Advocacy: ISASS Proposed Recommendations / Coverage Criteria for Minimally Invasive Sacroiliac Joint Fusion 2015
Coverage Indications, Limitations, and/or Medical Necessity

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Introduction

The sacroiliac joint (SIJ) is a cause of chronic lower back pain. SI joints are paired diarthrodial articulations of the sacrum and ilium. The SI joint serves as the biomechanical mediator between the spine and pelvis. The subchondral bone, capsule, and surrounding ligaments of the SIJ are innervated by spinal nerves.(1)

Because SIJ pain can be confused with lumbar and hip pain, proper diagnosis of SIJ pain is key to appropriate patient management. Patients with 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 the physician's office; in combination, these tests are thought to be predictive of SI joint pain.(2) 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 SI joint block with local anesthetic (e.g., lidocaine). An acute reduction in pain of 75%(3,4) (using visual analog scale) or more compared to immediately prior to the block is diagnostic as a positive test and indicates that the injected joint is the pain generator based on published studies. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test.(5) Because other pathologic processes can coexist with SIJ pain, in order to assure that SI joint pain is the primary (or only) diagnosis, the physician should ensure that non-SIJ causes of pelvic or lower back pain are ruled out 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.

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of typical history, physical examination showing bilateral SIJ pain with maneuvers (listed above) that stress the SIJ, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SI joint block.

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents, opioids), physical therapy, 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 (ADLs), cannot walk up or down stairs, may require a wheelchair, may require chronic opioid treatment). Patients with a diagnosis of SIJ pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SIJ fusion.

Coverage Rationale for Open and Minimally Invasive SIJ Fusion

Open fusion of the SIJ can provide pain relief but recovery times are long and the complication rate is high.(6-10) Patients can experience significant intraoperative bleeding and require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for minimally invasive SIJ fusion.(14)

Minimally invasive fusion of the SIJ has been performed with several types of implants, including triangular, porous, titanium coated implants (11-19,24-28), hollow modular screws (20-22), titanium cages (23,29), and allograft dowels(6) (Table 1). These devices are placed either inside or across the SIJ using a minimally invasive surgical approach. Minimally invasive SIJ fusion provides pain relief by acutely stabilizing the painful SI joint with subsequent fusion. In addition to outcomes published of multiple retrospective case series (11-15,17-22,24,25,27-31), published results from a prospective multicenter randomized controlled trial (RCT) of minimally invasive SIJ fusion vs. non-surgical management (NSM)(17,33) and a multi-center prospective single-arm trial(16,32) have substantiated high rates of pain relief, improvement in functional measures (SF-36, ODI and EQ-5D) and a low rate of both revisions (<5%) and serious adverse events. Furthermore, these improvements are significantly greater in patients treated with MIS SIJ fusion compared to NSM; at 6 months, VAS scores improved by 52 points in the fusion group compared to 12 points for NSM. ODI improved 27 points in the surgery group vs. 4.6 points in NSM patients at 6 months, EQ-5D scores improved by 0.29 in the fusion group ($p<.001$) vs. 0.06 points in the NSM group. Mean scores for all SF-36 domains improved significantly in the surgery group while no improvement was seen for any domain in the NSM group. Mean SF-36 Physical Component Summary (PCS) improved by 12.5 points in the surgery group vs. 1.3 points in the NSM group at 6 months. All values were highly statistically significant ($p<.001$). After 12 months, subjects assigned to SIJ fusion still had significant reductions in pain and disability, as well as improved quality of life. Thirty-five subjects from the nonsurgical group opted to crossover (allowed per protocol) and undergo the implant procedure, with subsequent similarly good results at 6 months post-surgery. In a multicenter retrospective review of 263 patients undergoing either open or minimally invasive SIJ fusion, the latter was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 (-2.7 points on 0-10 scale vs. -6.2 points) and 2-year (-2.0 vs. -5.6 points) follow-up (all differences are statistically significant.).(14) Two published studies report that favorable outcomes achieved at one year are sustained long term (up to 5-years).(15,19)

The complication rate for minimally invasive SI joint fusion is low. Importantly, the rate of removal or revision is less than 2%. (16,17,26,32,33) Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection.

In cases of bilateral SI joint pain, bilateral SIJ fusion may occasionally be indicated and is usually performed serially to minimize the impact on rehabilitation (i.e., patients who undergo simultaneous bilateral fusion procedures may be wheelchair or bedbound for several weeks, possible slowing overall recovery).

Indications/Limitations of Coverage

Patients who have all of the following criteria may be eligible for minimally invasive SIJ fusion:

- Significant SIJ 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;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (see list provided above) and cause the patient's typical pain.(2)
- Confirmation of the SIJ as a pain generator with ≥ 75%(3,4) acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic.
- 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, SIJ steroid injection. 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 ruled out (e.g., L5/S1 compression, hip osteoarthritis).

Minimally invasive SIJ fusion is NOT indicated for patients with the following:

- 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.

In rare instances, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon fluoroscopically-guided intra-articular SI joint block with local anesthetic.

Bilateral SIJ fusion is probably best performed serially to ensure that fusion of both joints is necessary (i.e., pain/disability continues after the first fusion in spite of conservative treatment and a nerve block of the unfused joint results in more than 75% reduction in pain). If bilateral fusion is performed at the same operative session, the surgeon must document both medical necessity and why serial fusion is not indicated in the patient.

It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed.

Coding

The American Medical Association recommends minimally invasive SI joint fusion be coded using CPT code 27279. Revision and/or removal of the SI joint implant would typically be coded using 22899 (unlisted procedure, spine) or 27299 (unlisted procedure, pelvis or hip joint) depending on the type of approach and procedure performed, whether within the global period of the fusion, or not.

Table 1: ICD-10-CM Diagnosis

ICD-10-CM Diagnosis Code	Code Descriptor
M46.1	Sacroiliitis, not elsewhere classified
M53.2x8	Thoracic or lumbosacral neuritis or radiculitis, unspecified
M53.3	Disorders of sacrum
S33.2xxA	Dislocation of sacroiliac and sacrococcygeal joint
S33.6xxA	Sprain of sacroiliac joint
099.89	Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium
094	Sequelae of complication of pregnancy, childbirth and the puerperium

Documentation Requirements

- A complete history and physical documenting the likely existence of SI joint pain;
- Performance of a fluoroscopically- guided SI joint block on the affected side (or both sides, see discussion above) which shows at least a 75% acute reduction in pain;
- A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs and/or opioids (unless contraindicated) and one of the following: (1) an adequate period of rest, (2) an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment, (3) SI joint steroid injections into the affected joint with inadequate response or return of pain after weeks to months, or (4) radiofrequency ablation of the affected SI joint with either inadequate response or return of pain after weeks to months;
- SI joint pain has continued for a minimum of six months; and
- All other diagnoses that could be causing the patient’s pain have been ruled out.

Surgeon Qualifications

- Minimally invasive SIJ fusion is a surgical procedure performed only by orthopedic or neurologic surgeons who have successfully completed a residency in that specialty as well as at least one specialized training course in the procedure. Training should include device placement in cadavers under supervision of a surgeon experienced in the procedure.
- Surgeons performing minimally invasive SIJ fusion should be specifically credentialed and/or privileged by at least one hospital to perform the procedure

Table 2: MIS SIJ Fusion Surgery Published Literature

Inclusion criteria: indexed in PubMed, English language, fusion of the SI joint described as minimally invasive or percutaneous, clinical outcomes available. Single patient case reports, imaging studies, and technique reports with no clinical outcomes are excluded

Cohort studies including prospective, retrospective, single and multi-center							
Author, Year	**Study design**	**N**	**Implant**	**Technique**	**Demographics** *Mean (±SD) or (range), unless otherwise specified*	**Results** *Mean (±SD) or (range) unless otherwise specified*	**Complications (n)**
Polly 2015 (33)	Prospective, multi-center, randomized controlled trial (surgical arm reported herein)	102	iFuse Implant System	Lateral approach	Age: 50.2 (26-72) years Sex: 75F/27M Prior lumbar fusion: 39% Follow-up: 12mo	VAS: 82.3 (11.9) pre-op, 28.3 (29.3) at 12mo ODI: 57.2 (12.8) pre-op, 28.1 (20.8) at 12mo Surgical time: 44.9 (22.3) min EBL: 32.7 (32.8) mL Hospital stay: 0.8 (range 0-7) days	Procedure-related adverse events within the first 6mo (180 days): neuropathic symptoms (2), postoperative medical problems (4: urinary retention, nausea/ vomiting, atrial fibrillation), SIJ pain or trochanteric bursitis (4), surgical wound problems (4), iliac fracture (1), asymptomatic physical examination finding (1)
		35 of 46 (NSM patients that crossed over after 6mo visit)	iFuse Implant System	Lateral approach	Age: 53.0 (11.5) years Sex: 20F/15M Follow-up: 6mo post-fusion	VAS: 83.9 pre-op, 35.8 at 6mo post MIS SIJ fusion ODI: 58.3 pre-op, 30.2 at 6mo post MIS SIJ fusion	

Duhon 2015 (32)	Prospective, Multi-center	172	iFuse Implant System	Lateral approach	Age: 50.9 (26-72) years Sex: 102F/70M Prior lumbar fusion: 44% Follow-up: 12mo	VAS: 7.98 pre-op, 3.0 at 12mo ODI: 55.2 pre-op, 31.4 at 12mo 91% would have surgery again SF-36 PCS: 31.7 pre-op, 48 at 12mo Surgical time: 46.6 (16.1) min EBL: 51(range 5-800) mL Hospital stay: 0.8 (range 0-7) days	Device-related: Neuropathy (2), fall (1), hip pain (1), mild SIJ pain (1). Procedure-related: Wound infection/drainage (5), buttocks/SIJ pain (5), post-op nausea (3), neuropathy (2), staple irritation (1), numbness at wound (1), gluteal artery bleeding (1), urinary retention (1), fall causing SIJ pain (1).
Whang 2015 (17)	Prospective, multi-center, randomized controlled trial (surgical arm reported herein)	102	iFuse Implant System	Lateral approach	Age: 50.2 (26-72) years Sex: 75F/27M Prior lumbar fusion: 38% Follow-up: 6mo	VAS: 82.3 (11.9) pre-op, 29.8 (29.3) at 6mo ODI: 62.2 (14.5) pre-op, 31.9 (22.7) at 6mo Surgical time: 44.9 (22.3) min EBL: 32.7 (32.8) mL Hospital stay: 0.8 (range 0-7) days	Trochanteric bursitis (4), surgical wound problems (4), iliac fracture (1), hairline ilium fracture (1), nerve root impingement (1)

Vanaclocha 2014 (15)	Single center case series	24	iFuse Implant System	Lateral approach	Age: 47.4 (32-71) years Sex: 15F/9M Prior lumbar fusion: 2 Follow-up: 23 mo (1-4.5 years)	VAS: 8.7 pre-op, 1.7 at 1yr, 2.1 at 4.5yrs ODI: 54.1 pre-op, 14.3 at 1yr, 16.3 at 4.5yrs Surgical time: 48 (range 40-65) min, EBL: 58 (range 40-70) mL	Immediate post-op pain (4-resolved), temporary post-op radiculopathic pain (2)
Rudolf 2014 (19)	Single center case series	17	iFuse Implant System	Lateral approach	Age: 58 (36-85) years Sex: 13F/4M Prior lumbar fusion: 8 (47%) Follow-up: 60 mo Bridging bone: 87% (13/15)	VAS: 8.3 (1.4) pre-op, 3.4 (2.4) at 1yr, 1.4 (2.6) at 2yrs, 2.4 (2.2) at 5yrs ODI: 21.5 (22.7) at 5yrs Surgical time: 65 (18) min	No intraoperative complications, hematoma (1), cellulitis (2), deep wound infection secondary to diverticulitis (1)
Sachs 2014 (18)	Multi-center, Retrospective	144	iFuse Implant System	Lateral approach	Age: 58 (30-89)years Sex: 30F/10M Prior lumbar fusion: 62% Follow-up: 16 (12-26) mo	VAS: 8.6 pre-op, 2.7 at follow-up 91% Very or somewhat satisfied 91.7% would have surgery again Surgical time: 73min EBL: 31mL Hospital stay: 0.8 days	No intraoperative complications. 28 post-op complications, most common: fall (5), trochanteric bursitis (4), piriformis syndrome (3), facet pain (3). 1 implant revision (1-year revision rate 0.7%),

Duhon 2013 (16)	Prospective, Multi-center	32 (effective-ness) 94 (safety)	iFuse Implant System	Lateral approach	Age: 50.2 (12.6) years Sex: 21F/11M Prior lumbar fusion: 69% Follow-up: 6 mo	VAS: 76.2 (16.2) pre-op, 29.3 (23.3) at 6mo ODI: 55.3 (10.7) pre-op, 38.9 (18.5) at 6mo SF-36 PCS: 30.7 (4.3) pre-op, 37 (10.7) at 6mo 88.5% (23/26) success rate Surgical time: 48 (16.1) min EBL: 59 (95) mL Hospital stay: 0.8 days	No implant revision or removal, 6 AEs probably or definitely procedure-related (2 nausea, 2 wound infections, 1 cellulitis, 1 buttock pain)
Sachs 2013 (11)	Single center, Retro-spective case series	40	iFuse Implant System	Lateral approach	Age: 58 (30-81) years Sex: 30F/10M Prior lumbar fusion: 30% Follow-up: 12 mo	VAS: 8.7 (1.5) pre-op, 0.9 (1.6) at 12mo 98% reached MCID 100% patient satisfaction	Piriformis syndrome (1), new LBP (1), facet joint pain (8), trochanteric bursitis (2)
Cummings 2013 (27)	Single center, Retro-spective case series	18	iFuse Implant System	Lateral approach	Age: 64 (39-81) years Sex: 12F/6M Prior lumbar fusion: 61% Follow-up: 12 mo	VAS: 8.9 (1.9) pre-op, 2.3 (2.1) at 12mo 90% reached MCID ODI: 52.6 (18.8) pre-op, 13.2 (12.6) at 12mo SF-12 PCS: 37.8 (10.4) pre-op, 44.6 (10.5) at 12mo	Trochanteric bursitis (3), hematoma (1), fluid retention (1), toe numbness (1), implant malposition (1)

Gaetani 2013 (13)	Single center, Retro-spective case series	10	iFuse Implant System	Lateral approach	Age: 53.2 (36-71) years Sex: 12F Prior lumbar fusion: 8.3% Follow-up: 10 (8-18) mo	VAS: 7.7 (1.3) pre-op, 3 (1.2) at follow-up ODI: 31.4 (6.3) pre-op, 12 (3.5) at follow-up RDQ: 17.6 (1 pre-op, 3 (4.1) at follow-up Surgical time: 65 (16) min EBL: <45 mL 3 month CT scans show initial fusion	Local hematoma (2), low back pain (1)
Schroeder 2013 (28)	Single center, Retro-spective case series	6	iFuse Implant System	Lateral approach	Age: 50 (25-60) years Sex: 6F/0M Prior lumbar fusion: 100% (deformity correction) Follow-up: 10.25 (4-15)mo	VAS: 7.83 pre-op, 2.67 at follow-up ODI: 22.1 pre-op, 10.5 at follow-up Hospital stay: 2 days (range 1-4) Bony bridging seen in 4 patients	No intraoperative or post-operative complications.
Rudolf 2013 (25)	Single center, Sub-group analysis	40	iFuse Implant System	Lateral approach	*Subgroup analysis from Rudolf 2012 to assess effect of prior lumbar fusion on outcomes. Follow up: 12 and 24 months		
		18	*No prior fusion Age: 49(12) Sex: 12F/6M			VAS decrease at 12mo: -5.94 (3.3) VAS decrease at 24mo: -5.47 (2.88) Surgical time: 60(19) min	Superficial cellulitis (2), wound infection (1), revision for implant malposition (1)

		15	*Prior lumbar spinal fusion Age: 58(11) Sex: 11F/4M			VAS decrease at 12mo: -3.5 (3.46) VAS decrease at 24mo: -5.81 (3.5) Surgical time: 64(19) min	Superficial cellulitis (2), buttock hematoma (1), revision for implant malposition (1)
		7	*Concomitant lumbar pathology treated non-surgically Age: 58(17) Sex: 3F/4M			VAS decrease at 12mo: -3.71 (3.11) VAS decrease at 24mo: -4.79 (4.28) Surgical time: 64(19) min	None
Endres 2013 (29)	Single center, Retro-spective case series	19	DIANA cage *[Product not approved for use in the US]*	Posterior, Longitudinally inserted into SI joint	Age: 60.9 (36-76) years Sex: 5F/14M Prior lumbar fusion: 100% Follow-up: 13.2 (6-24) mo	VAS: 8.5 (7.5-9) pre-op to 6.0 (2.2-9) at follow-up ODI: 64.1 (40-82) pre-op to 56.97 (8-82) at follow-up EBL: <150mL Hospital stay: 7.3 (3-10) days Fusion rate: 78.9% (15/19 joints), defined as lack of loosening and evidence of bone bridging around the implant	No neurovascular complications

Mason 2013 (22)	Retro-spective case series	55	HMA screw packed with DBM	Lateral approach	Age: 57 years Sex: 46F/9M Prior lumbar fusion: 40% Follow-up: 36 (12-84) mo	VAS: 8.05 (1.9) pre-op, 4.48 (2.81) at follow-up SF-36PCS: 26.6 (15.2) pre-op, 43 (22.68) follow-up Majeed scoring: 36.18 (15.08) pre-op, 64.78 (20.18) follow-up	Post-op nerve pain requiring reoperation (2)
Rudolf 2012 (12)	Single center, Retrospecti ve case series	50	iFuse Implant System	Lateral approach	Age: 54 (24-85) years Sex: 34F/16M Prior lumbar fusion: 44% Follow-up: 40 (24-56) mo	VAS: 7.6 pre-op, 2.0 at follow-up 82% reached MCID 82% patient satisfaction Surgical time: 65 (26) min	Superficial cellulitis (3), deep wound infection (1), hematoma (2), reoperation (3)
Sachs 2012 (24)	Single center, Retrospecti ve case series	11	iFuse Implant System	Lateral approach	Age: 65 (45-82) years Sex: 10F/1M Prior lumbar fusion: 18% Follow-up: 12 mo	VAS: 7.9 (2.2) pre-op, 2.3 (3.1) at 12mo Surgical time: 77.5 (31.8) min EBL: 21.8 (18.9) mL	Piriformis syndrome (1), low back pain (1)
McGuire 2012 (6)	Retrospecti ve case series	37	Fibular allograft dowels	Posterior, Longitudinally inserted into SI joint	Age: 42.5 (23-63) years Sex: 34F/3M Follow-up: 39.6 (8-62) mo	Baseline VAS: 9.1 Final VAS: 3.4 Fusion rate: 89.5%	Nonunion requiring revision (4) (10.5%)

Khurana 2009 (21)	Retro-spective case series	15	HMA screw packed with DBM	Lateral approach	Age: 48.7 (37.3-62.6) years Sex: 11F/4M Prior lumbar fusion: 40% Follow-up: 17 (9-39) mo	SF-36 PF: 37.15 (14.28) pre-op, 79.33 (12.52) at follow-up Majeed's: 37 (18-54) pre-op, 79 (63-96) at follow-up Good to excellent results: 13/15 EBL: < 50 ml Hospital stay: 2.7 (1-7) days	No post-operative neurological or wound complications.
Al-Khayer 2008 (20)	Retrospecti ve case series	9	HMA screw packed with DBM	Lateral approach	Age: 42 (35-56) years Sex: 9F Follow-up: 40 (24-70) mo	VAS decreased: 8.1 (7-9) to 4.6 (3-7) ODI decreased: 59 (34-70) to 45 (28-60) EBL: <50 ml Hospital stay: 6.9 (2-11) days Return to work: 44.44%	Deep wound infection requiring debridement and IV antibiotics (1)
Wise 2008 (23)	Single center Prospective cohort	13	Titanium cage packed with BMP	Posterior, Longitudinally inserted into SI joint	Age: 53.1 (45-62) years Sex: 12F/1M Prior lumbar fusion: 61.5% Follow-up: 29.5 (24-35) mo	Back VAS improved by 4.9 pts Leg VAS improved by 2.4 pts EBL: < 100 ml Hospital stay: 1.7 days Fusion rate: 89% (17/19 joints) on CT at 6mo	Reoperation via open arthrodesis secondary to nonunion and persistent pain (1)

Comparative cohort studies of open surgery vs MIS							
Author, year	**Study design**	**N**	**Implant**	**Technique**	**Demographics** *Mean (±SD) or (range), unless otherwise specified*	**Results** *Mean (±SD) or (range), unless otherwise specified*	**Complications**
Ledonio 2014 (30)	Single center Retrospective, comparative cohort study	22	iFuse Implant System	Lateral approach	**<u>MIS Cohort</u>** Age: 47.9 (13.1) years Sex: 17F/5M Prior lumbar fusion: 64% Follow-up: median 15 (12-26) mo	ODI: 61.5 (12.5) pre-op, 52 (16.9) at follow-up Surgical time: 68.3 (26.8) min EBL: 40.5 (31.4) mL Hospital Stay: 2.0 (1.5) days	(1) pulmonary embolism that resolved with treatment, (2) revisions due to halo formation on the sacral side with recurring sacroiliac joint pain
		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	**<u>Open Cohort</u>** Age: 51 (9.4) years Sex:13F/9M Prior lumbar fusion: 50% Follow-up: median 13 (11-33) mo	ODI: 61.8 (10.8) pre-op, 47.4 (21.7) at follow-up Surgical time: 128 (27.9) min EBL: 168.8 (479.0) mL Hospital Stay: 3.3 (1.1) days	Pulmonary embolism (1), revision due to failed implant and nerve root irritation (2)
Ledonio 2014 (31)	Multi-center Retrospective, comparative cohort study	17	iFuse Implant System	Lateral approach	**<u>MIS Cohort</u>** Age: median 66 (39-82) years Sex: 11F/6M Prior lumbar fusion: 82% Follow-up: 12 mo	*Values reported as median (range)* ODI: 53 (14-84) pre-op, 13 (0-38) at 12 mo Surgical time: 27 (18-72) min Hospital Stay: 1 (1-2) days	Transient trochanteric bursitis (3), hematoma (1), transient toe numbness (1), revision due to malpositioned implant (1)

		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	**<u>Open Cohort</u>** Age: median 51 (34-74) years Sex: 82F/32M Prior lumbar fusion: 47% Follow-up: 24 mo	*Values reported as median (range)* ODI: 64 (44-78) pre-op, 46 (10-80) at 12 mo Surgical time: 128 (73-180) min Hospital Stay: 3 (2-6) days	Pulmonary embolism (1), revision due to failed implant and nerve root irritation (2)
Graham-Smith 2013 (14)	Multi-center Retro-spective comparative cohort study	114	iFuse Implant System	Lateral approach	**<u>MIS Cohort</u>** Age: 57.4 (14.0) years Sex: 82F/32M Prior lumbar fusion: 47.4% Follow-up: 24 mo	VAS: 8.3 (1.6) pre-op, 2.3 (2.6) at 12mo, 1.7 (2.9) at 24mo MCID: 86% reached at 12mo, 82% at 24mo Surgical time: 70 (24) min EBL: 33 (27) mL Hospital stay: 1.3 (0.5) days	No intraoperative. Postop repositioning of implants (4), 3.5% (4/114).

		149	Screws, plates	Open posterior approach	**<u>Open Cohort</u>** Age: 45.8 (11.3) years Sex: 103F/46M Prior lumbar fusion: 23.5% Follow-up: 24 mo	VAS: 7.1 (1.9) pre-op, 4.6 (3.0) at 12mo, 5.6 (2.9) at 24mo MCID: 61% reached at 12mo, 50% at 24mo Surgical time: 163 (25) min EBL: 288 (182) mL Hospital stay: 5.1 (1.9) days	No intraoperative. Postop removal of implants (66), 44% (66/149).

NOTE: Two systematic reviews of the literature exist:

- Zaidi 2015 (34) – reviews SI joint fusion including open and MIS.
- Heiney 2015 (35) – reviews MIS SI joint fusion utilizing a lateral transarticular technique.

Abbreviations: F: female; M: male; EBL: estimated blood loss; mo: month; ODI: Oswestry Disability Index; VAS: Visual Analog Scale; NSM: Non-surgical management; DBM: demineralized bone matrix; HMA: hollow modular anchorage; BMP: bone morphogenic protein.

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