iFuse is the Only SI Joint Fusion Implant with an FDA Cleared Indication citing clinical studies that demonstrated improvement in pain, patient function, and quality of life

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SAN JOSE, Calif., June 13, 2016 -- SI-BONE, Inc., a medical device company that pioneered the use of the iFuse Implant System® (“iFuse”), a minimally invasive surgical (MIS) device indicated for fusion for certain disorders of the sacroiliac (SI) joint, announced that the U.S. Food and Drug Administration (FDA) has cleared a 510(k) to allow modification of its indication statement noting that clinical studies have demonstrated that treatment with the iFuse Implant System improve pain, patient function and quality of life. The revised indication statement is based on extensive safety and effectiveness data from retrospective studies as well as three prospective clinical trials.

"SI-BONE’s strong clinical evidence demonstrating consistently positive results across multiple clinical trials makes it much easier for our regulatory team and the Agency to process our regulatory applications, such as this premarket notification to update the indication statement," said Roxanne Dubois, Vice President of Quality and Regulatory Affairs at SI-BONE, Inc.

The iFuse ImplantSM has a unique patented triangular shape that provides 31 times the rotational resistance of a screw. It is the only commercially available SI joint fusion device with published clinical evidence, including three large multicenter prospective studies, that demonstrates safety and effectiveness. Currently, there are more than 40 peer reviewed publications supporting positive clinical outcomes, safety, biomechanics, and economic benefits of iFuse.

“This is a significant milestone in the evolution of the treatment of SI joint dysfunction and clearly sets iFuse apart from any other surgical treatment option,” said Jeffrey Dunn, President and CEO of SI-BONE. “No other surgical treatment option for SI joint dysfunction is supported by prospective data and now with over 21,000 procedures performed worldwide, iFuse is clearly the surgical treatment of choice for SI joint dysfunction due to SI joint disruption or degenerative sacroiliitis.”

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About SI-BONE, Inc.
SI-BONE, Inc. (San Jose, California) is a 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 develops, manufactures and markets minimally invasive products for the SI joint. 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, and allow for biological fixation to support long term fusion. The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life. 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

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