NEWS RELEASE

Orthofix Announces FDA 510(k) Clearance for the Rodeo Telescopic Nail

5/9/2024

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc**. (NASDAQ:OFIX), a leading global spine and orthopedics company, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market its Rodeo™ Telescopic Nail.

The Rodeo Telescopic Nail by Orthofix is an innovative device to surgically treat deformities or fractures in patients suffering from osteogenesis imperfecta. (Photo: Business Wire)

The Rodeo Telescopic Nail is an innovative device indicated to surgically treat deformities or fractures in patients suffering from osteogenesis imperfecta (OI). The nail implant serves to stabilize the patient's limb while also elongating (or telescoping) to accommodate the natural growth of pediatric patients.

The Rodeo system is designed to address many of the biomechanical and procedural challenges associated with current OI telescopic rod systems. Specifically, its patented design provides the strength and reliable bone fixation required when implanting in the inherently fragile bone associated with OI patients. The implant procedure is streamlined and the system's instrumentation and sterile pack configurations aid in optimizing efficiency in the operating room and eliminate the need to sterilize trays leading up to the surgery, thereby reducing procedural costs, O.R. time, and risks of contamination.

"The launch of the Rodeo Telescopic Nail represents Orthofix's continued commitment to address the underserved pediatric market with specialized solutions tailored to the specific needs and unique conditions, such as OI, of this patient population," said Kim Elting, President of Global Orthopedics. "The Rodeo system has been very well received in Europe, and we are pleased to be able to announce this limited U.S. market release during National OI Awareness Week and join in educating others about this genetic bone disorder that is present at birth."

Often referred to as brittle bone disease, OI affects both males and females equally throughout the world with a prevalence estimated to be one in 10,000 births. A child born with OI may have bones that break easily or form abnormally. In more severe cases, it can involve hundreds of fractures that occur without apparent cause.

Orthofix will be exhibiting at the EPOSNA Annual Meeting (Booth #24) May 8-11 in National Harbor, Maryland, and featuring the Rodeo Telescopic Nail in an educational symposium entitled “Osteogenesis Imperfecta Disease: Shared Experiences on Different Techniques and the Latest Solutions.”

The Rodeo Telescopic Nail will be available soon at select institutions in the U.S.; it has been in clinical use in a limited number of European countries since 2022 with more than 170 surgeries performed to date.

For more information about Orthofix’s full portfolio of pediatric solutions, please visit **OrthofixKids.com.**

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 Securities and Exchange Commission 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.

Media Relations

Denise Landry

DeniseLandry@orthofix.com

214.937.2529

Investor Relations

Louisa Smith, Gilmartin Group

IR@orthofix.com

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