Thursday, June 2, 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

Andrew Riddle

Your email

andrew.riddle@si-bone.com

Your phone number

(310) 401-0269

Surgeon's name

Charles Chang

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

In person

Was this attempt successful?

Yes

Complaint Overview

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

Tuesday, May 24, 2022

Which device(s) was/were affected?

iFuse-3D

Revision implant/instrument

Part number(s), if available

N/A

Lot number(s), if available

N/A

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)	Inadequate engagement in sacrum
Is doctor willing to share CT images with SI-BONE?	CT done, doctor NOT willing to share
Imaging type used during initial surgery	Navigation (e.g., O-arm)
Was initial surgery attended by SI-BONE staff member?	Yes
Name of SI-BONE staff member attending initial surgery	Andrew Riddle

(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?	No other cause determined or suspected
Were any SI-BONE implants removed or adjusted as a result of this problem?	No, no implants were adjusted or removed

Describe revision procedure.

Patient was originally brought in for an SI joint fusion. The patient had prior lumbar fusion surgery with pelvic (S2AI) fixation, and we were only able to fit two iFuse-3D implants in the primary SIJ fusion surgery due to S2AI crossing the SI joint and taking up available room for a third implant. Patient got better over the course of 1+ years but pain returned. Patient was sent for two additional diagnostic SI injections, confirming new pain was originating from the SI joint. Dr. Chang brought the patient back in for a revision and decided to keep the two original implants and add a third iFuse-3D to further immobilize the joint and promote fusion across the joint. He was successfully able to add a third implant during the revision procedure and has not shared the results of the revision procedure with me.

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