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Innovator Spotlight: Vertos Plans To Expand Reach Of Minimally Invasive Lumbar Decompression

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By Reed Miller

NEW PROFESSIONAL CONSENSUS GUIDELINES RECOMMEND VERTOS Medical's minimally invasive lumbar decompression (MILD) system as an alternative to epidural steroid injections for patients with lumbar stenosis. The company is planning to raise more capital to expand its commercial operation so it can reach more patients that could benefit from MILD.

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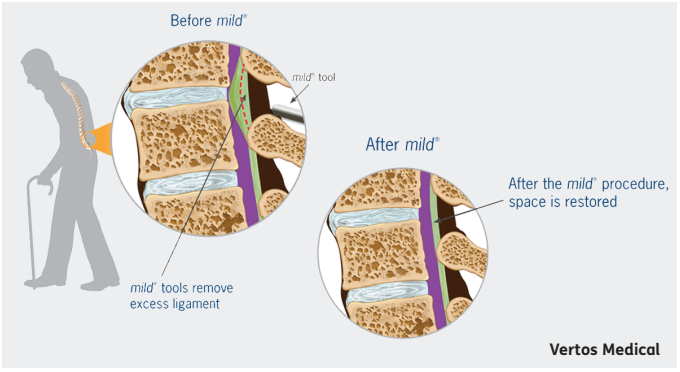
Vertos Medical Inc. is planning a major commercial expansion by the end of 2019 to support its minimally invasive lumbar decompression (MILD) system to treat lumbar stenosis.

"We are contemplating doing a large expansion to make this procedure available to others," Vertos CEO Eric Wichems told *Medtech Insight*. "We're anticipating another injection of money to be able to really hit the ground running on these patients and treating them."



Lumbar spinal stenosis is a degenerative narrowing of the lower spinal canal that causes pain, numbness, or tingling in the lower back and legs, which can make it hard for the patient to stand or walk. The MILD procedure removes hypertrophic ligamentum flavum to restore space in the spinal canal and relieves pain by taking pressure off the nerves. The procedure requires no general anesthesia, no implants, no stitches, and is performed in about one hour.

Vertos' MILD system is designed to remove tissue without damaging the ventral fibers of the ligamentum flavum by accessing the spine through a 5.1 mm portal behind thecal sac. The MILD system includes an epidurogram to give the operating physician constant visualization of the treatment during the procedure.

Vertos, formerly known as X-Sten, was founded in 2005 and the US Food and Drug Administration cleared MILD in 2006. It received a CE mark in February 2019. The MILD procedure has been performed in over 20,000 patients and evaluated in more than 13 clinical studies and 20 publications, but the company believes it will be able to bring MILD to a much larger patient population once it expands its overall commercial operation.

In the near term, Vertos is trying to bring MILD to patients with lumbar stenosis who are not candidates for surgery and instead are being treated with epidural steroid injections as well as patients who still had significant symptoms after trying epidural steroid injections. About 400,000 people in the US fit into this category annually, but the ultimate market for MILD is probably much bigger than that, according to Wichems.

"We see this as an essentially endless supply of patients that we could and want to treat," Wichems said.

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The company secured a $28m financing round led by MVM Life Science Partners in June 2017. Other investors include Aweida, Mercury Fund, Leerink Revelation Partners, ONSET Ventures and Pitango Venture Capital.

"Now our commercialization is going well and so we're looking to take this to the next level toward the end of this year and having a big cash infusion, so we can expand even more," Wichems said.

Developing The Evidence

The US Centers for Medicare and Medicaid Services issued a national coverage with evidence development policy for MILD in 2017. (***Also see "Medicare Slightly Expands Coverage For Spine Procedure, But Policy Remains Trial-Limited" - Medtech Insight, 14 Dec, 2016.***) Two trials sponsored by Vertos meet the requirement for Medicare coverage under this policy, the MILD Medicare Claims Study and the randomized MiDAS ENCORE study.

Two-year results from 274 patients in MiDAS ENCORE, announced in September 2018, showed the benefits of MILD were durable for at least two years with no evidence of new spinal instability. Two years after the procedure, the patients treated with MILD showed better outcomes than the patients treated with epidural steroid injection, including greater improvements on the Oswestry Disability Index, Numeric Pain Rating Scale and the Zurich Claudication Questionnaire. There were no serious device or procedure-related adverse events, but 1.3% experienced a non-major device or procedure-related adverse event.

Wichems said that preliminary studies have shown that patients treated with MILD experience "a dramatic improvement" in walking and standing distance as well as an increase in total walking time compared to baseline, so Vertos has initiated the randomized Mild MOTION study to show the benefits of MILD on those functional measures. In addition to the standard measurements of pain and mobility, patients in Mild MOTION will also wear monitors to track their walking time and walking distance.

Wichems said Mild MOTION will serve as a "capstone study." The expected improvements in patients' ability to walk and stand without pain are functional improvements that will appeal to a "much broader stakeholder group," he said. "We wanted to have a level one study that can provide the types of data that [let's us] easily talk to patients, to payers and to other policy-makers."

New Guidelines Support MILD

Vertos expects demand for MILD procedures to get a boost from the recent publication of new professional consensus guidelines supporting percutaneous image-guided lumbar decompression procedures, including MILD.

"The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment," released in March, determine that the evidence supporting percutaneous image-guided lumbar decompression is Level 1, the highest level possible under the US Preventive Services Task Force criteria. The MIST guidelines point out that Vertos' MILD is currently the only available system for image-guided technique meeting CMS' definition of percutaneous image-guided lumbar decompression.

The authors of the MIST guidelines include key opinion leaders among spine interventionalists, pain specialists, neurosurgeons and anesthesiologists. The guidelines provide an algorithm to help physicians select the best treatment for patients diagnosed with lumbar spinal stenosis. The guidelines state that direct decompression with MILD should be considered for patients with spinal instability and ligamentum flavum hypertrophy who are not candidates for open surgery and/or fusion.

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Founded: 2005

Founders: Dave Solsberg and Don Schomer

Number of Employees: > 60

Financing Total To Date: Confidential

Investors: Aweida, Mercury Fund, Leerink Revelation Partners, MVM Life Science Partners LLP, Onset Ventures and Pitango Venture Capital

Board of Directors: Ittai Harel, Hugo Harrod, Daniel Pelak, Rob Kuhling, and Eric Wichems

Executive Physician Council: Tim Deer, Aaron Caldoney, Sudhir Diwan, Nagy Mekhail, Jason Pope and Jay Grider

"What has been missing, until this [MIST] paper, is consensus guidelines on diagnosis of lumbar spinal stenosis and treatment for these types of conditions … specifically minimally invasive spine treatments," Wichems said. "Having something like this is a very critical step in the adoption and the standard of care pathway that a therapy goes through when it goes to widespread adoption. [These guidelines represent] a significant milestone for [spine] interventionalists, but also for these therapies that are designed to treat underlying conditions for spinal stenosis."

The guidelines "create a compelling and logical consideration for using [MILD] as the first-in-line [therapy] after the failure of conservative care," he explained. "It's an important milestone for our company and for our therapy because it's a consensus opinion. It's also an important milestone for interventional pain physicians, because they are solidly making opinions about interventional procedures beyond just injections."

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