



SI-BONE, Inc. Adds SI Joint Specific Patent to IP Portfolio - Total U.S. Issued Patents now 16

March 25, 2015

SAN JOSE, Calif., March 24, 2015 -- SI-BONE, Inc., a medical device company that pioneered minimally invasive surgical (MIS) fusion for certain disorders of the sacroiliac (SI) joint with the iFuse Implant System, announced that the United States Patent and Trademark office has granted a new patent titled *Systems and Methods for the Fusion of the Sacral-Iliac Joint* (8,986,348).

SI-BONE's newest patent describes placing an "elongated implant structure having a longitudinal axis and a rectilinear cross section transverse to the longitudinal axis and including an exterior surface region treated to provide bony in-growth or through-growth along the implant structure... with an axially applied, non-rotational force." The patent also describes a "fusion cage structure" and an insertion path that is "created in a non-invasive manner without prior removal of cartilage." In addition, the patent describes "inserting the bone fixation implant through the postero-lateral insertion path" and also includes an implant "defined by at least one apex." With the addition of this latest patent, the company now has 16 issued US patents with another allowed and 26 pending. Outside of the US, SI-BONE has one granted patent and 44 pending.

"This broad patent adds to SI-BONE's extensive patent portfolio describing fusion methods that can be used to develop products for the SI joint and other areas of the body. This patent also describes an SI joint insertion path that is somewhat different than SI-BONE's current technique," said Scott Yerby, PhD, Vice President and Chief Technology Officer.

Clinical publications have identified the [SI joint](#) as a pain generator in 15% to 30% of low back pain patients.¹⁻⁴ In addition, the prevalence of [SI joint pain](#) in post-lumbar fusion, so called "failed back surgery" patients, has been shown to be up to 43%.⁵ Of these patients, some may have degenerative sacroiliitis or SI joint disruptions. Initial treatment options for patients with SI joint disorders typically involve non-surgical management and, when non-surgical management of the SI joint fails, surgical options such as the iFuse procedure may be considered.

SI-BONE, Inc. received original 510(k) clearance in November 2008 from the Food and Drug Administration (FDA) to market its iFuse Implant System. The CE mark for European commercialization was obtained in November 2010. The iFuse Implant System is a minimally invasive surgical option that uses titanium implants coated with a porous, titanium plasma spray (TPS) that acts as an interference surface, designed to help decrease implant motion, provide immediate fixation and allow for biological fixation to support long term fusion.

The iFuse System is intended for sacroiliac joint fusion for conditions including SI joint dysfunction that is a direct result of SI joint disruptions and degenerative sacroiliitis. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: www.si-bone.com/risks.

###

About SI-BONE, Inc.

[SI-BONE, Inc.](#) (San Jose, California) is the leading sacroiliac joint medical device company dedicated to the development of tools and products for patients with low back issues related to certain SI joint disorders. The company has developed, and is manufacturing and marketing, minimally invasive products for patients with certain SI joint disorders. SI-BONE has an experienced management team with extensive experience in orthopedic and spine medical devices. SI-BONE and iFuse Implant System are registered trademarks of SI-BONE, Inc. ©2015 SI-BONE, Inc. All Rights Reserved.

- 1 Bernard TN, Kirkaldy-Willis WH. Recognizing specific characteristics of nonspecific low back pain. *Clinical Orthopedics and Related Research*. 1987;217:266-80.
- 2 Schwarzer AC, Aprill CN, Bogduk N. The Sacroiliac Joint in Chronic Low Back Pain. *Spine*. 1995;20:31-7.
- 3 Maigne JY, Aivaliklis A, Pfefer F. Results of Sacroiliac Joint Double Block and Value of Sacroiliac Pain Provocation Tests in 54 Patients with Low Back Pain. *Spine*. 1996;21:1889-92.
- 4 Sembrano JNa, Polly DW. How Often is Low Back Pain Not Coming From The Back? *Spine*. 2009;34:E27-32.
- 5 DePalma M, Ketchum JM, Saullo TR. Etiology of Chronic Low Back Pain Patients Having Undergone Lumbar Fusion. *Pain Medicine*. 2011;12:732-9.

Disclosures

a Investigators in a clinical research study sponsored by SI-BONE, but they have no financial interest in the company.

*Although the recently issued patent describes "bony in-growth" and "through-growth," the current iFuse Implant is cleared for "biological fixation" in the US.

