NEWS RELEASE

Orthofix Announces Publication in The Spine Journal of Five-Year Data for the M6-C Artificial Cervical Disc

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With more than 100,000 implantations worldwide, the M6-C and M6-L discs continue to demonstrate strong clinical performance, safety and patient benefits

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc**. (NASDAQ:OFIX), a leading global spine and orthopedics company, today announced the publication of the five-year results from the U.S. clinical study comparing the **M6-C™ artificial cervical disc** with anterior cervical discectomy and fusion (ACDF). Published in **TheSpine Journal**, patients treated with the M6-C disc demonstrated superior clinical success at 60 months compared to ACDF patients. Secondary findings indicated significant improvements in neck and arm pain, function, and quality of life scores. The M6-C patient group maintained the flexion-extension and lateral bending motion reported at earlier time points. The publication of this data coincides with the recognition that more than 100,000 implantations of the M6-C artificial cervical disc and the M6-L artificial lumbar disc (only available outside the U.S.) have been performed worldwide since the product's first introduction in 2006.

The Orthofix M6-C™ artificial cervical disc is a next-generation artificial disc developed to replace an intervertebral disc damaged by cervical disc degeneration. The M6-C disc is designed to restore motion to the spine and is an alternative to cervical fusion. (Photo: Business Wire)

"Publication of this data is important as it validates the strong clinical performance observed in the five-year data from the U.S. IDE study," said lead author Dr. Frank Phillips, Professor of Orthopedic Surgery at Rush University Medical Center in Chicago and the Principal Investigator for the FDA clinical trial. "Artificial cervical disc replacement is becoming the gold standard of care for indicated patients who may otherwise be facing cervical disc fusion. Data from this study show that the M6-C artificial disc demonstrated superior five-year achievement of clinical success when compared to ACDF controls. In addition, significantly more subjects in the M6-C group reported improved pain and physical functioning scores than observed in ACDF subjects, with no difference in re-operation rates or safety outcomes."

A prospective, non-randomized, concurrently controlled clinical trial, the M6-C IDE study was conducted at 23 sites

in the United States with an average patient age of 44 years. The study evaluated the safety and effectiveness of the M6-C artificial cervical disc compared to ACDF for the treatment of single-level symptomatic cervical radiculopathy with or without cord compression. The overall success rate for the protocol-specified primary endpoint for the M6-C disc patients was 82.3 percent as compared to 67.0 percent in the control group. The rates of M6-C disc subsequent surgical interventions (SSI) were 3.1 percent, device or procedure-related serious adverse events (SAE) were 3.1 percent and were similar to ACDF rates of SSI at 5.3 percent and SAE failure equaling 4.8 percent. The M6-C disc received U.S. Food and Drug Administration (FDA) approval in February 2019 based on the two-year results of this study.

“To date there have been more than 100,000 implantations of M6 artificial disc technology in 20 countries around the world,” said Kevin Kenny, President, Orthofix Global Spine. “We are proud of this life-changing technology that has helped so many people get back to enjoying their lives.”

About the M6-C Artificial Cervical Disc

The M6-C artificial cervical disc is designed to maintain the natural behavior of a functional spinal unit by replicating the biomechanical characteristics of the native disc and is indicated as an alternative to cervical fusion. The unique design of the M6-C disc features a compressible viscoelastic nuclear core and an annular structure construct that allows for shock absorption at the implanted level, as well as providing a controlled range of motion when the spine transitions in its combined complex movements.

Orthofix invites those attending the Cervical Spine Research Society (CSRS) Annual Meeting in Las Vegas, November 29 through December 2, 2023, to visit booth #109 to learn more about the company’s full portfolio of cervical solutions.

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 approximately 68 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, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France, and São Paulo, Brazil. To learn more, visit **Orthofix.com.**

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, 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**. 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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