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## Academic Opinion Leaders in the Field of Spine Surgery & Sacroiliac Joint Experts attend SI-BONE's National Summit on the Diagnosis of Sacroiliac Pathology

### **Meeting focuses on development of a consensus diagnostic process with the goal of sharing this diagnostic strategy with surgeons worldwide**

Minneapolis, Minnesota (September 16, 2009). SI-BONE, Inc. a San Francisco Bay-area, medical device company, announced the first ever meeting of thought leading spine surgeons to review data and develop a clinical diagnostic process for identification of SI Joint pathology, a frequent cause of low back pain.

Some of the assembled spine experts included Steven Garfin (former president of NASS, Chief of Orthopedics at UCSD), John Glaser (MUSC-Charleston), Arnold Graham-Smith (Jacksonville, FL), Leonard Rudolf (Lebanon, NH), Nick Shamie (UCLA), EJ Donner (Loveland, CO) and Jonathan Sembrano and Charles Ledonio (U of MN), and Mark Reiley (founder of Kyphon). The group was selected in order to have a balance of academicians and private practitioners with significant clinical expertise in diagnosis of LBP due to SI Joint pathology and over 400 SI Joint fusion procedures between them.

The SI Joint's primary responsibility is to transfer the weight of the upper body to the lower extremities. Despite the large number of patients with SI Joint symptoms today, most of the treatment focus in the spine has been centered on the disc. According to the speakers and numerous scientific clinical publications, 15-25% of individuals who present with lower back complaints actually had problems in their SI Joint. In the U.S., it is estimated over one million patients annually with low back pain (LBP) complaints may have SI Joint problems like degenerative arthritis and/or mal-unions of pelvic trauma. According to the group, this patient population may be underserved in terms of identifying the actual causes of LBP, and in formulating definitive treatment.

The Summit group reviewed over 80 peer-reviewed publications on SI Joint diagnosis to ascertain what diagnostic methodologies would yield the most practical clinical applications in spine surgery. Currently, according to Mark Reiley, MD, "orthopedic surgery residents are rarely taught to consider SI Joint arthritis and/or old SI Joint trauma as the cause of the patient's problems and few, if any, lumbar imaging extends below S1 to examine this joint."

Diagnosing SI Joint difficulties can be difficult. Individual clinical tests are not highly reliable. Because of this, the orthopedic surgery community has insufficiently addressed this important joint. As a result, diagnosis and treatment of SI Joint dysfunction have become the purview of physical therapists, who provide temporary relief through muscle strengthening techniques, and sometimes a pelvic belt for support.

To counter this trend, the Summit group determined that a combination of 3-5 diagnostic

tests are optimal for evaluating an LBP patient suspected of having SI Joint pathology. These tests include provocative maneuvers, positioning and pain injection exams. Significantly, most of these tests alone have low sensitivity in determining the SI Joint as a source of LBP, but combined have a greater likelihood of providing the rationale for intervention to treat SI Joint pathology. However, it was the consensus of the attendees that the diagnosis of SI Joint Disease should include one injection that alleviates at least 75%, or 2 injections that both alleviate at least 50%, of the patient's pain.

Steven Garfin, MD, who moderated the Summit, responded to a question on Summit outcomes: "I came into the meeting with a modest amount of knowledge regarding SI Joint pathology related to chronic LBP and came away, as I suspect the other attendees did, with an increased awareness that there may be instances where the SI Joint should be considered in the diagnosis, and that many surgeons do not evaluate this possible cause/source for complaints." He further commented that, "the Summit group agreed to work closely to bring understanding of the SI Joint diagnostic challenge and share their findings with other spine surgeons throughout the US and the world."

Several treatments available heretofore have shown limited effectiveness. The SI-BONE implant has shown early efficacy in reducing SI Joint symptoms. A multicenter study is being planned to determine its effect on SI Joint pathology over a period of 3 months to 2 years. The study will evaluate pain reduction and implant stability over time with the SI-BONE less invasive surgical implant. Referring specialists and physiatrists need to have an outlet for unsatisfied LBP patients. Some patients have residual syndromes after hip arthroplasty or lumbar spine procedures. For some, the SI Joint is the sole symptom generator. The surgeon can now focus further treatment appropriately and avoid unsuccessful repeat procedures often seen in failed lumbar spine surgery syndrome.

SI-BONE's iFuse Implant is an FDA-cleared device for treatment of pelvic fractures due to sacroiliitis and traumatic disruptions. Having a small incision surgical option to treat an unmet clinical need like SI Joint Dysfunction should prove to be an enormous benefit to both surgeons and patients alike. In response to increasing awareness of the SI Joint as a symptom generator, SI-BONE, Inc. developed an innovative, patented, intramedullary implant to treat the SI Joint. This surgical procedure requires only a minimal incision and uses small, titanium implants. The implants are coated with a porous plasma spray that acts as an interference surface to help decrease implant motion. These implants have greater thickness and improved metallurgy and are able to produce a much stronger construct than that of pins or screws. The implant system from SI-BONE has been used successfully in approximately 1,000 cases of dysfunctional foot joints.

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The SI Joint Diagnostic Summit was sponsored by SI-BONE, Inc. for the invited attendees.

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#### **About SI-BONE, Inc.**

SI-BONE, Inc. (Cupertino, California) is a leading spinal medical device company dedicated to diagnosing and treating patients with low back issues related to sacroiliac (SI) joint pathology. The company has developed and is manufacturing, and marketing less invasive implants for SI Joint pathology. SI-BONE has an experienced management team with extensive experience in spine medical devices. The company's goal is to help surgeons improve lives through its proprietary technology. Please visit [www.si-bone.com](http://www.si-bone.com).