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, leading to pain and reduced mobility. 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 1.2 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. Numerous palliative treatment options exist to manage LSS symptoms. These treatments 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, 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 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 15,000 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.

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

X-ray-guided (using fluoroscopy) to Ensure Continuous Safety:

- Visualization of the *mild*® devices and treatment area before and during the procedure
- All activity is posterior to the dura (delicate sac that surrounds the spinal cord)

Outpatient Procedure:

- No general anesthesia required
- Small incision – 5.1 mm (size of a baby aspirin)
- No stitches
- No implants

Low Complication Rate:

- No dural tears, nerve root damage or blood loss requiring transfusion reported in any clinical trials.[6]
- Adverse event rate <0.1% in more than 15,000 commercial cases.[5]

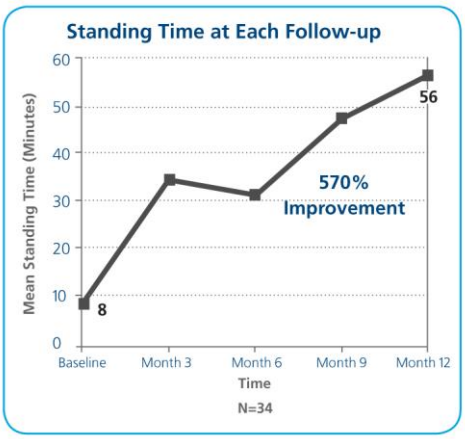
For detailed information on the potential risks associated with the *mild*® procedure, visit www.Vertosmed.com/products.

Clinical Studies

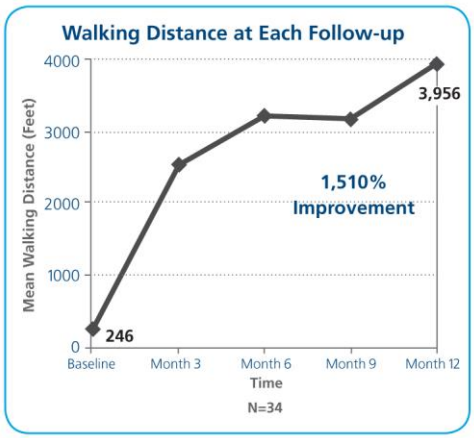
The *mild*® procedure and devices have been proven to be safe and effective in 11 clinical trials and more than 16 physician-reviewed clinical journal articles. Data have shown that *mild*® patients are able to stand longer and walk farther with less pain.[3] No major complications related to the devices 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]

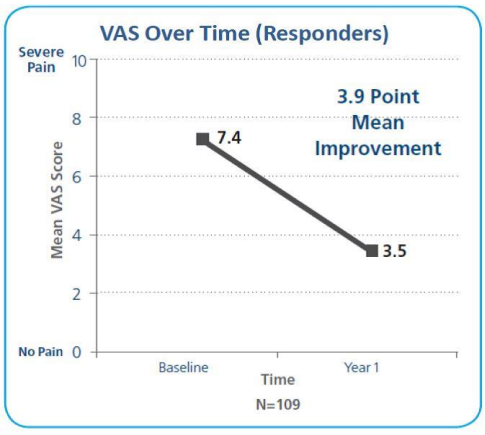


Standing time increase:
From 8 min. to 56 min.

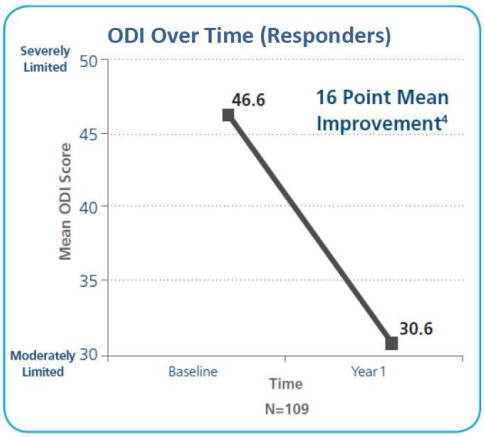


Walking distance increase:
From 246 ft. to 3,956 ft.

Long Term Efficacy – Meta-Analysis I at 1 Year[4, 7, 8]



Pain reduced in 81% of patients at 1 year
Mean pain reduced by 53%



Mean mobility increased by 34%

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] Longitudinal Medicare Database, Quorum Consulting.

[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. [2]Responders defined as VAS reductions ≥ 1. [3]The published approximate MCID for the ODI version utilized in this study is 6.0 (Fritz, J.M., et al. (2001), A Comparison of a Modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Physical Therapy*, 81(2): 776–788.

[5] Data provided by Vertos Medical Inc. June 2013.

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

[7] Responders defined as VAS reductions ≥ 1.

[8] The published approximate MCID for the ODI version utilized in this study is 6.0 (Fritz, J.M., et al. (2001), A Comparison of a Modified Oswestry Low Back Pain Disability Questionnaire and the Quebec Back Pain Disability Scale. *Physical Therapy*, 81(2): 776–788.

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