Wednesday, June 1, 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

Dawn Griffin

Your email

dawn.griffin@si-bone.com

Your phone number

(248) 390-8601

Surgeon's name

William Hakeos

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

Text

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

Once his office reached out I was able to follow up and review the removal tray with him. Patient was have SIJ pain and he wanted to address it by removing and using a competitive product.

Complaint Overview

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

Tuesday, March 1, 2022

Which device(s) was/were affected?

iFuse

Part number(s), if available

7045-90
7045-90
7035-90

Lot number(s), if available

10755
10292
10A17

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:	No CT was done
Is doctor willing to share CT images with SI-BONE?	CT not done
Imaging type used during initial surgery	C-arm/fluoro only
Was initial surgery attended by SI-BONE staff member?	No
Name of SI-BONE staff member attending initial surgery	Dave Furey

(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
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?	Yes, one or more implants were adjusted or removed

Describe revision procedure.

All 3 implants were removed. He then replaced with 2 competitive SI screws however they were not placed in the bony voids left from iFuse. He did not use allograft to backfill either.

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