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Publication of Data Further Confirms Effectiveness of the Orthofix Cervical-Stim Device in Improving Fusion Rates

Patients at high risk for ACDF surgery failure saw a significant increase in bone fusion when treated with pulsed electromagnetic field stimulation

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V., (NASDAQ:OFIX), a global medical device company focused on musculoskeletal healing products and value-added services, today announced the publication of new data in *Bone & Joint Research* from a study evaluating the effect of pulsed electromagnetic field (PEMF) treatment for patients who have an increased risk for pseudoarthrosis (failure for the vertebrae to fuse) after anterior cervical discectomy and fusion (ACDF) procedures.

Study findings showed that after ACDF surgery, use of PEMF stimulation significantly increased the fusion rate relative to the control group at six and 12 months for participants who were at risk for pseudoarthrosis.[1] Participants included patients who had a risk factor that could impair their cervical spine fusion success; or they had a risk factor and received at least a two- or three-level arthrodesis.

"Anterior cervical discectomy and fusion procedures are common spinal operations in the U.S. However, successful spine fusion can be impaired in some patients, leaving them at risk for pseudoarthrosis which ultimately impacts their long-term recovery," said Dr. Richard D. Guyer, orthopedic spine surgeon and Chairman of the Texas Back Institute Research Foundation in Dallas and senior author of the paper. "This is the first published report to show that PEMF treatment significantly increased fusion rates at both six and 12 months in high-risk patients who underwent ACDF surgery."

The evaluations were conducted with historical data from Orthofix's prospective, randomized, multicenter U.S. Food and Drug Administration (FDA) investigational device exemption PMA study of 323 patients conducted in 2014 and a new multicenter, retrospective cohort study consisting of 274 patients enrolled at three institutions. In the new study, participants were required to have one or more risk factors for pseudoarthrosis. All patients were treated with PEMF following ACDF surgery. The primary endpoint was fusion at six and 12 months as determined by the presence of continuous bridging bone on plain films as assessed by the treating surgeon.

"This data is important as it builds on the findings of the original Orthofix PMA study that proved the safety and effectiveness of PEMF stimulation with the Cervical-Stim device," said James Ryaby, Ph.D., Chief Scientific Officer for Orthofix. "The results published in *Bone & Joint Research* support the use of PEMF treatment for high-risk ACDF patients and should help surgeons feel confident when prescribing this therapy."

The Orthofix Cervical-Stim device is currently approved by the FDA as an adjunct to cervical spinal fusions. The device is the only bone growth therapy device approved by the FDA as a noninvasive, adjunctive treatment option for cervical fusion in high risk patients. To learn more, please visit bonegrowththerapy.com.

About Orthofix

Orthofix International N.V. is a global medical device company focused on musculoskeletal healing products and value-added services. The Company's mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has four strategic business units: BioStim, Extremity Fixation, Spine Fixation, and Biologics. Orthofix products are widely distributed via the Company's sales representatives and distributors. For more information, please visit www.orthofix.com.

Forward-Looking Statements

This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries, are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements. The forward-looking statements in this release do not

constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to risks described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as well as in other reports that we file in the future. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release.

[1.] Coric D, Bullard DE, Patel VV, et al. Pulsed electromagnetic field stimulation may improve fusion rates in cervical arthrodesis in high-risk populations. Bone Joint Res 2018;7:124-130.

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Orthofix International N.V.
Investor Relations
Mark Quick, 214-937-2924
markquick@orthofix.com
or
Media Relations
Denise Landry, 214-937-2529
deniselandry@orthofix.com

Source: Orthofix International N.V.