Complaint Reporting

Monday, January 13, 2025

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 Nicole Hammel

Customer name Felix Rössinger

How did you learn about this issue? (select all that apply)? I heard about it from someone else

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

I got a call from the OR. They only told me that Dr. Rössinger would like to do a Revision.

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, January 8, 2025

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, January 1, 2014

Indicate affected device(s) (choose all that apply) iFuse (original)

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

We don't have Part Numbers. It is a case from 2014.

Lot number(s)

I don't have a lot number

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? Other problem

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

(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

Describe problem in detail

Medical history: Due to a treatment resistant SiJ affection, arthrodesis was performed at the beginning of 2014 using a DIANA screen. With Continental persistence of the right gluteal pain with radiation into the right leg basically as preoperatively an additional Implantation of iFuse was performed in fall 2014. subsequently again no relief of Symptoms. Furhter attemps at treatment with denervation and neurostimulation were also unseccessful. The patient complains of right gluteal pain with radiation to the outer and back of the right leg.

Did patient undergo revision surgery to address this problem? Yes

Revision Procedure

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

Please indicate date of revision procedure Friday, January 10, 2025

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

Medical history: Due to a treatment resistant SiJ affection, arthrodesis was performed at the beginning of 2014 using a DIANA screen. With Continental persistence of the right gluteal pain with radiation into the right leg basically as preoperatively an additional Implantation of iFuse was performed in fall 2014. subsequently again no relief of Symptoms. Furhter attemps at treatment with denervation and neurostimulation were also unseccessful. The patient complains of right gluteal pain with radiation to the outer and back of the right leg.

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:

We used the Revision System with the chissels without any problem.

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.