



Complaint - Revision - Post Market - Feedback Reporting

Use this form to submit information about a complaint related to an SI-BONE product to Quality Affairs. Contact QA@si-bone.com if you have any questions.

Select the type of problem you are reporting

Problem with individual device or individual patient

General Feedback about SI-BONE Product

This is only for non complaint information. Examples: surgeon suggestions, meeting discussions, etc. For complaints, go back and select "Problem..."

Contact Info

Use this to record your attempts to contact and gather information from the surgeon.

Your name

Samir Aziz

Your email

samir@freedomortho.co.uk

Your phone number

(779) 921-1242

Surgeon's name

Mr. Bill Harcourt

Contact #1: How did you attempt to contact the surgeon?

In person

Was this attempt successful?

Yes

Complaint Overview

Enter information about surgery that resulted in a problem with any SI-BONE implant, instrument or accessory (e.g., drill bit, pin).

Date you first heard of problem with SI-BONE product.

Tuesday, March 14, 2023

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery.

Sunday, March 1, 2020

Which device(s) was/were affected?

iFuse

iFuse-3D

Part number(s), if available

iFuse Solid 35mm could only be removed

Lot number(s), if available

N/A

Product Complaint or Adverse Event?

Decide what type of report you are submitting.

Use this form to submit information about a complaint related to an SI-BONE product to Quality Affairs. Contact QA@si-bone.com if you have any questions.

What is the nature of the problem you are reporting?

Product complaint that caused or may have caused an adverse event or revision procedure

Product Complaint Without Adverse Event

Use this form to report an SI-BONE product problem that was NOT associated with a patient adverse event.

Examples include:

- Damaged instrument
- Broken pin
- Bent pin
- Pin advancement but no patient injury
- Problem with packaging

If a damaged part injured a patient, go back and click on "Product complaint that caused or may have caused an adverse event."

Select Adverse Event Type

Select from the choices below. Your choice guides which section to complete.

If the first 3 do not apply, select "Other".

If a product problem occurred that did NOT cause a patient problem, go back and complete the "Product Complaint Without Adverse Event" section.

What problem did patient have?

Implant malposition causing nerve irritation

Symptomatic Implant Malposition Form

Use this form if patient experienced symptomatic implant malposition resulting in nerve irritation.

On which side(s) were SI-BONE implants placed during initial surgery?

Both

Which operated side showed postoperative symptoms (i.e., symptoms related to implant malposition)?

Both

Did any SI-BONE staff attend initial surgery?

Unknown

Name of SI-BONE staff in attendance at initial surgery Unkown

(Information should be from SI-BONE staff who attended initial surgery)

The surgeon completed all steps in the IFU, including:

- Patient setup (table, spine neutral position, prone or supine position)
- Inspection of instruments and implants prior to use
- Proper views (lateral, inlet and outlet) obtained during use of instruments and placement of implants that clearly showed recommended anatomic landmarks
- Appropriate implant starting position
- (If performed) proper use of neuromonitoring guide pin and equipment
- Use of length gauge for implant length selection
- Were standard wound closure techniques used?

See summary of IFU steps. Did surgeon complete all steps as shown above?

I don't know

If one or more steps was inaccurately done, describe:

N/A

Were any SI-BONE implants removed or adjusted as a result of this problem?

Yes

Did the patient have SI joint pain relief following the initial procedure? How long was the pain relief ? Yes - 2 years

Date of revision surgery

Wednesday, March 15, 2023

Diagnosis / Reason for the iFuse revision surgery?

Revision SIJF
Bilateral
Male
1968/ 55

Post 3 years SIJF after lumbar fusion - Surgeon/ Centre Unkown
c/o Mr. Harcourt for 1 year 2022
Presented adjacent stenosis post lumbar fusion
5/1 fusion 4/5 ALIF 3/4 Fusion
Decompression by Mr. Harcourt unmasked SIJ Pain
SIJ pain Followed post fusion
Bilateral leg pain
Block twice
Diagnostic steps followed 2022

Details of iFuse revision surgery (Treatment):

Op
Right side first
Inferior iFuse3D engaged with extraction device
Would not extract
Plan B - Osteotomes used (Hospital own instruments as Revision was not communicated at the time of booking until the day before - hospital error)

iFuse3D fixed solid and would not extract - no movement
iFuse3D Superior & iFuse Solid Inferior firmly fixed in ilium not in sacrum - could not extract
Next stage - implant insertion to ensure 3 points of fixation
40mm iFuse3D
Left
Extraction of inferior iFuse Solid
Osteotomes advanced down all 3 planes
Extraction device engaged
Successful extraction of iFuse Solid 30mm
Extraction of superior iFuse3D
Osteotomes advanced down all 3 planes
iFuse3D Superior would not extract and remained insitu
iFuse3D anterior insertion of Cranial/ Central/ Caudal trajectories successful.
No surgical complications.
The void was not filled with graft for the extraction site.

For above question, be specific and include all steps of the revision surgery and any complications.

- Was the implant adjusted, removed or added?
- Were the explant holes filled with bone graft?
- Were osteotomes and the/or the removal adapter used?
- Was any non-iFuse hardware installed?

Was the iFuse Removal System Instrument Set (P/N 400132) and chisels used to explant the iFuse Implant(s)?

No

Patient's outcome following the iFuse revision surgery: Were the patient's pain complaints resolved?

Awaiting to hear back from Mr. Harcourt.

Pain Did Not Improve or Recurred

Use this form if pain did not improve OR pain improved but then recurred

(Information should be from SI-BONE staff who attended initial surgery)

The surgeon completed all steps in the IFU, including:

- Patient setup (table, spine neutral position, prone or supine position)
- Inspection of instruments and implants prior to use
- Proper views (lateral, inlet and outlet) obtained during use of instruments and placement of implants that clearly showed recommended anatomic landmarks
- Appropriate implant starting position
- (If performed) proper use of neuromonitoring guide pin and equipment
Use of length gauge for implant length selection
- Were standard wound closure techniques used?

Surgical Wound Problem

Use this form if patient developed postoperative surgical wound problem (infection, dehiscence).

Other Problem

Use this section ONLY if the patient problem is **NOT**:

- Implant malposition causing nerve irritation
- Pain did not improve or recurred
- Surgical wound problem

Potential Warranty Case

Please help evaluate whether this case could qualify for SI-BONE's warranty policy.

Did patient's situation meet all of the following?

Did patient undergo a revision procedure that met all of the following:

- 1. The initial procedure involved placement of 3 SI-BONE implants on the affected side*
- 2. The revision procedure:*
 - Was completed within 1 year of the initial procedure*
 - Was completed at the same hospital or within the same hospital system as the initial procedure*
 - Was completed during a separate hospitalization from the initial procedure*
- 3. The patient followed all physician instructions after the initial procedure*

Did patient's situation meet warranty criteria shown above?

No, not all of the above apply

Comment on warranty

3 points of fixation achieved on the right side

4 points of fixation achieved on the left side

Revision completed circa 3 years since initial procedure

Number 3 unknown