National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT355 iFuse for treating chronic sacroiliac joint pain

Consultation comments table

Final guidance MTAC date: 20 July 2018

There were 13 consultation comments from 5 consultees:

- 1 manufacturer
- 1 competitor manufacturer
- 1 NHS professional
- 1 healthcare professional (private)
- 1 other

The comments are reproduced in full, arranged in the following groups (comparators, cost, corrections, clarifications)

#	Consultee ID	Role	Page	Section	Comment	NICE response
Theme 1: comparators						
1	1	Healthcare professional (private)	-	-	Thank you for inviting the Pelvic Partnership to comment on this document. We note that throughout the document that physiotherapy is mentioned as a generic treatment. We have a concern that in current practice there are significant variations in what type of physiotherapy treatment is offered. This may range from a sheet of exercises, to a course of hands-on manual therapy which involves assessment and treatment of the joint alignment, musculature around the pelvis, back and lower limbs, and specific exercise programmes which relate to the individual woman. We are concerned that this invasive and expensive treatment option may be undertaken before an appropriate course of hands-on physiotherapy has been offered, and as a result women are not offered the least invasive (and less expensive for the NHS) option. We further note that prolotherapy treatment is not offered as an alternative to steroid injections, either in the research analysis or economic analysis, which we agree are not an effective long-term solution to chronic sacro-iliac pain in the treatment comparisons. We are reassured that the health economic and patient-reported outcomes for the iFuse indicate that this is a significantly better option for those who have not responded to other modalities and support the recommendation that this should be adopted. However, we remain concerned that this treatment could be offered to women whose symptoms could have resolved with access to alternative less invasive treatment in the form of manual physiotherapy treatment or prolotherapy injections first. This is our experience as a support group, where we hear from women who have been offered physiotherapy which has consisted of exercise and advice, and who then go on to have manual physiotherapy and find that their symptoms usually resolve completely. We are pleased to note that iFuse is being offered over SIJ fusion, which is something that we regularly receive negative feedback about, and that when iFuse is undertaken, the outcomes seem to be very positive. Our main concern therefore is to raise the issue that iFuse may not be required in the first place.	Thank you for your comment. Prolotherapy treatment was not included in the evaluation scope as there is no evidence comparing iFuse with prolotherapy and expert advice suggested that it is not standard treatment in the NHS. Recommendation 1.2 states that iFuse should only be offered after physiotherapy has been tried and is unsuccessful.
2	4	Competitor manufacturer	-	-	Thank you for the opportunity to provide comments to the draft guidance: iFuse for treating chronic sacroiliac joint pain. We are requesting that NICE consider these comments to establish guidance for MIS SIJ Fusion, REGARDLESS OF THE MANUFACTURER OR IMPLANT SHAPE, medically necessary for patients when the medical appropriateness criteria are met (criteria to follow). While we agree with NICE's draft guidance, we believe that any guidance for this procedure should be for the procedure itself; in this case, minimally invasive sacroiliac joint fusion. The determination of which manufacturer brand of implant to use should be at the discretion of the consulting surgeon, based on their clinical and professional determination with informed decision making with their patients. We would like to provide the following insight as to why we believe this: 1. Most importantly, there are no head to head, controlled, clinical trials published that substantiate one device has superiority over another device. However, recently a peer reviewed paper was published (Araghi, A et al, Pain and Opioid use Outcomes Following Minimally Invasive Sacroiliac Joint Fusion with Decortication and Bone Grafting: The Evolusion Clinical Trial. The Open Orthopaedics Journal, 2017, 11, 1440-1448) that that shows clinical study evidence that a cylindrical implant (the SImmetry System) demonstrated comparative effectiveness to the triangular shaped implant system (iFuse). Most notably from this data is that the SImmetry System demonstrated a significantly greater reduction in opioid usage following surgery than the triangular implant. There's no reason the SImmetry System cylindrical implant should be excluded from this policy if medical appropriateness criteria are met. 2. All the medical devices designed for minimally invasive sacroiliac joint fusion (n>25), regardless of shape and design, are designed to cross the sacroiliac joint in order to stabilize the SI joint and prevent motion. 3. A patient's anatomy is often what dictates the specific implant utilized. Providing guidelines on the use of a single device (iFuse) will result in complications, revisions, and unacceptable outcomes in patients. 4. In the case of an iFuse failure requiring a revision, the only option available to the surgeon would be another iFuse implant even though in many of these cases a replacement iFuse implant may be contraindicated. Since the surgeon would not have the option to use a threaded implant, or other type of implant, an open procedure with the associated greater patient risks and costs may be performed. 5. There is no advantage to the total cost of care (procedure cost, length of stay, health outcomes, etc.) between iFuse implants and other minimally invasive sacroiliac joint fusion implants that are of different design. Upon review of this draft guidance document, we noticed the published literature references consists of cohorts treated exclusively with the iFuse implant. There has been data recently published on the use of cylindrical, threaded implants with decortication and bone graft that demonstrates high fusion rates and significant improvement in pain scores at 12 & 24 months (attached). This is the only published data for this procedure that utilized a radiographic successful fusion as a primary outcome. Additionally, another clinical trial (clinicaltrials.gov identifier NCT02074761) is currently enrolling patients evaluating fusion rates at 12 and 24 months along with pain, disability and quality of	Thank you for your comment. NICE medical technologies guidance evaluates a single medical technology based on the claimed advantages of introducing the specific technology compared with current management of the condition. It is not a multiple technology assessment and does not compare evidence for all similar technologies in a broader class. These principles are described in further detail in the medical technologies evaluation programme methods guide, and in the medical technology guidance overview page. This text states that the case for adoption is based on claimed advantages of introducing the specific technology compared with current management of the condition. It also states that the specific recommendations in the medical technologies guidance on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages. In 2017, NICE produced interventional procedures guidance on minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain. This guidance considered the safety and efficacy of minimally invasive sacroiliac joint surgery for all available devices.

					life, and early results from this study are published as well (attached). It does not appear these clinical data were reviewed as they are not referenced in the draft guidance. The SIJ is a well-known cause of pain in the lumbopelvic hip complex. There are many possible etiologies including, but not limited to, degenerative sacroiliitis, primary osteoarthritis, post-traumatic osteoarthritis or incongruence, adjacent joint degeneration as a result of lumbar spinal conditions and procedures, and idiopathic causes. Low back pain is a worldwide epidemic and one of the top 3 causes of health related chronic pain. Because SIJ pain can be confused with lumbar and hip pain, proper diagnosis of SIJ pain is key to appropriate patient management. It is important to perform a very thorough diagnostic workup and to be very selective of the patients who receive this procedure. The patients treated for SIJ pain typically report pain in the buttocks, with possible radiation into the groin or upper legs. Specific physical examination tests that stress the SIJ (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver, sacral sulcus tenderness) are typically performed. In combination, these tests are thought to be predictive of SIJ pain. Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration). The diagnosis of SIJ pain is confirmed by performing a fluoroscopy guided percutaneous SIJ block with local anesthetic (e.g., lidocaine). An acute reduction in pain of 50% (using visual analog scale) or more compared to immediately prior to the block is considered a positive test and indicates that the injected joint is the pain generator based on published studies. Because other pathologic processes can coexist with SIJ pain, in order to assure that SIJ pain is the primary (or only) diagnosis, it is important to rule out any non-SIJ causes of pelvic or lower back pain on the basis of history, physical exam and/or imaging; examples of alternative diagnoses include pelvic fracture, tumor, infection, skeletal deformity, hip arthritis, and degeneration of the L5/S1 disc or other base-of-spine pathologies. Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents, opioids), physical therapy, and steroid injections into the SIJ and radiofrequency ablation of the SIJ. Most patients respond adequately to conservative treatment. However, a small number of patients do not have satisfactory pain relief and may be functionally disabled (e.g., cannot sit or stand for more than five minutes, cannot perform normal activities of daily living cannot walk up or down stairs, may require a wheelchair, may require chronic opioid treatment). The patients that are considered for this procedure experience pain for a minimum of six months and do not respond to an adequate course of non-surgical treatment. Surgery is their last alternative; not the first recommendation. With the introduction of new technologies over the past several years, spine procedures are becoming less invasive, progressing from an open surgical technique to a minimally invasive/percutaneous approach. The traditional method of fusing the SIJ is via an open surgical approach. This technique can provide pain relief but recovery times are long and the complication rate is high. There are sufficient risk factors associated with the open technique that this should be reserved for those patients who are not candidates for the minimally invasive procedure. A minimally invasive approach allows the surgeon the option to perform a complex joint fusion without the complications associated with a traditional open approach. In contrast to the open surgical procedure, this surgical approach is intended to provide joint stabilization through a small incision with minimal blood loss, bone and ligament preservation, reduced hospital stay, and faster patient recovery. Recent advancements in medical technologies, imaging modalities, and MIS-specific implants have offered surgeons this option. In 2008, the first MIS device for SIJ fusion became available. Today over 35,000 have been performed. To date, there are >25 implant systems available for utilization in this procedure including cylindrical threaded, triangular, porous, titanium coated, hollow modular screws, titanium cages, and allograft dowels. These devices are placed either inside or across the SIJ using a minimally invasive surgical approach. All perform the same function – stabilization of the joint resulting in bridging of the bone with alleviation of pain. Listed below are the guidelines within the current ISASS Policy Statement on Minimally Invasive Sacroiliac Joint Surgery. We agree with NICE on the proposed criteria for this procedure, which are within the guidelines and limitations set forth by this Society. We feel that these guidelines address an accurate assessment in diagnosing the SI joint as a true pain generator, as well as identify the appropriate patient to be considered a candidate for this procedure. Indications for coverage include: • Significant SI joint pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living because of pain from the SI joint(s); • SI joint pain confirmed with typical pain reproduction on at least 3 positive physical provocative examination maneuvers that stress the SI joint;	

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					• Confirmation of the SI joint as a pain generator with ≥ 50% acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic. This improvement is specifically accomplished in the immediate post-injection period when the anesthetic agent is active (i.e., 4 hours dependent on the agent, dose level, and concentration); • Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti- inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SI joint steroid injection or rhizotomy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability; • Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been clearly considered, investigated and ruled out. Limitations to coverage include: • Less than 6 months of back pain; • Failure to pursue conservative treatment of the SIJ (unless contra-indicated); • Pain not confirmed with a diagnostic SIJ block; • Existence of other pathology that could explain the patient's pain. Thank you for your time and consideration of our comments. Attached please find a copy of the 2 clinical publications referenced above. We are happy to discuss our comments as needed. Feel free to contact me at [redacted]. Respectfully, [redacted] Director of Marketing Enclosures: Pain and Opioid use Outcomes Following Minimally Invasive Sacroiliac Joint fusion with Decortication and Bone Grafting: The Evolusion Clinical Trial Minimally Invasive Sacroiliac Joint Fusion: 2-Year Radiographic and Clinical Outcomes with a Principles-Based SIJ Fusion System	
Theme 2: costs						
3	5	Manufacturer	-	-	SI-BONE UK Ltd. has looked closely at the Consultation Report and the accompanying economic model for cost savings of the iFuse Procedure versus the stepped non-surgical care pathway. We would like to lower the price point of the surgical accessories included as an input in the economic model from £275 down to £136. This price reduction would take the total iFuse consumables costs down to £3925, which would then equate to the average selling price in the UK. Based upon this price reduction, our calculations now show the time horizon for cost savings of the iFuse procedure would be 8 years rather than 9 years. If this suggested price reduction does not result in a lowering of the time horizon then we would not lower the price. Interestingly, the price of our procedure has only a modest effect on the time horizon.	Thank you for your comment. The committee asked the EAC to rerun the model with the lower priced consumables and agreed that it resulted in cost savings for iFuse after 8 years. The committee determined this price change did not change the conclusions of the guidance and so updated the cost saving reported in section 1.3 and in the cost savings section of section 4.
Theme 3a: corrections, number of implants						
4	2	NHS professional	-	2.1	Typically 3 implants are used not 2. 2 implants are used if there if there are anatomical differences making the insertion of 3 implants unsafe. Therefore the costings should be checked that this is for 3 implants.	Thank you for your comment. The reference to 2 implants was an error which was introduced during the writing of the consultation document. The correct number of 3 implants was

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						used throughout the cost modelling and in the assessment report. This error has been corrected and the medical technology guidance now refers to 3 implants.
5	5	Manufacturer	-	2.1	"At the end of the first paragraph the consultation document states “Typically, 2 implants are used per joint depending upon the size of the pelvis.” This statement is an error. Typically, 3 implants are placed. In a small portion of cases only 2 implants are placed secondary to anatomic constraints. Our internal company data show that 3 implants have been used in over 90% of the 32,000 iFuse cases performed to date worldwide. The percentage of three implant cases in the UK is similar. Approximately 5% of cases are performed with 4 implants and approximately 5% of cases are performed with 2 implants. The published clinical evidence is all based upon procedures performed with 3 implants in the vast majority of cases, including the 3 prospective clinical trials (INSITE, IMIA, and SIFI) described in the assessment report. Published biomechanical data shows that 3 implants provide more stability than 2 implants (Lindsey – World J Orthop 2018).1 Three (3) implants provide additional biomechanical stability and additional implant porous surface area for biologic fixation/fusion. The clinical expert, Mr. Mark Thomas, commented during the last committee meeting that he uses 3 implants in all cases except those where the anatomy would preclude safe placement of 3 implants. In addition, the economic model uses three implants and the resultant costs of three implants as an input. It would be inappropriate to recommend 2 implants and then rely on an economic analysis that is predicated on the costs of 3 implants. SI-BONE requests changing the language to “Typically, 3 implants are placed…”"	Please see response to comment 4.
6	5	Manufacturer	-	4.10	"The consultation document states “an overnight stay in hospital would usually be needed after having iFuse implanted, and that 2 (or occasionally 3) implants are used per joint treated.” We believe, that this (as in comment number 1 above) is an error. Typically, 3 and on rare occasion 2 or 4 implants are placed. As mentioned above, the published clinical evidence demonstrating the safety and effectiveness of the iFuse procedure was based upon cases performed with three implants in the vast majority of cases. In addition, the economic model and the economic results discussed by the committee are based upon iFuse procedure costs using three implants. We recommend changing the language to “…3 (or occasionally 2 or 4) implants are used per joint treated.”"	Please see response to comment 4.
Theme 3b: corrections, surgeon specialism						
7	2	NHS professional	-	2.4	The surgery is carried out by specialist surgeons - either spinal surgeons or pelvic surgeons. It is carried out in specialist centres but not necessarily tertiary centres.	Thank you for your comment. The committee decided to amend the guidance. The reference to tertiary centres has been removed and section 2.4 now states: “Invasive procedures and surgical treatments for chronic sacroiliac joint pain are usually done by spinal surgeons and orthopaedic trauma pelvic surgeons working in specialist centres.”
8	5	Manufacturer	-	2.4	"At the end of the first paragraph the consultation document states, “Invasive procedures and surgical treatments for chronic sacroiliac joint pain are usually done by specialist back surgeons working in tertiary centres.” We agree that specialist back surgeons, both orthopedic surgeons and neurosurgeons, perform the iFuse procedure. We would like to clarify that sacroiliac joint fusion, both open and minimally invasive, is also frequently performed by orthopedic trauma pelvic surgeons. Several orthopedic trauma pelvic surgeons are performing the iFuse procedure in the UK. We would be pleased to provide surgeon names if requested."	Thank you for your comment. The committee decided to amend the guidance. Section 2.4 has been updated to include reference to orthopaedic trauma pelvic surgeons.
Theme 3c: corrections, diagnosis						
9	5	Manufacturer	-	4.7	"The first sentence reads, “The clinical experts stated that sacroiliac joint pain is often misdiagnosed as pain originating from the hip joint, and that sacroiliac joint dysfunction may sometimes not be considered as the cause for back pain.” Low back pain could also originate from the lumbar spine, not just the hip, as pain patterns are quite similar to that of the sacroiliac joint. We would like to suggest changing the wording to state, “…often misdiagnosed as pain originating from the lumbar spine or hip joint, and that sacroiliac joint dysfunction may sometimes not be considered as the cause for back pain.”"	Thank you for your comment. The committee decided to amend the guidance and section 4.7 has been updated as suggested.

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10	5	Manufacturer	-	4.6	"The consultation document states …" "before iFuse is considered (that is, confirmation that the pain originates from sacroiliac joint dysfunction). The diagnosis needs to be corroborated by a trial of steroid joint injections. If the signs and symptoms are characteristic and the steroid joint injections provide pain relief, a diagnosis of chronic sacroiliac joint pain can be confirmed. MRI and CT scanning may also provide useful diagnostic information, particularly in people with multiple back issues." We recommend that the language in this paragraph be modified to provide clarification and clear distinction between diagnostic SI joint injections and therapeutic SI joint injections. Diagnostic injections entail placement of a small amount (2.5 ml or less) of local anesthetic into the SI joint under fluoroscopic guidance. The patient is then evaluated in the immediate post procedure time frame (30-60 minutes) to determine the response to the diagnostic injection (what percentage of the patient's SI joint pain was relieved by the diagnostic/anesthetic injection). The diagnostic injection is the current reference standard for confirming the diagnosis of SI joint pain. A therapeutic injection includes steroid in the injectate and is provided as a non-surgical treatment option. There is no evidence that response to steroid injections is a valid diagnostic test. There have been no randomized trials of response of SI joint pain to intraarticular steroid injections. We would like to emphasize that to date, there are no imaging tests that are diagnostic for SI joint pain/pathology. This was stated in the NICE IPG on minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain. We agree that CT and MRI provide useful diagnostic information to rule out concomitant spine, pelvis, and/or hip pathology. "	Thank you for your comment. The committee decided to amend the guidance. Section 4.6 has been updated for factual accuracy and now reads: "The diagnosis needs to be confirmed by injecting local anaesthetic into the joint under image guidance. If the signs and symptoms are characteristic and the local anaesthetic joint injection provides pain relief, a diagnosis of chronic sacroiliac joint pain can be confirmed. MRI and CT scanning may also provide useful diagnostic information, particularly in people with multiple back issues."
Theme 3: clarifications						
11	5	Manufacturer	-	-	"The consultation document states, "The company sponsored 9 of the 12 included studies, and in each study at least 1 author was a company employee." We would like it to clarify authorship is just referring to the 9 sponsored studies so it is clear it is not referring to the 3 non-sponsored studies also. SI-BONE requests adding the word "sponsored" so it reads, "The company sponsored 9 of the 12 included studies, and in each sponsored study at least 1 author was a company employee."""	Thank you for your comment. Section 3.1 has been updated as suggested.
12		Manufacturer	-	-	"The consultation document states "A company representative stated that the first iFuse devices were implanted in 2010 and that there are, to date, no reports of device failure after 2 years." As the company representative present at that committee meeting, I would like to clarify that, to date, the company has identified no device failures (no implant breakage). In addition, no trends have been identified that would indicate that late failure of the procedure (loss of device fixation) is a concern. Review of the company complaints data base has identified only a very small number of cases of late revision surgery for loss of device fixation (after five years). Citations 1. Lindsey DP, Kiapour A, Yerby SA, Goel VK. Sacroiliac joint stability: Finite element analysis of implant number, orientation, and superior implant length. World J Orthop. 2018 Mar 18;9(3):14-23. doi: 10.5312/wjo.v9.i3.14. eCollection 2018 Mar 18. "	Thank you for your comment.
13	3	Other	-	-	"Thank you for the opportunity to comment on the draft for the above medical technology draft guidance I wish to confirm that the Department of Health and Social Care has no substantive comments to make, regarding this consultation"	Thank you for your comment

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