



OSSIO Announces U.S. Launch and First Commercial Use of the New OSSIOfiber™ Bone Pin for Hammertoe Correction

New Category Offers Surgeons Strong, Secure Fixation and “Biologically Friendly” Approach to Restoring Patient Stability and Mobility with No Permanent Implant Left Behind

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WOBURN, Mass.--(BUSINESS WIRE)--OSSIO, Inc., an orthopedic fixation company, today announced the U.S. launch and first commercial use of the OSSIOfiber™ Bone Pin Family for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis and bone grafts. The first commercial cases were hammertoe repairs successfully performed at Polaris Surgery Center in Westerville, Ohio by Gregory Berlet, MD, Christopher Hyer, DPM, and Mark Prissel, DPM, foot and ankle surgeons and partners at the Orthopaedic Foot & Ankle Center in Worthington, Ohio.

The OSSIOfiber™ Bone Pin Family received 510(k) market clearance from the U.S. Food and Drug Administration (FDA) in January and the initial product offering is applicable for use in the foot and ankle segment for the treatment of forefoot conditions where hardware removal surgeries are prevalent. Offering a new category of non-permanent fixation material, the OSSIOfiber™ Intelligent Bone Regeneration Technology features a first of its kind, proprietary bio-integrative material that provides stability and secure bone fixation during the healing process and gradual integration into the native anatomy, ultimately leaving no permanent hardware behind. Combining unparalleled mechanical strength and natural bone healing in a non-permanent implant, OSSIOfiber™ is designed to fully incorporate into the native anatomy without any adverse biologic response.

“OSSIOfiber™ brings forward a real paradigm shift in how we approach bone fixation. The new bio-integrative implant is truly unique in that it provides immediate stable fixation that physiologically adapts with the bone during the healing process,” said Dr. Berlet. “I am honored to have performed the inaugural cases in the United States together with Drs. Hyer and Prissel and look forward to adding implants made from this innovative bio-material technology to my treatment arsenal.”

Additional procedures utilizing the OSSIO*fiber*[™] platform are planned in limited markets in the coming weeks, with full commercialization and availability in all states set to occur in the third quarter of 2019. Over the next year, OSSIO anticipates streamlined adoption of OSSIO*fiber*[™] among the orthopedic and podiatric surgeon communities, given the implant's innovative bio-integrative design and overall ease-of-use, requiring no changes to surgeons existing techniques.

“While forefoot disorders are highly treatable, secondary procedures to remove hardware are often warranted, causing a significant cost burden on the patient, physician and healthcare system as a whole,” said Dr. Hyer. “We’ve been waiting for a new option in the orthopedic fixation space for decades and OSSIO*fiber*[™] shows real promise to become the first credible replacement to permanent implants. Having this new treatment option at the ready will fundamentally impact our approach to treating these patients by avoiding permanent device-related post-operative complications and secondary removal surgeries.”

Since receiving FDA clearance, OSSIO has made significant headway in executing against key commercial related milestones, including:

- Hiring experienced area sales directors and independent sales distributors
- Securing \$22 million in financing to accelerate strategic growth
- Completed all manufacturing validations to meet anticipated demand
- Identified the first 25 sites ready to participate in early limited market release
- Completed enrollment in the European Hammertoe Clinical Trial

“The U.S. market anticipation for OSSIO*fiber*[™] has been overwhelmingly positive to date,” said Brian Verrier, CEO, OSSIO. “We are poised to initiate broader U.S. commercialization of the implant system in the coming weeks, offering surgeons and their patients a new standard of care in orthopedic fixation.”

The proprietary OSSIO*fiber*[™] technology can address many surgical applications through the manufacturing of endless implant designs, including pins, screws and plates. The company intends to pursue multiple applications in the distal extremity, trauma, sports, reconstruction, pediatrics, and spine segments. For more information on OSSIO*fiber*[™] please visit www.ossio.io.

About OSSIO*fiber*[™] Intelligent Bone Regeneration Technology

Designed for rapid bone in-growth, regeneration and replacement, OSSIO*fiber*[™] Intelligent Bone Regeneration Technology is a first-of-its-kind implant material stronger than cortical bone that leaves nothing permanent behind. OSSIO*fiber*[™] is engineered to provide the strength required for functional fixation and allows for full integration into the native anatomy without adverse biological response. OSSIO*fiber*[™] implants utilize existing reimbursement and surgical techniques. The OSSIO*fiber*[™] Bone Pin Family represents the first of several regulatory approvals for the company and is cleared for use in the United States for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis and bone grafts in the presence of appropriate additional immobilization.

About OSSIO

OSSIO is an orthopedic fixation company committed to transforming the orthopedic experience for patients, physicians and payors. Founded in 2014, its vision is to provide the first credible replacement to metal implants in the multi-billion-dollar global orthopedic fixation market with its OSSIO*fiber*[™] Intelligent Bone Regeneration

Technology. OSSIO's development headquarters is located in Caesarea, Israel, and its commercial headquarters is in Woburn, Massachusetts. For more information on the company visit www.ossio.io.

Forward-looking statements contained herein are based on estimates and assumptions of OSSIO management and are believed to be reasonable, though they are inherently uncertain and difficult to predict.

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