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# Orthofix Secures FDA and CE Mark Approvals for New PhysioStim Bone Growth Stimulators

*Devices unveiled today at AAOS Annual Meeting in New Orleans*

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V., (NASDAQ:OFIX), a global medical device company focused on musculoskeletal healing products and value added services, announced the U.S. Food and Drug Administration (FDA) and European CE Mark approvals for its next-generation PhysioStim™ bone growth stimulators.

This press release features multimedia. View the full release here:
http://www.businesswire.com/news/home/20180307005078/en/


Orthofix PhysioStim Bone Growth Stimulator (Photo: Business Wire)

The PhysioStim devices provide a non-surgical treatment option for patients who have a nonunion fracture to an extremity that has shown no visible signs of healing. These Class III medical devices use a pulsed electromagnetic field (PEMF) signal to induce a low-level electrical field at the fracture site which stimulates bone healing.

"We are proud to provide physicians with these next-generation devices that will enable them to redefine how patients with nonunion fractures are treated," said Brad Niemann, President of the Orthofix BioStim strategic business unit. "These devices are built on our proprietary PEMF technology platform. Together with our spinal fusion stimulators, they are currently the No. 1 prescribed bone growth stimulators in the U.S."

The PhysioStim devices will be accompanied by a new application for mobile devices, STIM onTrack™. Designed for use with smartphones and other mobile devices, STIM onTrack is free and available in the U.S. through the iTunes App Store. The STIM onTrack mobile app includes a first-to-market feature that enables physicians to remotely view patient adherence to their prescription. Additionally, the app engages patients in their recovery process through treatment calendars, therapy reminders and educational resources.

"Bone growth stimulation therapy is a safe, effective and proven treatment for patients who have a fracture to an extremity that won't heal," said James Ryaby, Ph.D., Chief Scientific Officer at Orthofix. "When patients follow their prescription, their rate of successful healing is improved. The new mobile app is a great tool to foster better adherence to the prescribed treatment because it empowers the patient to take an active part in their recovery."

The PhysioStim devices come in different models and are designed to anatomically fit the patient's body. Specific applications are for treatment of nonunion fractures to the arm, hand, wrist, clavicle, shoulder, hip, thigh, lower leg, ankle or foot. The devices can be worn over clothing, casts or internal and external surgical fixation devices. To learn more, please visit bonegrowththerapy.com.

Orthofix invites those attending the AAOS Annual Meeting to visit Booth #2351, Hall D to learn more about our next-generation bone growth stimulation devices.

A leader in the bone growth stimulation market, Orthofix is dedicated to expanding indications for the use of PEMF devices. The Company is currently conducting three investigational device exemption (IDE) clinical trials to collect safety and effectiveness data of the Physio-Stim™ system for osteoarthritis of the knee, the RCStim™ system as an adjunctive treatment to surgical repair of full thickness rotator cuff tears and the Cervical-Stim™ system for treating odontoid fractures.

**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.

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