Orthofix Announces First US Patient Implants Following FDA Approval of the M6-C Artificial Cervical Disc Designed to Treat Cervical Disc Degeneration

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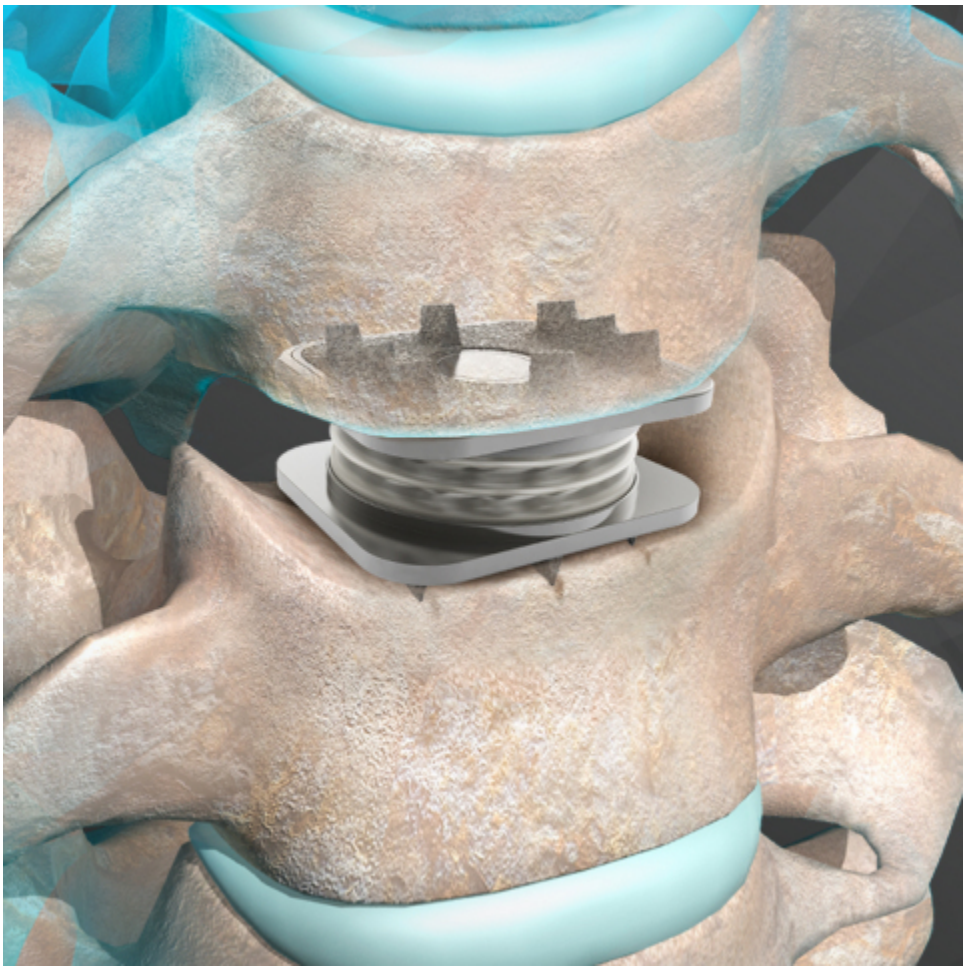
The M6-C Disc is the Only Artificial Disc Available in the US that offers Compression like a Natural Disc

LEWISVILLE, Texas--(BUSINESS WIRE)--Apr. 23, 2019-- Orthofix Medical Inc. (NASDAQ:OFIX), a global medical device company focused on musculoskeletal products and therapies, today announced the first commercial implants of patients with the M6-C ™ artificial cervical disc. The Center for Disc Replacement at Texas Back Institute (TBI) in Dallas, Texas recently implanted four patients suffering from single level cervical disc degeneration with the newly approved M6-C disc -- a next-generation artificial disc developed to replace an intervertebral disc damaged by cervical disc degeneration. Designed with an artificial viscoelastic nucleus and fiber annulus that mimics the anatomic structure of a natural disc, the M6-C device is the only artificial cervical disc available in the U.S. that enables compression or “shock absorption” at the implanted level. The disc also provides a controlled range of motion when the spine transitions in its combined complex movements.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20190423005343/en/



The M6-C™ artificial cervical disc is a next-generation artificial disc developed to replace an intervertebral disc damaged by cervical disc degeneration. (Photo: Business Wire)

Drs. Scott Blumenthal, Jack Zigler, and Richard Guyer, orthopedic surgeons and co-medical directors for the Center for Disc Replacement at TBI, completed the initial commercial cases.

“The M6-C disc represents the continued evolution of artificial disc technology with its unique single piece compressible design and motion characteristics that mimic a person’s natural disc -- features that have not been available in the U.S. until now,” said Blumenthal. “Our center was fortunate to be a part of the U.S. FDA IDE clinical study that provided data for the approval of the M6-C disc. Because of this, we now have study patients that are several years post-implant that are doing very well with this device. We are excited to be able to offer this next-generation option to patients with cervical disc degeneration who are candidates for artificial disc replacement.”

One such patient is Randy Fulton, an active duty firefighter and participant in the clinical study. “I was injured in a house fire that almost ended my career,” said Fulton, Fire Chief of the Pantego, Texas Fire Department. “Participating in the clinical study and receiving the M6-C disc helped me regain the natural movement that my disc had prior to being injured. It gave me a second chance to do what I love, which is to be a firefighter.”

“We are excited to begin providing access to this life-changing technology,” said Global President of Orthofix Spine Brad Niemann. “Orthofix is releasing the M6-C artificial cervical disc in 2019 through a controlled, limited market launch in the U.S. This is accompanied by an extensive training and education curriculum for surgeons in order to assist them in providing the best possible patient outcomes.”

The M6-C artificial cervical disc was developed to replace an intervertebral disc damaged by cervical disc degeneration. Designed to restore physiologic motion to the spine at the treated level, the M6-C disc is an alternative to cervical fusion for certain patients who are eligible for a total disc replacement. The M6-C artificial cervical disc preserves motion by restoring biomechanical function at the treated level after native disc removal and designed to potentially reduce subsequent degeneration of adjacent vertebral segments. Orthofix recently launched a new patient education website, www.M6disc.com, as a resource for those wishing to learn more about the device and the cervical disc replacement procedure.

The M6-C disc received U.S. Food and Drug Administration (FDA) approval in February 2019. Prior to U.S. launch, the device had received CE Mark approval for distribution in the European Union and other international geographies. To date there have been more than 45,000 implants of the M6-C

artificial cervical disc outside of the U.S. The M6-C disc was developed by Spinal Kinetics, a company acquired by Orthofix in April 2018.

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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