Tuesday, June 20, 2023

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

This is only for non complaint information. Examples: surgeon suggestions, meeting discussions, etc. For complaints, go back and select "Problem..."

Contact Info

Use this to record your attempts to contact and gather information from the surgeon.

Your name

Scott Goode

Your email

sgoode@si-bone.com

Your phone number

(801) 821-1444

Surgeon's name

Mark Stouffer

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

Phone

Was this attempt successful?

Yes

Complaint Overview

Enter information about surgery that resulted in a problem with any SI-BONE implant, instrument or accessory (e.g., drill bit, pin).

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

Friday, May 26, 2023

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

Thursday, May 25, 2023

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?

Decide what type of report you are submitting.

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

Use this form to report an SI-BONE product problem that was NOT associated with a patient 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

Use this form if patient experienced symptomatic implant malposition resulting in nerve irritation.

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

Scott Goode

(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:

Steps were done correctly

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 25, 2023

Diagnosis / Reason for the iFuse revision surgery?

SI joint pain

Details of iFuse revision surgery (Treatment):

Doctor simply removed the implant that appeared to be impinging on the latera cortex of the S1 foramen

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?

Unknown

Pain Did Not Improve or Recurred

Use this form if pain did not improve OR pain improved but then 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

Use this form if patient developed postoperative surgical wound problem (infection, dehiscence).

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

Please help evaluate whether this case could qualify for SI-BONE's warranty policy.

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