

Orthofix Announces Publication of New Data Supporting Use of PEMF Stimulation in Lumbar Spine Fusion Procedures for Patients at Risk of Pseudarthrosis

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LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a leading global spine and orthopedics company, today announced the publication of new data from a prospective, multicenter study investigating Pulsed Electromagnetic Field (PEMF) stimulation as an adjunct therapy to lumbar spinal fusion procedures in patients at risk for pseudarthrosis. Published in the **International Journal of Spine Surgery**¹, patients treated with the **SpinalStim™** bone growth therapy device demonstrated a high rate of successful fusion with significant improvements in pain, function and quality of life, despite having risk factors for pseudarthrosis.

Image of the Orthofix SpinalStim Bone Growth Therapy device.

(Graphic: Business Wire)

“Patients with risk factors such as a prior failed fusion, the need for a multilevel fusion, nicotine use, osteoporosis or diabetes often have a difficult

time healing after lumbar fusion surgery,” said lead author Dr. Marc Weinstein, an orthopedic spine surgeon at the Florida Orthopaedic Institute in Tampa, Florida. “These risk factors contribute to complications and pseudarthrosis, which can prolong pain and ultimately reduce quality of life. This data reinforces the use of PEMF stimulation after lumbar fusion surgery to improve outcomes regardless of the patients’ risk factors.”

The prospective study conducted at 10 centers across the U.S. analyzed a total of 142 patients with one or more risk factors for pseudarthrosis. Participants were assigned in-home use of the SpinalStim bone growth therapy device for six months following surgery. Fusion was determined by radiographic imaging at 12 months. Successful fusion for patients with one, two or three or more risk factors was 88.5 percent, 87.5 percent and 82.3 percent respectively. Patient reported outcomes that measure disability, function, pain, quality of life, and overall well-being were also evaluated with significant improvements noted when compared to baseline.

“The SpinalStim bone growth therapy device provides a noninvasive and cost-effective means to augment spinal

fusion procedures that enables the patient to continue their healing at home,” said Kevin Kenny, President, Orthofix Global Spine. “This new data is important as it adds to the body of evidence supporting the use of PEMF for high-risk patients who face challenges with bone fusion healing.”

About the SpinalStim Bone Growth Therapy Device

The SpinalStim device is the only bone growth stimulation therapy system that is FDA-approved as both an adjunct treatment for lumbar spinal fusion and as a nonsurgical treatment for spinal pseudarthrosis. The device utilizes PEMF technology that provides 360 degrees of treatment coverage around the fusion site² and has an overall success rate of 92 percent³ in treating spinal fusion surgery patients. Use of the SpinalStim device is supported by the North American Spine Society’s coverage recommendation⁴.

1. Weinstein MA, Beaumont A, Campbell P, Hassanzadeh H, Patel V, Vokshoor A, Wind J, Radcliff K, Aleem I, Coric D. Pulsed Electromagnetic Field Stimulation in Lumbar Spine Fusion for Patients With Risk Factors for Pseudarthrosis. *Int J Spine Surg*. 2023 Oct 26;8549. doi: 10.14444/8549. Epub ahead of print. PMID: 37884337.
2. Zborowski M, Androjna C, Waldorff EI, Midura RJ. Comparison of therapeutic magnetic stimulation with electric stimulation of spinal column vertebrae. *IEEE Transactions on Magnetics*, Vol. 51, No. 12, December 2105, 5001009. Erratum in *IEEE Transactions on Magnetics*, Vol. 53, No. 2, February 2017, 9700101.
3. PMA P850007/S6. February 1990.
4. [Spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx](https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx).

About Orthofix

Orthofix is a leading global spine and orthopedics company with a comprehensive portfolio of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions, and a leading surgical navigation system. Its products are distributed in approximately 68 countries worldwide.

The Company is headquartered in Lewisville, Texas, where it conducts general business, product development, medical education and manufacturing, and has primary offices in Carlsbad, CA, with a focus on spine and biologics product innovation and surgeon education, and Verona, Italy, with an emphasis on product innovation, production, and medical education for orthopedics. The combined company’s global R&D, commercial and manufacturing footprint also includes facilities and offices in Irvine, CA, Toronto, Canada, Sunnyvale, CA, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France, and São Paulo, Brazil. To learn more, visit [Orthofix.com](https://www.orthofix.com).

Forward-Looking Statements

This news release may include forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “intends,” “predicts,” “potential,” “continue” or other comparable

terminology. Orthofix cautions you that statements included in this news release that are not a description of historical facts are forward-looking statements that are based on the Company's current expectations and assumptions. Each forward-looking statement contained in this news release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: the ability of newly launched products to perform as designed and intended and to meet the needs of surgeons and patients, including as a result of the lack of robust clinical validation; and the risks identified under the heading "Risk Factors" in Orthofix Medical Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the Securities and Exchange Commission (SEC) on March 6, 2023. The Company's public filings with the Securities and Exchange Commission are available at **www.sec.gov**. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. Orthofix does not intend to revise or update any forward-looking statement set forth in this news release to reflect events or circumstances arising after the date hereof, except as may be required by law.

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