Thursday, August 17, 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..."

**Your name** John Quinn

**Your email** john.quinn@si-bone.com

**Your phone number** (925) 405-2729

**Person who provided feedback** Dr fulkerson

**Date you received feedback about SI-BONE product** Tuesday, August 15, 2023

**Provide details of feedback/ post market information.**

Revised classic 3-D with IFUSE torq 13.5x70. Patient was complaining of nerve pain + SIJ pain.

## Contact Info

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

**Your name** John Quinn

**Your email** John.quinn@si-bone.com

**Your phone number** (925) 405-2729

**Surgeon's name** Eric Fulkerson

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

**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, August 11, 2023

**Which device(s) was/were affected?** iFuse

**Part number(s), if available**

Unknown

**Lot number(s), if available**

unknown

# 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?** Pain did not improve or recurred

# Symptomatic Implant Malposition Form

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

*(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?

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?

# Pain Did Not Improve or Recurred

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

**Best description of time course of pain recurrence:** Pain got better but then recurred

**How long was SI joint pain relieved before recurrence of pain symptoms?** 6 years

**Compared to preoperative level, pain now is** Less

**CT imaging to evaluate pain recurrence shows:** CT was done and doctor has shared findings with me

**CT findings (check all that apply)** Unknown reasonings for pain

**Is doctor willing to share CT images with SI-BONE?** CT done, doctor NOT willing to share

**Imaging type used during initial surgery** C-arm/fluoro only

**Was initial surgery attended by SI-BONE staff member?** No

*(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

**Were any additional causes of low back / pelvic pain evident or discovered during workup?** I don't know

**Were any SI-BONE implants removed or adjusted as a result of this problem?**

Yes, one or more implants were adjusted or removed

**Describe revision procedure.**

Patient described pain around 6 years after initial surgery. Removed Classic fuse implant and replaced with 13.5mm TQ revision implant in S1. Left distal 2 implants in place. Classic implants showed osseointegration, and placement did not show any danger signs. unknown reasoning for SI Pain

# 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