Subject ID 7 ID 8 mydob

Informed Consent Form Signed : 9 confrmdt
d d / m m / y y

ELIGIBILITY

Inclusion Criteria (Note: all questions must be answered Yes to qualify)	Yes	No
1. Age 21-70 at time of screening	10 inc1	
2. Patient has lower back pain for >6 months or >18 months for pregnancy induced lower back pain	11 inc2	
3. Diagnosis of the SI joint as the primary lower back pain generator 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 at least 3 of 5 physical examination maneuvers specific for SI joint pain (Compression, Östgaard 4P (Thigh Thrust), Patrick's (Faber), Long Ligament Test, and Gaenslen's), and c. Patient has improvement in lower back pain NRS of at least 50% of the pre injection NRS score after fluoroscopic controlled injection of local anesthetic into affected SI joint(s) (including previous documented test <6 months ago)	12 inc3	
4. Baseline Oswestry Disability Index (ODI) score of at least 30%	13 inc4	
5. Baseline lower back pain score of at least 50 on 0-100 point VAS	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	

Exclusion Criteria (Note: All questions must be answered No to qualify)	Yes	No
1. Severe lower back pain due to other causes, such as lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, and lumbar vertebral body fracture	17 exc1	
2. Sacroiliac pathology caused by auto-immune disease (e.g. ankylosing spondylitis) and/or neoplasia (e.g. benign or malignant tumor) and/or crystal arthropathy	18 exc2	
3. History of recent (<1 year) fracture of the pelvis with documented malunion, non-union of sacrum or ilium or any type of internal fixation of the pelvic ring.	19 exc3	
4. Spine surgery during the past 12 months.	20 exc4	
5. Previously diagnosed or suspected osteoporosis (defined as prior T-score <-2.5 or history of osteoporotic fracture)	21 exc5	
6. Documented osteomalacia or other metabolic bone disease	22 exc6	
7. Any condition or anatomy that makes treatment with the iFuse Implant System infeasible	23 exc7	
8. Known allergy to titanium or titanium alloys	24 exc8	
9. Use of medications known to have detrimental effects on bone quality and soft-tissue healing	25 exc9	
10. Prominent neurologic condition that would interfere with physical therapy	26 exc10	
11. Current systemic infection or local infection at the SI joint	27 exc11	
12. Currently pregnant or planning pregnancy in the next year	28 exc12	
13. Known or suspected drug or alcohol abuse	29 exc13	
14. Diagnosed psychiatric disease (e.g., schizophrenia, major depression, personality disorders) that could interfere with study participation	30 exc14	
15. Patient is participating in an investigational study or has been involved in an investigational study within 3 months of surgery	31 exc15	

Subject ID 7 ID 8 mydob

SI JOINT INJECTION

Information from SI joint injection performed within 6 months prior to evaluation for eligibility may be used. .

	9 LEFT	10 RIGHT
Date of injection procedure:	11 sijinjdtl	12 sijinjdtr
Amount of local anesthetic injected:	13 amtan cc	14 amtan cc
Pain level immediately prior to injection:	15 p 0-10 scale	16 p 0-10 scale
Half hour after injection, pain NRS:	17 p 0-10 scale	18 p 0-10 scale
One hour after injection, pain NRS:	19 p 0-10 scale	20 p 0-10 scale

Subject ID: 7 ID | 8 mydob Visit Date: 9 basevisdt

DEMOGRAPHICS

Date of birth:	10 dob	*(mm/yy)*
Date consent form signed:	11 consdt	*(dd/mm/yy)*
Gender:	12 gender	Female
Weight:	13 wtkg	kg
Height:	14 heigh	cm
Smoking status	Current smoker 15 Former smoker →	Quit in 16 quityr *(yyyy)*
	Never smoker	

SIGNIFICANT GENERAL MEDICAL HISTORY

Record Body System Number from below table and describe condition. Please record a single condition per line

1 = Head, Eyes, Ears, Nose, Throat	6 = Neurological	11 = Psychiatric
2 = Cardiovascular	7 = Endocrine/Metabolic	12 = Surgery
3 = Respiratory	8 = Hematological	13 = Allergies
4 = Gastrointestinal	9 = Genitourinary	14 = Other
5 = Musculoskeletal (non-spine)	10 = Dermatological	

Body System No.	Condition
18 med	19 medcond1
20 med	21 medcond1
22 med	23 medcond1
24 med	25 medcond1
26 med	27 medcond1
28 med	29 medcond1
30 med	31 medcond1
32 med	33 medcond1
34 med	35 medcond1
36 med	37 medcond1
38 med	39 medcond1
40 med	41 medcond1
42 med	43 medcond1

17 *No baseline medical conditions*

If more space needed, use narrative form.

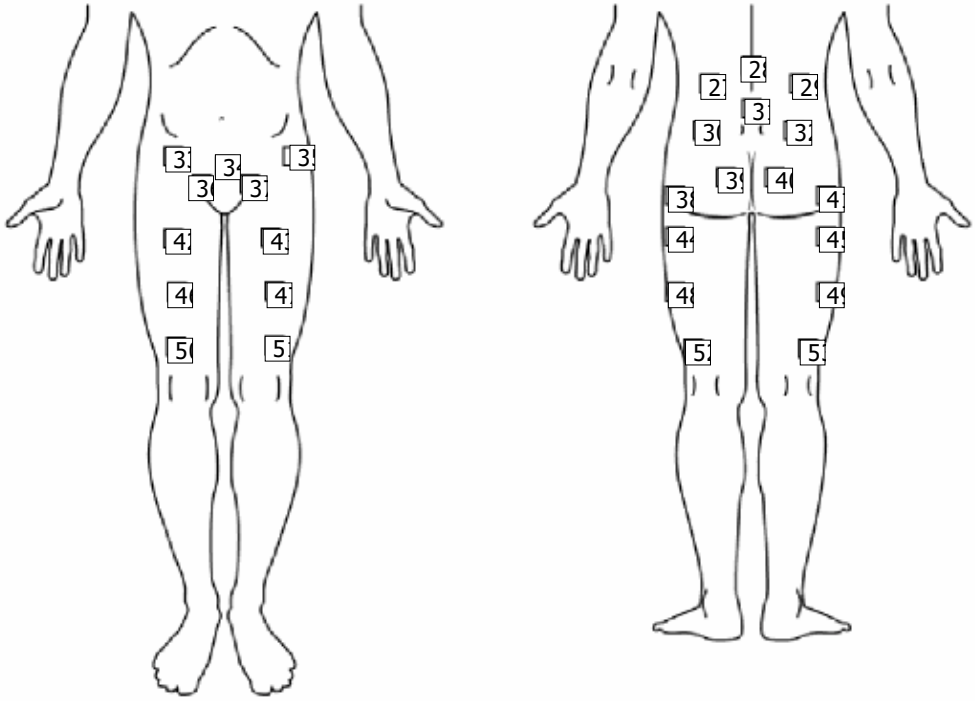
Subject ID: 7 ID | 8 mydob

SI JOINT PAIN HISTORY

Date SI joint pain started	9 pa / 10 painst mm/yyyy
Pain began in peripartum time period?	11 painperi No
Pain radiates down leg?	12 painradle No
Pain in groin?	13 paingroir No
Pain worse with sitting?	14 painsit No
Pain worse rising from chair?	15 painris No
Pain worse with walking?	16 painwalk No
Pain worse with climbing stairs?	17 painclimt No
Pain worse descending stairs?	18 paindesc No
Has subject had **physical therapy** specifically directed at SI joint?	19 priorpt Yes → Number of courses of PT in last 2 years: 20
Has subject had **steroid injections** of SI joint aimed at treating pain?	21 priorste Yes → Number of SIJ injections in last 5 years: 22
Has subject had **prolotherapy** of SI joint?	23 priorpro Yes → Number of prolotherapy injections in last 5 years: 24
Has subject had **RF ablation** of SI joint?	25 priorrfa Yes → Number of RF ablations in last 5 years: 26

SI Joint Pain Location

Check box over every location where patient experiences moderate-to-severe pain.



Subject ID: 7 ID | 8 mydob

OTHER BACK PROBLEMS

Has patient had back surgery or interventional back procedures before

9 No

		Date (mm/yyyy)
1	10 backsurg1	11 b / 12 backs
2	13 backsurg2	14 b / 15 backs
3	16 backsurg3	17 b / 18 backs
4	19 backsurg4	20 b / 21 backs
5	22 backsurg5	23 b / 24 backs
6	25 backsurg6	26 b / 27 backs

Does patient have history of hip problems?

28 hohip Yes

Current hip diagnoses: 29 hipdxs

Affected side(s) (choose all that apply): 30 Right 31 Left

Prior surgical/non-surgical treatments for hip problems:

	Treatment for hip problem	Date (mm/yyyy)
1	32 hiptrt1	33 h / 34 hiptrt
2	35 hiptrt1	36 h / 37 hiptrt

History of sacral trauma and/or insufficiency fracture?

38 hosactr Yes → Describe: 39 sacdxs

Prior treatments:

	Treatment	Date (mm/yyyy)
1	40 sactrt1	41 s / 42 sactrt
2	43 sactrt1	44 s / 45 sactrt

Does patient have Pubis Symphysis pain?

46 hopubs Yes → Describe: 47 pubsymds

Prior treatments:

	Treatment for Pubis Symphysis pain	Date (mm/yyyy)
1	48 pubtrt1	49 p / 50 pubtr
2	51 pubtrt1	52 p / 53 pubtr

Subject ID: 7 ID | 8 mydob

Medications Taken Specific to Lower Back or SI Joint Pain

Enter medications taken in last 2 weeks specific for lower back pain. If not taking, check box.

Class	Not Taking	Medication Name (use generic name)	Average Daily Dose, mg
Non-opioid analgesics (aspirin, paracetamol, NSAIDs)	9	10 nonopoid1	11 nonopic
		12 nonopoid2	13 nonopic
		14 nonopoid3	15 nonopic
Mild opioids with or without non-opioid (codeine, dihydrocodeine)	16	17 narcmild1	18 narcmilc
		19 narcmild2	20 narcmilc
		21 narcmild3	22 narcmilc
Strong opioids with or without non-opioid	23	24 narcstrong1	25 narcstrc
		26 narcstrong2	27 narcstrc
		28 narcstrong3	29 narcstrc

OTHER MEDICATIONS TAKEN AT BASELINE

Enter any medication used on a regular basis for conditions **other than** lower back/SI joint pain. 30 **NONE**

Medication Name*	Reason for Use
31 othmed1	32 othmedreas1
33 othmed1	34 othmedreas1
35 othmed1	36 othmedreas1
37 othmed1	38 othmedreas1
39 othmed1	40 othmedreas1
41 othmed1	42 othmedreas1
43 othmed1	44 othmedreas1
45 othmed1	46 othmedreas1
47 othmed1	48 othmedreas1

*Example: hydrochlorothiazide for hypertension.

If more space needed, use narrative form.

Subject ID: 7 ID | 18 mydob

PATIENT QUESTIONNAIRES

Zung Depression Scale done?	8 zungdn No
EQ-5D done?	9 eq5ddn No
Walking distance done?	10 walkddn No
Ambulatory status done?	11 ambdn No
Work status done?	12 workdn No

RANDOMIZATION

Randomize patient after all baseline assessments are done. For randomization assignments:

- Go to siboneclinical.com
- Click on randomization tab
- Enter patient ID number
- Click Randomize
- **Record randomization ID and assignment below**.

Randomization ID: 13 randID

Subject randomized to: 14 Conservative management / iFuse

Subject ID: 7 ID | 8 mydob

Visit date: 9 priorprocdt

PRIOR TO IFUSE PROCEDURE

Preoperative Motor Exam

Muscle Group	Left	Right
Knee extension (L3)	10	11
Ankle dorsiflexion (L4)	12	13
Extensor hallicus longus (L5)	14	15
Ankle plantar flexion (S1)	16	17

Scoring system:
0 – No muscle contraction
1 – Trace of muscle contraction
2 – Active movement without gravity
3 – Active movement against gravity
4 – Active movement against gravity, some movement
5 – Normal, active movement against full resistance

Preoperative Sensory Exam

	LEFT	RIGHT
Sensory deficit on neurologic exam?	18 sensdefL Yes → Specify dermatome:	25 sensdefR Yes → Specify dermatome:
	19 L1	26 L1
	20 L2	27 L2
	21 L3	28 L3
	22 L4	29 L4
	23 L5	30 L5
	24 S1	31 S1

Preoperative Reflexes Exam

Reflex	Left	Right
Knee Jerk	32	33
Ankle Jerk	34	35

Scoring system: 0 – Absent 1 – Diminished 2 – Normal 3 - Hyper-reflexive

Staged Procedure

Is a staged procedure planned?

Staged procedure means the investigator plans to treat the contralateral SI joint in next month or two.

36 staged Yes → Complete a second procedure form after the second procedure is performed.

Subject ID: 7 ID | 50 mydob

IFUSE PROCEDURE

Surgery Information

Procedure date:	8 procdt	*(dd/mm/yy)*
Which is the current target SI joint?	9 targsij	Right
Start time (initial incision)	10 pr | 11 pr	(24 hour clock)
End time of surgery (closure complete)	12 pr | 13 pr	(24 hour clock)
Total fluoroscopy time:	51 fluorot	minutes
Estimated blood loss	14 ebl	cc

iFuse Devices Used

Implant #	Diameter		Length								
	4	7	30	35	40	45	50	55	60	65	70
1	16 impdiam1		17 implen1								
2	19 impdiam2		20 implen2								
3	22 impdiam3		23 implen3								
4	25 impdiam4		26 implen4								

iFuse Placement Results

Implant #	Pin: Were you able to advance pin in the appropriate trajectory? Yes	Pin No	Drill: Were you able to drill hole into the sacral cortex? Yes	Drill No	Broach: Did broach create necessary channel suitable for implantation of iFuse? Yes	Broach No	Implantation: Were you able to deliver iFuse implant to the intended location? Yes	Implantation No
1	28 pin1		29 drill1		30 bro1		31 deliv1	
2	33 pin2		34 drill2		35 bro2		36 deliv2	
3	38 pin3		39 drill3		40 bro3		41 deliv3	
4	43 pin4		44 drill4		45 bro4		46 deliv4	

Surgical Complications

Any complications during pinning, drilling, broaching or implantation? 47 proccom Yes → Describe below

Complication description:

48 compdesc

Adverse Events

Any adverse events/complications during procedure? 49 procadv Yes → Complete AE form

Subject ID: 7 ID | 8 mydob

SECOND IFUSE PROCEDURE

9 s NOT APPLICABLE

Use this form to record information from iFuse placement on **contralateral side** for subjects undergoing **bilateral surgery.**

Surgery Information

Procedure date:	10 procdt	*(dd/mm/yy)*
Which is the current target SI joint?	11 targsij Right	
Start time (initial incision)	12 pr 13 pr	(24 hour clock)
End time of surgery (closure complete)	14 pr 15 pr	(24 hour clock)
Total fluoroscopy time:	16 fluorot	minutes
Estimated blood loss	17 ebl	cc

iFuse Devices Used

Implant #	Diameter 4	Diameter 7	Length 30	35	40	45	50	55	60	65	70
18 1	19 impdiam1		20 implen1								
21 2	22 impdiam2		23 implen2								
24 3	25 impdiam3		26 implen3								
27 4	28 impdiam4		29 implen4								

iFuse Placement Results

Implant #	Pin: Were you able to advance pin in the appropriate trajectory? Yes	Pin No	Drill: Were you able to drill hole into the sacral cortex? Yes	Drill No	Broach: Did broach create necessary channel suitable for implantation of iFuse? Yes	Broach No	Implantation: Were you able to deliver iFuse implant to the intended location? Yes	Implantation No
1	30 pin1		31 drill1		32 bro1		33 deliv1	
2	34 pin2		35 drill2		36 bro2		37 deliv2	
3	38 pin3		39 drill3		40 bro3		41 deliv3	
4	42 pin4		43 drill4		44 bro4		45 deliv4	

Surgical Complications

Any complications during pinning, drilling, broaching or implantation? 46 proccom Yes → Describe below

Complication description: 47 compdesc

Adverse Events

Any adverse events/complications during procedure? 48 procadv Yes → Complete AE form

Subject ID: 7 ID | 8 mydob

PRIOR TO DISCHARGE (IFUSE ONLY)

Postoperative Radiography

9 CT done → Date performed: 10 postopctdt

CT not done because: 11 ctnotdnreas

Postoperative Motor Exam

Muscle Group	Left	Right
Knee extension (L3)	12 k	13 k
Ankle dorsiflexion (L4)	14 k	15
Extensor hallicus longus (L5)	16	17
Ankle plantar flexion (S1)	18	19

Scoring system:
0 – No muscle contraction
1 – Trace of muscle contraction
2 – Active movement without gravity
3 – Active movement against gravity
4 – Active movement against gravity, some movement
5 – Normal, active movement against full resistance

Postoperative Sensory Exam

	LEFT	RIGHT
Sensory deficit on neurologic exam?	20 sensdefl Yes → Specify dermatome:	27 sensdefr Yes → Specify dermatome:
	21 L1	28 L1
	22 L2	29 L2
	23 L3	30 L3
	24 L4	31 L4
	25 L5	32 L5
	26 S1	33 S1

Postoperative Reflexes Exam

Reflex	Left	Right
Knee Jerk	34	35
Ankle Jerk	36	37

Scoring system:
0 – Absent
1 – Diminished
2 – Normal
3 - Hyper-reflexive

Adverse events

Any adverse events prior to hospital discharge? 38 aepriord Yes → Complete AE form

Discharge Information

Hospital discharge date: 39 hospdisdt *dd/mm/yy*

Subject ID: 7 ID | 8 mydob

9 Page not Applicable

PRIOR TO DISCHARGE SECOND PROCEDURE (IFUSE ONLY)

Postoperative Radiography

10 CT done → Date performed: 11 postopctdt

CT not done because: 12 ctnotdnreas

Postoperative Motor Exam

Muscle Group	Left	Right
Knee extension (L3)	13	14
Ankle dorsiflexion (L4)	15	16
Extensor hallicus longus (L5)	17	18
Ankle plantar flexion (S1)	19	20

Scoring system:
0 – No muscle contraction
1 – Trace of muscle contraction
2 – Active movement without gravity
3 – Active movement against gravity
4 – Active movement against gravity, some movement
5 – Normal, active movement against full resistance

Postoperative Sensory Exam

	LEFT	RIGHT
Sensory deficit on neurologic exam?	21 sensdefl Yes → Specify dermatome:	28 sensdefr Yes → Specify dermatome:
	22 L1	29 L1
	23 L2	30 L2
	24 L3	31 L3
	25 L4	32 L4
	26 L5	33 L5
	27 S1	34 S1

Postoperative Reflexes Exam

Reflex	Left	Right
Knee Jerk	35	36
Ankle Jerk	37	38

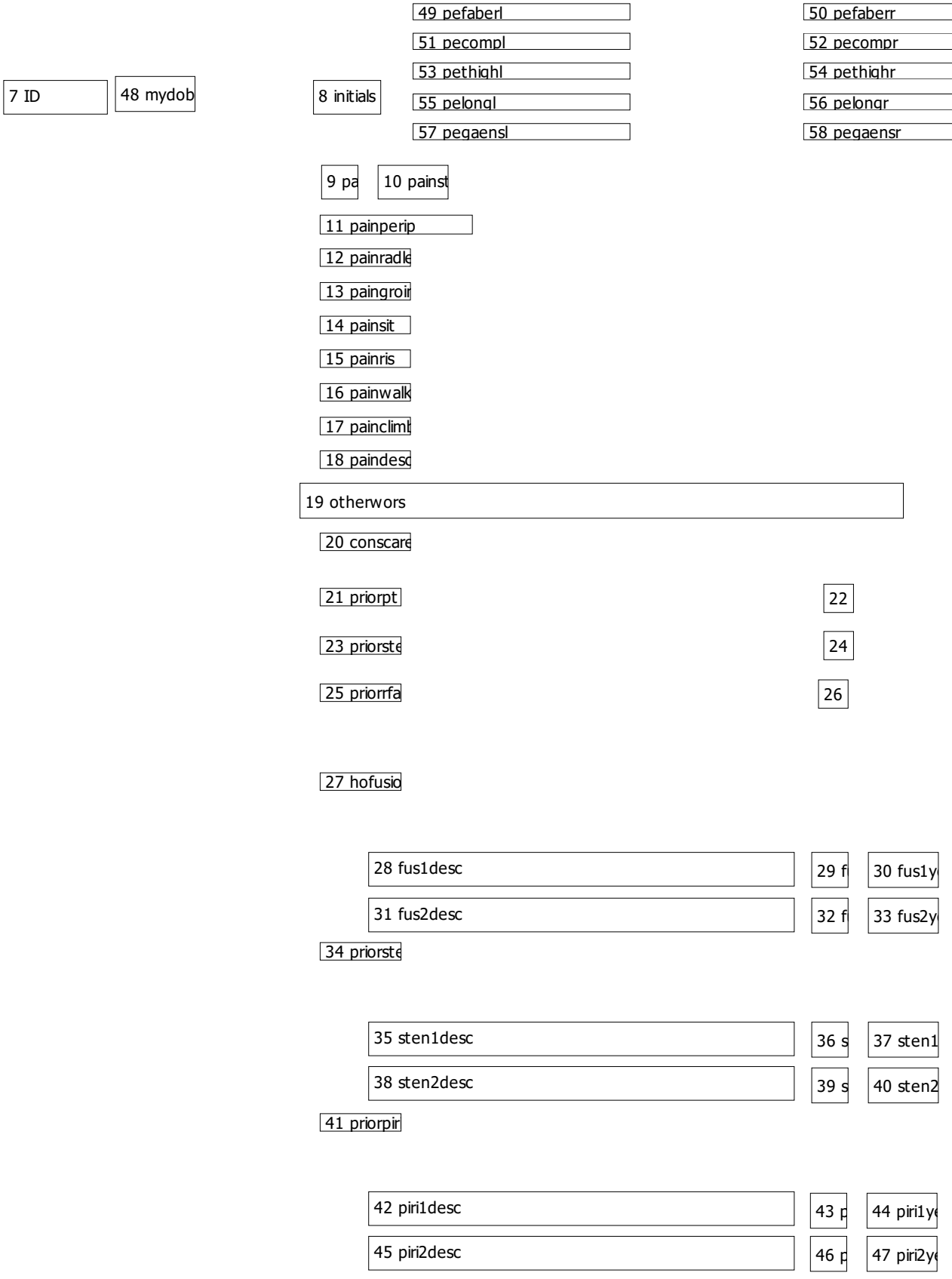
Scoring system:
0 – Absent
1 – Diminished
2 – Normal
3 - Hyper-reflexive

Adverse events

Any adverse events prior to hospital discharge? 39 aepriord Yes → Complete AE form

Discharge Information

Hospital discharge date: 40 hospdisdt *dd/mm/yy*


49 pefaberl
50 pefaberr
51 pecompl
52 pecompr
53 pethighl
54 pethighr
7 ID
48 mydob
8 initials
55 pelongl
56 pelongr
57 pegaensl
58 pegaensr
9 pa
10 painst
11 painperip
12 painradle
13 paingroir
14 painsit
15 painris
16 painwalk
17 painclimt
18 paindesc
19 otherwors
20 conscare
21 priorpt
22
23 priorste
24
25 priorrfa
26
27 hofusio
28 fus1desc
29 f
30 fus1y
31 fus2desc
32 f
33 fus2y
34 priorste
35 sten1desc
36 s
37 sten1
38 sten2desc
39 s
40 sten2
41 priorpir
42 piri1desc
43 p
44 piri1y
45 piri2desc
46 p
47 piri2y

Subject ID: 7 ID

BASELINE SIDE

This form used internally to designate which side is the "target" side at baseline.

Target side: 8 targside

Display of information from other forms:

INJECTION

	9 LEFT	10 RIGHT
Date of injection procedure:	11 sijinjdtl	12 sijinjdtr
Amount of local anesthetic injected:	13 amtar cc	14 amtar cc
Pain level immediately prior to injection:	15 p 0-10 scale	16 p 0-10 scale
Half hour after injection, pain NRS:	17 p 0-10 scale	18 p 0-10 scale
One hour after injection, pain NRS:	19 p 0-10 scale	20 p 0-10 scale

PHYSICAL EXAMINATION (BASELINE)

Provocative Test	Left SI Joint		Right SI Joint	
FABER	21 pefaberl	Not Done	22 pefaberr	Not Done
Compression	23 pecompl	Not Done	24 pecompr	Not Done
Thigh Thrust	25 pethighl	Not Done	26 pethighr	Not Done
Long Ligament Test	27 pelongl	Not Done	28 pelongr	Not Done
Gaenslen's	29 pegaensl	Not Done	30 pegaensr	Not Done

ACTIVE STRAIGHT LEG RAISING TEST (BASELINE)

Right	31 aslrr	not done
Left	32 aslrl	not done

Scoring system: 0 – not difficult at all; 1 – minimally difficult; 2 – somewhat difficult; 3 – fairly difficult; 4 – very difficult; 5 – unable to do

6 visitseq

Subject ID 7 ID 8 mydob

SCHEDULED FOLLOW-UP STUDY VISIT

Visit Date: 9 fuvisdt *(DD/MM/YY)*

Patient Questionnaires

Has the subject completed all patient questionnaires 10 fucompq No → reason: 11 reasptnd

Adverse Events Since Last Contact

Has the subject experience an adverse event since last visit? 12 aelastvis Yes → complete AE form

Medications Taken Specific to Lower Back or SI Joint Pain

Enter medications taken in last 2 weeks specific for lower back pain. If not taking, check box.

Class	Not Taking	Medication Name (use generic name)	Average Daily Dose, mg
Non-opioid analgesics (aspirin, paracetamol, NSAIDs)	13	14 nonopoid1	15 nonop
		16 nonopoid2	17 nonop
		18 nonopoid3	19 nonop
Mild opioids with or without non-opioid (codeine, dihydrocodeine)	20	21 narcmild1	22 narcmi
		23 narcmild2	24 narcmi
		25 narcmild3	26 narcmi
Strong opioids with or without non-opioid	27	28 narcstrong1	29 narcstr
		30 narcstrong2	31 narcstr
		32 narcstrong3	33 narcstr

Radiography

Only for iFuse patients prior to discharge and 12 months post iFuse procedure.

CT scan performed? 34

- Yes. Date of CT: 35 ctdt
- Required but not done because:
- Not required, not an iFuse patient
- Not required during this visit

Be sure to send CD to sponsor!

36 ctnotdnsp

37 LCUser 38 LCDate 39 LCTime

6 visitseq

Subject ID 7 ID 8 mydob

Visit ID:

Physical Examination

Provocative Test	Left SI Joint		Right SI Joint	
FABER	9 pefaberl	Not Done	10 pefaberr	Not Done
Compression	11 pecompl	Not Done	12 pecompr	Not Done
Thigh Thrust	13 pethighl	Not Done	14 pethighr	Not Done
Long Ligament Test	15 pelongl	Not Done	16 pelongr	Not Done
Gaenslen's	17 pegaensl	Not Done	18 pegaensr	Not Done

Subject ID 7 ID | 8 mydob **Visit ID:**

Active Straight Leg Raising Test

Right	9 aslrr	not done
Left	10 aslrl	not done

Scoring system: 0 – not difficult at all 1 – minimally difficult 2 – somewhat difficult
3 – fairly difficult 4 – very difficult 5 – unable to do

6 visitseq

Subject ID 7 ID 8 mydob

BACK-RELATED HEALTHCARE UTILIZATION NOT REQUIRED BY STUDY

Since the last study visit, how many of each of the following, back-related healthcare activities has the subject had **outside of the clinical trial**? **Do not include any procedure required by clinical trial.**

	No	Yes	
1. Surgery		11 hcusur	Date of surgery: 9 surgdt Surgery type: 10 surgtype Reason for surgery: 12 surgreas
2. Consultations		13 hcucor	

Type of Care	Number of Visits	Type of Care	Number of Visits
Acupuncture	14 co	Home social worker	15 co
Chiropractise	16 co	Pain clinic	17 co
Physical therapy	18 co	Physician office	19 co
Emergency room	20 co	Psychiatric	21 co
Home health care	22 co	Other: 23 constypeother	24 co

3. Hospitalization	25 hcuhos			
	26	Nursing home	27 ho days	Reason: 28 hospnhreas
	29	Rehabilitation center	30 ho days	Reason: 31 hosprehabreas
	32	Hospital	33 ho days	Reason: 34 hosphospreas
4. Medical Equipment	35 hcume			
	36	Belt		Cost 37 mecBelt €
	38	Brace		Cost 39 mecBrac €
	40	Walking aid		Cost 41 mecWAid €
	42	Other: 43 meothsp		Cost 44 mecOth €
5. Radiology	45 hcurad			

	Num examinations
46 MRI	47 radn
48 CT	49 radn
50 X-ray (radiograph)	51 radn

6. Interventional Procedures	52 hcuinte	Type	Num procedures
		53 Steroid injections	54 intn
		55 Prolotherapy	56 intn
		57 RF ablation	58 intn
		59 Other: 60 intOthersp	61 intn

6 visitseq

Subject ID: 7 ID | 10 mydob

Visit ID:

VAS

Read VAS value from worksheet and enter here.

VAS pain rating for lower back	8 vaslb	range (0-100)
VAS pain rating for leg	9 vassi	range (0-100)

Subject ID: 7 ID | 8 mydob

Visit ID: 6 visitseq

OSWESTRY DISABILITY INDEX

Enter values from worksheet completed by patient.

1	9	6	10
2	11	7	12
3	13	8	14 or 15 Not answered
4	16	9	17
5	18	10	19

Total score: 20 odit %

Note: Score each of the 10 ODI questions on a 0-5 scale:

0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable

Subject ID: 7 ID | 14 mydob

Visit ID: 6 visitseq

EQ-5D

Enter values from worksheet completed by patient.

1. Mobility	8	(1-3)
2. Self-care	9	(1-3)
3. Usual activities	10	(1-3)
4. Pain / discomfort	11	(1-3)
5. Anxiety / depression	12	(1-3)
6. Health today	13 eqv	(0-100)

Note: Valid values for EQ-5D questions 1-5 are 1, 2 or 3.

6 visitseq

Subject ID 7 ID 8 mydob

ZUNG DEPRESSION SCALE

Place check mark in correct column	A little of the time	Some of the time	Good part of the time	Most of the time
1. I feel down-hearted and blue.	9 zung1			
2. Morning is when I feel the best.	10 zung2			
3. I have crying spells or feel like it.	11 zung3			
4. I have trouble sleeping at night.	12 zung4			
5. I eat as much as I used to.	13 zung5			
6. I still enjoy sex.	14 zung6			
7. I notice that I am losing weight.	15 zung7			
8. I have trouble with constipation.	16 zung8			
9. My heart beats faster than usual.	17 zung9			
10. I get tired for no reason.	18 zung10			
11. My mind is as clear as it used to be.	19 zung11			
12. I find it easy to do the things I used to.	20 zung12			
13. I am restless and can't keep still.	21 zung13			
14. I feel hopeful about the future.	22 zung14			
15. I am more irritable than usual.	23 zung15			
16. I find it easy to make decisions.	24 zung16			
17. I feel that I am useful and needed.	25 zung17			
18. My life is pretty full.	26 zung18			
19. I feel that others would be better off if I were dead.	27 zung19			
20. I still enjoy the things I used to do.	28 zung20			

Total score: 32 zungtotal

6 visitseq

Subject ID: 7 ID | 11 mydob

Visit ID:

Overall Assessment of Disease State

Compared to baseline, how would you rate your current disease state:	10	Much Better Better Same Worse

Satisfaction

Current level of satisfaction with the treatment assigned to you	8	Very dissatisfied Somewhat dissatisfied Somewhat satisfied Very satisfied
Would you undergo the treatment assigned to you again?	9	Definitely NOT Don't know (no opinion) Definitely YES

6 visitseq

Subject ID 7 ID 12 mydob

WORK STATUS

Work status	8	Working normal hours and type of work Working with limitations Not working due to lower back pain Not working due to other reason than lower back pain Retired
Work type	9 worktype	N/A
Number of days of sick leave due to the SI pain during the past 3 months	10 sick days	11 N/A

6 visitseq

Subject ID | 7 ID | 8 mydob

AMBULATORY STATUS

Ability to walk	9	Ambulatory without assistance Ambulatory with assistive device (cane, crutch, walker) Cannot walk

WALKING DISTANCE

How far can you walk at a normal pace?	10	Less than 100 meter 100 to 500 meters 0.5 to 1 kilometer More than 1 kilometer

6 visitseq

Subject ID 7 ID 8 mydob

Physical Therapy Received

Since the last study visit, how many sessions of **physical therapy** has the subject had as part **of the clinical trial**?

Total number of sessions received:	9 nums	
Date FIRST session:	10 PTfirstdt	*dd/mm/yy*
Date LAST session:	11 PTlastdt	*dd/mm/yy*

Cognitive Behavior Treatment

Since last study visit, how many sessions of **cognitive behavior treatment** has the subject had as part **of the clinical trial**?

Total number of sessions received:	12 num	
Date FIRST session:	13 CBTfirstdt	*dd/mm/yy*
Date LAST session:	14 CBTlastdt	*dd/mm/yy*

6 visitseq

Subject ID

7 ID

8 mydob

9	10 nonopoid1	11 nonop
	12 nonopoid2	13 nonop
	14 nonopoid3	15 nonop
16	17 narcmild1	18 narcm
	19 narcmild2	20 narcm
	21 narcmild3	22 narcm
23	24 narcstrong1	25 narcst
	26 narcstrong2	27 narcst
	28 narcstrong3	29 narcst

6 unsv

Subject ID: 7 ID | 18 mydob

UNSCHEDULED VISIT

Use this form for visit to study physician that was NOT scheduled as part of the study.

Unscheduled visit date: 8 unsvisdt

Reason for Visit

Reason for unscheduled visit: 9 reasvisit

Notable physical examination findings: 10 ☐ Normal ☐ Not normal

↓

11 pedesc

If visit occurred because of adverse event, please complete Adverse Event Form.

Imaging Results

If imaging done as a result of this unscheduled visit, what did imaging show?

Type of imaging performed: 12 ☐ X-ray 14 ☐ MRI 13 ☐ CT 15 ☐ Other: 16 uothimgspec

Imaging results:

17 imgres

Subject ID: 7 ID | 8 mydob

CROSSOVER

Subjects may crossover from Conservative Management to iFuse treatment or any other interventional or surgical treatment **after the 6 month evaluation**. (No crossover before 6 months!)

Conservative Management patients crossing over to iFuse should be followed as crossover subjects for at least 12 months after the iFuse procedure.

Date subject crossed over:* 9 crossdt

Reason for crossover:

10 Continued pain

11 Other: 12 crossreasothsp

*Example: date of iFuse surgery.

Inform study sponsor immediately of the crossover decision.

Subject ID 7 ID | 13 mydob

STUDY EXIT

Exit date: 8 exitdt

Study exit due to:

9 ☐ Completion of study as planned

Discontinued prematurely due to:

☐ Withdrawal of consent

☐ Adverse event preventing participation

☐ Death → **Adverse Event Form**

10 ☐ Lost to follow-up

Note: At least 5 documented attempts to contact patient must be included in the patient's study records; Site to confirm that the patient is not deceased.

☐ Other (*explain*):

11 reasexitother

INVESTIGATOR'S STATEMENT:

12 ☐ **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.**

Subject ID: 7 ID | 13 mydob

Deviation #: 6 devID

PROTOCOL DEVIATION

Deviation timing: 8 devtime

- Study exit
- Adverse event
- Unscheduled
- Other: 9 devtimothr

Deviation type: (select one) 10

- Written consent form not completed prior to procedure
- Patient did not meet eligibility criteria
- Protocol-required test/procedure not done
- Protocol-required test/procedure done but not according to protocol
- Protocol-required test/procedure done outside window
- Protocol-required visit not done
- Protocol-required visit done outside window
- Other (specify): 11 devtypeother

Description of deviation: 12 devdesc

6 AEID

Subject ID: 7 ID | 8 mydob

Adverse event #: 22 aesumm | 23 aebody

COMPLETE ONE FORM FOR EACH ADVERSE EVENT

Event start date: 9 aestartdt *(dd/mm/yy)*

Event short description: (Example: "GI bleeding")
10 aedesc

Describe event in more detail:
11 aedesclong

Was iFuse explanted because of this AE?
12 ☐ No
Yes→ Reason for explantation: 13 expreason

Event severity: *(Check one)*

	Term	Definition
14 ☐	Mild	The AE is transient and easily tolerated by the subject.
	Moderate	The AE causes the subject discomfort and interrupts the subject's usual activities.
	Severe	The AE causes considerable interference with the subject's usual activities; may be incapacitating and may require hospitalization.

Event relatedness:

	Not related	Possibly related	Probably related	Definitely related	N/A
Relation to the **iFuse device**	15 aerelatdev				
Relation to the **iFuse placement procedure**	16 aerelatproc				
Relation to a **pre-existing condition** ↓	17 aerelatpre	↓	↓	↓	
If "possibly", "probably" or "definitely" related, to a pre-existing condition, enter pre-existing condition here →	18 precond				

Relatedness definitions:

- **Not related**: The AE is due to an underlying or concurrent illness or effect of another device, drug or intervention and is not related to the study device, device procedure or general surgery.
- **Possibly related**: The causal and/or temporal relationship to the study device, device procedure or general surgery, is equally or less likely than other plausible explanations.
- **Probably related:** The causal and/or temporal relationship to the study device, device procedure or general surgery, is likely or significantly more likely than other plausible explanations.
- **Definitely related**: A clinical event that can only be attributed to the device, device procedure or general surgery.

6 AEID

Subject ID: 7 ID | 8 mydob

Adverse event #:

Event consequences: *(Check all that apply)*

- 9 Led to death
- Led to a serious deterioration in the health of the subject that :
  - 10 resulted in a life-threatening illness or injury
  - 11 resulted in a permanent impairment of a body structure or a body function
  - 12 required hospitalization or prolongation of existing hospitalization
  - 13 resulted in medical or surgical intervention to prevent permanent impairment to body structure or function
- 14 None of above

How was event treated:

- 15 No treatment provided
- 16 Medical therapy → 17 aemedtreat
- 18 Procedure intervention → 19 aeproctreat
- 20 Surgical intervention → 21 aesurgtreat
- 22 Other: → 23 aeothtreat

Event Outcome: 24 aeout

Ongoing

Other: 25 aeoutother

Date of outcome determination: 26 aeoutdt *(dd/mm/yy)*

(Outcome = event resolved or stabilized)

Event reported to Ethics Committee?

27 Yes → Date: 28 aeirbrptdt *(dd/mm/yy)*

(***Note: Please provide a copy to sponsor***)

No → Reason: 29 reasnotrep

Subject ID: 7 ID | 9 mydob

Narr #: 6 narrID

NARRATIVE

Add any information here:

8 narr

Subject ID: 7 ID | 13 mydob | Malf #: 6 devmalfl

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: 8 devmalfdt *(dd/mm/yy)*

Device malfunction of: 9 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

10 malftypeother

Detailed explanation of malfunction: 11 malfdet

Was there adverse event related to malfunction or failure? 12 aemalf Yes→ **Adverse Event Form**

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

Note: If a device manufactured by SI-BONE malfunctions or fails, please return it to SI-BONE for evaluation.