



February 6, 2018

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

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V., (NASDAQ: OFIX), a global medical device company focused on musculoskeletal healing products, today announced the 510(k) clearance and U.S. limited market launch of the FORZA® XP Expandable Spacer System.

This press release features multimedia. View the full release here:
<http://www.businesswire.com/news/home/20180206005329/en/>



FORZA® XP Expandable Spacer System by Orthofix (Photo: Business Wire)

Designed to restore normal disc height in patients suffering from degenerative disc disease, the FORZA XP Expandable Spacer System can be expanded after insertion into the disc space in order to fit the patient's anatomy. Made primarily of titanium alloy, these expandable interbodies are used for PLIF (Posterior Lumbar Interbody Fusion) and TLIF (Transforaminal Lumbar Interbody Fusion) procedures. Unlike the incremental expansion offered by some expandable interbody devices, the Orthofix System allows for a continuous controlled expansion and a custom fit to the disc space. Once the desired expansion is achieved the device features automatic locking which further adds to its ease of use.

"The FORZA XP Expandable Spacer System is a strong addition to our robust portfolio and makes Orthofix competitive in one of the fastest growing segments in spine," said Ray Fujikawa, President of Orthofix Spine Fixation. "This new system offers an industry-leading 6.5mm starting height and also enables surgeons to place bone graft material inside the device after implantation. The ability to pack our new expandable device with bone graft post expansion is extremely important to ensure proper contact of the material with the vertebral endplates."

The FORZA XP Expandable 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. The FORZA XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation such as the Orthofix Trinity ELITE® allograft tissue and the Firebird® Spinal 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 orthopedic and spine 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, 2016, 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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