OSSIO Awarded FDA 510(k) Clearance for OSSIO*fiber*® Compression Screw Portfolio

Company Successfully Surpasses 1,000th Implantation Milestone for its Strong and Bio-integrative OSSIOfiber® Technology

WOBURN, Mass., October 19, 2020 – OSSIO, Inc., an orthopedic fixation technology company, today announced that its OSSIO*fiber*® Compression Screw Portfolio has received 510(k) market clearance from the U.S. Food and Drug Administration (FDA) for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis and bone grafts of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization. This is the third FDA clearance for the company's OSSIO*fiber*® Intelligent Bone Regeneration Technology, which uses proprietary bio-integrative material to provide stability and secure bone fixation while leaving no permanent hardware behind. To date, more than 1,000 OSSIO*fiber*® implantations have been successfully conducted in the United States.

OSSIO's Compression Screw Portfolio will initially comprise a 4.0mm-diameter cannulated, headless, partially threaded compression screw in lengths ranging from 26mm to 60mm. The bio-integrative implant is the only compression screw on the market that combines the necessary strength for bone fixation with the ability to fully integrate into the surrounding anatomy without adverse foreign body reactions and stress shielding, and avoids potential patient discomfort or implant related complications that are often associated with permanent metal hardware. Studies show that implants made from OSSIO*fiber*® provide easy insertion and secure fixation with rapid bone attachment in as little as two weeks following surgery, and gradual, safe incorporation and complete integration into the surrounding anatomy within 18 to 24 months.

"I've utilized OSSIO*fiber*® implants in numerous foot and ankle procedures, from the complex to the routine, and I've been continually impressed by their ability to provide strong and stable fixation, natural healing and complete bio-integration, resulting in a quick return to improved function and quality of life for my patients," said Tom San Giovanni, MD, Director of Foot & Ankle Surgery, Department of Orthopedic Innovation at Miami Orthopedics & Sports Medicine Institute, who recently performed the 1,000th OSSIO*fiber*® implantation as part of a first interphalangeal fusion of the hallux (great toe) procedure. "With compression screws being one of the most widely used fixation tools used today, OSSIO's latest contribution to the fixation market shows real promise in successfully addressing multiple lower and upper extremity injuries. I look forward to adding this portfolio of innovative headless compression screws to my surgical repertoire."

OSSIO will commercially launch the OSSIO*fiber*® Compression Screws in the United States in early 2021 and plans to expand its portfolio in varying diameters (3.5-6.5mm), lengths and geometry to address many trauma and extremity procedures.

OSSIO*fiber*® 1,000th Implant Milestone
The company recently reached its 1,000th procedural milestone utilizing OSSIO*fiber*® implants, including both the OSSIO*fiber*® Hammertoe Fixation System and OSSIO*fiber*® Trimmable Fixation Nail System. Since 2019, U.S. surgeons have used the implants in a variety of orthopedic procedures – including forefoot, midfoot, hindfoot and hand/wrist – with high satisfaction rates and no reported revision cases to date.

"We are incredibly proud of the innovation we've brought to the orthopedic fixation market with our OSSIO*fiber*® technology. As demonstrated in clinical studies, and as we currently see in real-time clinical practice, our proprietary strong and bio-integrative platform continues to successfully deliver," said Brian Verrier, CEO, OSSIO. "The achievement of our 1,000th implant milestone, along with the recent FDA clearance for our Compression Screw Portfolio, further showcase our commitment to changing a 100-year-old standard-of-care in orthopedic fixation, transforming the patient experience and improving the overall healthcare economics of orthopedics."

OSSIO*fiber*® Intelligent Bone Regeneration Technology can address many surgical applications through the manufacturing of endless implant designs, including nails, screws, staples, 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 (which includes the OSSIO*fiber*® Trimmable Fixation Nail System) 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, USA. 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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