

Orthofix Announces First US Pediatric Implant of the Fitbone Limb-Lengthening System

9/1/2021

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced the first U.S. pediatric patient implanted with the **Fitbone™** intramedullary lengthening system implant for limb lengthening of the femur and tibia bones.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20210901005263/en/>

Image of the Fitbone™ intramedullary lengthening system for limb lengthening of the femur and tibia bones. (Photo: Business Wire)

The Fitbone system is the only intramedullary limb lengthening solution cleared by the U.S. Food

and Drug Administration (FDA) for pediatric and adult use and is available in a 9mm, 11mm and 13mm sizes to address the specific needs of patients. The system is now compatible with the OrthoNext™ digital platform, the only software tool in the market for deformity analysis and preoperative planning for pediatric and adult orthopedic procedures. The OrthoNext software features a reverse planning method module that simulates the target position, osteotomy level and blocking screw placement — enabling a more accurate preoperative assessment.

“Deformity correction and limb lengthening can be challenging to plan,” said Dr. David Frumberg, an orthopedic surgeon who directs the Limb Restoration and Lengthening Program in New Haven, Conn., and performed the first U.S. pediatric patient implant. “The OrthoNext digital planning module has really helped streamline my preoperative planning, specifically when using the Fitbone system in adolescent patients where the exact limb alignment is crucial.”

“At Orthofix, we are committed to being at the forefront of solutions like the Fitbone intramedullary lengthening system that improve outcomes and quality of life for patients needing limb lengthening,” said Orthofix President of Global Orthopedics Paul Gonsalves. “We are pleased to be able to offer a technology that enables surgeons to provide exceptional care for pediatric patients.”

The Fitbone system consists of the implanted intramedullary nail, a subcutaneously implanted receiver, and an external control set that enables the patient or their caregiver to manage the distraction phase at home. The system is designed to provide accurate and controlled limb lengthening, with more than 3,500 cases performed in 15 countries since its development. With appropriate preoperative planning, it allows achievement of axial and torsional bone alignment intraoperatively, as part of the limb-lengthening procedure.

The Fitbone intramedullary lengthening system is available through a U.S. Food and Drug Administration 510(k) clearance and in European Countries under the CE Mark approval.

Orthofix is the only orthopedic company that offers a comprehensive portfolio of both internal and external fixation solutions for limb reconstruction and deformity correction. For those attending the American Academy of Orthopaedic Surgeons annual meeting in San Diego, please visit booth 2517 to learn more about the Fitbone intramedullary lengthening system.

About Orthofix

Orthofix Medical Inc. is a global medical device with a spine and orthopedics focus. The Company's mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patients' lives. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedic products are distributed in more than 60 countries via the Company's sales representatives and distributors. For more information, please visit www.Orthofix.com.

Forward-Looking Statements

This communication contains 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, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. 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," or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "2020 Form 10-K"). In addition to the risks described there, factors that could cause or contribute to such differences may include, but are not limited to: the risk that surgeons may be slow to adopt the Fitbone intramedullary lengthening system; the risk that future patient studies or clinical experience and data may indicate that treatment with the Fitbone intramedullary lengthening system does not improve patient outcomes as much as previously believed, or otherwise call into question the benefits of its use to patients, hospitals and surgeons; the risk that the product may not perform as intended and may therefore not achieve commercial success; the risk that competitors may develop superior products or may have a greater

market position enabling more successful commercialization; the risk that insurance payers may decline to reimburse healthcare providers for the use of our products.

This list of risks, uncertainties and other factors is not complete. We discuss some of these matters more fully, as well as certain risk factors that could affect our business, financial condition, results of operations, and prospects, in reports we file from time-to-time with the SEC, which are available to read at www.sec.gov. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

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