

Orthofix Announces FDA Clearance and First Patient Implant of the 3D-Printed FORZA Titanium TLIF Spacer System with Nanovate Technology

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Designed for TLIF procedures, the 3D-printed FORZA Ti Spacer System further expands the comprehensive line of PEEK, PTC, and now Titanium interbody solutions offered by Orthofix for transforaminal lumbar applications

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and extremities focus, today announced the U.S. Food and Drug Administration 510(k) clearance and first patient implant of the **FORZA™ Ti TLIF Spacer System**. Developed to help optimize Transforaminal Lumbar Interbody Fusion (TLIF) procedures, the FORZA Ti Spacer with Nanovate™ Technology is a titanium 3D-printed interbody featuring an optimized design, porosity and surface that allows bone to grow into and through the spacer. Interbody implants are spacers that surgeons insert between the vertebrae during spinal fusion surgery to help relieve pressure on nerves and hold the vertebrae in place while fusion occurs.

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

<https://www.businesswire.com/news/home/20210422005292/en/>

Image of the 3D-printed FORZA Ti Spacer System for TLIF procedures. (Photo: Business Wire) “The 3D-printed surface technology, titanium material, and implant design all play a role in the bone growth process during fusion,” said Gary Rosenberg, D.O., an orthopedic spine surgeon operating at Orange County Global Medical Center in Santa Ana, CA who performed the first patient implant procedure. “The intuitive instrumentation allows for easy insertion, and the optimized porosity and surface features support our goal of fostering bone growth in order to aid with the patient’s fusion.”

The FORZA Ti TLIF Spacer System with Nanovate Technology is available in the U.S. through a targeted commercial release.

“Following quickly behind the recent launch of our new cervical interbody, the CONSTRUX™ Mini Ti Spacer System,

we are excited to introduce our newest 3D-printed titanium lumbar interbody system,” said Orthofix President of Global Spine Kevin Kenny. “The result of our intense focus on bringing solutions to market to meet the current needs of surgeons, the FORZA Ti TLIF Spacer System with our innovative Nanovate Technology will be a key differentiator for surgeons. It will provide access to advanced fusion technology backed by studies that support the proven biological effects of nanoscale features applied to interbody devices.”

The FORZA Ti TLIF Spacer System features include:

- 3D-printed porous titanium with macro, micro, and nanoscale surface features
- Nanoscale surface that has been shown to increase proliferation and alkaline phosphatase activity (an early osteogenic differentiation marker) in human stem cells in vitro*
- Endplates with 400 micron pores and 50-percent porosity designed to help facilitate bone ingrowth**
- Functional gradient porous structure with 80-percent porosity at the midline of the implant which allows for increased fluoroscopic visualization
- Large open graft window for packing bone-grafting material
- Bulleted nose to assist with distraction
- Straightforward instrumentation for easy implantation

Featuring Orthofix’s unique Nanovate Technology, the FORZA Ti TLIF Spacer System is one of many products with nanotechnology FDA clearance including the recently launched CONSTRUX Mini Ti Spacer System, CONSTRUX Mini PTC Spacer System, the Pillar™ SA PTC Spacer System, and the FORZA™ PTC Spacer System. When compared to solid PEEK devices, the 3D-printed endplates of implants show a significant increase in growth factors involved in osteogenesis and osteoblast maturation resulting in a more favorable osteogenic environment for bone ingrowth.

*As suggested in an in vivo ovine lumbar spinal fusion model

**In vitro performance may not be representative of clinical performance

About Orthofix

Orthofix Medical Inc. is a global medical device and biologics company with a spine and extremities 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 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, 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 FORZA Ti Spacer System; the risk that future patient studies or clinical experience and data may indicate that treatment with the FORZA Ti Spacer System 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

Source: Orthofix Medical Inc.