Subject ID: 7 ID Initials: 8 initials

SCREEN FAILURE DATA CAPTURE

Screening date: 9 scrfldt (dd/mon/yyyy) (can be last date of screening if multiple days)

Indicate below **ALL** the known reasons this subject failed the screening process. Check all that apply.

- [10] Inclusion criteria not met → list any/all code numbers: 11 incnotmet
- [12] Exclusion criteria met → list any/all code numbers: 13 excnotmet
- [14] Does not wish to be randomized to CT (6 mo or 12 mo)
- [15] Insurance or patient denial for cost of iFuse procedure on study
- [16] Want iFuse outside of clinical trial
- [17] Not willing to complete all study required follow up visits
- [18] Concerns about future pregnancy options
- [19] Up front refusal of CT at 6 or 12 months, or CT at 5 years
- [20] Distance from home to site
- [21] Anticipated conflicts with work
- [22] Caregiver responsibilities
- [23] Relocation
- [24] Other (describe): 25 sfothersp

Note on screening: Each inclusion and exclusion criteria must be carefully verified and investigator must sign off on eligibility to enroll. Careful screening is accomplished through medical records review and patient interview. Sponsor will ask that any deviation to eligibility be reported immediately and will ask site to report to IRB.

Subject | 7 ID Initials: 8 initials 9 confrmdt

ELIGIBILITY CRITERIA

INCLUSION CRITERIA (NOTE: ALL QUESTIONS MUST BE ANSWERED YES TO QUALIFY)	Yes	No
1. Patient age 21-70 at time of screening.	10 inc1	
2. Patient has suspected SI joint pain for ≥6 months inadequately responsive to conservative care.	11 inc2	
3. Diagnosis of sacroiliac joint dysfunction on one or two sides to be treated on study that is a direct result of sacroiliac joint disruptions and/or degenerative sacroiliitis and is based on ALL of the following: a. Patient has pain at or close to the posterior superior iliac spine (PSIS) with possible radiation into buttocks, posterior thigh or groin and can point with a single finger to the location of pain (Fortin Finger Test), and b. Patient has positive findings on at least 3 physical examination maneuvers that stress the target SI joints), and c. Patient has block on any study targeted side with improvement in SI joint pain numeric rating scale (NRS) at 30 or 60 minutes of at least 50% after injection of local anesthetic into any affected SI joint with an immediate pre-block NRS of at least 5.	12 inc3	
4. Baseline Oswestry Disability Index (ODI) score of at least 30%	13 inc4	
5. Baseline (average over the last week) SI joint pain score of at least 50 on 0-100 mm visual analog scale* on any side to be treated under the study.	14 inc5	
6. Patient has signed study-specific informed consent form.	15 inc6	
7. Patient has the necessary mental capacity to participate and is physically able to comply with study protocol requirements.	16 inc7	
8. Patient's insurance coverage for SI joint treatment has been considered and plan is to submit all study-related healthcare to insurance / the patient (any required pre-authorization should be completed prior to randomization on study).	28 inc8	
9. Investigator believes patient is appropriate candidate for surgery using iFuse-3D Implant.	29 inc9	

EXCLUSION CRITERIA (NOTE: ALL QUESTIONS MUST BE ANSWERED NO TO QUALIFY)	Yes	No
1. Patient has bilateral SI joint symptoms with VAS pain scores ≥50 on both sides and patient refuses to undergo bilateral treatment according to the study protocol.	17 exc1	
2. Patient is currently pregnant, actively trying to become pregnant or is planning to become pregnant in the next year.	18 exc2	
3. Severe back or hip pain due to other causes, such as lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, lumbar vertebral body fracture, piriformis syndrome, femoral acetabular impingement, labral tear or hip osteoarthritis. Patients with low back pain VAS ratings more than 50 should be carefully considered; they should not participate if the investigator believes these non-SIJ conditions would impair improvement from SIJ treatment.	19 exc3	
4. SI joint dysfunction due to an alternative explanation such as: a. Inflammatory sacroiliitis (e.g., ankylosing spondylitis or other HLA-associated spondyloarthropathy) b. Tumor c. Infection d. Acute or unstable fracture.	20 exc4	
5. History of recent (<1 year) major non-pregnancy-related trauma to pelvis.	21 exc5	
6. Surgeon believes patient body habitus prevents surgery.	22 exc6	
7. Previously diagnosed osteoporosis (defined as prior T-score <-2.5 or history of osteoporotic fracture) or prior/current use of drug therapy for osteoporosis.	23 exc7	
8. Prior fracture of any bone related to cancer/tumor (i.e., pathologic fracture).	24 exc8	

Subject ID: 7 ID Initials: 8 initials

ELIGIBILITY CRITERIA (CONT'D)

	Yes	No
9. Prior diagnosis of tumor in sacrum or ilium.	9 exc9	
10. Unstable fracture of sacrum and or ilium involving the targeted SIJ.	10 exc10	
11. Osteomalacia or other metabolic bone disease.	11 exc11	
12. Diagnosed or suspected chronic rheumatologic condition (e.g., rheumatoid arthritis, lupus).	12 exc12	
13. Any known condition or anatomical deformity or variation that makes treatment with the iFuse 3D Implant infeasible.	13 exc13	
14. Any known health condition that could prevent long-term follow-up required in this study.	14 exc14	
15. Known allergy to titanium or titanium alloys.	15 exc15	
16. Use of medications known to have detrimental effects on bone quality and soft-tissue healing.	16 exc16	
17. Current local or systemic infection that raises the risk of surgery.	17 exc17	
18. Patient currently receiving or seeking short- or long-term worker's compensation related to the SI joint or low back pain, currently receiving disability remuneration related to SI joint or low back pain, and/or currently involved in injury litigation related to the SI joint or low back pain.	18 exc18	
19. Patient is a prisoner or a ward of the state.	19 exc19	
20. Patient has known or suspected active drug or alcohol abuse.	20 exc20	
21. Patient is unwilling to sign the study-associated opioid contract.	21 exc21	
22. Diagnosed uncontrolled psychiatric disease (e.g., schizophrenia, major depression, personality disorders) that could interfere with study participation.	22 exc22	
23. Patient is participating in an investigational study or has been involved in an investigational study within 3 months prior to evaluation for participation.	23 exc23	
24. Patient has known or suspected fibromyalgia.	24 exc24	

UNDERLYING DIAGNOSIS

This study includes patients with SI joint dysfunction due to degenerative sacroiliitis and/or sacroiliac joint disruption. Please indicate what you think is the most likely diagnosis.

DIAGNOSIS (LEFT SI JOINT)

25
- N/A
- Sacroiliac joint disruption (SD)
- Degenerative sacroiliitis (DS)

DIAGNOSIS (RIGHT SI JOINT)

26
- N/A
- Sacroiliac joint disruption (SD)
- Degenerative sacroiliitis (DS)

Subject ID: 7 ID Initials: 8 initials

SI JOINT INJECTION

SI joint injection is a screening/eligibility test. Information from SI joint injection performed within 3 months prior to evaluation for eligibility may be used as long as all requirements specified in the protocol were satisfied. Otherwise, a new SI joint injection must be performed.

If both sacroiliac joints are injected for study entry, complete 2 forms (1 for each joint).

INJECTION INFORMATION

Date of injection procedure:	9 sijinjdt (dd/mon/yyyy)
Physician who performed SI joint injection:	10 sijphys last name only
Side injected (fill one CRF for each side done):	11 sijinjside Left
Arthrogram of SI joint showed successful access of target joint?	12 arthrosuc No, joint could not be accessed with needle r reason: 13 arthroreas
Leakage of contrast outside of joint during procedure?	14 No leakage / Minor leakage (estimated <0.5 cc outside of joint) / Major leakage (estimated >0.5 cc outside of joint)
Local anesthetic used: **(check all that apply)**	15 Lidocaine 16 Bupivacaine (Marcaine) 17 Other: 18 anesothersp
Was steroid included in the SI joint injection?	19 sterinj Yes → name of steroid: 20 stermedname

PATIENT RESPONSES

Pain NRS immediately prior to injection (0-10 scale):	21 0-10 scale → **If less than 5, patient has insufficient pain attributed to this SI joint. Do not consider this side included in study.**
30 minutes after injection, pain NRS:	22 0-10 scale 28 NRS30type Phone
60 minutes after injection, pain NRS:	23 0-10 scale 29 NRS60type Phone
Decrease in SI joint pain of at least 50% at 30 or 60 minutes after SI joint blocking?	24 sijpred50 No → **Patient must have a 50% pain reduction in at least one SI joint to be study eligible.**

Subject ID: 7 ID Initials: 8 initials

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Subject ID: 7 ID Initials: 8 initials

BASELINE EXAMINATION

DEMOGRAPHICS

Visit date:	9 basevisdt (dd/mon/yyyy)	Date of birth:	10 dob (dd/mon/yyyy)
Date consent form signed:	11 consdt (dd/mon/yyyy)	Sex	12 gender Female
If female, total number of times pregnant	13 (don't double count if twins)	14 N/A	
Weight:	15 wtlbs lbs OR 16 wtkg kg		
Height:	17 ht feet 18 height inches OR 19 height cm		
Ethnicity (choose one):	20 ethnic Not Hispanic or Latino		
Race	21 race	Native Hawaiian or other Pacific Islander American Indian or Alaska Native Other 22 raceother	

SI JOINT PAIN HISTORY

Month/Year SI joint pain started: 23 p / 24 painst mon/yyyy

SIJ / Back pain prior to first pregnancy? 25 painpriorfpreg N/A

Has subject had at least **6 months of conservative care**? 26 conscare No → **Do not enroll. Study requires that patient have back pain not responsive to at least 6 months of conservative care.**

Has subject had **physical therapy** specifically directed at SI joint? 27 priorpt Yes → Number of courses of PT in last 2 years: 28

A course of PT is a group of continuous sessions.

Has subject had **steroid injections** of SI joint aimed at treating pain? 29 priorster Yes → Number of SIJ injections in last 5 years: 30

Has subject had **RF ablation** of SI joint? 31 priorrfa Yes → Number of RF ablations in last 5 years: 32

Has subject had prior SI joint fusion? 33 priorsijf Yes → date of prior SIJ fusion: 34 priorsijfdt

Which side fused: 35 sijsidefused Left

OPIOID CONTRACT

Date opioid contract signed: 36 opsigdt (dd/mon/yyyy)

Subject ID: 7 ID Initials: 8 initials

9 h

OTHER BACK PROBLEMS

Has subject had lumbar or lumbosacral spine fusion?	10 No Yes → date of most recent lumbar fusion: 11 f / 12 fus1y (mon/yyyy)
Does subject have history of lumbar spine stenosis? Note: If patient has severe back pain from any cause → patient not eligible	13 priorster Yes → List prior injection/surgical treatments **Treatment for lumbar stenosis** / **Date (mon/yyyy)** 1 14 sten1desc — 15 s / 16 sten1 2 17 sten2desc — 18 s / 19 sten2
Does subject have history of piriformis syndrome?	20 priorpiri Yes → Prior treatments for piriformis syndrome **Treatment for piriformis syndrome** / **Date (mon/yyyy)** 1 21 piri1desc — 22 p / 23 piri1y
Does subject have history of hip problems? Note: If patient has severe hip pain from any cause → patient not eligible	24 hohip Yes Current hip diagnoses: 25 hipdiag Affected side(s) (choose all that apply): 26 Right 27 Left Prior surgical/non-surgical treatments for hip problems: **Treatment for hip problem** / **Date (mon/yyyy)** 1 28 hip1desc — 29 h / 30 hip1y 2 31 hip2desc — 32 h / 33 hip2y
History of sacral trauma?	34 hosactr Yes → Describe: 35 sactraum Prior injection/surgical treatments: **Treatment for trauma** / **Date (mon/yyyy)** 1 36 sitrau1desc — 37 s / 38 sitrau 2 39 sitrau2desc — 40 s / 41 sitrau
History of lumbar sagittal imbalance?	42 sagimb Yes → Describe: 43 sagimbdes

FORTIN FINGER TEST (PERFORM ON BOTH SIDES FOR ALL)

Left Side Date (dd/mon/yyyy): 44 fftdtfftdtL	Right Side Date (dd/mon/yyyy): 46 fftdtR
45 Positive	47 Positive
Negative (if negative, not eligible)	Negative (if negative, not eligible)

NICOTINE USE

Smoking status		
48	Current smoker	How many years: 49 yrssm
	Former smoker	Year quit: 50 quityr
	Never smoker	

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Subject ID: 7 ID Initials: 8 initials

SIGNIFICANT GENERAL PAST/CURRENT MEDICAL AND SURGICAL HISTORY

Please record a single surgery, diagnosis or existing sign and/or symptom per line.

9 **No history of medical conditions**

#	Condition
1	10 medcond1
2	14 medcond2
3	15 medcond3
4	16 medcond4
5	17 medcond5
6	18 medcond6
7	19 medcond7
8	20 medcond8
9	21 medcond9
10	22 medcond10
11	23 medcond11
12	24 medcond12
13	25 medcond13
14	26 medcond14

If more space needed, use narrative form.

Subject ID: 7 ID Initials: 8 initials

Please enter total daily dose in mg. Call SI-BONE if you need help converting to mg.

MEDICATIONS

MEDICATIONS TAKEN SPECIFIC TO SI JOINT PAIN

Enter medications taken in the last 7 days specific for SI joint pain/symptoms. If not taking, check box.

Class	Not Taking	Medication Name (use generic name)	
Opioids	9	**Name**	**Total daily dose (mg)**
		10 narc1	11 narc1dose
		12 narc2	13 narc2dose
		14 narc3	15 narc3dose
		16 narc4	17 narc4dose
		18 narc5	19 narc5dose
Non-steroidal anti-inflammatory agents	20	**Name**	**Total daily dose (mg)**
		21 nsaid1	22 nsaid1dose
		23 nsaid2	24 nsaid2dose
		25 nsaid3	26 nsaid3dose
Other pain medications for pain	27	**Name**	**Total daily dose (mg)**
		28 othmed1	29 otrmed1dose
		30 othmed2	31 otrmed2dose
		32 othmed3	33 otrmed3dose
		34 othmed4	35 otrmed4dose
		36 othmed5	37 otrmed5dose

Examples of Opioid medications include:
Codeine, propoxyphene (Darvon), propoxyphene and acetaminophen (Darvocet N), meperidine (Demerol), hydromorphone (Dilaudid), morphine, oxycodone, oxycodone and acetaminophen (Percocet, Roxicet), hydrocodone and acetaminophen (Lortab, Anexsia), tramadol (Ultram).

STUDY # 023 Plate # 017 Visit # 001

Subject ID: 7 ID Initials: 8 initials

OTHER MEDICATIONS TAKEN AT BASELINE

Enter any medication used on a regular basis for all conditions **other than** SI joint pain.

9 NONE

Medication Name*	Reason for Use
10 basemed1	11 basemedreas1
12 basemed2	13 basemedreas2
14 basemed3	15 basemedreas3
16 basemed4	17 basemedreas4
18 basemed5	19 basemedreas5
20 basemed6	21 basemedreas6
22 basemed7	23 basemedreas7
24 basemed8	25 basemedreas8
26 basemed9	27 basemedreas9

*Example: hydrochlorothiazide for hypertension.

STUDY # 023 Plate # 018 Visit # 001

Subject ID: 7 ID Initials: 8 initials

Both sides must be evaluated on every patient for the study. Patients with strongly positive findings on both sides should be carefully evaluated so that determination of unilateral vs. bilateral can be made at study entry.

PHYSICAL EXAMINATION

Enter results of baseline or screening physical examination of both SI joints.

PRE-OPERATIVE SI JOINT EVALUATION

Provocative Tests Required on Both Sides	Left SI Joint			Right SI Joint		
	Pos	Neg	ND	Pos	Neg	ND
Distraction	9 distracl			10 distracr		
Thigh Thrust	11 thighl			12 thighr		
FABER	13 faberl			14 faberr		
Compression	15 compl			16 compr		
Gaenslen's	17 gaenl			18 gaenr		
Other, name: 19 othtestnm1	20 othr1l			21 othr1r		
Other, name: 22 othtestnm2	23 othr2l			24 othr2r		

Physician or delegated healthcare practitioner performing tests (last name): 25 whodidpexam

PAIN, DISABILITY AND QUALITY OF LIFE INSTRUMENTS

Use the checklist to ensure all baseline questionnaires are completed.

VAS	26 vasdn	Yes
ODI	27 odidn	Yes
EQ-5D	28 eq5ddn	Yes
Ambulatory and work status	29 ambdn	Yes
SIJ pain map & SIJ pain with activity	30 mapdn	Yes
Active straight leg raise (both sides)	31 aslrdn	Yes
5 times sit to stand test	32 sstdn	Yes
Transitional timed up and go	33 ttugdn	Yes

Each of the items here are critical baseline assessments. Without baseline assessments, improvements at follow-up cannot be determined. **Please make sure each are completed using the list *below. Any "no" is a protocol* deviation.**

Note: Baseline VAS and ODI are from screening period and do not need to be repeated unless a delay is encountered in study treatment according to protocol.

STUDY # 023 Plate # 019 Visit # 001

Subject ID: 7 ID Initials: 8 initials

RANDOMIZATION

Randomize patient after all baseline assessments are done and after insurance authorization (or authorization from patient for out-of-pocket payment) is received for iFuse procedure. Randomization refers to when the CT is done. For randomization assignments:

- Go to siboneclinical.com and log in
- Click on randomization tab
- Enter patient ID number
- Click Randomize
- Print screen and file in regulatory binder
- **Record randomization ID and assignment below**.

Date Randomized 9 randdt (dd/mon/yyyy)

Randomization ID: 10 randID

Subject randomized to:

1 Study CT at 6 month visit (and 5 year visit)
Study CT at 12 month visit (and 5 year visit)

Note: Randomized CT timing is the first CT on study (to 6 or to 12 month time point). The 5 year CT is required for all.

STUDY 023 Page # 021 Visit # 002

Subject ID: 7 ID Initials: 8 initials

IFUSE-3D PROCEDURE (1 FORM PER SIDE IF BILATERAL TREATMENT)

Procedure date: 9 procdt (dd/mon/yyyy)

Surgery type: 10 Unilateral → 11 targsij Left

Bilateral → Both sides qualified and this form is for the 12 bilside second side

Start time (initial incision) 13 pr : 14 pr (24 hour clock)

End time of surgery (closure complete) 15 pr : 16 pr (24 hour clock)

Estimated blood loss 17 ebl Cc

GRAFT USE

Was allograft or autograft used? 18 graftused Yes → Describe how it was obtained and prepared:

(if yes, enter amounts below) 19 graftdes

IFUSE-3D DEVICES IMPLANTED

Enter information only for devices implanted into subject.

Implant Side		iFuse-3D Length (mm)								cc auto/allograft used:
Right	Left	35	40	45	50	55	60	65	70	
20 impside1		21 implen1								22 amtgr cc
23 impside2		24 implen2								25 amtgr cc
26 impside3		27 implen3								28 amtgr cc
29 impside4		30 implen4								31 amtgr cc

If any device not implanted, indicate disposition:

32 devdisp Discarded

TECHNICAL COMPLICATIONS

Any technical complications during implantation? 33 techcom Yes → Complete Device Deficiency or Malfunction form.

Any technical complications related to the auto or allograft? 34 graftcomp Yes → Describe: 35 techcompgraftdes

ADVERSE EVENTS

Any adverse events/patient complications during procedure? 36 aeduring Yes → Complete AE form(s)

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37 LCUser 38 LCDate 39 LCTime

Subject ID: 7 ID Initials: 8 initials

PRIOR TO DISCHARGE

ADVERSE EVENTS

Any adverse events prior to hospital discharge? 9 aedisc Yes → Complete AE form(s)

DISCHARGE INFORMATION

Hospital discharge date: 10 hospdcdt (dd/mon/yyyy)

Total length of stay 1 Discharged same day OR 12 los nights in hospital

6 visitseq

STUDY 023 Page # 031

Subject ID: 7 ID Initials: 8 initials

SCHEDULED FOLLOW-UP STUDY VISIT

Visit date: 9 fuvisdt
dd/mon/yyyy

Please make sure you collect all study questionnaires. These are the heart of the study! Thanks!

Were the following assessments given to the subject?

VAS	10 fuvasdn	Yes
ODI	11 fuodidn	Yes
EQ-5D	12 fueq5dd	Yes
Ambulatory and work status	13 fuambdn	Yes
Satisfaction	14 fusatdn	Yes
SIJ pain map & SIJ pain with activity	15 fumapdn	Yes
Self-efficacy	16 fuself	Yes
Active straight leg raise	17 fuaslrdn	Yes
5 times sit to stand test	18 fusstdn	Yes
Transitional timed up and go	19 futtugdn	Yes

SIJ AND WALKING

Was there any other reason besides SI joint pain that may be affecting the subject's ability to walk?

20 OthRsCal Yes → If yes, explain: 21 WalkLimitDes

CT SCAN (6-MONTH, 12-MONTH, 5-YEAR VISIT ONLY)

Was CT scan done at this visit?

6 months: 22 ctdone6 No → reason: 23 ctndrs6

12 months: 24 ctdone12 No → reason: 25 ctndrs12

5 years 26 ctdone5y No → reason: 27 ctndrs5y

CONTRALATERAL SIJF

Was SI joint fusion of the "other" side performed since last study visit? 28 contrasijf Yes on → 29 consijfdt

30 ctrecdt

Version D 19APR2018

31 LCUser 32 LCDate 33 LCTime

6 visitseq

Subject ID: 7 ID Initials: 8 initials

OPIOID MEDICATIONS FOR SI JOINT PAIN

Enter all opioid medications taken over the past 7 days for SI joint pain.

Class	Not Taking	Medication Name (use generic name)	
		Name	Total daily dose (mg)
Opioids	9	10 narc1	11 narc1dose
		12 narc2	13 narc2dose
		14 narc3	15 narc3dose
		16 narc4	17 narc4dose
		18 narc5	19 narc5dose

Examples of opioid medications include: Codeine, propoxyphene (Darvon), propoxyphene and acetaminophen (Darvocet N), meperidine (Demerol), hydromorphone (Dilaudid), morphine, oxycodone, oxycodone and acetaminophen (Percocet, Roxicet), hydrocodone and acetaminophen (Lortab, Anexsia) and tramadol (Ultram).

Was subject reminded of signed opioid contract at this visit? 20 remcontr No→ complete Protocol Deviation form

6-MONTH VISIT ONLY

Over the course of 6 months following one or more iFuse surgeries, how many sessions of post-operative SIJ-directed PT sessions did subject receive?

Right side = 21 num session(s) Left side = 22 num session(s)

Note that postoperative rehabilitation is not a study requirement.

ADVERSE EVENTS SINCE LAST CONTACT

Has the subject experience an adverse event since last visit? 23 aelastvis Yes → complete AE form(s)

6 visitseq

Subject ID: 7 ID Initials: 8 initials

CONTRALATERAL PROCEDURES

Was planned contralateral iFuse done?
(Note: this triggers contralateral cycle)

9 plancontra No

Was unplanned contralateral iFuse done? (i.e., unplanned at baseline)
(Note: beyond scope of study, contralateral cycle not triggered)

10 unplanco No

For planned contralateral procedures, calendar is reset.
For unplanned contralateral procedure, results are beyond study scope and calendar not reset. Contralateral procedure likely represents an adverse event; if so, please ensure that adverse event is reported.

6 visitseq

Subject ID: 7 ID Initials: 8 initials

PHYSICAL FUNCTION TESTS

Note: these physical function tests are done at baseline and at all follow-up visits.

At baseline, subject must watch demonstration video prior to test. At each follow up visit this is optional, as needed.

1st Leg - Active Straight Leg Raise (least painful side should be first tested side)

9 ASLR1side left

10 0 (not difficult at all)
1 (minimally difficult)
2 (somewhat difficult)
3 (fairly difficult)
4 (very difficult)
5 (unable to perform)

If not attempted, reason: 11 aslr1ndrs

If not completed, at what point was test aborted, and why?

12 aslr1whenab

When asked, did patient note any other medical condition that made this difficult today (please specify)?

13 aslr1medcon

2nd Leg - Active Straight Leg Raise

14 ASLR2sid left

15 0 (not difficult at all)
1 (minimally difficult)
2 (somewhat difficult)
3 (fairly difficult)
4 (very difficult)
5 (unable to perform)

If not attempted, reason: 16 aslr2ndrs

If not completed, at what point was test aborted, and why?

17 aslr2whenab

When asked, did patient note any other medical condition that made this difficult today (please specify)?

18 aslr2medcon

General comments on ASLR:

19 aslrcom

6 visitseq

Subject ID: 7 ID Initials: 8 initials

5 Times Sit to Stand	Time: 9 ss5sec (seconds) If not attempted, reason: 10 ss5ndrs If not completed, at what point was test aborted and why? 11 ss5whenab When asked, did patient note any other medical condition that made this difficult today (please specify)? 12 ss5medcon
General comments on 5XSST:	13 ss5com
Transitional Timed Up & Go	Time: 14 ttugse (seconds) 15 m 0-10 (Rate maximum pain during this test) 16 c 0-10 (Rate "current" pain – pain after performing the test) If not attempted, reason: 17 ttugndrs If not completed, at what point was test aborted and why: 18 ttugwhenab When asked, did patient note any other medical condition that made this difficult today (please specify)? 19 ttugmedcon
General comments on TTUG:	20 ttugcom

6 visitseq

Subject ID: 7 ID Initials: 8 initials

VAS

If not done using iPad (iPad automatically transfers data to DataFax for you), enter raw values here.

Collect SIJ pain ratings on both sides for all subjects.

SI JOINT PAIN

Left side		Right Side	
VAS pain rating for **SIJ** (pelvis/buttocks)	9 vassij mm	VAS pain rating for **SIJ** (pelvis/buttocks)	10 vass mm

LOW BACK PAIN

VAS for low back pain 11 vasl mm

☐ If any pain rating is more than 20 points higher than the prior assessment, explain why:

12 painincrrs

Potential reasons: fall, bad day, medication problems, implant malposition, radiolucencies, etc.

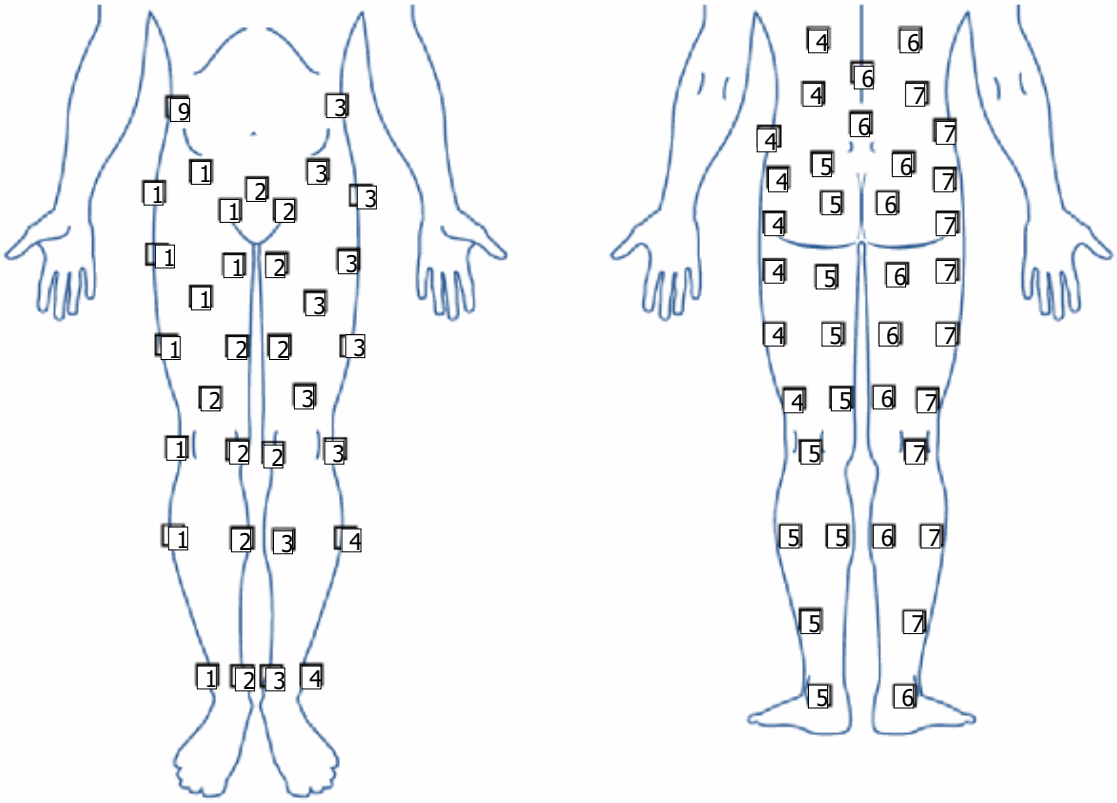
Please note: for increases in SIJ or back pain ≥ 20mm from last required study visit, consider carefully for report of Adverse Event.

Subject ID: 7 ID Initials: 8 initials

6 visitseq

SI JOINT PAIN LOCATION (PAGE 1)

Check any box below that was checked by the subject on the corresponding source document worksheet as causing current pain:



80 N/A the subject did not check any boxes.

6 visitseq

Subject ID: 7 ID Initials: 8 initials

AMBULATORY AND WORK STATUS

AMBULATORY STATUS

Thinking back over the last 7 days describe your general ability to walk:

9
- I can walk fully without any assistance
- I can walk but with assistive device (cane, crutch, walker)
- I cannot walk (wheelchair- or bed-bound)

WORK STATUS

What is your current work status?	10 Working full-time Working less than full time because of SI joint pain Working less than full time because of health reasons unrelated to SI joint pain Working less than full time for personal reasons Not working at all because of SI joint pain Not working at all because of health reasons unrelated to SI joint pain Not working for personal reasons (e.g., retired, at-home parent)
Have you returned to work since your SI-BONE surgery? (follow-up visits only)	11 Yes on → 12 rtwdt No Not applicable, I was not working prior to surgery
If you didn't have SIJ pain, how many more hours would you work per week?	13 n hours

14 n

15 workout

16 h

17 othrscwsp

Subject ID: 7 ID Initials: 8 initials 6 visitseq

ODI

If not done using iPad (iPad automatically transfers data to DataFax for you), enter raw data here.

Section 1: Pain Intensity

- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- 9 The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.
- **Not answered / declined**

Section 2: Personal Care (washing, dressing, etc.)

- I can look after myself normally without causing extra pain.
- I can look after myself normally but it is very painful.
- It is painful to look after myself and I am slow and careful.
- 1 I need some help but manage most of my personal care.
- I need help every day in most aspects of self-care.
- I do not get dressed, wash with difficulty and stay in bed.
- **Not answered / declined**

Section 3: Lifting

- I can lift heavy weights without extra pain.
- I can lift heavy weights but it gives extra pain.
- Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- 1 Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- I can lift only very light weights.
- I cannot lift or carry anything at all.
- **Not answered / declined**

Section 4: Walking

- Pain does not prevent me walking any distance.
- Pain prevents me walking more than one mile.
- Pain prevents me walking more than a quarter of a mile.
- 1 Pain prevents me walking more than 100 yards.
- I can only walk using a stick or crutches.
- I am in bed most of the time and have to crawl to the toilet.
- **Not answered / declined**

Section 5: Sitting

- I can sit in any chair as long as I like.
- I can sit in my favorite chair as long as I like.
- Pain prevents me from sitting for more than 1 hour.
- 1 Pain prevents me from sitting for more than half an hour.
- Pain prevents me from sitting for more than 10 minutes.
- Pain prevents me from sitting at all.
- **Not answered / declined**

Section 6: Standing

- I can stand as long as I want without extra pain.
- I can stand as long as I want but it gives me extra pain.
- Pain prevents me from standing for more than 1 hour.
- 1 Pain prevents me from standing for more than half an hour.
- Pain prevents me from standing for more than 10 minutes.
- Pain prevents me from standing at all.
- **Not answered / declined**

Section 7: Sleeping

- My sleep is never disturbed by pain.
- My sleep is occasionally disturbed by pain.
- Because of pain I have less than 6 hours sleep.
- 1 Because of pain I have less than 4 hours sleep.
- Because of pain I have less than 2 hours sleep.
- Pain prevents me from sleeping at all.
- **Not answered / declined**

Section 8: Sex Life (if applicable)

- My sex life is normal and causes no extra pain.
- My sex life is normal but causes some extra pain.
- My sex life is nearly normal but is very painful.
- 1 My sex life is severely restricted by pain.
- My sex life is nearly absent because of pain.
- Pain prevents any sex life at all.
- **Not answered / declined**

Section 9: Social Life

- My social life is normal and causes me no extra pain.
- My social life is normal but increases the degree of pain.
- Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- 1 Pain has restricted my social life and I do not go out as often.
- Pain has restricted social life to my home.
- I have no social life because of pain.
- **Not answered / declined**

Section 10: Traveling

- I can travel anywhere without pain.
- I can travel anywhere but it gives extra pain.
- Pain is bad but I manage journeys over two hours.
- Pain restricts me to journeys of less than one hour.
- 1 Pain restricts me to short necessary journeys under 30 minutes.
- Pain prevents me from travelling except to receive treatment.
- **Not answered / declined**

Total score:

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Subject ID: 7 ID Initials: 8 initials

EQ-5D

If not done using iPad (iPad automatically transfers data to DataFax for you), enter raw values here.

Mobility

9
- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

10
- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities
(e.g. work, study, housework, family or leisure activities)

11
- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

12
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

13
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Health today 14 eqv (0-100)

Subject ID: 7 ID Initials: 8 initials 6 visitseq

SATISFACTION

If not done using iPad (iPad automatically transfers data to DataFax for you), enter raw data here.

Current level of satisfaction with SIJ pain relief from iFuse-3D surgery	9	Very satisfied Somewhat satisfied Somewhat dissatisfied Very dissatisfied
Would you undergo the iFuse-3D surgery again if needed?	10	Would definitely HAVE iFuse-3D treatment again for the same condition Might have iFuse-3D treatment again for the same condition Would definitely NOT HAVE iFuse-3D treatment again for the same condition

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6 visitseq

Subject ID: 7 ID Initials: 8 initials

SELF-EFFICACY

If not done using iPad (iPad automatically transfers data to DataFax for you), enter raw data here.

Please mark the confidence level the subject indicated on the self-efficacy form:

9

- Very confident
- Somewhat confident
- Not confident
- N/A

6 visitseq

Subject ID: 7 ID Initials: 8 initials

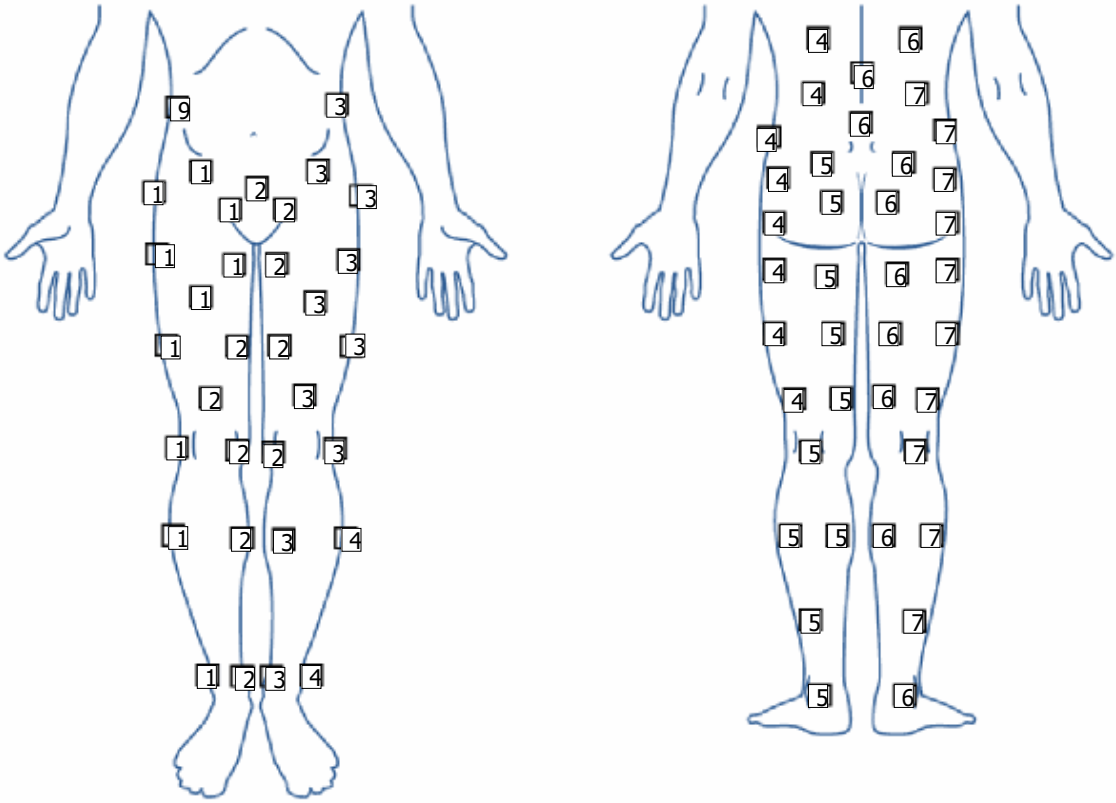
SIJ PAIN WITH ACTIVITY (PAGE 3)

Enter answers for each from patient questionnaire:

Sitting on a chair squarely (evenly on both buttocks)	9 pain	Walking more with toes touching first:	20 pa
Sitting on a chair on your left buttock:	10 pa	Walking more with heels touching first:	21 pa
Sitting on a chair on your right buttock:	11 pa	Lying on your left side:	22 pa
Standing up from sitting in a chair:	12 pa	Lying on your right side:	23 pa
Sitting down onto a chair from standing:	13 pa	Lying on your back:	24 pa
Walking up stairs:	14 pa	Lying on your stomach:	25 pa
Walking down stairs:	15 pa	Rolling over in bed:	26 pa
Walking up an incline:	16 pa	Transitioning from lying down to sitting up:	27 pa
Walking down an incline:	17 pa	Bending forward at waist:	28 pa
Getting into a car:	18 pa	Twisting to your left at waist:	29 pa
Getting out of a car:	19 pa	Twisting to your right at waist:	30 pa

SI JOINT WORST PAIN LOCATION (PAGE 2)

Check the single box that the subject "circled" on the corresponding source worksheet as causing the most pain:



80 N/A the subject did not circle any single box.

81 N/A the subject circled multiple boxes.

STUDY 023 Page # 101 Visit # 101

Subject ID: 7 ID Initials: 8 initials

STUDY EXIT

Date subject completed or discontinued from the study: 9 exitdt (dd/mon/yyyy)

Study exit due to:

10 ☐ Completion of study as planned → Skip to Investigator Statement

Discontinued prematurely due to:

11 ☐ Withdrawal of consent
☐ Adverse event preventing participation
☐ Death → **Adverse Event Form**
☐ Lost to follow-up
☐ Other (explain):

Note: At least 3 documented attempts to contact patient must be included in the patient's study records; Site to confirm that the patient is not deceased.

12 reasexitother

General comment on exit:

17 exitcom

INVESTIGATOR'S STATEMENT:

13 ☐ **I have reviewed all of the data captured on this subject's Case Report Forms and verify that all data accurately reflect the information in the source documents.**

6 AEID

STUDY 023 Page # 121

9 issaemm

Subject ID: 7 ID Initials: 8 initials

ADVERSE EVENT

COMPLETE ONE FORM FOR EACH ADVERSE EVENT

AE term: (diagnosis if known) 10 aedesc

AE start date: 11 aestartdt Date site became aware of AE: 12 aeawaredt

Date AE reported to sponsor: 13 aerptspdt

Is this a Serious Adverse Event? 14 issae Yes → complete section below

Did this AE result in death? 15 aedeath Yes

Is this a serious deterioration in health? 16 isserdet Yes → complete section below:

Serious deterioration in the health of the subject, that resulted in:

- 17 a life-threatening illness or injury
- 18 a permanent impairment of a body structure or a body function
- 19 in-patient or prolonged hospitalization
- 20 medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- 21 fetal distress, fetal death or a congenital abnormality or birth defect

If this AE qualifies as an SAE the Sponsor must be informed within 24 hours of site becoming aware of event meeting the definition. Any of the following are acceptable methods of communication: completion of form in datafax, email, phone, fax, etc.

Was this a non-serious AE that developed into an SAE? 22 nonserb Yes → Date event became SAE: 23 serdt

Action(s) Taken (Check all that apply):

24 None 25 Study Discontinuation 26 Medical Therapy 27 Surgery 28 Procedure 29 Other

Explain: 30 aeacttaken

31 intcomm

Subject ID: 7 ID Initials: 8 initials

Relationship (Determined by PI)

Relation to iFuse-3D device: 9 aerelatdev N/A

Relation to iFuse-3D placement procedure: 10 aerelatproc N/A

Relation to another procedure done for SI joint problem: 11 aerelatprocNSM N/A

If 'possibly,' 'probably,' or 'definitely' to an SIJ-related procedure, describe procedure: 12 relprocdes

Relation to pre-existing condition: 13 aerelprex Yes If yes, provide medical history item number: 14 rel

Is this AE related to another AE entered in EDC? 15 relotherae Yes → AE number: 16 relot

Severity (Determined by PI - see definitions below)

17 aesev Severe

Mild = AE transient & easily tolerated
Moderate = AE causes discomfort & interrupts subject's usual activities
Severe = AE causes considerable interference with subject's usual activities; may be incapacitating and may require hospitalization

Event Status

18 Event resolved on: 19 aeoutdt

Event resolved with sequelae on: 20 aeresseqsp

Ongoing (please update this form at each study visit until study exit)

Death on: 21 aedeathdt

Comments: (Provide other relevant medical information regarding AE/SAE, i.e., additional medications, tests performed, etc. that may be useful for review of event **OR** to record any additional follow-up information relating to resolution of previously-reported event).

22 aecomm

INVESTIGATOR'S STATEMENT:

23 **I have reviewed and attest to the accuracy of all of the data captured on this adverse event form.**

Subject ID: 7 ID Initials: 8 initials

REVISION

A revision occurs when a study subject undergoes a second operation to revise previous iFuse implants. Do not complete for "contralateral fusion" unless the contralateral side was revised.

Side revised: 9 revisedside Both

Original surgery date for revised side: 10 insurgdt dd/mon/yyyy

Revision surgery date: 11 revsurgdt dd/mon/yyyy

Reason for revision: 12 reasrev

Description of revision: 13 revdes

Revision performed by (last name): 14 revperfby

6 devID

STUDY 023 Page # 131

Subject ID: 7 ID Initials: 8 initials

PROTOCOL DEVIATION

Deviation timing

9 devtime

Study exit

Adverse event #: 10 aeID

Other: 11 devtimothr

Deviation type: (select one)

12

- Written consent form not completed prior to study activity
- Required HIPAA Authorization not completed prior to study activity
- Patient did not meet eligibility criteria (describe specifics below.)
- Protocol-required test/procedure not done (describe specifics below).
- Protocol-required test/procedure done but not according to protocol (describe specifics below).
- Protocol-required test/procedure done outside window (describe specifics below).
- Protocol-required visit not done (describe specifics below).
- Protocol-required visit done outside window (describe specifics below).
- Other (specify): 13 devtypeother

Description of deviation and corrective action if necessary:

14 devdesc

Did you report deviation to IRB?

15 Yes, date reported on: 16 devrptdt

Not required to report, reason: 17 reasdevnotrep

Deviation pre-approved by sponsor?

18 devpreapp Yes

INVESTIGATOR'S STATEMENT:

19 **I have reviewed this deviation report and attest to its accuracy.**

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20 LCUser 21 LCDate 22 LCTime

6 narrID

Subject ID: 7 ID Initials: 8 initials

NARRATIVE

What page is being referred to in this narrative? 9 narrpageref

Add any information here:

10 narr

11 narrdate

12 LCUser 13 LCDate 14 LCTime

6 devmalfl

STUDY 023 Page # 152

Subject ID: 7 ID Initials: 8 initials

DEVICE DEFICIENCY OR MALFUNCTION

A device deficiency is any problem related to the identity, quality, durability, reliability, safety or performance of the device. This includes reporting of device deficiencies/malfunctions that did not lead to an AE but could have if: 1) suitable action had not been taken, 2) intervention had not been made, or 3) circumstances had been less fortunate. Use this form only for deficiencies or malfunctions of SI-BONE products.

Date of malfunction / failure: 9 devmalfdt (dd/mon/yyyy)

Device lot number: 10 lotnum

Device malfunction of: 11 malftype

- Broach did not create a sufficient channel for implantation
- Impactor did not direct the placement of the implant into the proper location
- Parallel Pin Guide did not provide adequate spacing between the pins
- Removal Tool did not engage with the implant during intraoperative adjustment or removal
- Packaging problem

12 malftypeother

Detailed explanation of malfunction: 13 malfdet

Was there adverse event related to malfunction or failure? 14 aemalf Yes→ **Complete Adverse Event Form and indicate AE #:** 15 aen

If more space is needed, use a Narrative Summary form.

Note: If a device manufactured by SI-BONE malfunctions or fails, please follow SI-BONE instructions on handling of device.

Version D 19APR2018

16 LCUser 17 LCDate 18 LCTime