# Procedure Description and Clinical Evidence

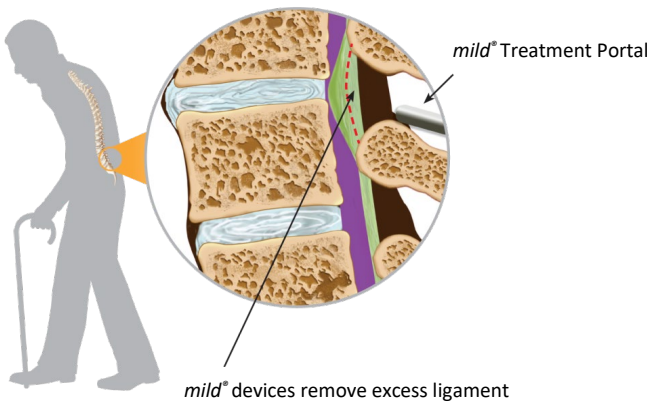
## Procedure Description

*mild*® is an FDA-cleared, safe, outpatient, minimally invasive, durable, and therapeutic procedure that treats LSS. *mild*® decompresses the spinal canal by removing small portions of lamina and hypertrophic ligamentum, which helps restore space in the spinal canal. The restoration of space reduces pressure on the nerves, improves mobility, and reduces pain. The procedure is performed through a 5.1-mm treatment portal (smaller than the size of a baby aspirin) via a posterior approach using live fluoroscopy, which provides constant visualization of the treatment area throughout the procedure. A key safety feature is the minimally invasive design of the procedure itself, which requires no general anesthesia, no implants, no stitches, and is typically performed in less than one hour.

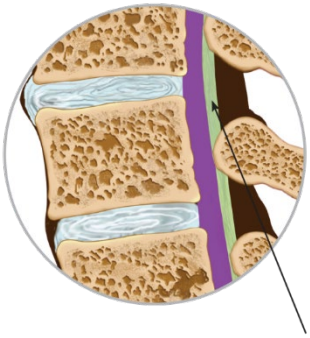
## Procedure Objective

***"Removing a Kink in a Drinking Straw"***

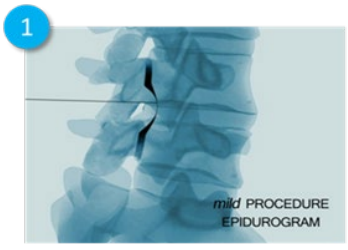
Before




After

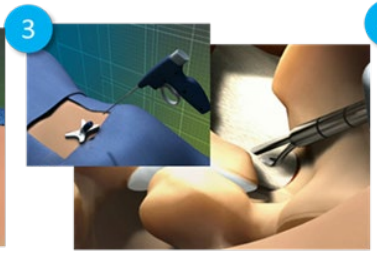

*mild*® restores space in the spinal canal

## Procedural Steps

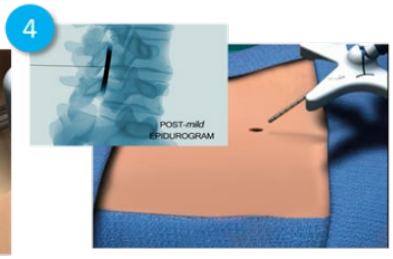



Perform epidurogram to visualize procedure


Create 5.1-mm treatment portal




Decompress using specialized tools




Remove devices & close with Steri-Strip™


MM-304 Rev 1

Vertos Medical Inc.
Aliso Viejo, CA

Established Procedure with Robust Clinical Evidence

Over a decade's worth of robust data is available to validate the safety and long-term effectiveness of the *mild*® procedure:

- 30,000+ patients treated to date
- 14 clinical studies conducted at leading interventional pain institutions across the United States
- 20+ peer-reviewed journal articles published to date, including the most recently published, Level-1, 2-year data from the CMS-approved MiDAS ENCORE study[1]

Safety:

- Clinically demonstrated equivalent safety profile to epidural steroid injections (ESIs)[1]
- No major device-related complications reported in any clinical trial[2]
- Adverse event rate <0.1% in more than 30,000 commercial cases
- Proven to be the superior treatment for neurogenic claudication compared to current standard of care (ESI) – Level-1 evidence from CMS-approved study[1]

Efficacy: Clinically proven long-term efficacy[1]:

MiDAS ENCORE Study at 2 Years[1]

The results of all primary and secondary efficacy-outcome measures achieved significant clinically meaningful improvement

- 72% of patients saw a clinically significant improvement in function
- No surgery or reoperation in 94.4% of patients
- 95% of patients with 5 or more comorbidities presented higher response rates than the ENCORE population as a whole


*ODI mean improvement: 10-point improvement is clinically significant.

**NPRS mean improvement: 2-point improvement is clinically significant.

Cleveland Clinic Study at 1 Year[3]


2018 MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment:[4]

- Percutaneous Image-Guided Lumbar Decompression: *mild* is the only image-guided technique meeting the CMS definition of PILD, and as such PILD will refer to *mild* for the purposes of this section.
- Direct decompression (PILD) should be considered if instability exists and patients are not candidates for open surgery and/or fusion, with the presence of LF hypertrophy.
- Based on a systematic review of the available literature for PILD, the consensus committee has determined that there is sufficient support to warrant Level-1 evidence using the USPSTF (United States Preventive Services Task Force) criteria.

References

[1] Staats PS, Chafin TB, Golovac S, et al; 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;43:789-794.

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

[3] Mekhail, N., et al. 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.

[4] 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*. 27 October 2018. doi:10.1111/papr.12744.