Procedure Fact Sheet

mild® – For the Treatment of Lumbar Spinal Stenosis (LSS)

Market Overview for Lumbar Spinal Stenosis

Lumbar spinal stenosis (LSS) is primarily a degenerative, age-related narrowing of the lower spinal canal that causes pressure on the nerves and neurogenic claudication symptoms, leading to pain and reduced mobility. Neurogenic claudication is common in LSS patients and symptoms typically include pain, tingling, or numbness in the lower back, legs, or buttocks when standing or walking. Discomfort can be relieved by sitting or bending forward. LSS is a common condition, with more than two million Americans diagnosed and treated each year.[1] Onset generally occurs after age 50.

Historically, patients diagnosed with LSS had to choose between palliative, short-term treatments and more invasive, longer-term procedures. Palliative treatment options are low-risk and include physical therapy, acupuncture, exercise and chiropractic care. In addition, symptom management can include the use of medications, epidural steroid injections, spinal cord stimulators, and pain pumps. These options do not treat the underlying cause of the symptoms, and therefore typically only provide temporary relief.

In the past, when patients' symptoms could no longer be managed with these treatments, they faced the prospect of more invasive surgical procedures such as laminotomy (partial removal of the lamina, a plate of bone in the vertebrae), laminectomy (removal of the entire lamina and the ligaments that are attached to it) or spinal fusion (the permanent joining of two or more vertebrae to eliminate movement between them). Each of these carries substantial risk of complications[2] and results in changes to the natural anatomy and structural stability of the spine. The *mild*® procedure presents an option that treats neurogenic claudication, one of the leading underlying causes of LSS symptoms, in a safe and minimally invasive way that provides lasting relief for patients.[3*]

The *mild* Procedure and Devices

Created by Vertos Medical, *mild*® is a safe procedure that can help many patients diagnosed with LSS stand longer and walk farther with less pain.[3] It is a short, outpatient procedure performed through an incision the size of a baby aspirin that requires no general anesthesia, no implants and no stitches. The procedure has a reported positive-response rate of 81 percent[4] and more than 20,000 patients have undergone the procedure nationwide.[5]

mild® is a proprietary technology of Vertos Medical Inc. It is cleared by the U.S. Food and Drug Administration for decompression of the lumbar spine and is covered by Medicare nationwide.

How *mild* Works

One of the significant contributors to LSS is an excess of ligament tissue (called hypertrophic ligamentum flavum) between the vertebrae. A physician can use *mild*® devices to remove small portions of excess tissue through a small incision (about the size of a baby aspirin). This restores space in the spinal canal, which reduces the compression of the nerves. The procedure is performed using fluoroscopy, which gives the physician continuous X-Ray visualization of the treatment area and is a key safety feature.

Key Safety Features

Safe by Design:

- Tiny incision – 5.1 mm (size of baby aspirin)
- Safest decompression procedure[8]
- Constant visualization of the instruments and treatment area via epidurogram
- All activity is posterior to the dura (delicate sac that surrounds the spinal cord)

Outpatient Procedure:

- No general anesthesia required

- No stitches
- No implants
- No hospital stay

Low Complication Rate:

- Clinically demonstrated equivalent safety profile to epidural steroid injections (ESI).[7]
- No major device-related complications reported in any clinical trial.[6]
- Adverse event rate <0.1% in more than 20,000 commercial cases.[5]

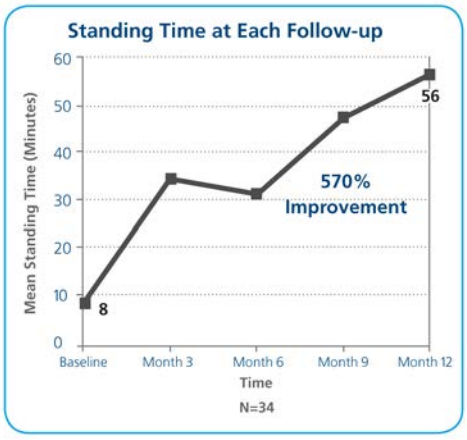
For detailed information on the potential risks associated with the *mild*® procedure, visit www.Vertosmed.com/products.

Clinical Studies

The *mild*® procedure and devices have been proven to be safe and effective in 13 clinical trials and more than 20 physician-reviewed clinical journal articles. Data have shown that *mild*® patients are able to stand longer and walk farther with less pain.[3] No major complications related to the devices or the procedure have been reported in any clinical trial.[6]

Key Study Outcomes: Proven Efficacy

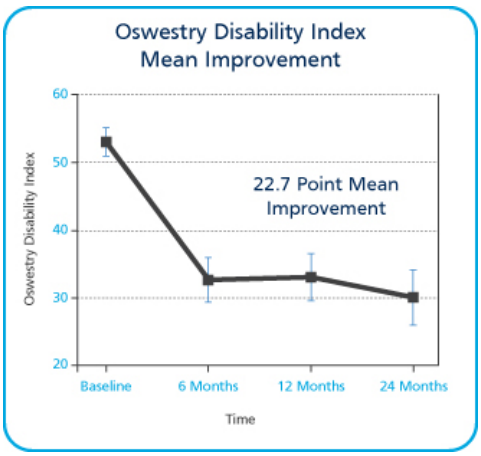
Functional Outcome Improvement – Cleveland Clinic Study at 1 Year[3]



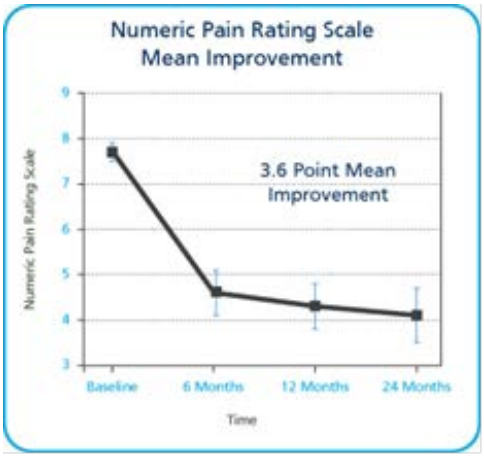
Standing time increase:
From 8 min. to 56 min.

Walking distance increase:
From 246 ft. to 3,956 ft.

Functional and Pain Improvement – MiDAS ENCORE Study Two-Year Data[8]



Functional Improvement by 22.7 points



Pain reduction by 3.6 points

mild® Comparative Study – Two-Year Outcomes[9]

mild® Comparative Safety vs. Other Decompression Options

2-YEAR OUTCOMES	*mild*[1]	Spacers	Surgical Decompression	Fusion
Reoperation	5.6%	20.0% (Superion®)[2] 14.4%–26.0% (X-STOP®)[2,4]	6–7.8%[3,4]	12.5–16.9%[5,6,7]
Device- and procedure-related AEs	1.3%	Device-Related: 11.6% (Superion)[2] 7.5% (X-STOP)[2] Procedure-Related: 14.2% (Superion)[2] 15.9% (X-STOP)[2]	9.9% intra-operative & 12.3% postoperative[3]	23.3%[8] 18% early/6% late[8]
Device- and procedure-related serious AEs	0%	8.4% (Superion®)[2] 9.5% (X-STOP®)[2]		
Lumbar spine fractures	0%	16.3% (Superion®)[2] 8.5% (X-STOP®)[2]	–	4.2%[7]
Removal of hardware	No implants	16.3% (Superion®)[2] 12.4% (X-STOP®)[2]	No implants	4.3%[7]

Physicians Certified to Perform *mild*

The *mild*® procedure can only be performed by qualified physicians who have attended training provided by the manufacturer, Vertos Medical. Familiarity with fluoroscopic imaging techniques and expertise in the epidural space are key qualification requirements. The most common physician specialty offering the procedure is the Interventional Pain Specialist although other physicians can offer the procedure if they have the required skills. To locate a *mild*® physician in your area, visit www.mildprocedure.com.

Vertos Medical Inc.

Vertos Medical is a leader in the treatment of patients suffering from LSS. Its proprietary technologies include *mild*®, which offers an outpatient, minimally invasive, fluoroscopically-guided treatment of LSS. For more information, visit www.Vertosmed.com.

* Cleared for lumbar decompression, Vertos *mild*® is designed to treat lumbar spinal stenosis (LSS).

For more information, visit www.mildprocedure.com.

References:

[1] 2012 data from Health Market Science report for Vertos Medical 2013.

[2] Major complications include dural tear and blood loss requiring transfusion. Weinstein, James N., et al., for the SPORT Investigators. (2008), Surgical vs. Nonsurgical Therapy for Lumbar Spinal Stenosis. *New Engl J Med*, 358: 794–810. doi: 10.1056/NEJMoa0707136.

[3] Mekhail, Nagy, et al. (2012), Functional and Patient-Reported Outcomes in Symptomatic Lumbar Spinal Stenosis Following Percutaneous Decompression. *Pain Practice*, 12(6): 417–425. doi: 10.1111/j.1533-2500.2012.00565.x.

[4] Levy, Robert, et al. (2012), Systematic Safety Review and Meta-Analysis of Procedural Experience Using Percutaneous Access to Treat Symptomatic Lumbar Spinal Stenosis. *Pain Medicine,* 13(12): 1554-1561. doi: 10.1111/j.1526-4637.2012.01504.

[5] Data provided by Vertos Medical Inc. July 25, 2018.

[6] Based on *mild*® procedure data collected in all clinical trials.

[7] Benyamin, R., et al. (2016), *mild*® is an Effective Treatment for Lumbar Spinal Stenosis with Neurogenic Claudication: MiDAS ENCORE Randomized Controlled Trial, Pain Physician, 19: 229-242, ISSN 1533-3159.

[8] Staats PS, Chafin TB, Golovac S, Kim CK, Li S, Richardson WB, Vallejo R, Wahezi SE, Washabaugh EP, Benyamin RM, 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;43:789-794.

[9] *mild*® Comparative Study – Two-Year Outcomes Chart References:

[1] Staats PS, Chafin TB, Golovac S, et al. 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 Sep 7. Epub

[2] Food and Drug Administration (US) [Internet]. [Silver Spring, MD]: CDRH; 2015. Superion® InterSpinous Spacer Summary of Safety & Effectiveness Data. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140004b.pdf

[3] Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. N Engl J Med. 2008;358:794-810.
[4] 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. 2013;38:1436-1442.
[5] Irmola TM, Hakkinen A, Jarvenpaa S, Marttinen I, Vihtonen K, Neva M. Reoperation rates following instrumented lumbar spine fusion. Spine. 2017 Jun 13 [Epub ahead of print].
[6] Forsth P, Olafsson G, Carlsson T, et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. N Engl J Med. 2016;374:1413-1423.
[7] Ong KL, Auerbach JD, Lau E, Schmier J, Ochoa JA. Peroperative outcomes, complications, and costs associated with lumbar spinal fusion in older patients with spinal stenosis and spondylolisthesis. Neurosurg Focus. 2014;36:E5.
[8] 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;60:684-690.
[9] Fritzell P, Hagg O, Wessberg P, Nordwall A. 2001 Volvo Award Winner in Clinical Studies: Lumbar Fusion Versus Nonsurgical Treatment for Chronic Low Back Pain. Spine. 2001;26:2521-2534.

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