



September 23, 2015

## Orthofix Announces Publication of Data Confirming the Clinical Benefits of Trinity Evolution Cellular Bone Allograft in Foot and Ankle Procedures

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ:OFIX), a diversified, global medical device company, today announced results from the largest study conducted to date evaluating the safety and effectiveness of their cellular bone allograft (CBA), Trinity Evolution<sup>®</sup>, in foot and ankle arthrodesis (fusion) procedures. Published online in [Foot & Ankle International](#), patients treated with Trinity Evolution demonstrated per joint fusion rates of 86.8 percent at 12 months follow-up. Additionally, successful fusion significantly correlated with improvements in pain, function, and Quality Of Life (QOL), even in patients with comorbidities such as obesity, diabetes and smoking.

"The goal of arthrodesis in foot and ankle fusion procedures is to decrease pain and improve function and quality of life by reversing disability associated with arthritis, trauma, diabetes and a variety of other conditions," said Dr. James Nunley, Professor of Orthopaedic Surgery and Director of Foot & Ankle Surgery at Duke University Medical Center and senior author of the journal article. "This study observed fusion rates using Trinity Evolution that were higher than or comparable to fusion rates in other published studies of autologous corticocancellous bone graft (autograft), a traditional gold standard used in foot and ankle procedures."

In this prospective, multicenter, open-label clinical study, Trinity Evolution was evaluated in 92 patients undergoing 153 foot and ankle fusion procedures. Compared with previous studies, this trial used prospective enrollment and included patients who were at high risk for bone fusion failure due to age, diabetes or obesity. The primary endpoint was successful fusion based on high resolution CT scans and radiographs assessed by an independent lab. Based on radiographic effectiveness, the study demonstrated a per joint fusion rate of 81.1 percent (124/153) at six months, which increased to 86.8 percent (112/139) at 12 months. Additionally, comorbid factors known to be associated with fusion failure (pseudoarthrosis), such as diabetes, age and obesity, did not have a negative effect in this study. There were no serious adverse events attributable to Trinity Evolution as determined by an independent consultant.

"This study is evidence of our commitment to invest in clinical research to provide physicians the information they need to make the best choices for their patients," said Orthofix Chief Scientific Officer James Ryaby, Ph.D. "We designed this study to include diabetic, obese and older patients often seen by foot and ankle specialists who might not respond well to traditional allograft and autograft materials. These results support Trinity Evolution as an important alternative to autograft and other bone growth materials in this difficult-to-treat patient population."

Procedures using autograft often require a second surgical site to harvest the bone. This can cause complications such as pain from the bone removal site and infection. In addition, the quality of the bone harvested can be poor, especially in older individuals or patients with other health issues.

### About Trinity Evolution

Trinity Evolution is a cryopreserved CBA from allograft donor bone that facilitates effective bone formation by providing an osteoconductive scaffold, osteoinductive growth factors and osteogenic cells. Trinity Evolution eliminates the need for harvesting autograft from patients, which reduces operating time and expense as well as discomfort and potential complications.

Processed by the [Musculoskeletal Transplant Foundation](#) (MTF), a nonprofit organization dedicated to providing quality tissue, Trinity Evolution is the predecessor of [Trinity Elite<sup>®</sup>](#), a moldable bone graft material that enables physicians to easily control the placement of tissue during procedures. To date there have been more than 135,000 procedures using Trinity Evolution and Trinity Elite.

### About Orthofix

Orthofix International N.V. is a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has four strategic business units that include BioStim, Biologics, Extremity Fixation and Spine Fixation. Orthofix products are widely distributed via the Company's sales representatives, distributors and its subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as the Musculoskeletal

Transplant Foundation and the Texas Scottish Rite Hospital for Children. For more information, please visit [www.orthofix.com](http://www.orthofix.com).

## **About MTF**

The Musculoskeletal Transplant Foundation, a non-profit organization based in Edison, NJ, is a national consortium comprised of leading organ procurement organizations, tissue recovery organizations and academic medical institutions. Since its inception in 1987, MTF has received tissue from more than 100,000 donors and distributed more than 6 million grafts for transplantation. For more information, visit [www.mtf.org](http://www.mtf.org).

## **Forward-Looking Statements**

This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries and are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements.

The forward-looking statements in this release do not constitute guarantees or promises of future performance. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release.

View source version on [businesswire.com](http://www.businesswire.com): <http://www.businesswire.com/news/home/20150923005258/en/>

Orthofix, International N.V.

Investor Relations:

Mark Quick, 214-937-2924

[markquick@orthofix.com](mailto:markquick@orthofix.com)

or

Media Relations:

Denise Landry, 214-937-2529

[deniselandry@orthofix.com](mailto:deniselandry@orthofix.com)

Source: Orthofix International N.V.

News Provided by Acquire Media