

OSSIO Announces U.S. Launch and First Commercial Use of the OSSIOfiber® Trimmable Fixation Nail System for Broad Utilization in Foot/Ankle and Hand/Wrist Procedures

New Biointegrative System Offers Screw-Like Stability with the Utility of a Trimmable Nail, Leaving No Permanent Implant Behind

WOBURN, Mass., July 22, 2020 – OSSIO, Inc., an orthopedic fixation company, today announced the U.S. launch and first commercial use of the OSSIOfiber® Trimmable Fixation Nail System to securely fixate bone fractures, osteotomies and arthrodeses for healing, ultimately leaving the patient's bone restored with no permanent hardware left behind. The first commercial cases were bunion and MTP fusion procedures performed successfully by Chris Hyer, DPM, Foot and Ankle Surgeon at Polaris Surgery Center in Westerville, Ohio.

Part of the OSSIOfiber® Bone Pin Product Family, which received [510\(k\) market clearance](#) from the U.S. Food and Drug Administration (FDA) in 2019, the OSSIOfiber® Trimmable Fixation Nail System includes strong, biointegrative Trimmable Fixation Nails in 2.4mm and 4.0mm diameters packaged with corresponding sterile, disposable instrumentation. These trimmable nails rival the performance of metal compression screws, combining the necessary strength for bone fixation with the ability to provide rapid bone in-growth, regeneration and replacement without adverse inflammation, therefore avoiding the costs, pain and complications often seen with permanent hardware. Additionally, the ability to trim the implants to any desired length enables customization to any patient anatomy and adaptability for a wide range of surgical indications including forefoot, midfoot, hindfoot and an array of hand/wrist applications.

“Having successfully utilized this new biointegrative option in my own clinical practice, it is clear that the OSSIOfiber® Trimmable Fixation Nails have real potential to replace metal compression screws and pins in numerous orthopedic procedures, with the ability to optimize bone healing while avoiding permanent implant-related post-operative complications,” said Dr. Hyer. “This novel trimmable nail system is exceptionally strong and well-designed, providing both the stability needed for solid fixation, natural healing and integration into the surrounding anatomy. The ease-of-use of the pre-sterilized, disposable instrumentation is excellent, the tapered ends of the nail allow for straightforward insertion into the bone tunnel and the implant can be easily trimmed for broad procedural utility.”

OSSIO's proprietary OSSIOfiber® technology is engineered from a high performing matrix of reinforcing mineral fibers yielding strength that is 1.5 times greater than cortical bone. The design features of the OSSIOfiber® Trimmable Fixation Nail System contribute to the ability to maintain compression, stability and fixation strength and strong pull-out strength. Additionally, the hexagonal shape of the trimmable nails resist rotation, which prevents loosening that often results in screw back-out.

Additional procedures utilizing the OSSIOfiber® Trimmable Fixation Nail System are planned across the United States in the coming weeks.

“We are pleased to bring our next biointegrative fixation system to market, providing surgeons and their patients with an alternative to metal screws and pins that deliver strength, stability and utility for multiple surgical applications – all while fully integrating into the patient’s bone and leaving nothing permanent behind,” said Brian Verrier, CEO, OSSIO. “Adoption of our OSSIOfiber® Bone Pin Family has been strong to date, with substantial customer utilization across the U.S. We look forward to bringing additional breakthrough technology platforms to market that utilize our proprietary OSSIOfiber® technology and deliver a new standard of care in orthopedic fixation.”

Earlier this year, the company received [FDA 510\(k\) Clearance for its OSSIOfiber® Hammertoe Fixation System](#). Approximately 700 hammertoe repairs have been conducted to date utilizing the implant.

“OSSIO continues to add promising, innovative solutions that offer an alternative to metal implants to our surgical toolbox,” said Erik Carlson, MD, Hand and Upper Extremity Specialist, Active Orthopaedics PC, and Chief of Orthopaedic Surgery, St. Mary's Hospital, Waterbury CT. “OSSIOfiber® technology has a strong performance track-record and continues to demonstrate excellent clinical outcomes in the foot and ankle space, with high surgeon and patient satisfaction across the board. I look forward to actively utilizing the customizable OSSIOfiber® Trimmable Fixation Nail System in applicable hand and wrist procedures.”

OSSIOfiber® 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 OSSIOfiber® please visit www.ossio.io.

About OSSIOfiber® Intelligent Bone Regeneration Technology

Designed for rapid bone in-growth, regeneration and replacement, OSSIOfiber® Intelligent Bone Regeneration Technology is a first-of-its-kind implant material stronger than cortical bone that leaves nothing permanent behind. OSSIOfiber® is engineered to provide the strength required for functional fixation and allows for full integration into the native anatomy without adverse biological response. OSSIOfiber® implants utilize existing reimbursement and surgical techniques. The OSSIOfiber® Hammertoe Fixation System and the OSSIOfiber® 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 (e.g., rigid fixation implants, cast, brace).

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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