IlluminOss Medical Receives FDA Clearance for Use in Femur and Tibia Fractures as a Supplement to Approved Hardware

East Providence, RI (October 29, 2020) – IlluminOss Medical, a medical device company focused on minimally invasive orthopedic fracture repair, today announced an expanded U.S. Food and Drug Administration (FDA 510k) clearance for its Photodynamic Bone Stabilization System. The new clearance allows IlluminOss to be used in femur and tibia fractures as supplemental fixation to FDA-cleared fracture fixation systems.

"Femur and tibia fractures can be challenging in aging patients where osteoporotic bone often lacks the strength required for reliable fixation with traditional hardware systems," said Robert Rabiner, Chief Technology Officer of IlluminOss. *"This new clearance allows the surgical community to use the IlluminOss intramedullary implant as a supplement to these systems and help prevent construct failures by dramatically improving the holding power of screws and other hardware."*

"Many lower limb fractures in the elderly, especially close to the knee joint, can be very difficult to achieve reliable stabilization due to poor bone quality," said Mike Mogul, Chairman of IlluminOss. *"As a minimally invasive means of supplementing hardware systems, IlluminOss provides substantial improvement in screw purchase and can optimize surgical outcomes. Surgeons can now securely affix their hardware anywhere along the length of the IlluminOss implant."*

The IlluminOss System is a minimally invasive approach for fracture repair and stabilization through a patient-conforming intramedullary implant. The system utilizes a light-curable liquid monomer, contained within an expandable balloon, to create a patient-conforming, rigid implant within the bone canal. The IlluminOss technology has been in clinical use in Europe since 2010, and in the US since 2018, with over 4,000 procedures to date.

In the US, the IlluminOss System is now indicated for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, ulna, clavicle, pelvis, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss Photodynamic Bone Stabilization System can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites. The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate FDA-cleared fracture fixation system.

About IlluminOss Medical

IlluminOss Medical, Inc. is a privately held, commercial-stage medical device company offering a unique, minimally invasive technology for fracture repair and stabilization. The Company utilizes a light-curable monomer contained within an expandable balloon to create a patient-conforming intramedullary implant for bone stabilization. The revolutionary, minimally invasive technology is particularly applicable for repair and treatment of osteoporotic and compromised bone. The IlluminOss system is CE-marked and FDA-cleared for a variety of anatomical sites, with further indications pending. IlluminOss is headquartered in East Providence, RI.

For additional information, including complete list of indications, contraindications, warnings, precautions and risks, visit www.illuminoss.com.

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