Friday, August 26, 2022

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

Contact Info

Your name

Francesca O'Mahoney

Your email

francesca.o'mahoney@si-bone.com

Your phone number

(077) 715-0877

Surgeon's name

Paul Davies

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

Email

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

Paul contacted me to say patient wanted implant removed

Complaint Overview

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

Tuesday, July 5, 2022

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

Friday, May 31, 2019

Which device(s) was/were affected?

iFuse-3D

Part number(s), if available

Cranial 7x50mm
central 7x 50mm
Caudal 7x40mm

Lot number(s), if available

Cranial- 2628241
Central- 2641531
Caudal- 2648181

Product Complaint or Adverse Event?

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

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?

Pain did not improve or recurred

Symptomatic Implant Malposition Form

(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?

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?

Pain Did Not Improve or Recurred

Best description of time course of pain recurrence: Pain got better but then recurred

How long was SI joint pain relieved before recurrence of pain symptoms? 1 year

Compared to preoperative level, pain now is Less

CT imaging to evaluate pain recurrence shows: CT was done and doctor has shared findings with me

CT findings (check all that apply) CT shows good placement of implants

Additional CT results / details

CT doesn't show malposition.
Implants seated in bone, not breaching foramen or sacrum.
Unsure why patient experiencing pain- surgeon said pain must be coming from another source.

Is doctor willing to share CT images with SI-BONE? CT done, doctor NOT willing to share

Imaging type used during initial surgery C-arm/fluoro only

Was initial surgery attended by SI-BONE staff member? Yes

Name of SI-BONE staff member attending initial surgery Samir Aziz

(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? Yes, all steps were completed accurately

Were any additional causes of low back / pelvic pain evident or discovered during workup? Yes, alternative diagnoses were discovered or suspected

Describe discovered or suspected other causes of pain

She has previous L4-S1 fusion
On 11th august had central implant removed but still complained of pain

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

No, no implants were adjusted or removed

Describe revision procedure.

Mr Davies tried to remove both the cranial and caudal implants.
First docking a pin down both implants to break away bone with a mallet.
With good effort, tried to attach removal adaptor to both implants but could not.
Did not want to use chisels so left implants in patient and closed up.
So no implants were removed and nothing else was implanted.

Surgical Wound Problem

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

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

Not completed within 1 year