

## IlluminOss Medical Receives Clearance to Expand Clinical Indications in the U.S.

Secures FDA Clearance for the Treatment of Traumatic, Fragility, Pathological and Impending Fractures

**East Providence, RI (September 13, 2018)** – <u>IlluminOss Medical</u>, a privately held, commercial-stage medical device company focused on minimally invasive orthopedic fracture repair, today announced that the IlluminOss Photodynamic Bone Stabilization System has received additional clinical clearance and is now indicated by the U.S. Food and Drug Administration (FDA) for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius and ulna.

"IlluminOss' minimally invasive approach is ideal for treating patients suffering from fragility fractures. With a rapidly increasingly geriatric population, we are seeing a significant rise in these fracture patterns, which are often associated with osteoporosis and/or other pathologic indications affecting bone quality," said Jeff Bailey, CEO, IlluminOss Medical. "Osteoporotic bones can be difficult to treat with conventional hardware such as plates, nails and screws, as reduction and subsequent hardware fixation may be difficult."

Using the IlluminOss System, a patient-conforming implant is created to provide strength and stability over the entire length of the implant supporting the weakened bone. Being introduced in a minimally invasive fashion, smaller incisions are thereby permitted and soft tissue injuries may be reduced. Surgeons using the IlluminOss System have reported shorter procedural times, patients returning to their daily living activities faster, less post-operative pain, less use of analgesic pain medications and reduced hospital stays.

"As people age they lose bone density and are more prone to osteoporosis, increasing their risk of incurring fragility fractures," said Marc Guijt, MD, University of Amsterdam. "Using the IlluminOss System, even patients with highly compromised bone quality may be treated in order to speed their return to daily activities and reduce complications. This has the potential to revolutionize the way fracture repair for the elderly may be approached."

The IlluminOss System received its initial de novo FDA clearance in January 2018 for fractures associated with metastatic bone disease in the U.S. and is now commercially available in the United States. Additionally, the IlluminOss System has been commercially available in international markets and been in clinical use since 2010.

## About IlluminOss Medical

IlluminOss Medical is a privately held, commercial-stage medical device company focused on designing, developing and marketing orthopedic fracture repair products that leverage its proprietary bone stabilization technology, the IlluminOss System.

IlluminOss' minimally invasive technology produces patient-specific intramedullary implants for fracture fixation by utilizing a light-curable polymer, contained within an expandable balloon catheter, to achieve bone stabilization. The revolutionary procedure uses a small percutaneous surgical approach, providing patients and clinicians with a fast, patient-specific method of orthopedic bone stabilization.

The company currently markets its products in international countries under a CE Mark for approved clinical applications through both a direct sales force and distribution networks and has obtained U.S. Food and Drug Administration (FDA) clearance.

Learn more at <u>www.illuminoss.com</u>.

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