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Orthofix Announces NASS Coverage Policy Recommendations for Electrical Bone Growth Stimulators

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ:OFIX), a diversified, global medical device company, is pleased to announce the North American Spine Society (NASS) has issued first-of-its-kind coverage recommendations for electrical bone growth stimulators. These evidence-based coverage policy recommendations support the use of pulsed electromagnetic field (PEMF) stimulation devices as an adjunct to spinal fusion surgery.

Dr. Richard Guyer, orthopedic spine surgeon, co-founder and director at the Texas Back Institute in Dallas said, "Bone growth stimulation devices are an important option for patients with risk factors that might inhibit the success of their spinal fusion procedures. By stimulating bone growth, we can often avoid the need for revision surgery."

The just-issued NASS coverage policy recommends the use of electrical stimulation for spinal fusion healing in all regions of the spine including cervical and lumbar regions. Orthofix is the only company with a bone growth (osteogenesis) stimulator approved by the U.S. Food and Drug Administration (FDA) as a noninvasive, adjunctive treatment option for cervical fusion.

"We are pleased that NASS has chosen to proactively examine the medical evidence and recommend electrical bone growth stimulation devices in order to assist payors, surgeons and patients by defining appropriate use and coverage positions," said Brad Niemann, President of the Orthofix BioStim strategic business unit. "This policy is important as it further validates the use of bone growth stimulators like the Orthofix CervicalStim and SpinalStim systems, for improving spinal fusion outcomes in patients at risk of a failed fusion."

The Orthofix CervicalStim™ and SpinalStim™ devices use a low-level pulsed electromagnetic field that helps activate and augment the body's natural healing process. These devices provide patients with a safe, noninvasive treatment option for promoting spinal fusion.

Orthofix invites those attending [NASS 2016](#) to visit Booth #615 to learn more about the Company's BioStim devices and the coverage recommendations.

About NASS

The North American Spine Society (NASS) is comprised of more than 8,000 members from several disciplines, including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research and physical therapy. As part of its mission to foster the highest quality, evidence-based and ethical spine care, NASS develops credible and reasonable [coverage recommendations](#) to assist payors, providers, and patients in defining appropriate and fair coverage decisions. NASS evidence-based coverage recommendations are developed to advocate for NASS' positions on various clinical and practice issues to ensure continued provision of quality spine care.

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, TX, 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 subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as Brown University, Sinai Hospital of Baltimore, Cleveland Clinic, Texas Scottish Rite Hospital for Children and the Musculoskeletal Transplant Foundation. 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 relating to: practices of health insurance companies and other third-party payors with respect to reimbursement for our PEMF devices; any future changes to the coverage determinations of NASS for electrical bone growth stimulators; and other risks described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, 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.

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