Orthofix Receives FDA 510(k) Clearance of G-Beam Fusion Beaming System

March 22, 2018

New system adds treatment options for Charcot foot and broadens the Company's Extremity Fixation portfolio of products

LEWISVILLE, Texas--(BUSINESS WIRE)--Mar. 22, 2018-- 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) 510(k)clearance for its new internal fixation system, the G-Beam™ Fusion Beaming System.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20180322005144/en/

G-Beam Fusion Beaming System by Orthofix (Photo: Business Wire)

Designed primarily for the treatment of Charcot foot, a debilitating condition where the bones in the foot weaken and collapse, the G-Beam devices can be implanted in the medial and lateral columns of the foot to provide alignment, stabilization and fixation.

"In my practice I often see patients whose uncontrolled diabetes has led to the development of Charcot foot, an extremely disabling condition that if left untreated, can lead to amputation," said Dr. William Grant, a podiatric surgeon from Virginia Beach, VA who designed the G-Beam system. "Using the G-Beam system allows us to anatomically realign the foot; enabling the bones to heal so these patients can return to a more normal independent lifestyle."

When the use of internal fixation is recommended, the G-Beam system is designed to fuse the medial and/or lateral columns, as well as bones in the hindfoot, in order to restore a stable foot that may ultimately reduce the probability of an amputation. The system comes with single-use, sterile-packed implants and an efficient, compact instrumentation tray.

"The G-Beam Fusion Beaming System is the next step in working towards our objective of becoming a recognized premium solution provider in the Charcot and Diabetic foot market segments," said Davide Bianchi, President of the Extremity Fixation business unit. "This system will allow us to establish ourselves in the internal fixation segment of Charcot treatment options, while leveraging our existing product lines, like TrueLok ™ and the TL-HEX ™."

About Charcot Foot

Charcot foot is a chronic and progressive joint disease causing weakening of the bones in the foot. It is a serious condition that can lead to deformity, disability and even amputation. Charcot foot can occur in people who have severe neuropathy (the loss of protective sensation in the limb) or nerve damage, a common diabetic foot complication. The World Health Organization estimates that more than 422 million people suffer from diabetes and that the number will more than double in the next 20 years. The prevalence of diagnosed Charcot foot in patients with diabetes is reported to be 0.08–7.5%. However, some studies suggest higher prevalence with as many as 13% of all diabetic patients and 29% of the neuropathic patients affected. To learn more about Charcot foot visit limbhealing.com.

The G-Beam Fusion Beaming System will be on display during the American College of Foot and Ankle Surgeons (ACFAS) annual meeting in Nashville TN, March 22-25. Orthofix invites those attending ACFAS to visit Booth #653 to learn more about this new internal fixation system.

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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Source: Orthofix International N.V.

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