Complaint Reporting

Wednesday, April 24, 2024

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.

Contact Info

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

Your name Megan Hinkle

Customer name Kraig Kristof

How did you learn about this issue? (select all that apply)? From the HCP or associated staff

Please provide any relevant details about your communication. Full complaint description will be captured on the following page:

Dr. Kristof stated that the patient was having recurrent pain following their SIJF. This pain had been consistent for 7 weeks. Imaging showed good placement of the implants, however, there was a questionable light projecting at the end of one of the implants. The surgeon opted to remove the implants and place shorter implants.

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. Wednesday, March 20, 2024

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, February 7, 2024

Indicate affected device(s) (choose all that apply) iFuse-3D

Part number(s) (please list the number of each part involved)(required)

REF- 7050M-90, 7050M-90

Lot number(s)

LOT- 9085791, 9085791

Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact QA@si-bone.com if you have any questions.

Did the product complaint result in a patient problem?

YES, potential or actual (Ex: required revision, patient adverse event)

Product Complaint Without Patient Problem

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

Examples include:

- Damaged instrument/implant
- Broken/ bent/ cut pin
- Pin advancement but no patient injury
- Packaging issue

If patient injury occured, go back and click YES to report patient problem.

(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?

Select Adverse Event Type

What problem did patient have?

Continued, recurrent, or new pain

Implant Malposition Form

Use this form if patient an implant malposition was detected.

(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?

Continued, recurrent, or new pain

Use this form if pain did not improve, pain improved but then returned, or new onset pain

Best description of time course of pain recurrence:

New pain, different from pre-op

How long did the patient experience pain relief? Less than 6 months

Were any additional causes of pain discovered during workup? No other cause determined or suspected

Describe discovered or suspected other causes of pain

Patient woke up from primary surgery with a new pain that persisted for 7 weeks.

If CT was performed, please email scan to QA@si-bone.com. CT results show: Dark areas around implant without a rind of bone

Additional CT results / details

Implants had good placement within the bony parameters. There was a refractory light shooting out from the end of one of the implants (there was nothing noted on fluoroscopy after the primary case or during the revision). Because the patient's pain was persistent, he opted to remove the implant.

Was initial surgery attended by SI-BONE staff member? Yes

Name of SI-BONE staff member attending initial surgery Megan Hinkle

(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

Please describe any steps inaccurately performed, or other details of the case

surgeon only placed 2 implants.

Did patient have revision surgery as a result of this problem? Yes

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

Revision Procedure

Complete this form as thoroughly as possible for a complaint involving a revision surgery.

Please indicate date of revision procedure

Wednesday, March 27, 2024

Reason for revision (e.g. nerve impingement, loosening, etc.). Please be as specific as possible:

Patient was still having persistent pain at week 7.

Which step(s) were performed during the revision? Choose all that apply:

iFuse implant was removed

Additional iFuse implant was placed

Please further describe the revision procedure (any issues with instrumentation or medical issues?. Be as specific as possible. Failure to provide details will result in continued follow up with you:

both 7.0 iFuse 3D implants were removed without any issues and replaced with shorted 10.75 iFuse implants.

To your knowledge, was the patient's issue resolved after surgery?

No

You may be contacted for further information if your submission is lacking critical details. We appreciate your thoroughness.