NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

iFuse implant system for treating chronic sacroiliac joint pain

1 Technology

1.1 Description of the technology

The iFuse implant system (SI-Bone) is intended for use in patients with sacroiliac joint dysfunction. It consists of a sterile, cannulated titanium implant and a surgical instrument system for implantation. The implant's innovations are its triangular shape which is designed to limit lateral and rotational movement and shear stresses around the implant; minimally invasive insertion, avoiding open surgery; and its porous metal coating which aims to facilitate bone on-growth. The instrument system uses guide wires inserted using x-ray guidance to accurately place the implant(s). The procedure includes a skin incision, muscle dissection, guide wire placement, drilling and broaching of bone, as well as placement of multiple iFuse implants. Typically 3 implants per joint are used depending on the size of the patient.

The device is implanted during a minimally invasive surgical procedure with the patient under general or spinal anaesthesia, involving a small incision made over the lateral buttock to allow entry to the lateral aspect of the ilium. The iFuse implants are then placed across the sacroiliac joint permanently uniting the ilium to the sacrum. The procedure involves inserting a fluoroscopically directed guide wire into the sacroiliac joint. A drill is then placed over the guide wire and a hole is prepared for the implant, which is also inserted over the guide wire across the joint.

1.2 Regulatory status

iFuse implant was CE marked as a class IIb medical device in 2010; the instruments comprising the instrument system are class I and class IIa devices.

1.3 Claimed benefits

The claimed benefits to patients in comparison with the current standard of care are:

- Improved pain relief
- Improved function
- Higher patient satisfaction
- Lower blood loss
- Quicker return to work

The claimed benefits to the healthcare system in comparison with the current standard of care are:

- Reduced operative times
- Reduced length of stay in hospital
- Less operative morbidity
- Lower indirect costs
- Lower direct costs

1.4 Relevant diseases and conditions

The iFuse implant system was notified to MTEP for the treatment of chronic sacroiliac joint pain, specifically after conservative management, analgesia, physical therapy and joint injections or ablative techniques have proved unsuccessful.

It is estimated that the prevalence of sacroiliac joint pain in patients presenting with lower back pain ranges from 15% to 30% and can result from either intra-articular causes, for example arthritis or infection, or extra-articular causes, including enthesopathy, ligamentous injury or fractures.

Low back pain can present with different levels of severity – for example, some people may be able to continue to work and lead active lives, while others may be severely disabled or unable to work. Low back pain is common in working-age adults (particularly between the ages of 40 and 60 years). A UK survey in 1998 reported that 40% of adults had had low back pain lasting for longer than 1 day in the previous 12 months.

1.5 Current management

The current standard of care for patients with chronic sacroiliac joint dysfunction consists of escalating non-surgical treatment, typically beginning with pharmacological treatment (nonsteroidal anti-inflammatory medications and/or opioids) and physiotherapy focused specifically on the sacroiliac joint. For patients who do not respond to first-line measures, additional, more invasive procedures are considered, typically sacroiliac joint steroid injections followed by sacroiliac joint radiofrequency ablation. If these measures are inadequate, minimally invasive sacroiliac joint fusion (MISIJF; iFuse) would then be considered; open sacroiliac joint fusion may also be considered as an alternative treatment option.

NICE has published interventional procedures guidance on the procedure of which iFuse is a potential component: minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain. The guidance recommends that the evidence for the procedure is adequate for it to be carried out in patients with a confirmed diagnosis of unilateral or bilateral sacroiliac joint dysfunction due to degenerative sacroiliiitis or sacroiliac joint disruption, with standard arrangements for clinical governance, consent and audit.

2 Reasons for developing guidance on iFuse implant system for chronic sacroiliac joint pain

The committee's main considerations were as follows:

- The committee considered that iFuse may offer an effective treatment to patients with symptomatic sacroiliac joint dysfunction who have not responded to conservative management, and that it may be considered as an alternative to other surgical procedures.

- The committee noted that sacroiliac joint dysfunction is likely to be currently underdiagnosed as a cause of low back pain and that there may be an unmet clinical need for treating this chronic condition. It considered that there is the potential for cost savings through the use of iFuse as an alternative to conservative or more invasive treatment.

- The committee considered that there is an adequate published evidence base to evaluate the potential benefits of iFuse and that medical technology guidance would be useful to guide clinicians in its application in UK clinical practice.

3 Statement of the decision problem

	Scope issued by NICE
Population	People with unresolved sacroiliac joint dysfunction
Intervention	iFuse implant system

Comparator(s)	• open sacroiliac joint fusion surgery using screw or cage systems
	• non-surgical or conservative management, including:
	  ○ optimisation of medical therapy,
	  ○ individualised psychological and physical therapy with provision of adequate information and reassurance
	  ○ steroid injections
	• sacroiliac joint denervation

Outcomes	The outcome measures to consider include: **Patient outcomes** • back/ sacroiliac joint pain relief (including medicine use and post-operative pain scores); • improvement in function and disability from back pain (measured using Oswestry disability index (ODI) or other valid disability scale); • blood loss during surgery; • patient satisfaction; • patient health-related quality of life; • radiographic evidence of union and absence of loosening (x-ray or CT scan to measure bone growth across the fused joint); • time to return to work/normal activities; • peri-operative morbidity and device-related adverse events; • postoperative infection or complications; • reoperation rates. **System outcomes** • procedure time and resources • length of hospital stay.
Cost analysis	Comparator(s): Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters.
Subgroups to be considered	• women of reproductive age • number of implants inserted • unilateral versus bilateral sacroiliac joint implants • previous lumbar surgery
Special considerations,	People with chronic sacroiliac pain or lower back pain lasting more than one year may be considered disabled under the Equality Act

including those related to equality	2010, if the condition has a substantial and long-term negative effect on their ability to do normal daily activities. Women may experience SIJ dysfunction due to the mechanism of childbirth.	
Special considerations, specifically related to equality issues	The sacroiliac joint and its free movement is critical to normal, vaginal delivery in childbirth. Women of reproductive age having SIJ implants would require caesarean section deliveries after iFuse implant insertion. Most people having surgical interventions for SIJ pain are female but over usual reproductive age.	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	Yes
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- NICE clinical guideline Low back pain and sciatica in over 16s: assessment and management
- NICE interventional procedure guidance Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Royal College of Physicians
- Royal College of Nursing
- Royal College of General Practitioners
- Royal College of Physicians of Edinburgh
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England
- British Association of Spinal Surgeons (BASS)
- British Orthopaedic Society
- British Orthopaedic Research Society

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Royal College of Physicians
- Royal College of Nursing
- Royal College of General Practitioners
- Royal College of Physicians of Edinburgh
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Royal College of Surgeons of England
- British Association of Spinal Surgeons (BASS)
- British Orthopaedic Society
- British Orthopaedic Research Society

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Action on Pain
- Back Care
- Fighting Back
- Pain Concern
- Pain Relief Foundation
- Pelvic Partnership