



Restore. Regrow. Renew.

OSSIO Receives FDA 510(k) Clearance for OSSIOfiber® Hammertoe Fixation System

Complete Offering of Implant Sizes and Shapes Provides Surgeons and their Patients an Intelligent Bone Regeneration Alternative to Metal Fixation

WOBURN, Mass – OSSIO, Inc., an orthopedic fixation company, today announced that its OSSIOfiber® Hammertoe Fixation System has received 510(k) market clearance from the U.S. Food and Drug Administration (FDA) for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis and bone grafts. These novel bio-integrative implants with disposable, sterile instrumentation now come in three sizes, with both straight and angled configurations for better customization among various patient anatomies.

The OSSIOfiber® Bone Pin Family initially received [510\(k\) market clearance](#) from the FDA in January 2019 and was later commercialized as part of a [limited market release](#) for use in the foot and ankle segment for the treatment of common forefoot conditions, such as hammertoe, where hardware removal surgeries are prevalent. The OSSIOfiber® Hammertoe Fixation System comprises the company's breakthrough OSSIOfiber® Intelligent Bone Regeneration Technology, a new category of fixation material that combines unparalleled mechanical strength and natural bone healing in a non-permanent implant. Made from a proprietary natural mineral fiber matrix, its bio-integrative material properties provide surgeons with a more biologically friendly way to restore patient stability and mobility while leaving nothing permanent behind.

“With more than 500 successful hammertoe repairs conducted to date utilizing the OSSIOfiber® Hammertoe Implant, along with the completion of our European multi-center study confirming the overall safety and positive performance of our proprietary technology, confidence in achieving excellent clinical outcomes and high surgeon and patient satisfaction continues to grow,” said Brian Verrier, CEO, OSSIO. “Launching the broader hammertoe offering along with several other OSSIOfiber® product platforms over the next year will serve a broader orthopedic fixation market that aspires to avoid the risks, costs and trade-offs associated with permanent implants. We are dedicated to providing surgeons and their patients with a more intelligent way to restore, regrow and renew bone.”

In 2019, OSSIO completed enrollment in its European multi-center clinical trial designed to assess the safety and performance of the OSSIOfiber® Hammertoe Fixation System. Trial results demonstrated fusion rates well above historical literature, dramatic improvements in pain and quality-of-life scores from baseline, radiographic evidence of good bio-integration with the surrounding anatomy, and no evidence of adverse biological response or serious adverse events associated with the OSSIOfiber® implant at six months follow-up. Additionally, all 25 patients that participated in the trial communicated high satisfaction rates with the OSSIOfiber® Hammertoe Fixation System and would recommend the technology to others. These findings will serve to support OSSIO's Conformité Européene (CE) Mark application for approval of the OSSIOfiber® Hammertoe Fixation System later this year.

“These trial results are truly impressive and further validate the growing clinical and commercial evidence supporting the performance of the OSSIOfiber® Hammertoe Fixation System. The patients participating in the trial under my care have self reported a rapid return to full function and appreciate

the fact that nothing permanent is left within the body following healing, providing them with further peace-of-mind,” said Dr. Luke Cicchinelli, co-principal investigator, Vigo, Spain. “The innovative OSSIO*fiber*[®] technology has ushered in a new era in orthopedic fixation – one that offers strong, secure fixation to restore full function and then allows the body to forget the implant ever existed.”

OSSIO*fiber*[®] Intelligent Bone Regeneration Technology can address many surgical applications through the manufacturing of endless implant designs, including nails, screws, anchors 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*[®] Hammertoe Fixation System and the OSSIO*fiber*[®] Bone Pin Family are 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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