Wednesday, July 6, 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

Megan Hinkle

Your email

megan.hinkle@si-bone.com

Your phone number

(419) 619-1366

Surgeon's name

Joel Siegal

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

In person

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

We did not find out about the case until the day prior and were not made aware it was a revision. I discovered it was a revision when the assistant took the first image of the sacrum. The surgeon did not provide a lot of information about the case.

Complaint Overview

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

Thursday, May 26, 2022

Which device(s) was/were affected?

iFuse-3D

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?

unknown

Compared to preoperative level, pain now is

Same

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

Implants could have started more anteriorly in the ilium.

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

Mike Schwamel

(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?

I don't know

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

No, no implants were adjusted or removed

Describe revision procedure.

2 additional iFuse implants were placed

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

Unknown date of original procedure. The surgeon and nurse were unable to give me this information.