

# Orthofix Announces FDA Clearance and First Patient Cases With the TrueLok EVO Ring Fixation System

3/16/2022

Designed for complex limb reconstruction and deformity correction procedures, the system features radiolucent rings and struts for clearer visualization under X-ray

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced the U.S. Food and Drug Administration 510(k) clearance and the first patient cases with the **TrueLok™ EVO Ring Fixation System**. Designed for complex limb reconstruction and deformity correction procedures, the TrueLok EVO system is the only circular fixator on the market that features both radiolucent rings and struts to enable clear radiographic visualization. This innovative design allows physicians to better assess bone anatomy both during surgery and post-operative care. The TrueLok EVO system is also the first circular external fixation kit available as a preassembled frame in ready-to-use single use sterile packaging, allowing for ease of application and potential time-saving during surgery, particularly when treating post-traumatic injuries.

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

<https://www.businesswire.com/news/home/20220316005167/en/>

The TrueLok EVO system is the only circular fixator on the market that features both radiolucent rings and struts to enable clear radiographic visualization.

(Photo: Business Wire)

“We are constantly evolving our solutions to meet surgeons’ and patients’ needs,” said Orthofix President of Global Orthopedics Paul Gonsalves. “Orthofix ring fixation systems are the preferred solutions to thousands of surgeons worldwide and have been used to treat more than 80,000 patients to date. Today we are proud to launch the TrueLok EVO system as part of our portfolio of solutions to help healthcare professionals restore patient anatomy, mobility and quality of life.”

The TrueLok EVO system is an advanced external-fixation system made of carbon fiber, making the device lightweight for improved patient comfort while maintaining the same simple, stable and versatile benefits of the

original TrueLok Ring Fixation system. The TrueLok EVO system has MR conditional clearance, enabling patients, in specific conditions, to have an MRI with the fixator applied if needed.

“External ring fixation systems provide an important treatment option for patients in need of deformity correction or complex limb reconstruction,” said Dr. Amgad Haleem, Associate Professor of Orthopedic Surgery at the University of Oklahoma Health Sciences Center in Oklahoma City, who performed the first U.S. cases. “Packaged as a sterile preassembled frame set, the TrueLok EVO frame presents a streamlined configuration that helps reduce the time needed to prepare the device for the procedure. Additionally, the radiolucent rings and struts make it easier to visualize under X-ray the precise placement of the device on the bone during surgery. Together, these advancements enable us to better treat adults and children across a wide range of bone deformity and trauma conditions.”

The TrueLok EVO system is intended for fixation of open and closed fractures, limb lengthening by metaphyseal or epiphyseal distractions, treatment of nonunion or pseudarthrosis of long bones and correction of bony or soft tissue defects or deformities in adult and pediatric groups (excluding newborns). The TrueLok EVO system may be used in a hybrid frame construction with the ProCallus™ Fixator, XCaliber™ Fixators and the Galaxy Fixation™ system. It is also compatible with the TrueLok and TL-HEX™ systems.

Orthofix invites those attending the American Academy of Orthopaedic Surgeons Annual Meeting in Chicago, March 22-26, 2022 to visit booth #2044 to learn more about the TrueLok EVO system.

## 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 [Orthofix.com](http://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 “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 TrueLok EVO Ring Fixation System; the risk that future patient studies or clinical experience and data may indicate that treatment with the TrueLok EVO Ring Fixation 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](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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220316005167/en/): <https://www.businesswire.com/news/home/20220316005167/en/>

Alexa Huerta  
Investor Relations  
Tel 214 937 3190  
[alexahuerta@orthofix.com](mailto:alexahuerta@orthofix.com)

Denise Landry  
Media Relations  
Tel 214 937 2529  
[deniselandry@orthofix.com](mailto:deniselandry@orthofix.com)

Source: Orthofix Medical Inc.