



NEWS RELEASE

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New Class of Orthopedic Implants for Intramedullary Biologic Fixation of Fractured Long Bones Validated in Preclinical Models

CBSET, IlluminOss Medical Data Published in *Journal of Biomedical Materials Research*

*IlluminOss System provides minimally invasive approach to replace splints, casts, metal fixator plates and intramedullary rods to stabilize high load-bearing bones**

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LEXINGTON, Mass., April 10, 2015 – CBSET, a not-for-profit preclinical research institute dedicated to biomedical research, education, and advancement of medical technologies, announced today it has published efficacy data showing that percutaneous intramedullary fixation can provide for stabilization of bone fractures while avoiding the need for large tissue-dissections. Results of this study have been published in the *Journal of Biomedical Materials Research Part B: Applied Biomaterials*.

“Our study validates the intramedullary application of a light-curable photodynamic bone stabilization system from study sponsor IlluminOss Medical as a biocompatible and feasible method for fracture fixation repair in load-bearing bones, such as the long bones of the leg,” said principal investigator Brett G. Zani, Ph.D., Director of Applied Sciences, CBSET. “The data demonstrated that the IlluminOss System did not disrupt bone formation when injected into intact bones, but did lead to increasing levels of cortical bone from 8 to 26 weeks when used in the fracture gap.”

The IlluminOss System is commercially available in international markets under a CE Mark for approved clinical applications through both a direct sales force and distribution networks. It combines the use of proven medical polymers and traditional balloon catheter technology to provide a completely new technology for patient-specific, percutaneous orthopedic implants. The implant begins as a liquid monomer that is completely contained within a Dacron or PET balloon. Once inside a patient’s bone, it conforms to the geometry of that patient’s intramedullary canal, whereas traditional rigid intramedullary rods have only small discrete contact points. Now, international surgeons have the option to use the IlluminOss product alone or in conjunction with traditional hardware and screws for multiple types of fractures.



IlluminOss® System

“CBSET’s preclinical expertise is widely respected and its validation of our bone stabilization system brings us another step closer to having our technology recognized for its potential to be a truly disruptive alternative to fracture repair,” said Robert Rabiner, President & Founder of IlluminOss Medical. “We have been very pleased with the results that surgeons internationally have achieved using the IlluminOss System and now, as we begin treating patients as part of first U.S. clinical trial, we expect to see similarly positive benefits for patient outcomes. The efficacy data that CBSET has published supports the effectiveness of our approach.”

“IlluminOss represents a significant innovation in orthopedic trauma, providing patients with fracture fixation options that are metal-free and delivered in a minimally-invasive manner,” said Peter Markham, President, CEO and a co-founder of CBSET. “We are proud to have helped IlluminOss validate its novel technology. Since 2006, we have set the medtech gold standard for cutting-edge preclinical science, helping more than 400 companies transform their early-stage concepts into innovative therapies.”

To learn more about these results and the services provided by CBSET, please contact: Dr. Erica Smith, Director, Business Development: +1-781-296-5319, esmith@cbset.org

* The IlluminOss™ System is approved for sale in Europe and for investigational use in the U.S.

[About the IlluminOss System](#)

The IlluminOss™ System is the world's first and only percutaneous, patient-specific, fracture-stabilization system. This minimally invasive procedure incorporates the use of a thin-walled PET balloon, which is infused with a liquid monomer, inserted into the intramedullary canal conforming to the shape of the patient's specific anatomy. The device forms as an implant once the surgeon activates the visible light within the PET balloon. Once cured, the implant provides longitudinal strength and rotational stability over the length of the implant. The IlluminOss System is CE-marked for light to low load-bearing bones.

About CBSET

CBSET – **Concord Biomedical Sciences & Emerging Technologies** – is the preclinical research leader in critically important therapeutic fields such as interventional cardiology, renal disease and dialysis, chronic drug-resistant hypertension, women's health, minimally invasive surgery, orthopedics, biological and synthetic tissue repair, drug delivery, bioresorbable devices, and combination medical device and drug-eluting products. CBSET occupies a 35,000-square-foot, state-of-the-art facility near Boston that includes a vivarium, catheterization/imaging labs, surgical suites, dedicated labs for SEM, histopathology/pathology, and drug metabolism and pharmacokinetics. CBSET offers the latest equipment for fluoroscopy, echocardiography (TEE/TTE), electrophysiology, IVUS, optical coherence tomography (OCT), endoscopy/laparoscopy, surgical video recording, histology, microradiography, and SEM (Scanning Electron Microscopy).

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