mild®

HELP YOUR LSS PATIENTS STAND LONGER & WALK FARTHER WITH LESS PAIN

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LUMBAR SPINAL STENOSIS (LSS) WITH NEUROGENIC CLAUDICATION

Vertos MEDICAL

LSS PATIENT POPULATION

LSS is one of the most commonly diagnosed and treated pathologic conditions affecting the spine

2M

Patients in LSS treatment[1]

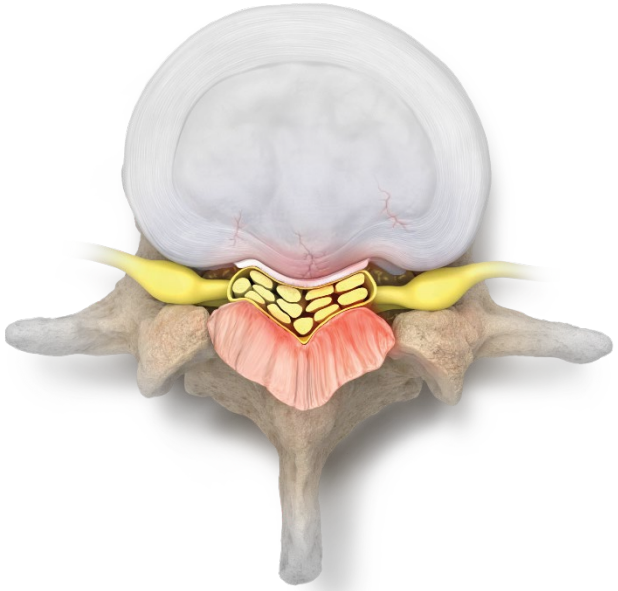
LSS is prevalent in 10–15% of patients aged 60+[2]

YOU SEE THESE PATIENTS EVERYDAY

Easy to identify due to limited mobility and pain

LSS SYMPTOMS & NEUROGENIC CLAUDICATION

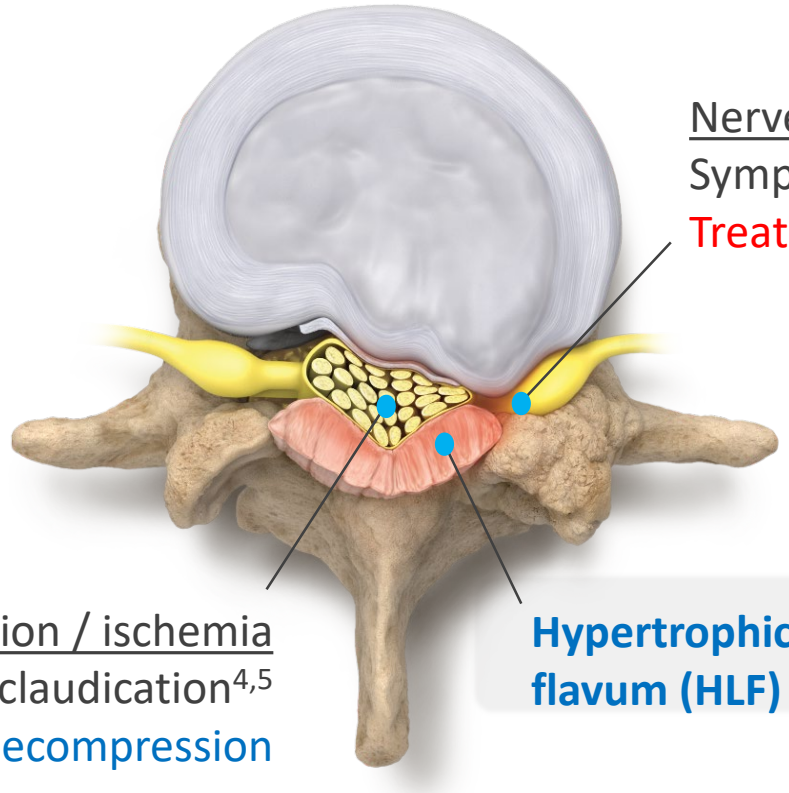
Neurogenic claudication (NC) is a common symptom of LSS



Narrowing of spinal canal leads to LSS and NC symptoms

of LSS patients have neurogenic claudication[3]

mild REMOVES A ROOT CAUSE OF NC



Nerve root inflammation
Symptom: radicular pain[4]
Treatment: anti-Inflammatory[4]

Thecal sac compression / ischemia
Symptom: neurogenic claudication[4,5]
Treatment: decompression

Hypertrophic ligamentum flavum (HLF)

Decompression is required to effectively treat LSS with NC

mild REMOVES THE PROBLEM & LEAVES NOTHING BEHIND

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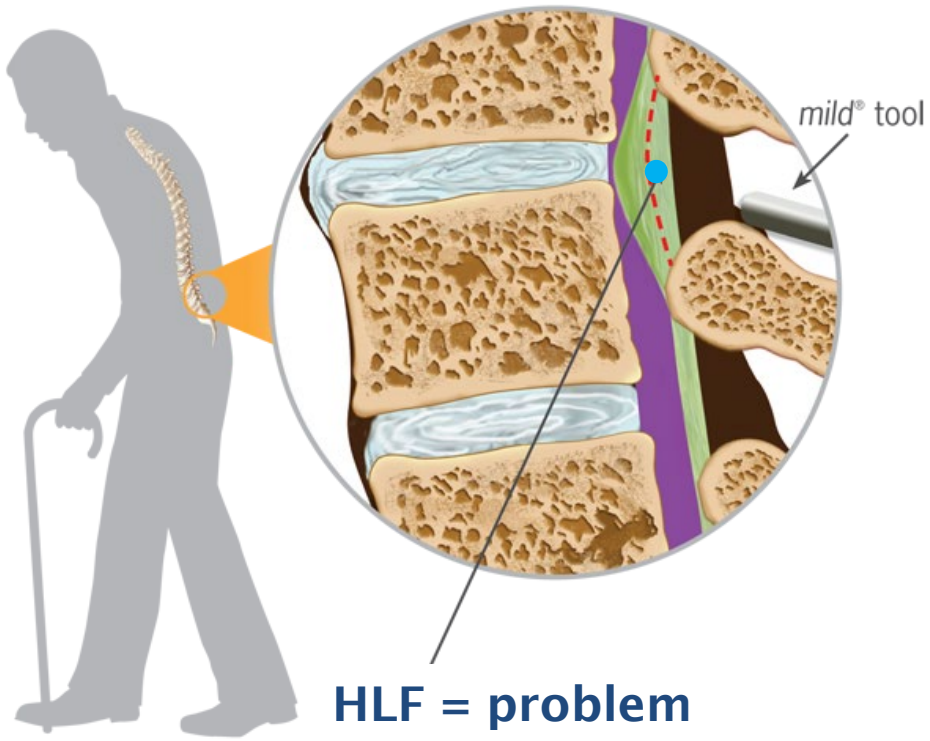
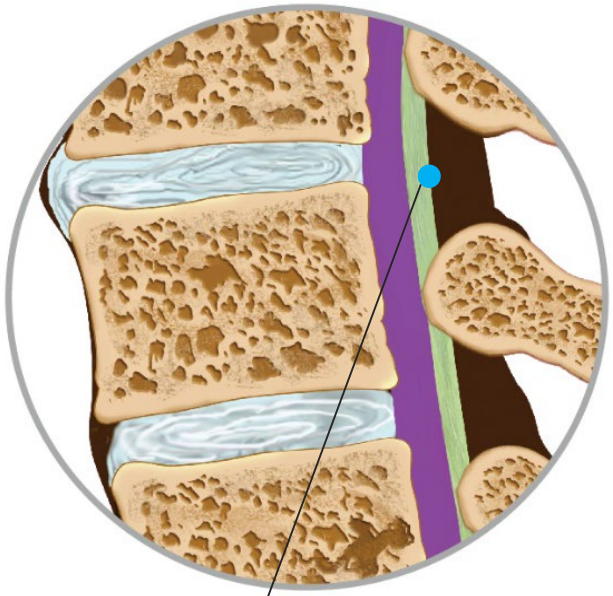
Before *mild*



HLF = problem

After *mild*



Debulking the ligament reduces spinal canal pressure and helps to alleviate NC symptoms[6]

THE NEXT LEAST INVASIVE CHOICE TO TREAT NC

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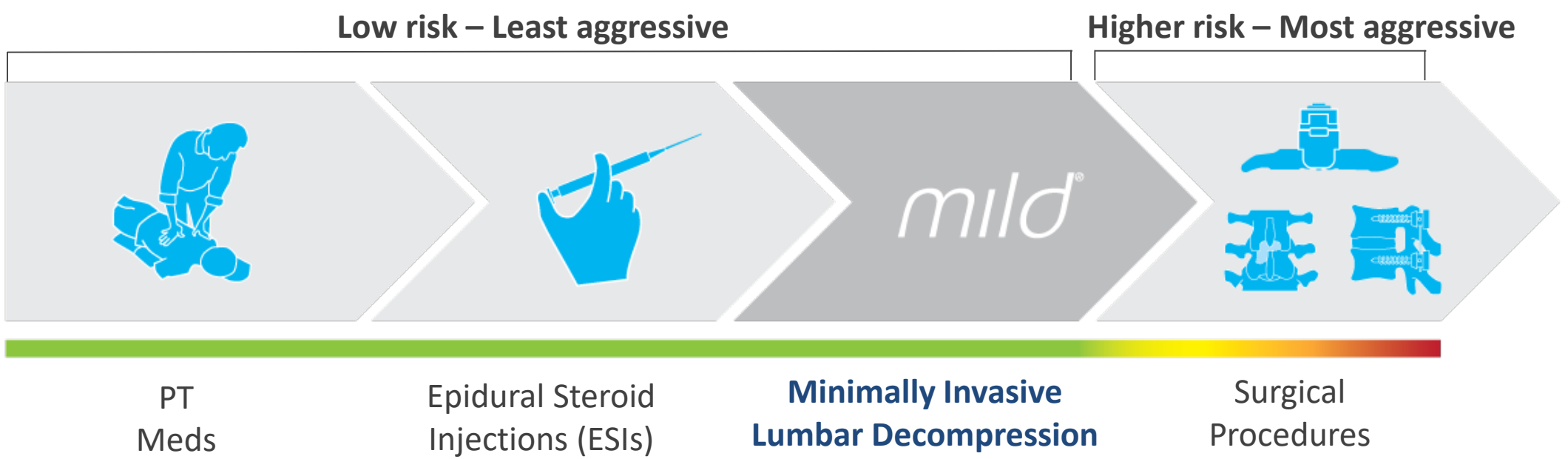
mild offers a durable and safe early LSS treatment option



LSS TREATMENT ALGORITHM

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PATIENT OUTCOMES & SAFETY

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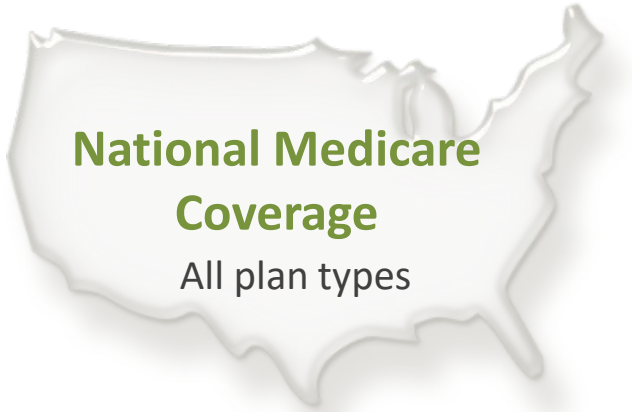
ESTABLISHED PROCEDURE

>25k patients treated to date

14 clinical trials including **Level 1** data[6]

Published in **20+** peer-reviewed journal articles

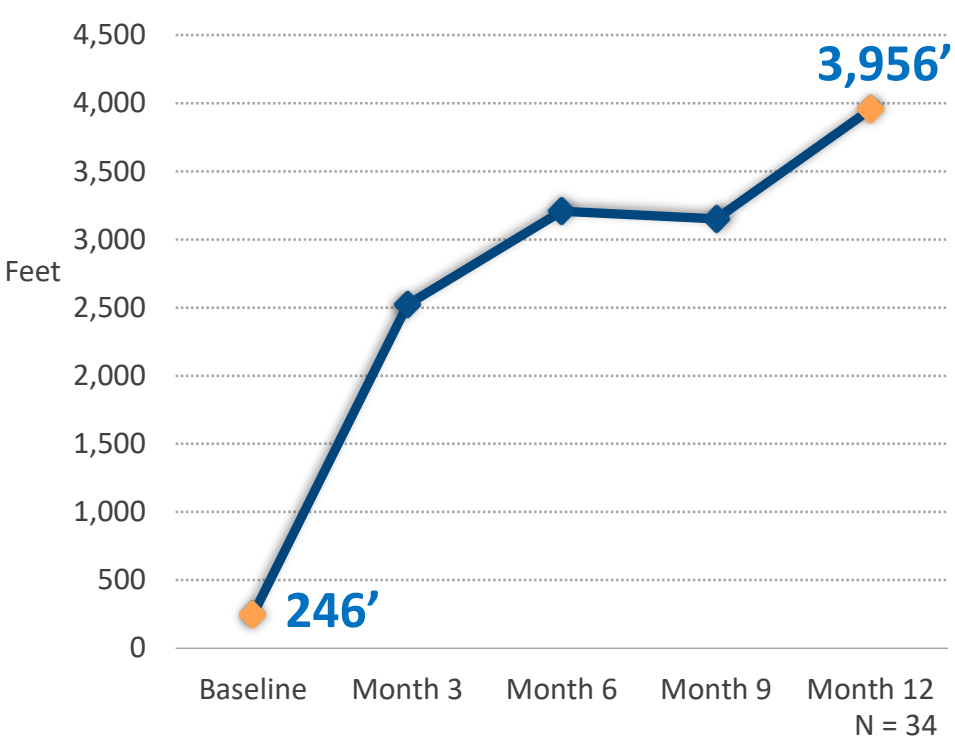


Simple coverage requirements

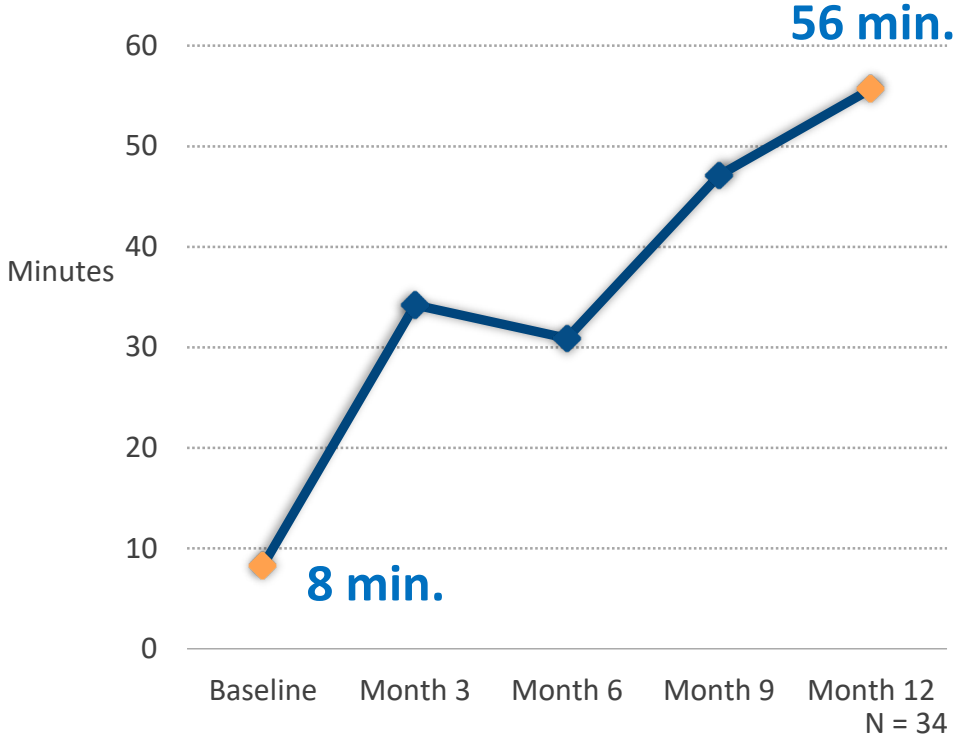
- Medicare beneficiaries- regardless of age
- Diagnosis of LSS with NC
- No surgery in lumbar region in previous 12 months (laminectomy, laminotomy, fusion, interspinous process decompression, or *mild*)

WALKING & STANDING IMPROVEMENT

Mean walking distance at each follow-up



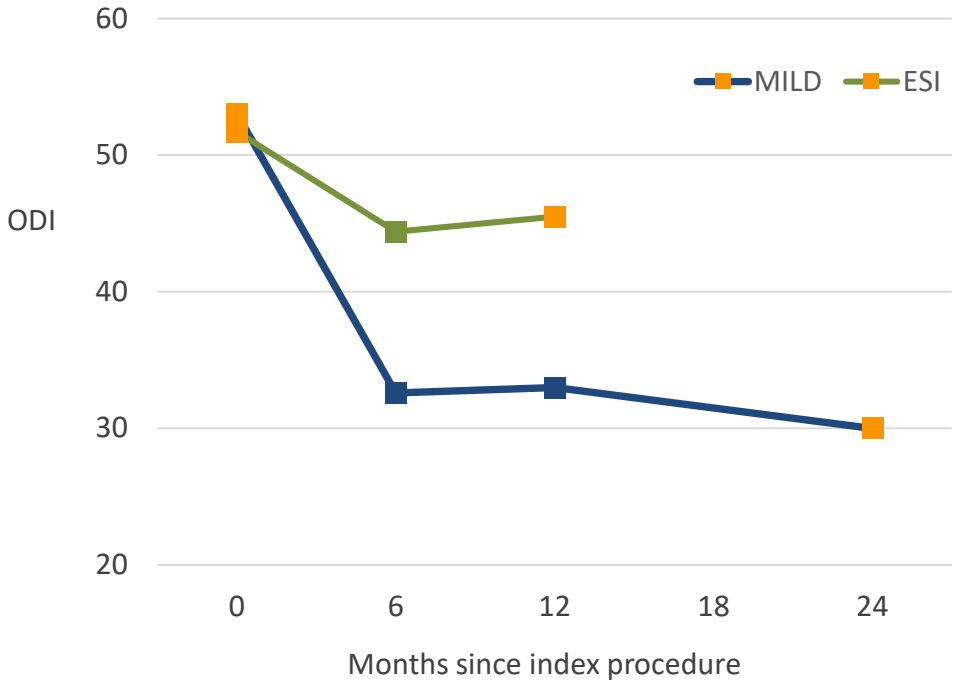
Mean standing time at each follow-up



Cleveland Clinic Study, 1-year Outcome[8]

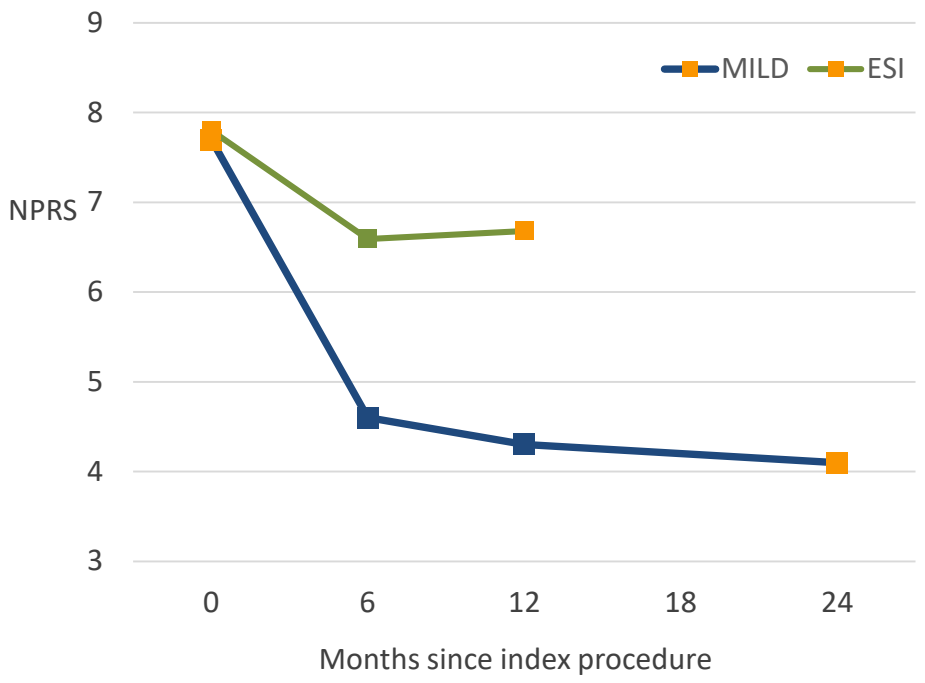
DURABLE FUNCTION & PAIN IMPROVEMENT

Oswestry Disability Index (ODI)



Mean ODI improvement of 22.7-points at 2 years
(10-point improvement is clinically significant)

Numeric Pain Rating Scale (NPRS)

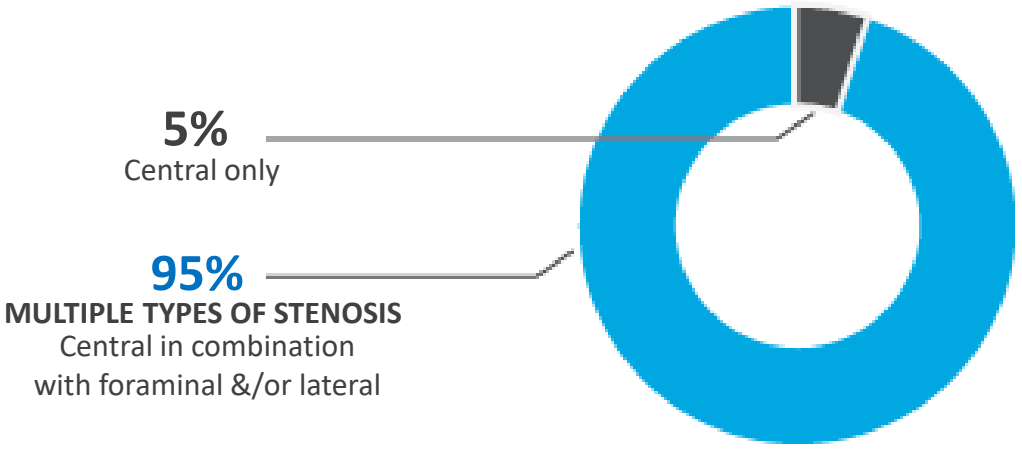


Mean NPRS improvement of 3.6-points at 2 years
(2-point improvement is clinically significant)

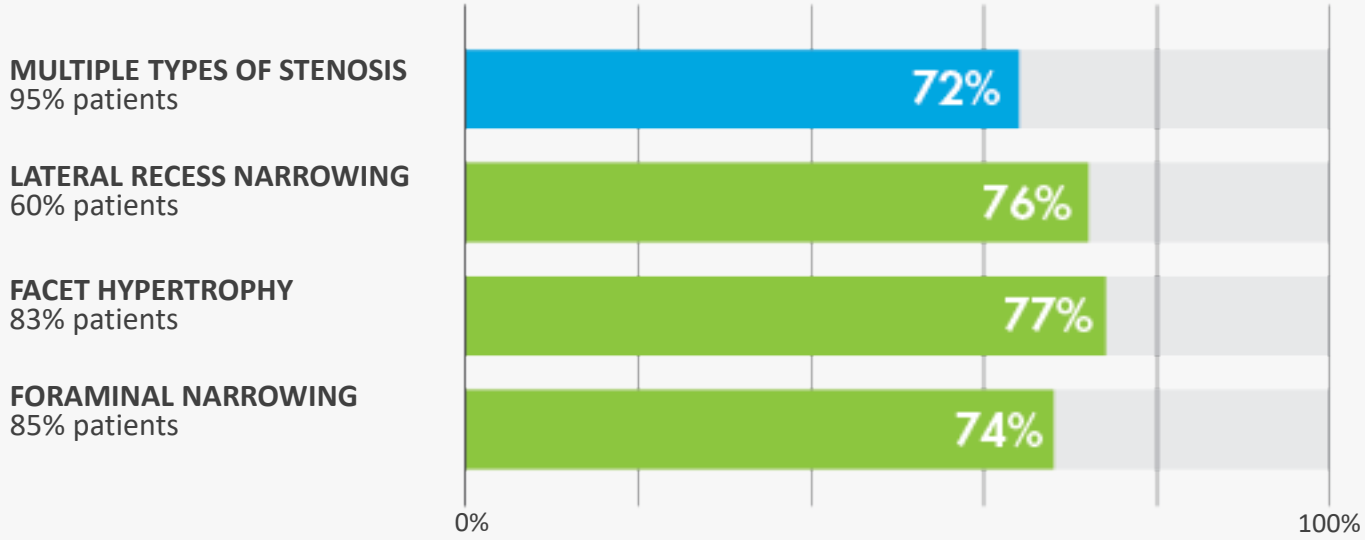
MIDAS ENCORE Study, 2-year Outcomes[6]

SIGNIFICANT IMPROVEMENT IN PATIENTS WITH COMORBIDITIES

% Patients by stenosis type(s)



ODI Response Rate*



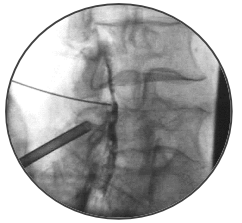
*Percent of patients achieving ODI improvement of ≥ 10 points at 2 year follow-up.

MIDAS ENCORE Study, 2-year Outcomes[6,7]

OUTPATIENT PROCEDURE SAFE BY DESIGN

Tiny incision
Size of a baby aspirin

Instruments
Designed for safety



Constant visualization
Via epidurogram

No implants

No general anesthesia

No sutures

CLINICALLY PROVEN TO BE AS SAFE AS AN ESI[6]

2-year Outcomes	*mild*[6]	Interspinous Spacers (ISS)		Surgical Decompression[10,11]	Fusion[12-16]
		Superion®[9]	X-STOP®[9,10]		
Reoperation	5.6%	20.0%	14.4–26.0%	6–7.8%	12.5–16.9%
Device- and procedure-related AEs	1.3%	Device-related 11.6%	7.5%	Intraoperative 9.9%	23.3%
		Procedure-related 14.2%	15.9%	Postoperative 12.3%	18% early – 6% late
Device- and procedure-related serious AEs	0%	8.4%	9.5%		
Lumbar spine fractures	0%	16.3%	8.5%	—	4.2%
Removal of hardware	No implants	16.3%	12.4%	No implants	4.3%

Clinically demonstrated safest decompression procedure[17]

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PATIENT IDENTIFICATION, CONSULTATIONS & ASSESSING OUTCOMES

Vertos MEDICAL

STEP 1: IDENTIFY PATIENTS WITH NC SYMPTOMS

Pain, numbness and/or heaviness PRESENT when:

Standing

Walking

Pain, numbness and/or heaviness RELIEVED by:

Bending

Sitting

Limited functionality is a key indicator of NC

NC ASSESSMENT QUESTIONS

NC ID questions

1. Where do you experience discomfort?
2. Does sitting or bending forward relieve your discomfort?
3. How long can you stand before you need to rest?
4. How far can you walk before you seek relief?
5. Which daily activities are affected due to your discomfort?

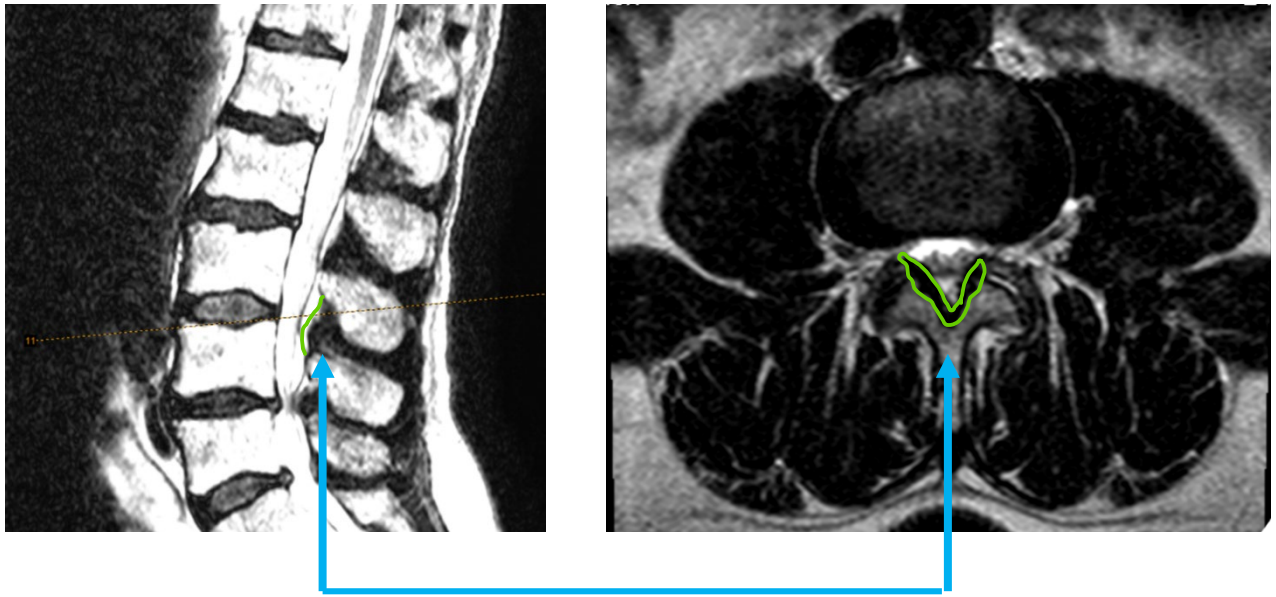
Document ICD-10 M48.062 on patient file

Educational tools to guide a simple and efficient patient ID process

STEP 2: CONFIRM WITH IMAGING

Use MRI to CONFIRM:

- Lumbar spinal stenosis
- Hypertrophic ligamentum flavum verified ≥ 2.5 mm
- Spinal stability: ≤ grade 2 spondylolisthesis
- Interlaminar access



NC symptoms are caused by hypertrophic ligamentum flavum (HLF), which contributes to 50-85% of spinal canal narrowing[18]

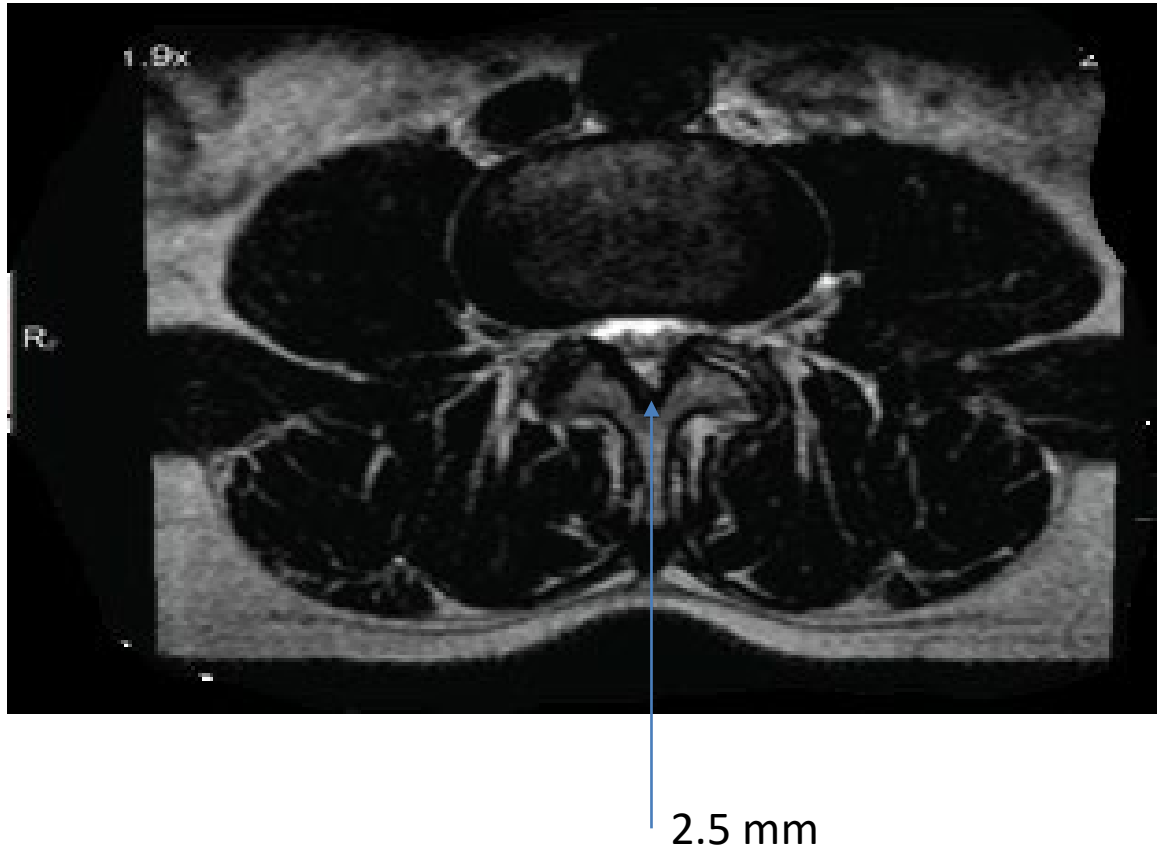
Use ESI as a diagnostic tool

- Post interlaminar ESI, administer contrast
- Assess ligament thickness/buckling
- Follow-up with MRI review to confirm assessment and plan procedure

Limited dye flow will highlight HLF and levels impacted

LOOK FOR THE LIGAMENT

What does a 2.5mm ligament look like?



- 2.5 mm is the starting point and all spinal canals are different. Look for the thickened ligament impinging on the central canal.
- If there is a ligament ≥2.5mm, *mild* is least invasive step in the LSS treatment algorithm.

STEP 3: EDUCATE CANDIDATES & SET EXPECTATIONS

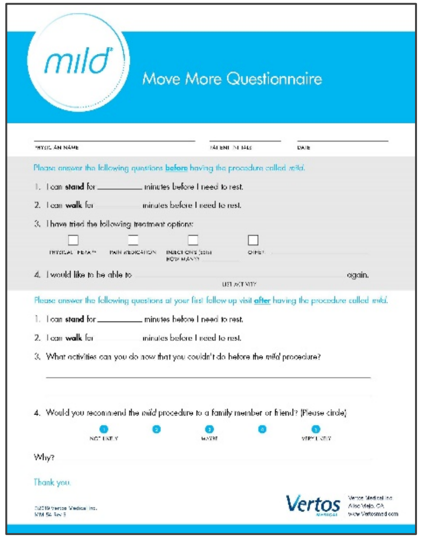
mild is a safe procedure that can help patients stand longer and walk farther with less pain[7]

Performed through a tiny incision, smaller than a baby aspirin:

5.1 mm

- Low complication risk
- Outpatient procedure
- No general anesthesia
- No stitches
- No implants
- Resume light activities within a few days

STEP 4: CONDUCT FOLLOW-UP VISITS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Move More Questionnaire

PHYSICIAN NAME ______ PATIENT INITIALS ______ DATE ______

Please answer the following questions **before** having the procedure called *mild*.

1. I can **stand** for ______ minutes before I need to rest.
2. I can **walk** for ______ minutes before I need to rest.
3. I have tried the following treatment options:
   - ☐ PHYSICAL THERAPY
   - ☐ PAIN MEDICATION
   - ☐ INJECTIONS (ESIS) HOW MANY? ______
   - ☐ OTHER ______
4. I would like to be able to ______ (LIST ACTIVITY) again.

Please answer the following questions at your first follow up visit **after** having the procedure called *mild*.

1. I can **stand** for ______ minutes before I need to rest.
2. I can **walk** for ______ minutes before I need to rest.
3. What activities can you do now that you couldn't do before the *mild* procedure?
4. Would you recommend the *mild* procedure to a family member or friend? (Please circle)

   1 NOT LIKELY — 2 — 3 MAYBE — 4 — 5 VERY LIKELY

Why?

Thank you.

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Vertos Medical

Vertos Medical Inc.
Aliso Viejo, CA
www.Vertosmed.com

During follow-up visit:

- Assess and document post-op outcomes
- Inspect incision
- Discuss conditioning plan: PT prescription
- Schedule 6-month appointment to measure optimal outcomes and consider assessing for other treatments

Remember: Patients often report soreness from increased mobility and muscle use

During follow-up visit, remind patients of the Cleveland Clinic study results and functional improvement over time[8]

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MIST GUIDELINES & CLINICAL DECISION-MAKING WORKFLOW IN YOUR PRACTICE

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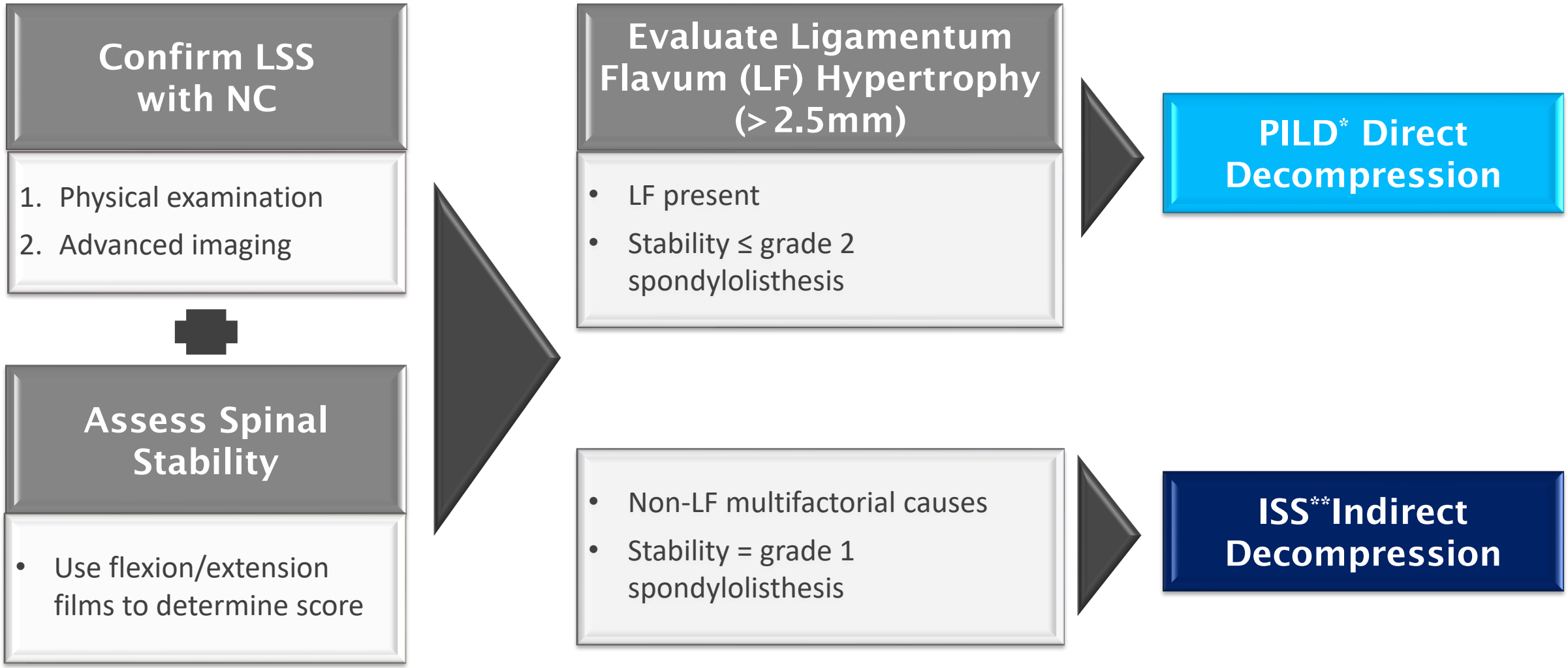
MIST GUILDELINES: DECISION MAKING WITH PREDOMINANT CENTRAL CANAL SPINAL STENOSIS[19]

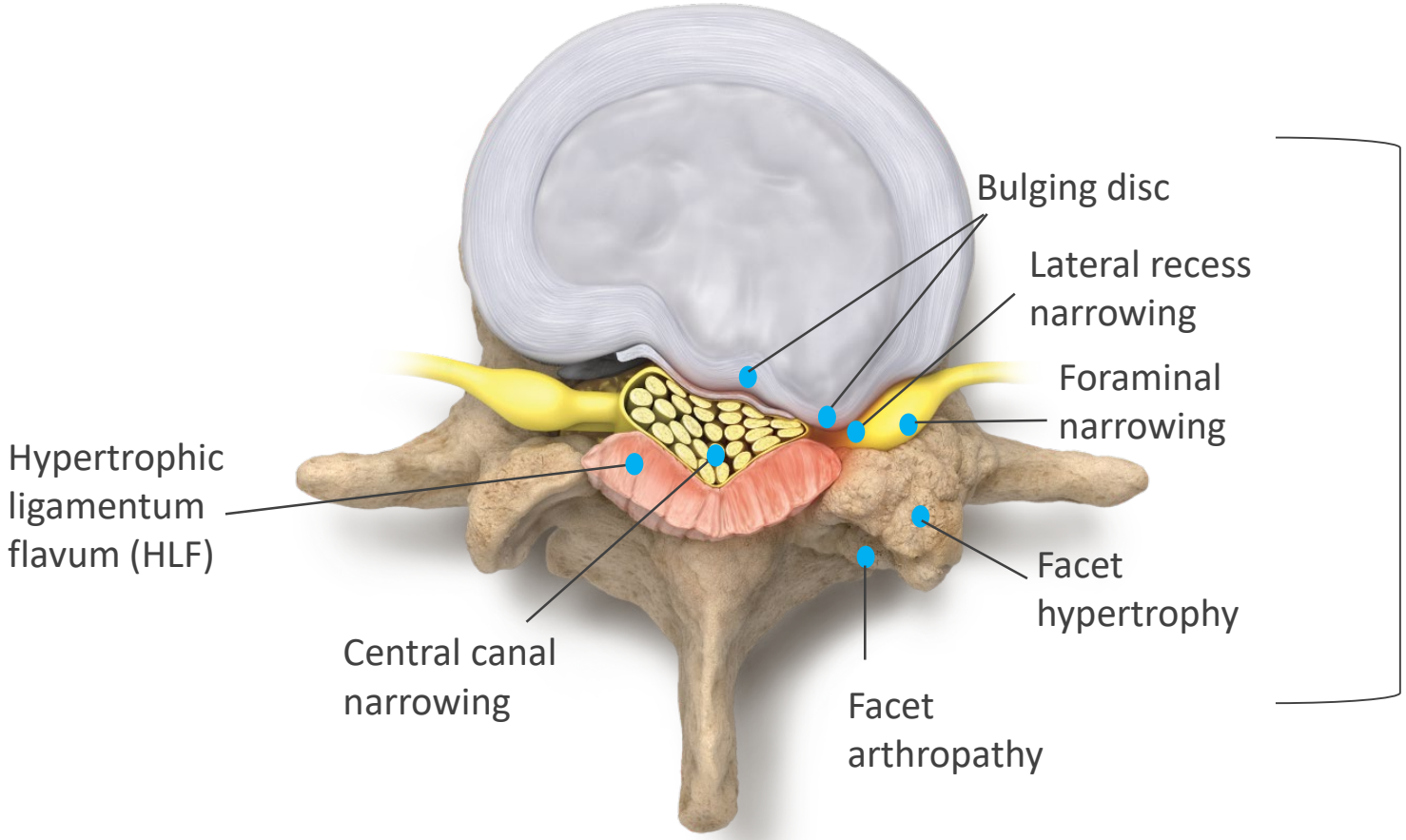


*Percutaneous Image-guided Lumbar Decompression

**Interspinous Spacers

MIST GUIDELINES: PILD TREATS COMORBIDITIES

Comorbidities have been shown to be positive predictors for success[19]



Lumbar spine with LSS and comorbidities

- Comorbidities are not contraindications
- *mild* has been shown to treat multifactorial etiologies

mild CLINICAL DECISION-MAKING WORKFLOW

Vertos MEDICAL

Identify NC

- Confirm symptomology
- Establish baseline mobility

Evaluate Imaging

- Symptomatic stenosis
- Assess ligament
- Evaluate stability (if needed)

mild® Procedure

- May add steroid after procedure to decrease inflammatory response
- Prescribe conditioning / core exercise program for 6 months

Consider Assessing at 6 Months to Treat Other Conditions

Administer ESI for Radicular Pain & Diagnostic

mild Planning

- Post interlaminar ESI, administer contrast
- Assess ligament thickness/buckling
- Determine access in contralateral oblique view

ESI Failure

Assess ESI Effectiveness

- Follow up at 2 weeks: Does discomfort persist?

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PRACTICE INTEGRATION & COMMITMENT

Vertos MEDICAL

WHERE *mild* FITS IN YOUR PRACTICE

Effective treatment for NC

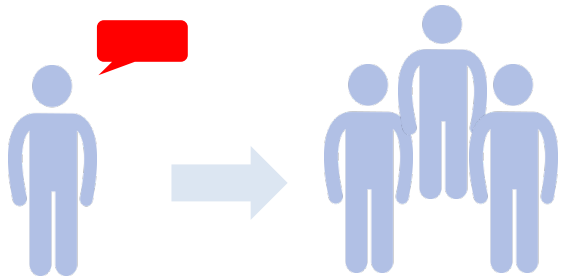
- Solution for undertreated population
- Patients stay in your practice longer
- Frequently need other treatments
- Does not eliminate future treatment options

Option for underserved patient population

- Not surgical candidates
- Can’t tolerate general anesthesia
- Early disease / don’t want surgery

Differentiate your practice

- Positive word of mouth
- Attract new patients
- Differentiator to referring physicians



INTEGRATION INTO YOUR PRACTICE

Staff engagement

Vertos access:

- Ensure patient evaluation is routine and patient flow process is in place
- Educate all patient touchpoints
- Assist in creating a trigger for MRI ordering and review
- Confirm radiologist is educated on *mild* and reports provide HLF measurement

Clinical efficiency

Scheduling:

- Schedule regular treatment times (weekly/monthly) and perform cases in blocks
- Perform cases solo once procedure comfort is established

Patient outcomes

Tracking:

- Ensure regular review of patient outcomes (walking/standing, pain) by practice staff

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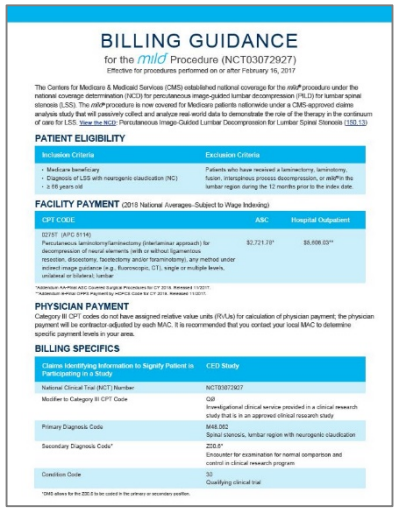
NATIONAL MEDICARE COVERAGE

Vertos MEDICAL

SIMPLE COVERAGE REQUIREMENTS & CLAIMS SUPPORT

All Medicare plan types covered (original, advantage, supplement)

- Medicare beneficiaries- regardless of age
- Diagnosis of LSS with NC
- No surgery in lumbar region in previous 12 months
  (laminectomy, laminotomy, fusion, interspinous process decompression, or *mild*)



BILLING GUIDANCE

for the *mild* Procedure (NCT03072927)

Effective for procedures performed on or after February 16, 2017

The Centers for Medicare & Medicaid Services (CMS) established national coverage for the *mild*® procedure under the national coverage determination (NCD) for percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS). The *mild*® procedure is now covered for Medicare patients nationwide under a CMS-approved claims analysis study that will passively collect and analyze real-world data to demonstrate the role of the therapy in the continuum of care for LSS. View the NCD: Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13)

PATIENT ELIGIBILITY

Inclusion Criteria	Exclusion Criteria
• Medicare beneficiary • Diagnosis of LSS with neurogenic claudication (NC) • ≥ 66 years old	Patients who have received a laminectomy, laminotomy, fusion, interspinous process decompression, or *mild*® in the lumbar region during the 12 months prior to the index date.

FACILITY PAYMENT (2018 National Averages–Subject to Wage Indexing)

CPT CODE	ASC	Hospital Outpatient
0275T (APC 5114) Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method under indirect image guidance (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar	$2,721.70*	$6,606.03**

*Addendum AA-Final ASC Covered Surgical Procedures for CY 2018, Released 11/2017.
**Addendum B-Final OPPS Payment by HCPCS Code for CY 2018, Released 11/2017.

PHYSICIAN PAYMENT

Category III CPT codes do not have assigned relative value units (RVUs) for calculation of physician payment; the physician payment will be contractor-adjusted by each MAC. It is recommended that you contact your local MAC to determine specific payment levels in your area.

BILLING SPECIFICS

Claims Identifying Information to Signify Patient is Participating in a Study	CED Study
National Clinical Trial (NCT) Number	NCT03072927
Modifier to Category III CPT Code	Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Primary Diagnosis Code	M48.062 Spinal stenosis, lumbar region with neurogenic claudication
Secondary Diagnosis Code*	Z00.6* Encounter for examination for normal comparison and control in clinical research program
Condition Code	30 Qualifying clinical trial

*CMS allows for the Z00.6 to be coded in the primary or secondary position.

The Reimbursement Group:

- Connects directly with your billers to ensure claims are set up properly and submitted correctly upon first submission
- Provides prior-auth support for Medicare Advantage & commercial payors

REFERENCES

[1]Health Market Science report for Vertos Medical (2013).
[2]Kalichman L, Cole R, Kim DH, et al. Spinal stenosis prevalence and association with symptoms: the Framingham Study. *Spine J.* 2009;9(7):545–550. doi: 10.1016/j.spinee.2009.03.005.
[3]Hall, S., Bartleson JD, Onofrio BM, Baker HL Jr, Okazaki H, O'Duffy JD. Lumbar spinal stenosis: Clinical features, diagnostic procedures, and results of surgical treatment in 68 patients. *Ann Intern Med.* 1985;103(2):271-275.
[4]Fukusaki, M, et al. Symptoms of Spinal Stenosis Do Not Improve After Epidural Steroid Injection. *Clinical Journal of Pain.* 1998;6;14(2):148-151.
[5]Porter, RW. Spinal stenosis and neurogenic claudication. *Spine.* 1996;Sep 1;21(17):2046-52.
[6]Staats PS, Chafin TB, Golovac S, for the MiDAS ENCORE Investigators. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. *Reg Anesth Pain Med*. 2018;43(7):789-794.
[7]MiDAS ENCORE: CMS-approved, prospective, multi-center, randomized controlled clinical study. Study on file with Vertos Medical (n=99).
[8]Mekhail N, Costandi S, Abraham B, Samuel SW. Functional and patient-reported outcomes in symptomatic lumbar spinal stenosis following percutaneous decompression. *Pain Pract.* 2012;12(6):417-425. doi: 10.1111/j.1533-2500.2012.00565.x.
[9]Food and Drug Administration (US). Superion® InterSpinous Spacer Summary of Safety & Effectiveness Data. Center for Devices and Radiologic Health (CDRH) division of FDA.gov. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140004b.pdf. Published May 20, 2015. Accessed December, 2018.
[10]Strömqvist BH, Berg S, Gerdhem P, et al. X-Stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year follow-up. *Spine (Phila Pa).* 2013;38(17):1436-1442. doi: 10.1097/BRS.0b013e31828ba413.
[11]Weinstein JN, Tosteson TD, Lurie JD, for the SPORT Investigators. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med.* 2008;358(8):794-810. doi: 10.1056/NEJMoa0707136.
[12]Irmola TM, Hakkinen A, Jarvenpaa S, Marttinen I, Vihtonen K, Neva M. Reoperation rates following instrumented lumbar spine fusion. *Spine (Phila Pa)*. 2018;43(4):295-301. doi: 10.1097/BRS.0000000000002291.
[13]Forsth P, Olafsson G, Carlsson T, et al. A randomized, controlled trial of fusion surgery for lumbar spinal stenosis. *N Engl J Med*. 2016;374(15):1413-1423. doi: 10.1056/NEJMoa1513721.
[14]Ong KL, Auerbach JD, Lau E, Schmier J, Ochoa JA. Perioperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis. *Neurosurg Focus.* 2014;36(6):E5. 10.3171/2014.4.FOCUS1440.
[15]Choi JM, Choi MK, Kim SB. Perioperative results and complications after posterior lumbar interbody fusion for spinal stenosis in geriatric patients over than 70 years old. *J Korean Neurosurg Soc*. 2017;60(6):684-690. doi: 10.3340/jkns.2017.0203.
[16]Fritzell P, Hagg O, Wessberg P, Nordwall A, for the Swedish Lumbar Spine Study Group. 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain. *Spine (Phila Pa).* 2001;26(23):2521-2534.
[17]Benyamin RM, Staats PS, for the MiDAS ENCORE Investigators. MILD® Is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized controlled trial. *Pain Physician*. 2016;19(4):229-242. ISSN 1533-3159.
[18]Hansson T, Suzuki N, Hebelka H, Gaulitz A. The narrowing of the lumbar spinal canal during loaded MRI: the effects of the disc and ligamentum flavum. *Eur Spine J*. 2009;18(5):679-686. doi: 10.1007/s00586-009-0919-7.
[19]Deer TR, Grider JS, Pope JE, et al. The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment. *Pain Pract*. 2019 Mar;19(3):250-274. doi: 10.1111/papr.12744. Epub 2018 Dec 2.