NEWS RELEASE

Orthofix Announces 510(k) Clearance and First Implant of Fitbone Transport and Lengthening System

7/9/2024

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc**. (NASDAQ:OFIX), a leading global spine and orthopedics company, today announced the 510(k) clearance and first U.S. implant of the Fitbone™ Transport and Lengthening System. Used to treat large bone defects in the femur and tibia due to trauma, infectious or malignant conditions, the device is the only intramedullary nail designed to transport or lengthen the bone through a single surgery.

The Fitbone™ Transport and Lengthening System, used to treat large bone defects in the femur and tibia due to trauma, infectious or malignant conditions, is the only intramedullary nail designed to transport or lengthen the bone through a single surgery. (Photo: Business Wire)

“Patients with defects to the femur and tibia can be difficult to treat and often have undergone multiple prior surgeries,” said Dr. David Frumberg, an orthopedic surgeon and Director of the Limb Restoration and Lengthening Program in New Haven, Conn., who performed the first U.S. implantation. “The Fitbone Transport and Lengthening System is a game-changing new option that enables bone to be transported across the defect, allowing very challenging problems to be treated without multiple follow-up surgeries.”

The Fitbone Transport and Lengthening System features the same motorized technology found in the Fitbone TAA Intramedullary Lengthening System, a product that has been in clinical use for more than 20 years and is supported by numerous **publications**. Implanted through a minimally invasive procedure, the system consists of the motorized intramedullary nail, a receiver and an external control set that enables the patient to manage the distraction phase at home. Once the treatment is complete, the nail and receiver are removed.

“The Fitbone Transport and Lengthening System further demonstrates our commitment to expanding surgical options for hard-to-treat conditions, specifically within trauma, that can have a big impact on a patient’s quality of life,” said Massimo Calafiore, Orthofix President and CEO. “We are proud of this milestone achievement and our continued innovation and advancement of the Fitbone product family that has already transformed the lives of so many patients.”

Orthofix is the only orthopedic company that offers a comprehensive portfolio of both internal and external fixation solutions for **limb reconstruction** and deformity correction procedures. Those attending the Limb Lengthening and Reconstruction Society (LLRS) Annual Meeting July 11-13 in Hollywood, Florida can learn more about the Fitbone Transport Nail and Limb Lengthening System as well as the company's full portfolio of orthopedic solutions by visiting the Orthofix booth. The Fitbone Transport and Lengthening System is currently available in the U.S. under a limited market release.

About Orthofix

Orthofix is a leading global spine and orthopedics company with a comprehensive portfolio of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions, and a leading surgical navigation system. Its products are distributed in more than 60 countries worldwide. The Company is headquartered in Lewisville, Texas, where it conducts general business, product development, medical education and manufacturing, and has primary offices in Carlsbad, CA, with a focus on spine and biologics product innovation and surgeon education, and Verona, Italy, with an emphasis on product innovation, production, and medical education for orthopedics. The combined Company's global R&D, commercial and manufacturing footprint also includes facilities and offices in Irvine, CA, Toronto, Canada, Sunnyvale, CA, Maidenhead, UK, Munich, Germany, Paris, France and São Paulo, Brazil.

Forward-Looking Statements

This news release may include forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," "continue" or other comparable terminology. Orthofix cautions you that statements included in this news release that are not a description of historical facts are forward-looking statements that are based on the Company's current expectations and assumptions. Each forward-looking statement contained in this news release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: the ability of newly launched products to perform as designed and intended and to meet the needs of surgeons and patients, including as a result of the lack of robust clinical validation; and the risks identified under the heading "Risk Factors" in Orthofix Medical Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the Securities and Exchange Commission (SEC) on March 5, 2024. The Company's public filings with the SEC are available at **www.sec.gov**. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. Orthofix does not intend to revise or update any forward-looking statement set forth in this news release to reflect events or circumstances arising after the date hereof, except as may be required by law.

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