

SI-BONE, Inc. Announces that NICE, the UK National Institute for Health and Care Excellence, Published Medical Technology Guidance Finding that the Evidence Supports Treatment of Sacroiliac Joint Pain with the iFuse Implant System®

October 3, 2018

The recommendation, unique to iFuse among sacroiliac joint fusion devices, concludes that using iFuse leads to improved pain relief, better quality of life and less disability compared to non-surgical management

SANTA CLARA, Calif., Oct. 3, 2018 /PRNewswire/ -- SI-BONE, Inc., a medical device company that developed the iFuse Implant System[®], or iFuse, for minimally invasive surgical treatment of the sacroiliac joint announced that NICE, the United Kingdom's (UK) National Institute for Health and Care Excellence, published medical technology guidance recommending iFuse for the treatment of chronic sacroiliac joint pain. The guidance specifically recommends:

- 1. The case for adopting iFuse to treat chronic sacroiliac (SI) joint pain is supported by the evidence.
- 2. iFuse should be considered for people with a confirmed diagnosis of chronic SI joint pain based on clinical assessment and a positive response to diagnostic injection of local anesthetic in the SI joint.
- 3. The procedure should only be carried out by surgeons who regularly use image-guided surgery for implant placement and have specific training and expertise in minimally invasive SI joint fusion surgery for chronic pain.
- 4. Using iFuse leads to improved pain relief, better quality of life and less disability compared with non-surgical management, and could lead to considerable clinical benefits for people with chronic sacroiliac joint pain.

NICE published the medical technologies guidance document, titled "iFuse for treating chronic sacroiliac joint pain (MTG39)," October 2, 2018. NICE has, to date, recommended no other device for the surgical treatment of the sacroiliac joint.

NICE was established in the UK in 1999, to improve outcomes for people using the NHS, the UK's National Health Service, and other public health and social care services. NICE does this by producing evidence-based guidance and advice for the use of health technology and clinical practice, and guidance for public sector workers on health promotion and social care services, and for users. Medical technologies guidance is a program within NICE to help NHS practitioners make consistent, evidence-based decisions about adopting new medical technologies.

About SI-BONE

SI-BONE is a medical device company that pioneered the iFuse Implant System, a minimally invasive surgical system for fusion of the sacroiliac joint to treat sacroiliac joint dysfunction. The SI joint is believed to be the last major joint with a clinically proven surgical treatment. The iFuse Implant, commercially available since 2009, is believed to be the only SI joint fusion device supported by multiple prospective clinical studies showing improved pain, patient function and quality of life resulting from treatment. There are over 60 peer-reviewed publications supporting the safety, effectiveness, and biomechanical and economic benefits unique to the iFuse Implant. This body of evidence has enabled multiple government and private payors to establish coverage of the SI joint fusion procedure exclusively when performed with the iFuse Implant System.

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. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit.

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