



## NEWS RELEASE

# Orthofix Announces More Than 5,000 Fitbone Intramedullary Limb-lengthening Devices Implanted Worldwide to Date and Over Twenty Years of Clinical History

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LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a leading global spine and orthopedics company, today announced **Fitbone™** TAA intramedullary limb-lengthening system has passed 5,000 devices implanted to date with more than 20 years of clinical history demonstrating safety and effectiveness in limb lengthening and deformity correction in adults and children.

Illustration of the Fitbone™ TAA intramedullary limb-lengthening system, a fully implantable system for correcting leg length and deformity discrepancies. (Photo: Business Wire)

"The ability to extend the femur or tibia bone with an internal motorized lengthening nail is an

important treatment option for patients who suffer from limb length discrepancies," said Professor Franck Accadbled, an orthopedic surgeon with the Department of Orthopaedic Surgery, CHU de Toulouse, Hospital des Enfants in Toulouse, France. "Clinical studies and the robust history of the Fitbone intramedullary system reinforce what we have seen in our extensive use of the device, giving us confidence it is a safe, viable option for lower limb lengthening."

The Fitbone intramedullary lengthening nail, acquired from Wittenstein SE in March 2020, is a fully implantable system for correcting leg length and deformity discrepancies. Implanted through a minimally invasive procedure, the system consists of the motorized intramedullary nail, a subcutaneously placed 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.

"Clinical experience and published, peer-reviewed data for the Fitbone intramedullary limb-lengthening system continue to reinforce the safety and efficacy of this life-changing technology," said Kim Elting, Orthofix President of Global Orthopedics. "We are the only company to offer a comprehensive portfolio of both internal and external

fixation solutions for limb reconstruction and deformity correction, and Fitbone is a key technology platform we intend to continue to build on to offer surgeons the best internal solutions for their patients.”

The Fitbone intramedullary lengthening system is available in the U.S. under a U.S. Food and Drug Administration 510(k) clearance and is the only lengthening nail with a pediatric indication. The system is also available in European and other countries under a CE Mark approval.

For those attending the American Academy of Orthopaedic Surgeons annual meeting in Las Vegas, please visit booth #1432 to learn more about the Fitbone intramedullary lengthening system. For more information about limb-lengthening solutions, please visit [limbhealing.com](http://limbhealing.com).

## About Orthofix

The newly merged Orthofix-SeaSpine organization 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 approximately 68 countries worldwide.

The Company is headquartered in Lewisville, Texas 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, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France and São Paulo, Brazil.

## Forward-Looking Statements

This news release includes 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 risk that future patient studies or clinical experience and data may indicate that treatment with the Fitbone 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; and the risk that insurance payers may decline to reimburse healthcare providers for the use of our products; 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, 2022, which was filed with the Securities and Exchange Commission (SEC) on March 6, 2023. The Company’s public filings with the Securities and Exchange Commission are available at [www.sec.gov](http://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.

Alexa Huerta  
Investor Relations  
Tel 214 937 3190  
[alexahuerta@orthofix.com](mailto:alexahuerta@orthofix.com)

Denise Landry  
Media Relations  
Tel 214 937 2529  
[deniselandry@orthofix.com](mailto:deniselandry@orthofix.com)

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