

# Orthofix Medical and LimaCorporate Announce Partnership to Provide Solution for Patients with High Hip Dislocation for the US Market

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LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, and LimaCorporate S.p.A., a global orthopedic company focused on digital innovation and patient-tailored hardware, today announced a licensing partnership for the U.S. market to provide a novel solution for patients with the challenging condition of chronic high dislocation of the hip.

This press release features multimedia. View the full release here:  
<https://www.businesswire.com/news/home/20220713005138/en/>

Orthofix's patented Fitbone™ intramedullary nail system (pictured) together with LimaCorporate's proprietary, patient specific, 3D-printed pelvic fixation device will meet the previously unmet need of patients with the challenging condition of chronic high dislocation of the hip. (Photo: Business Wire)

The partnership combines the unique limb-lengthening technology of Orthofix's patented **Fitbone™** intramedullary nail system with

LimaCorporate's proprietary, patient specific, 3D-printed pelvic fixation device. Once surgically implanted, the devices work together with the aim of allowing surgeons to distract the femur to an anatomically-correct position thereby correcting the leg-length discrepancy, reducing strain on the spine, and allowing for a total hip replacement to follow.

"We are excited to partner with LimaCorporate to bring together our complementary technologies to satisfy the previously unmet needs of patients requiring a personalized and unique complex hip replacement solution," said Kimberley Elting, President of Orthofix Orthopedics. "This solution will be the only offering in the U.S. for certain patients with hip dysplasia or abnormalities of the hip leading to leg-length discrepancy, and reflects the strength and versatility of the Fitbone platform."

"This new solution to treat chronic high hip dislocation is not currently cleared by the U.S. Food and Drug

Administration (FDA) and is only available through an FDA Compassionate Use Exemption,” added Elting.

Emmanuel Bonhomme, LimaCorporate CEO, stated, “This partnership is an important opportunity for us to explore new segments and support even more U.S. surgeons and their patients. Additionally, the collaboration with the ProMade Point of Care Center (PoC Center), which opened last year, will bring added value in terms of experience and knowledge combined with our market-leading technologies in custom prosthesis.”

LimaCorporate’s ProMade 3D-printed custom service, which incorporates design and manufacturing in its unique PoC Center, is located at the main campus of Hospital for Special Surgery (HSS) in New York City.

“This new treatment method has shown compelling results demonstrating improved patient outcomes in this challenging cohort, and I am pleased to see this procedure now being made available to surgeons in the U.S.,” said Professor Rainer Baumgart, M.D., the surgeon-inventor of the Fitbone limb-lengthening system.

## About the Fitbone Intramedullary Lengthening System

The Fitbone system consists of the implanted intramedullary nail, a subcutaneously implanted receiver, and an external control set that enables the patient or their caregiver to manage the distraction phase at home. The system is designed to provide accurate and controlled limb lengthening, with more than 3,500 cases performed in 15 countries since its development. With appropriate preoperative planning, it allows achievement of axial and torsional bone alignment intraoperatively, as part of the limb-lengthening procedure.

The Fitbone intramedullary lengthening system is available through a U.S. Food and Drug Administration 510(k) clearance and in European Countries under the CE Mark approval.

## About LimaCorporate

**LimaCorporate** is a global orthopedic company, focused on digital innovation and tailored hardware, which advances patient centered care. Its pioneering technological solutions are developed to empower surgeons and to improve patient outcomes from joint replacement surgery. Its primary focus is on providing reconstructive and custom-made orthopedic solutions to surgeons, enabling them to improve the quality of life of patients by restoring the joy of movement. Headquartered in Italy, the company operates directly in over 20 countries around the world. LimaCorporate offers products ranging from large joint revision and primary implants to complete extremities solutions including fixation.

## 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 [www.Orthofix.com](http://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, 2021 (the "2021 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 FDA approvals may be delayed or not be obtained; the risk that surgeons may be slow to adopt the Fitbone Intramedullary Nail System; the risk that future patient studies or clinical experience and data may indicate that treatment with the Fitbone Intramedullary Nail 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.

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