

# Orthofix Announces Presentation of Long-Term Evidence Highlighting the Clinical Management of Cervical Disc Arthroplasty at North American Spine Society Annual Meeting

10/10/2022

Data includes results from five-year multi-center IDE study in U.S. of the M6-C disc that also demonstrated strong clinical performance, safety and patient benefits

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced the presentation of long-term evidence highlighting the clinical management of cervical disc arthroplasty during the **North American Spine Society (NASS)** 2022 annual meeting October 12-15 in Chicago.

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

<https://www.businesswire.com/news/home/20221010005216/en/>

Orthofix M6-C Artificial Cervical Disc (Photo: Business Wire)

“We are pleased to sponsor the presentation of data supporting the clinical effectiveness of cervical disc arthroplasty including five-year data from our U.S. IDE study,” said Kevin Kenny, Global President of Orthofix Spine. “We are honored to have a distinguished surgeon panel that will provide their insights about cervical disc replacement and long-term outcomes of this therapy for patients suffering from degenerative disc disease.”

The presentation will be conducted on Wednesday, Oct. 12 at 12:00 pm in the Red Theater located in the Exhibit Hall by Dr. Armen Khachatryan, Dr. Frank Phillips, Dr. Josh Jacobs, Steve Kurtz, Ph.D., and Gunnar Andersson, Ph.D.

Highlights that will be presented include:

- Data recently released from a U.S. IDE study showing that the **M6-C™ disc** produced statistically significant benefits at five years, including:

- reduction in disability, with an NDI score of 8.0 – which indicates mild disability compared to 18.0 in the anterior cervical discectomy and fusion (ACDF) group
  - reduction in shoulder/arm pain VAS score of 0.5 – which was significantly better than the mean of 2.1 observed in the ACDF group
  - one of the lowest subsequent surgical intervention rates at 3.1 percent for the M6-C disc as compared to other FDA-approved artificial cervical discs
- Mechanisms of Failure in Bone Ingrowth and Biologic Fixation
  - Proposed Taxonomy and Classification of Bone remodeling in Cervical Disc Replacement (CDR)
  - Recommendation for long-term Clinical Management of CDR
  - Lessons Learned from artificial joint Hip and Knee Replacements: Implant performance and bone remodeling

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. The disc was first commercialized outside of the United States in 2006 and was approved by the U.S. Food and Drug Administration in 2019. To date, more than 70,000 M6-C discs have been implanted in over 20 countries, with 20 percent of these discs having been implanted for more than 10 years. The M6-C disc has a 0.7 percent worldwide complaint rate for all M6-C discs implanted to date.

Results of a Kaplan Meier analysis of the M6-C artificial cervical disc based on 16 years of real-world evidence suggest a global cumulative survivorship (percentage of implanted devices that are still intact and functional at a specific time period) of 99% at 10 years, consistent with other, proven, joint-arthroplasty devices such as hip and knee replacements.

To learn more about the **M6-C disc** and the full portfolio of **Orthofix** solutions, please visit us at NASS at booth #2416. View our M6-C interactive experience [here](#).

## About Orthofix

Orthofix Medical Inc. is a global medical device company with a spine and orthopedics focus. The Company's mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedics products are distributed in more than 60 countries via the Company's sales representatives and distributors. For more information, please visit [www.Orthofix.com](http://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, 2021 (the “2021 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 FDA approvals may be delayed or not be obtained; the risk that surgeons may be slow to adopt the M6-C artificial cervical disc; the risk that future patient studies or clinical experience and data may indicate that treatment with the M6-C artificial cervical disc 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](http://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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