



Complaint 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.

Contact Info

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

Your name Jake Krzeczowski

Customer name Andrew Manista

**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 Manista scheduled the revision with Jaclyn. I covered the case and learned from Dr Manista that the patient felt her top implant was causing her pain. Dr Manista wasn't convinced that was her actual pain generator, however, he removed the implant with our chisel set then packed the void with bone.

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 17, 2024

Date of original surgery (if revision is being reported) or alleged product failure Sunday, May 22, 2022

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

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

NA

Lot number(s)

NA

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 occurred, 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?

6-12 months

Were any additional causes of pain discovered during workup?

No other cause determined or suspected

Describe discovered or suspected other causes of pain

Dr Manista didn't share, it was only suspected that a different source other than the removed implant was the pain generator

If CT was performed, please email scan to QA@si-bone.com. CT results show:

No CT was done

Was initial surgery attended by SI-BONE staff member?

Yes

Name of SI-BONE staff member attending initial surgery

Jaclyn Softli

(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

The implants were all in good position, Dr Manista simply stated that he suspected that the patient had persistent pain not associated with the implant he removed.

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

Friday, May 17, 2024

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

Dr Manista thought there might have been some loosening of the implant in the ilium, however the implant position was good.

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

iFuse implant was removed

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 removal chisel set was engaged to the back of the implant with difficulty. The orientation guide was difficult to align to a face of the implant. The chisels then had to fight past bone and the back of the implant to achieve proper positioning. This caused two of the chisels to chip badly and then bend a bit while advancing towards the end of the implant. Dr Manista was able to chisel to the end of the implant on all 3 sides and remove the implant. He then packed the hole with bone.

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.