

Orthofix Announces Milestone – More Than 60,000 M6-C Artificial Cervical Discs Implanted Worldwide

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LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced that more than 60,000 **M6-C™ artificial cervical discs** have been implanted worldwide. The implant is a next-generation artificial disc designed to mimic the natural motion of a native disc. Developed to replace an intervertebral disc damaged by cervical disc degeneration, the M6-C disc is indicated as an alternative to cervical fusion. First approved for distribution under the CE Mark in the European Union and other international geographies, the M6-C disc received U.S. Food and Drug Administration (FDA) approval in 2019.

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

<https://www.businesswire.com/news/home/20210927005232/en/>

Illustration of the Orthofix M6-C artificial cervical disc. (Photo: Business Wire)

“The M6-C artificial cervical disc is continuing to establish a

market-leading position globally with more than 60,000 devices implanted worldwide,” said Orthofix President of Global Spine Kevin Kenny. “We are pleased to see the continued adoption of this state-of-the-art technology as our international success translates into the U.S. market.”

The M6-C disc is comprised of an artificial visco-elastic nucleus and fiber annulus. Like a natural disc, this unique construct allows for shock absorption at the implanted level and provides a controlled range of motion as the spine bends and translates in multiple planes. The M6-C disc is the only such device available in the U.S. with these features.

In August of 2021, Orthofix announced the **first patient implant** in a U.S. Investigational Device Exemption (IDE) two-level study of the M6-C disc. The study is evaluating patients treated for cervical degenerative disc disease at two contiguous vertebral levels with the M6-C disc compared to anterior cervical discectomy and fusion (ACDF) for symptomatic cervical radiculopathy.

Orthofix invites those attending the North American Spine Society annual meeting in Boston to visit booth #3308 to learn more about the M6-C artificial cervical disc.

About Orthofix

Orthofix Medical Inc. is a global medical device with a spine and orthopedics focus. The Company's mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patients' lives. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedic products are distributed in more than 60 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, 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, 2020 (the "2020 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 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. 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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Alexa Huerta

Investor Relations

Tel 214 937 3190

alexahuerta@orthofix.com

Denise Landry

Media Relations

Tel 214 937 2529

deniselandry@orthofix.com

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