IlluminOss Medical Receives FDA Clearance for Use in Fibula Fractures

Indication expansion follows recent clearance for use in fractures of the pelvis, the clavicle, and small bones of the hand and foot

East Providence, RI (August 17, 2020) – IlluminOss Medical, a medical device company focused on minimally invasive orthopedic fracture repair, today announced that it has received expanded U.S. Food and Drug Administration (FDA 510k) clearance for its Photodynamic Bone Stabilization System for treatment of fractures of the fibula.

The IlluminOss System is a minimally invasive approach for fracture repair and stabilization through a patient-specific 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, with over 4,000 procedures to date.

In the US, the IlluminOss System was previously cleared by the FDA for the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, ulna, clavicle, pelvis, metacarpals, metatarsals, and phalanges. IlluminOss can also be used in conjunction with FDA-cleared fracture fixation systems to provide supplemental fixation in all cleared anatomic sites.

"The IlluminOss technology offers a minimally invasive approach that spares soft tissues, which may lower the risk of wound complications, and can potentially drive better functional outcomes, including faster return to weight bearing and activities of daily living," said Robert Rabiner, Chief Technology Officer of IlluminOss. *"Fractures of the fibula, one of the long bones of the lower leg, are among the most common and can be particularly challenging to manage in elderly patients. Additionally, current treatment approaches such as plating have several disadvantages, including larger incisions and the potential for meaningful patient discomfort."*

"Quickly returning elderly fracture patients to the activities of daily living remains a significant challenge or opportunity in orthopedics," said Mike Mogul, Chairman of IlluminOss. *"The fibula clearance, in addition to the recently approved pelvic and clavicle indications, is yet another step toward IlluminOss' goal of providing minimally invasive fracture care in the majority of fractures faced by those elderly patients.*

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.

For media inquiries, please contact: Tessa Cicitta, HealthpointCapital, 212-935-7780 or tcicitta@healthpointcapital.com