First Ray Receives FDA 510(k) Clearance for Expanded Stealth Staple™ Product Line

LOGAN, Utah, March 15, 2017 – First Ray, a start-up medical device company focused on advanced surgical devices for improving outcomes for orthopaedic extremity procedures, announces that it has received FDA 510(k) clearance for new additions to the Stealth Staple™ System product family.

Previously, the company received clearance for its "Standard" size implants in different lengths, manufactured from titanium alloy. The new FDA clearance includes: "Standard" size implants manufactured from PEEK, "Small" size implants manufactured from titanium alloy or PEEK, and "Mini" size implants manufactured from titanium alloy. Standard size implants are well suited for hindfoot fusions and first tarsometatarsal joint fusions. Small size implants are well suited for midfoot fusions, first metatarsophalangeal fusions and carpal fusions. Mini size implants are well suited for carpometacarpal joint fusions, lesser metatarsophalangeal fusions, and fixation of Akin osteotomies. Surgeons now have the choice for radiopaque and, for the Standard and Small sizes, radiolucent implants.

The Stealth Staple™ System, an intraosseous small bone fixation system, represents a significant advancement for the treatment of arthrodesis, osteotomies and bone fractures. Current standard-of-care devices used to treat these indications are primarily bone plates and bone screws, or bone staples. Due to the prominence above the bone surface associated with these standard-of-care devices, there are notable clinical rates of device related pain, soft tissue irritation, and second surgeries for hardware removal. Since the Stealth Staple™ is completely contained within the bone upon implantation, clinical complications related to prominent hardware may be substantially reduced.

Another significant advancement provided by the Stealth Staple™ is the creation of controlled and evenly distributed compression across the opposing bone surfaces of an osteotomy or fracture. Finite element analysis and biomechanical testing have demonstrated superior strength, superior bone compression and superior resistance to gap formation compared to bone plate and screw systems (data on file).

First Ray is a development stage medical device company incubated and operated by Surgical Frontiers. Inquiries regarding distribution and commercialization partnerships are welcome.

About Surgical Frontiers

Surgical Frontiers funds, launches and operates start-up companies to develop advanced surgical technologies that are ready for clinical use. Focused primarily on musculoskeletal injuries and pathologies, the company collaborates with surgeons, industry, universities, and investors to bring advanced surgical technologies to the market that improve healthcare.

Contacts:

SURGICAL FRONTIERS

Mr. Lane Hale
Executive Vice President
lane@surgicalfrontiers.com
www.surgicalfrontiers.com
800-230-3710