

SCOUT Enrollment Press Release

Header: Spineology Completes Enrollment in IDE Trial for Mesh Fusion Implant

ST. PAUL, Minn. February 13, 2018 -- Spineology Inc., an innovator in anatomy-conserving spine surgery, is excited to announce that enrollment is now complete in the Company's SCOUT clinical trial. The SCOUT (Spineology Clinical Outcomes Trial) IDE, conducted under an FDA-approved protocol, is a prospective multicenter non-randomized performance goal investigation, designed to evaluate safety and effectiveness outcomes in instrumented lumbar interbody fusion procedures for the treatment of degenerative disc disease (DDD).

Spineology's deployable graft containment mesh implant is a uniquely porous device that deploys within the disc space as it is filled, permitting the contained bone graft to conform to the prepared vertebral body endplates. The system's design allows for disc space preparation and implant placement through a small cannula.

Spineology's OptiMesh® deployable graft containment implant received 510(k) clearance from FDA in 2003 for graft containment within the vertebral body. The SCOUT trial is designed to provide clinical data to support a regulatory submission for expanded indications, allowing the implant to be used with bone graft and supplemental posterior fixation in support of lumbar interbody fusion for treating painful DDD.

Dr. Stéphane Lavoie of DeLand, Florida enrolled the first SCOUT subject. As one of the top enrolling sites, Dr. Lavoie also enrolled the final study subject. "The Spineology interbody fusion system allows me to efficiently prepare the disc space for fusion through a very small access, reducing surgical time and trauma to the surrounding tissues. It has been exciting to participate in the clinical trial for this unique fusion system and I have been pleased with my patient outcomes."

"The unique deployable mesh allows me to create a confirming bone graft pack to support new bone growth," added Dr. Martin Krag, Professor of Orthopaedics at the University of Vermont Larner College of Medicine. "Importantly, patient satisfaction is very good. At our institution we have observed rapid and substantial improvements in pain and function scores for study subjects post-surgery."

Early results in the SCOUT trial have been encouraging. Dr. John Chi will be formally presenting interim SCOUT results at the upcoming meeting of the International Society for the Advancement of Spine Surgery (ISASS) to be held this April in Toronto, Canada. Dr. Chi is an Associate Professor of Neurosurgery at Harvard Medical School and the Director of Neurosurgical Spinal Oncology at Brigham and Women's Hospital, the top enrolling site in the SCOUT IDE trial.

The SCOUT trial includes 102 patients who were experiencing painful lumbar degenerative disc disease of at least six months' duration. Patients will be followed for 24 months minimum and the company is gathering data on hospital parameters, pain and function, patient satisfaction, safety and radiographic fusion. The list of nationwide study sites participating in the SCOUT IDE includes Brigham and Women's Hospital, University of Vermont, the Spine Institute of Louisiana, Florida Orthopaedic Associates, and Georgetown University, among others. Details of the study may be found at the NIH clinical trials website,

<https://clinicaltrials.gov/ct2/show/NCT02347410?spons=spineology&rank=1>.

Subsequent to appropriate follow-up, the clinical outcomes data collected will allow Spineology to submit a *De Novo* application to the FDA to seek marketing clearance for interbody mesh fusion indications in the US.

About Spineology Inc.

Spineology Inc. provides innovative, anatomy-conserving spinal technologies for surgeons and their patients. Spineology surgical techniques conserve spinal bone, ligament and muscle tissue. Spineology is committed to increasing procedural efficiency, reducing surgical morbidity and accelerating patient recovery. Learn more at spineology.com.

Spineology Contact:

John Booth, 651-256-8511
jbooth@spineology.com