Tuesday, May 24, 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

Andrew Hilton

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 11, 2022

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

Saturday, October 10, 2020

Which device(s) was/were affected?

iFuse-3D

Part number(s), if available

IFuse 3D 7mmx55mm

Lot number(s), if available

LOT-2692041

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?

Left

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

Left

Did any SI-BONE staff attend initial surgery?

Yes

Name of SI-BONE staff in attendance at initial surgery

Francesca O'Mahoney

(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

If one or more steps was inaccurately done, describe:

None

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 ?

Yes, immediate relief for 3 months and placement agreed at MDT post op with no pain

Date of revision surgery

Saturday, May 7, 2022

Diagnosis / Reason for the iFuse revision surgery?

SIJ pain gone completely post op.
9 months post op- sij feels a lot better but pain left anterior thigh and down to her foot and slight numbness.
Pain not intolerable so delayed it to see if pain would go away.
Scans didn't show malpositioning of implant, also implant placement was agreed at MDT post op.
COVID happened which delayed things further.
Agreed to remove superior left implant- during surgery the lateral, inlet and outlet views still didn't show malpositioning.

Details of iFuse revision surgery (Treatment):

Access through initial incision.
X-ray confirmed cranial implant positioning.
Sharp pin was tapped into the cranial implant using the mallet.
The pin was then removed and replaced with the removal adaptor which was threaded and the surgeon used the mallet to try and remove the implant but it was not moving (it had been 1year and 7 months so this was predicted).
The removal adaptor was then removed and replaced with the guide rod and tighten with the wrench.
The guide was placed over the guide rod mirroring the orientation of the cranial implant and the surgeon used a pen to mark the orientation on he patient so the new implant could follow the same orientation.
The alignment Blade was inserted into one of the free channels, advanced and then the Guide Rod Nut was tightened onto the Guide Rod.
The 50mm chisel was inserted into the other 2 free channels and advanced using the slotted mallet a few mm past the SIJ using fluoroscopic imaging.
The alignment guide was moved to another channel and a 50mm chisel was used to chisel around the 3rd side of the implant.
Threaded the Shaft onto the end of the Guide Rod Nut, using the slotted mallet, the surgeon removed the implant.
We saw visible ingrowth of bone on the implant.
No bone graft or non-iFuse hardware was used.
Final images taken and closed.

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)?

Yes

Patient's outcome following the iFuse revision surgery: Were the patient's pain complaints resolved?

Pain resolved post surgery.
Will follow up in 6 weeks.

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)
- 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?

No, not all of the above apply

Comment on warranty

Revision completed 1 year 7 months post surgery- delay due to covid.