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

Josh Hauxk

Your email

jhauck@si-bone.com

Your phone number

(916) 548-3376

Surgeon's name

Rudolph Schrot

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.

Wednesday, May 25, 2022

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

Tuesday, May 24, 2022

Which device(s) was/were affected?

iFuse-3D

Part number(s), if available

7050M-90
5630BDx2

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Lot number(s), if available

9045921
PTT-20-0203-0025
PTT-19-0805-0029

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?

Implant malposition causing nerve irritation

Symptomatic Implant Malposition Form

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

Right

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

Right

Did any SI-BONE staff attend initial surgery?

Yes

Name of SI-BONE staff in attendance at initial surgery

Josh Hauck

(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)

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- 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

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 ?

N/A

Date of revision surgery

Thursday, May 26, 2022

Diagnosis / Reason for the iFuse revision surgery?

Patient had unusual pain, Dr. Schrot wanted to back out implant 1 a couple kilometers as the neuromonitoring stimulation only recorded an EMG reading of 10, so he was concerned he place it too close to the foramen. He also backed up both of the allograft bone implant a few millimeters thinking they could be slightly too anterior and her pain could have come from that.

Details of iFuse revision surgery (Treatment):

Backed up implant #1 and both allograft bone implants a few millimeters, nothing removed entirely.

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?

Yes

Pain Did Not Improve or 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)

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- 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

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? Yes, all of the above apply

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