iFuse Implant System™ Receives CE Mark

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SAN JOSE, Calif., Nov. 15, 2010 /PRNewswire/ -- SI-BONE, Inc. (San Jose, California), a medical device company that is pioneering the use of a minimally invasive surgical (MIS) device to treat the sacroiliac (SI) joint announced today that it has received a CE mark for its iFuse Implant System™. A CE mark is the quality assurance certification requirement recognized by members of the European Union for sales into those countries. The company has also received ISO 13485 Certification, which demonstrates that it provides medical devices and related services that consistently meet customer and regulatory requirements.

The iFuse Implant System is a minimally invasive surgical (MIS) system comprised of titanium implants coated with a porous plasma spray that acts as an interference surface fit, which helps decrease implant motion. The iFuse has a substantial thickness and sophisticated metallurgy, which provides immediate post-operative fixation, accomplishing the goal of traditional open SI joint fusion through an MIS approach. Clinical publications have identified the SI joint as a pain generator for up to 22% of low back pain patients and that up to 75% of post-lumbar fusion patients develop SI joint degeneration within 5 years of surgery. These represent significant unmet clinical needs and, when conservative therapy fails, iFuse may provide an MIS option.

The first European surgeon training sessions were held in October and most recently for November in Salzburg, Austria. These sessions are presented by surgeon faculties who have performed dozens of iFuse surgeries in the United States. The company's European Training and Product Manager, Vanes Frison, is coordinating the labs.

Commenting on the CE Mark and EU launch, Jeff Dunn, President and CEO, said, "The iFuse Implant System provides spine surgeons with a unique minimally invasive surgical approach to SI joint fixation/fusion. The CE mark will allow
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