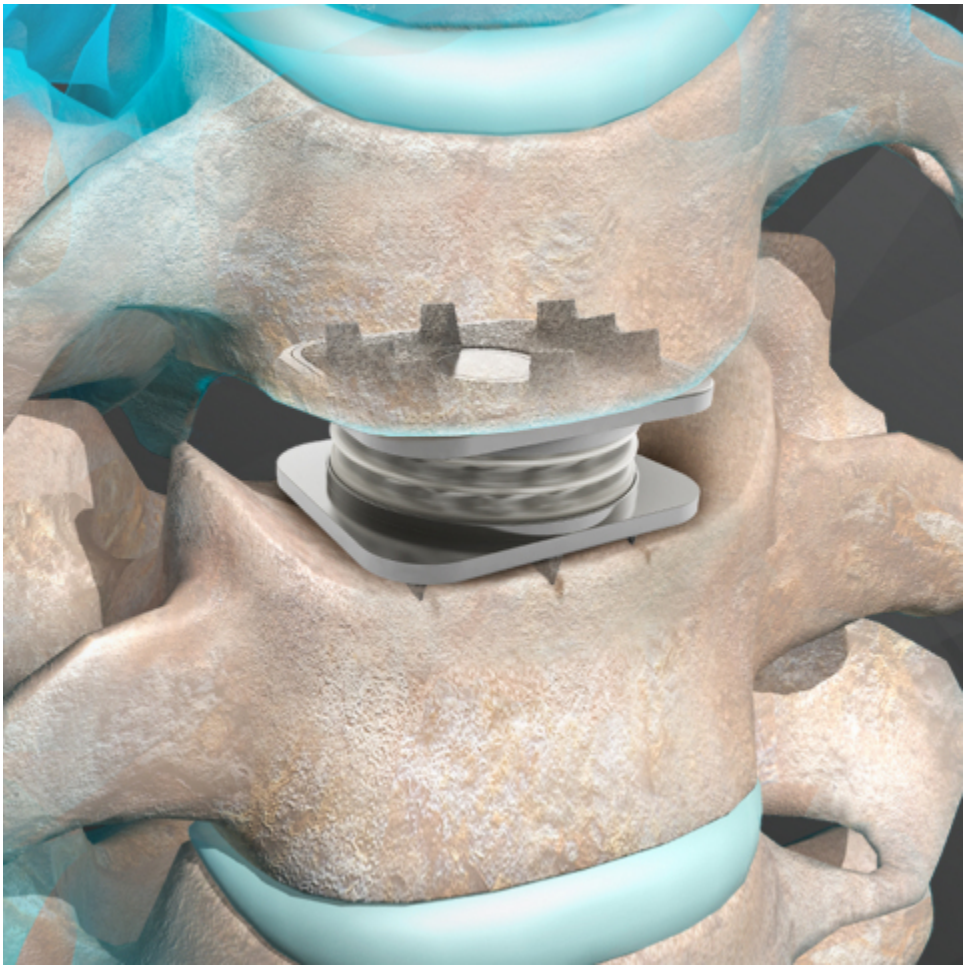
Full Two-Year Data from Orthofix M6-C Artificial Cervical Disc Study Shows Significant Improvement in Pain, Function and Quality of Life Scores

April 4, 2019

Presented for the First Time during ISASS, Data also Shows Reduction in Pain and Opioid Medication Use

LEWISVILLE, Texas--(BUSINESS WIRE)--Apr. 4, 2019-- Orthofix Medical Inc. (NASDAQ:OFIX), a global medical device company focused on musculoskeletal products and therapies, today announced the full two-year outcomes from its U.S. Investigational Device Exemption (IDE) study of the M6-C™ artificial cervical disc.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190404005010/en/



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)

Dr. Jack Zigler, orthopedic spine surgeon at Texas Back Institute and an investigator in the study, presented the study results during the International Society for the Advancement of Spine Surgery (ISASS) annual meeting in Anaheim, California.

The data demonstrates that patients treated with the M6-C artificial cervical disc had significant improvements in neck and arm pain, function and quality of life scores. Additionally, these patients had a significant difference in the reduction of pain and opioid medications use when compared to anterior cervical discectomy and fusion (ACDF) patients. At 24 months, patients in the ACDF group who were still using pain medications had a seven times higher rate of opioid use than those in the M6-C disc group.

“The results from the M6-C artificial cervical disc IDE clinical study continue to validate the positive outcomes of cervical disc arthroplasty versus discectomy with fusion,” said Zigler. “A significant reduction in pain, the maintenance or improvement of neurological function, and the preservation of natural disc motion after 24 months were all meaningful clinical benefits the M6-C disc patients experienced when compared to the fusion control. Additionally, patients receiving the M6-C disc were able to significantly lower their use of NSAIDs – and more importantly – significantly lower their use of opioid medications.”

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 86.8 percent at 24 months and 79.3 percent in the control group. This data statistically demonstrates that cervical disc replacement with the M6-C disc is not inferior to treatment with ACDF.

Secondary outcomes at 24 months include:

- Patients who received the M6-C disc demonstrated statistically significant improvement in the Neck Disability Index as measured at week six and months three, six, 12 and 24.
- Meaningful clinical improvement was seen in the following pain scores:
    - 91.2 percent of patients who received the M6-C disc reported an improvement in neck pain compared to 77.9 percent in patients who underwent the ACDF procedure.
    - 90.5 percent of the M6-C patients reported improvement in arm pain scores compared to 79.9 percent in ACDF

patients.

- Prior to surgery, 80.6 percent of the M6-C disc patients and 85.7 percent of the ACDF patients were taking some type of pain medication for the treatment of their cervical spine condition. At 24 months, the rate of M6-C patients who were still taking some type of pain medication dropped to 14.0 percent compared to 38.2 percent of the ACDF patients.
    - Of these, there was a seven times higher rate of opioid use with the ACDF patients than with patients who received the M6-C disc.
- There was a statistically significant difference in the average mean surgery time – 74.5 minutes for patients receiving the M6-C disc versus 120.2 minutes for those patients having the ACDF procedure.
- In addition, there was a statistically significant difference in the mean length of hospital stay – 0.61 days for the M6-C patients versus 1.10 days for ACDF patients.
- Subsequent surgery at the treated level was needed in 4.8 percent of the ACDF patients compared to 1.9 percent of the M6-C disc patients.
- There were no device migrations reported in the study.
- Overall patients receiving the M6-C disc reported a 92-percent satisfaction rate with the surgery, and 93 percent said they would have the surgery again.
- There were 3.8 percent serious adverse events related to the device or procedure in the M6-C disc group versus 6.1 percent in the ACDF group.

The M6-C disc received U.S. Food and Drug Administration (FDA) approval in February 2019 based on the results of this study.

“With the recent FDA approval of the M6-C artificial cervical disc, we are excited to be able to provide spine surgeons and their patients a new and innovative alternative to the ball-and-socket artificial disc designs currently available in the U.S.,” said Global President of Orthofix Spine Brad Niemann. “What makes the M6-C disc so unique is its physiologic single-piece design featuring an artificial nucleus and annulus that work together to mimic the biomechanical motion of a natural disc to include axial compression or shock absorption, which no other disc available in the U.S. has to offer.”

About the M6-C Artificial Cervical Disc

The M6-C artificial cervical disc is a next-generation intervertebral disc designed to restore physiologic motion to the spine and is indicated as an alternative to cervical fusion. The device is comprised of ultra-high molecular weight polyethylene fiber wrapped in a specific pattern, with multiple redundant layers that create a fiber matrix (artificial annulus). The fiber is then wound around a polycarbonate urethane polymer core creating an artificial nucleus. Like a natural disc, this unique construct allows for shock absorption at the implanted level, as well as provides a controlled range of motion when the spine transitions in its combined complex movements.

Orthofix is releasing the M6-C artificial cervical disc in 2019 through a controlled, limited market launch in the U.S. accompanied by an extensive training and education curriculum for surgeons.

The M6-C artificial cervical disc received CE Mark approval for distribution in the European Union and other international geographies in 2006; there have been more than 45,000 implants of the M6-C artificial cervical disc outside of the U.S. to date.

About Orthofix

Orthofix Medical Inc. is a global medical device company focused on musculoskeletal products and therapies. The Company’s mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, Orthofix’s spine and orthopedic extremities products are distributed in more than 70 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 (“the Exchange Act”), and Section 27A of the Securities Act of 1933, as amended, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. These forward-looking statements involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause Orthofix’s results to differ materially from historical results or those expressed or implied by such forward-looking statements. Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. 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. The potential risks and uncertainties that could cause actual growth and results to differ materially include, but are not limited to: the risk that spine 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, 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 refuse to reimburse healthcare providers for the use of our products; and other risks and uncertainties more fully described in Orthofix’s periodic filings with the Securities and Exchange Commission, including under the heading “Risk Factors” in our annual and quarterly reports. 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 further update any such statement to reflect new information, the occurrence of future events or circumstances or otherwise.

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