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## Orthofix Study Shows Pulsed Electromagnetic Field Therapy May Reduce Cellular Inflammation Associated with Disc Degeneration

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ:OFIX), a diversified, global medical device company, today announced results of a cellular study designed to determine how pulsed electromagnetic field (PEMF) therapy affects gene expression of intervertebral discs (IVD) cells in normal and inflammatory environments. Published online in <a href="https://doi.org/10.1016/jnas.2016/jn

"The results of this study are clinically important as they demonstrate PEMF has disease modifying activities that may, in the future, provide a minimally-invasive solution for patients living with painful degenerative disc disease," said Dr. Jeffrey C. Lotz, Ph.D., Professor and Vice Chair of Research, at the UCSF Department of Orthopaedic Surgery, and co-author of the journal article. "While an important first step, more studies are needed to determine if this is indeed a viable option for managing inflammation and impaired healing associated with painful intervertebral discs."

In an in-vitro human cell culture and microarray gene expression study, cells were stimulated to elicit the inflammatory environment associated with degenerative disc disease (DDD). The cells were exposed to the Orthofix Physio-Stim<sup>®</sup> PEMF for four hours daily. At day four, this study revealed that cells treated with PEMF showed a reduction in proinflammatory markers and a decrease in degeneration of the cellular matrix relative to the control group, although this reduction did not persist to day seven.

"We continue to support preclinical evaluation of PEMF technology to confirm and validate the potential for new clinical applications," said Orthofix Chief Scientific Officer and co-author James Ryaby, Ph.D. "We remain committed to furthering the body of clinical evidence that drives best medical practice and improved patient outcomes. We believe this study suggests that PEMF may be an important future treatment option for patients suffering from degenerative disc disease."

Intervertebral disc degeneration is one of the most common mechanical causes of chronic low back pain. It occurs when the usually rubbery discs lose integrity as a normal process of aging. In 2010, low back pain was ranked as the third most burdensome condition in terms of mortality or poor health in the U.S. by the National Institutes for Health.

The Orthofix Physio-Stim and Cervical-Stim<sup>®</sup> PEMF technology is approved by the U.S. Food and Drug Administration (FDA). These devices generate a uniform, low-level electrical field that helps activate and augment the body's natural healing process to enhance bone fusion.

The paper "Pulsed electromagnetic field (PEMF) treatment reduces expression of genes associated with disc degeneration in human intervertebral disc cells" was authored by Stephanie L. Miller, Dezba G. Coughlin, Erik I. Waldorff, James T. Ryaby, Jeffrey C. Lotz, and published online in *The Spine Journal* (2016). To receive a full copy of the paper, please contact the <a href="mailto:newsroom@elsevier.com">newsroom@elsevier.com</a>.

<u>The Spine Journal</u>, the official journal of the North American Spine Society, is an international and multidisciplinary journal that publishes original, peer-reviewed articles on research and treatment related to the spine and spine care, including basic science and clinical investigations.

## **About Orthofix**

Orthofix International N.V. is a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has four strategic business units that include BioStim, Biologics, Extremity Fixation and Spine Fixation. Orthofix products are widely distributed via the Company's sales representatives, distributors and its subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as the Musculoskeletal Transplant Foundation and the Texas Scottish Rite Hospital for Children. For more information, please visit <a href="https://www.orthofix.com">www.orthofix.com</a>.

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. Factors that could cause or contribute to such differences may include, but are not limited to, those risks described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as well as in other reports that we file in the future

The forward-looking statements in this release do not constitute guarantees or promises of future performance. 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.

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