

SOURCE: BioSET, Inc.



Feb 14, 2011 13:05 ET

## BioSET Announces Initiation of Clinical Trial for AMPLEX™ Osteobiologic Bone Graft Substitute for Foot and Ankle Fusion

ROCKVILLE, MD--(Marketwire - February 14, 2011) - **BioSurface Engineering Technologies, Inc. [BioSET]**, a privately held company developing synthetic growth factor mimetics for tissue repair, reported today that the Company has initiated a pilot clinical study in Canada of AMPLEX™ to facilitate foot and ankle fusion surgery. AMPLEX™ is an osteobiologic bone graft substitute that combines **BioSET's** proprietary B2A growth factor mimetic with a ceramic scaffold/carrier. B2A is a synthetic peptide that mimics the effect of bone morphogenetic protein (BMP-2) on bone growth and healing processes. In addition to this foot and ankle study, the AMPLEX™ osteobiologic device also is being investigated in lumbar spine fusion with approximately 35 patients enrolled in pilot clinical studies in both the United States and Canada.

#### Highlighted Links

[BioSET, Inc Website](#)
[AMPLEX Osteobiologics](#)

The first patient enrolled in the AMPLEX™ Foot and Ankle Fusion Study in Canada was treated successfully by Dr. Mark Glazebrook, Orthopaedic Surgeon and Associate Professor at Dalhousie University and Principal Investigator for the study, who performed the surgery at Queen Elizabeth II Health Sciences Center in Halifax.

Dr. Glazebrook commented, "Our first subject in this study of a very novel biologic graft material underwent a subtalar fusion for degenerative arthritis. My first impression is that AMPLEX™ handles quite reasonably and may prove to be a very safe and effective alternative to taking bone graft from elsewhere on the patient. Capital Health/QEII Orthopedic Research is excited to be participating in the first use of **BioSET's** AMPLEX™ in patients requiring surgical treatment of end stage ankle arthritis."

The AMPLEX™ Foot and Ankle study is a randomized, prospective, multi-center, controlled clinical study comparing AMPLEX™ to the current gold standard of autograft taken from either the iliac crest of the hip or from the tibia. As a pilot study to evaluate the safety and preliminary effectiveness of the novel osteobiologic construct, 24 subjects will be enrolled across three centers in Canada. To date 6 subjects have entered the study and completed their surgery.

Tom Roueche, President and CEO of **BioSET**, commented, "The promising early clinical results with our AMPLEX™ device in lumbar fusion led us to begin investigation in other surgical procedures where surgeons and patients seek an effective alternative to the painful harvesting of bone graft from a second surgical site. We thank our clinical investigators, their teams and most importantly, their patients for participating in our quest to provide robust and reliable scientific evidence in this very confounding field of bone grafts and bone regeneration."

#### About BioSurface Engineering Technologies, Inc.

**BioSET** is a private, clinical stage company developing proprietary therapeutic peptides as medical devices to improve bone and soft tissue repair. **BioSET** is believed to be the only company developing chemically synthetic peptide mimetics of native growth factors for advanced tissue regeneration. **BioSET** products incorporate their novel growth factor mimetics with procedure specific biomaterials to address multiple large and clinically relevant applications. The company's lead program combines **BioSET's** B2A osteo-promotive peptide with a resorbable bone scaffold to offer substantial safety and cost benefits to currently available bone grafting alternatives. **BioSET's** second peptide candidate is F2A, a potent angiogenic biologic which is being co-developed for soft tissue repair in sports medicine applications. For more information, please contact **BioSET** at: 301.795.6010 or visit [www.bioisetinc.com](http://www.bioisetinc.com).

[Back](#)

#### Contact:

Tom Roueche  
301.795.6010  
[Email Contact](#)

Privacy Statement | Terms of Service | Sitemap | © 2011 Marketwire, Incorporated. All rights reserved.  
Your newswire of choice for expert news release distribution.  
1-800-774-9473 (US) | 1-888-299-0338 (Canada) | +44-20-7562-6550 (UK)