

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Minimally invasive treatment of lumbar spinal stenosis with a novel interspinous spacer

Shay Shabat[1]
Larry E Miller[2,3]
Jon E Block[3]
Reuven Gepstein[1]

Purpose: To assess the safety and effectiveness of a novel, minimally invasive interspinous spacer in patients with moderate lumbar spinal stenosis (LSS).

Conclusion: Moderate LSS can be effectively treated with a minimally invasive interspinous spacer. This device is appropriate for select patients who have failed nonoperative treatment measures for LSS and meet strict anatomical criteria.

Evidence (2015)

Spine
SPINE Volume 40, Number 5, pp 275-282
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RANDOMIZED TRIAL

OPEN

Superion Interspinous Process Spacer for Intermittent Neurogenic Claudication Se to Moderate Lumbar Spinal Stenosis

Two-Year Results From a Randomized Controlled FDA-IDE Pivotal Trial

Vikas V. Patel, MD,* Peter G. Whang, MD,† Thomas R. Haley, DO,‡ W. Daniel Bradley, MD,§ Pierce D. Nunley, MD,¶ Raphael P. Davis, MD,‖ Larry E. Miller, PhD,**†† Jon E. Block, PhD,†† and Fred H. Geisler, MD, PhD‡‡

Methods. Patients presenting with intermittent neurogenic claudication secondary to moderate LSS who failed at least 6 months of nonsurgical management were randomly allocated to treatment with the Superion spacer or a control spacer (X-Stop) and followed for 2 years.

Evidence (2015)

Results. A total of 391 randomized patients were implanted with Superion (n = 190) or control (n = 201) spacers at 29 sites between August 2008 and December 2011. Device success was achieved in 99.5% of patients with ...nts. The primary composite endpoint of this study was met, which demonstrated that the Superion spacer was noninferior to the X-Stop spacer. Leg pain, the predominant patient complaint, decreased in severity by 70% during 2 years in each group. Most (77%) patients achieved leg pain clinical success (≥15 point improvement) at 2 years, with no significant differences between groups. Oswestry Disability Index clinical success (≥15% point improvement) was achieved in 65% of patients. The rates of complications and reoperations were similar between groups.

Results. A total of 391 randomized patients were implanted with Superion (n = 190) or control (n = 201) spacers at 29 sites

Evidence (2017)

Clinical Interventions in Aging

Open Access Full Text Article

Five-year du
process dec

Pierce D. Nunley, M.D., Vik
Jon E. Block, Ph.D., Fred H

RESULTS

1. At 5 years, 84% of patients demonstrated clinical success on at least two of three ZCQ domains.
2. Individual ZCQ domain success rates were:
   - 75% symptom severity
   - 81% physical function
   - 90% patient satisfaction

All percentages based on 5-year completers

Dovepress

3. Leg and back pain (VAS) success rates were:
   - 80% leg pain improvement
   - 65% back pain improvement
4. ODI success rate was 65%.
5. 75% of patients were free from re-operation, revision or supplemental fixation at their index level at 5 years.

s on at least two
of 88), 81% (71
g and back pain
success rate for
39%, 75%, 66%,
y (all $P<0.001$).

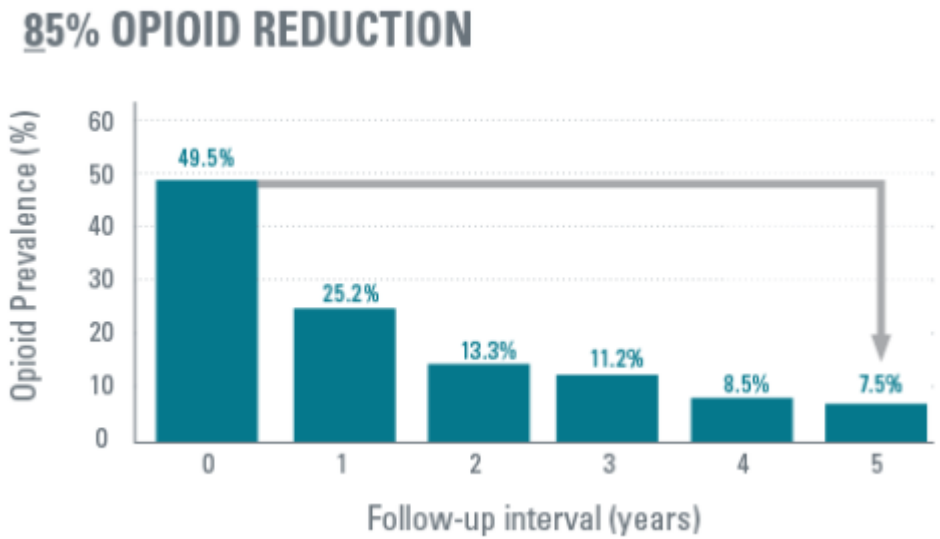
Within-group effect sizes were classified as very large for four of five clinical outcomes (ie, >1.0; all $P<0.0001$). Seventy-five percent of IPD patients were free from reoperation, revision, or supplemental fixation at their index level at 5 years.

Evidence (2018)

Journal of Pain Research
Dovepress
open access to scientific and medical research
Open Access Full Text Article
CLINICAL TRIAL REPORT

Interspinous process decompression is as with a reduction in opioid analgesia in pat with lumbar spinal stenosis

Pierce D Nunley[1]
Timothy R Deer[2]
Ramsin M Benyamin[3]
Peter S Staats[4]
Jon E Block[5]



Evidence (2019)

Medical Devices: Evidence and Research

Open Access Full Text Article

Interspinous Process Decc
Superion® Spacer For Lum
Real-World Experience Fr

Gene Tekmyster[1]
Dawood Sayed[2]
Kevin D Cairns[3]
Louis J Raso[4]
Christopher Kim[5]
Jon E Block[6]

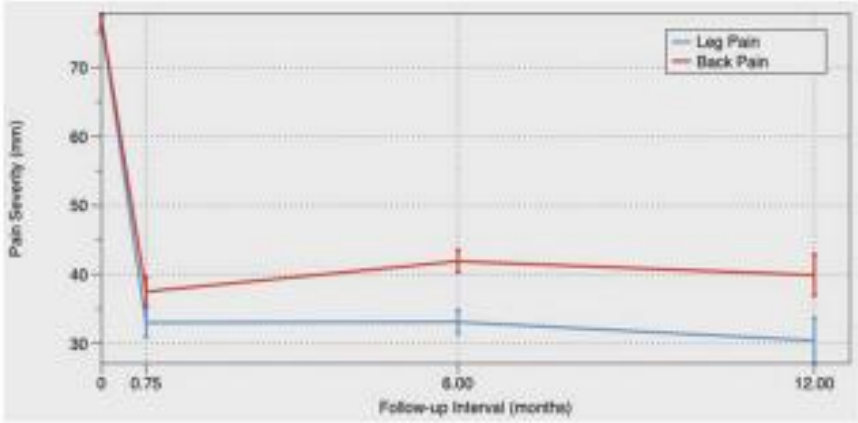
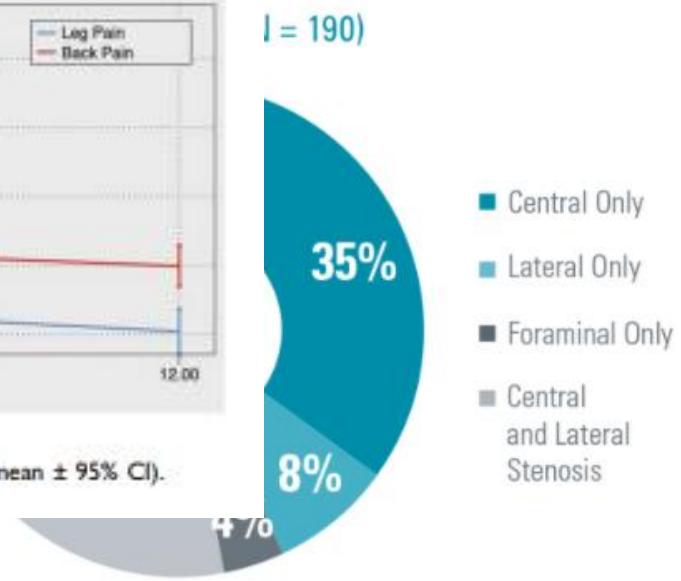


Figure 2 Leg and back pain severity by follow-up interval (mean ± 95% CI).



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Summary….

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Thank you….

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