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Orthofix Announces 510(k) Clearance and US Limited Market Launch of FORZA PTC Interbody Spacer System

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ:OFIX), a diversified, global medical device company, today announced the 510(k) clearance and U.S. limited market launch of the FORZA® PTC™ (Peek Titanium Composite) Spacer System. Designed and manufactured using a proprietary method, FORZA PTC spacers combine PEEK and 3D printed titanium end plates into a single porous interbody solution for lumbar spine fusion procedures. FORZA PTC interbody spacers are designed to restore normal disc height in patients suffering from degenerative disc disease.

"The Forza PTC Spacing Systems offer a unique porous technology that allows patient bone ingrowth into the surface of the implant as well as bone growth through the center of the device," said Dr. Scott Stanley, an orthopedic surgeon and co-developer of the device. "Additionally, the PEEK core allows for clear imaging so physicians can assess the patient's fusion maturation post-operatively to determine if enough healing has occurred for return to regular activities."

The FORZA PTC Spacer System represents the continuation of innovative PEEK Titanium Composite (PTC) interbody spacer products that began with the successful launch of CONSTRUX® Mini PTC™ into the anterior cervical interbody spacer market in 2013.

"We are excited to offer our surgeon customers this PEEK and titanium composite lumbar interbody technology," said Ray Fujikawa, President of Orthofix Spine Fixation. "The addition of the FORZA PTC Spacing System to our Lumbar Spine Fixation portfolio demonstrates our commitment to innovation in the spine market and to delivering solutions that help improve patients' lives."

The FORZA PTC interbody spacing device is designed to provide both the imaging benefits of PEEK and the bone ingrowth results of a porous titanium surface.

The titanium endplates of FORZA PTC are manufactured using advanced 3D printing technology to specific pore size, interconnectivity and porosity requirements. Literature has shown that interconnected pores greater than 300 microns in diameter are ideal for bone growth through porous biomaterials. The FORZA PTC interbody is designed with interconnected 400 micron diameter pores for potential bone ingrowth. This may compare favorably to the bone ongrowth potential of traditional plasma titanium coated interbodies with less than 100 micron pore diameter.

The FORZA PTC Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). The Forza PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, e.g. Firebird Spinal System. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with Forza PTC Spacer System.

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 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 the risks described in the "Risk Factors" section of our 2015 Annual Report on Form 10-K, 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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