














Search Results for Google

Sharing

-  Digg
-  delicious
-  Newsvine
-  Reddit
-  Twitter
-  Google
-  LinkedIn
-  Yahoo
-  Facebook
-  MySpace
-  Permalink



May 28, 2009 01:50 PM Eastern Daylight Time 

FDA Approves SBI's S.T.A.R.® Total Ankle Replacement System

- **FDA-approved Instructions for Use indicate S.T.A.R.® is superior in efficacy and comparable in safety to ankle fusion in clinical trials**
- **Only FDA-approved, three-piece, mobile-bearing total ankle replacement**
- **Only FDA-approved total ankle replacement to be used without cement**

NEW YORK--(BUSINESS WIRE)--Small Bone Innovations, Inc. (SBI), a leading provider of innovation, products, technology and education for the small bone & joint segment of the orthopedics industry, announced today that the U.S. Food and Drug Administration (FDA) has approved SBI's Scandinavian Total Ankle Replacement (S.T.A.R.®) system to treat U.S. patients. S.T.A.R. has received pre-market approval (PMA) to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.

S.T.A.R. has more than 19 years of clinical experience and the current design has been implanted in over 15,200 patients worldwide. Additionally, there have been 35 peer-reviewed clinical outcomes papers published on S.T.A.R.; SBI believes that this number of papers is more than any other mobile-bearing total ankle arthroplasty device.

A U.S. Investigational Device Exemption (IDE) Clinical Trial of S.T.A.R. was initiated in August, 2000 as a prospective, multi-center controlled pivotal study to compare the safety and efficacy of S.T.A.R. to ankle fusion (the current standard of care). The study, which followed patients for a minimum of 24 months, is the only U.S. IDE clinical trial to have been completed on a three-piece, mobile-bearing, non-constrained, uncemented total ankle replacement system.

More than 670 patients were enrolled in the pivotal and continued access phases of the IDE clinical trial. The lead investigators were Roger A. Mann, MD, of Oakland Bone & Joint Specialists, Oakland, CA and consulting surgeon at the Steadman-Hawkins Clinic, Vail, CO and Michael J. Coughlin, MD, of the Idaho Orthopaedic Institute at St. Alphonsus Regional Medical Center, Boise, ID.

Anthony G. Viscogliosi, Chairman & CEO of SBI, said: "The 'Instructions for

Use' and 'Patient Labeling' issued by the FDA indicate that 'S.T.A.R. patients had superior effectiveness compared to ankle fusion and had comparable safety results compared to ankle fusion in the clinical trials. No other total ankle replacement system can make this claim.'

Additionally, Mr. Viscogliosi continued, "S.T.A.R. was less invasive than fusion, with less blood loss, shorter operating time, and better pain relief. We are now able to provide surgeons and their patients with a proven, advanced technology that we believe will change the standard of care from fusion to total ankle arthroplasty."

Currently, there are a few 510(k) ankle replacement devices cleared for U.S. marketing as an alternative to fusion. All of these ankle replacements are fixed-bearing devices that limit motion and are indicated for use with bone cement.

"S.T.A.R. is the only FDA-approved total ankle replacement system for uncemented use, which allows for better bone in-growth, stabilization and bone preservation," Mr. Viscogliosi concluded.

Thomas A. Crowley, President of SBi, said: "We expect high patient demand for the S.T.A.R. total ankle replacement system and we will strategically manage that demand through a controlled introduction and surgeon training, supported by continued long term follow-up of patients for eight years."

Roger A. Mann, MD said: "There is already widespread awareness and interest in the S.T.A.R. ankle replacement among U.S. foot and ankle surgeons. For those of us who participated in the clinical trial and have observed the successful clinical outcomes among our patients, this may well be an important moment in orthopedics, similar to those we've seen in hip, knee and spine, when the gold standard transitioned from fusion to arthroplasty."

Surgeons mentioned in this release provide consulting services to SBi.

About Small Bone Innovations, Inc.

Small Bone Innovations, Inc. (SBi) was founded in 2004 by Viscogliosi Brothers, LLC, (VB), a New York-based merchant banking firm that specializes in the musculoskeletal/orthopedics sector. VB created SBi as the first company to focus purely on small bones & joints. By integrating established companies and professionals in the field, SBi offers a broad, clinically proven portfolio of products and technologies to treat trauma and diseases in small bones & joints. SBi has facilities in New York, NY, Morrisville, PA, Bourg-en-Bresse, France and Donaueschingen, Germany.

For more information on SBi, please visit: www.totalsmallbone.com

Forward-looking statements

This news release contains forward-looking statements as defined in the U.S. Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of risks and uncertainties impacting SBi's business including increased competition; the ability of SBi to expand its



operations and to attract and retain qualified professionals; technological obsolescence; general economic conditions; and other risks.

Contacts

Small Bone Innovations, Inc.
Grace Xenakis, 212-583-0370
ext. 2100
gxenakis@totalsmallbone.com

Permalink: <http://www.businesswire.com/news/google/20090528005952/en>



[Terms of Use](#) | ©2009 Business Wire
