SI-BONE® Complaint Reporting

Tuesday, May 7, 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 Douglas Musser

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:

The surgeon informed me that the patient returned complaining of new SI pain. When he looked at the imaging it appeared there was haloing around the implants. We discussed the removal process and he stated he would like to replace with TORQ.

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. Tuesday, February 20, 2024

Date of original surgery (if revision is being reported) or alleged product failure Monday, March 28, 2022

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

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

Superior implant- 7065M-90
Middle implant- 7050M-90

Lot number(s)

Superior implant- 2731821
Middle implant- 9044241

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: Pain got better but then recurred

How long did the patient experience pain relief? More than 12 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 complained of recurrent SI pain. Injections confirmed the SI joint was the location of pain.

If CT was performed, please email scan to QA@si-bone.com. CT results show: Dark areas around implant WITH boney rind

Additional CT results / details

Surgeon stated there was haloing around the implant and he suspected a pseudoarthrosis.

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

Name of SI-BONE staff member attending initial surgery Mike Schwamel

(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

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

Unknown as I did not attend the case and Mike is no longer with SI-BONE.

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

Monday, May 6, 2024

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

Surgeon observed haloing around the implants and suspected pseudoarthrosis.

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:

The superior and middle implant were removed using the removal system and replaced with TORQ 13.5mm implants. Both implants were difficult to remove. The middle implant had a large amount of ongrowth and ingrowth. The surgeon then decided to leave the 3rd implant in place.

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

Unknown

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