



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 Nicole Hammel

Customer name Karl Georg Vanas

**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:

On 06-13-2024 Dr. Vanas spoke to me about the upcoming revision. He described the Patients problem and showed the CT scan and considered the trajectory for the upcoming iliac screws. He determined that the iFuse implants needed to be revised.

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. Thursday, June 13, 2024

Date of original surgery (if revision is being reported) or alleged product failure Friday, December 15, 2023

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

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

Right side: 7.0 x 55 mm / 7.0 x 45mm / 7.0 x 40mm
Left side: 7.0 x 55 mm/ 7.0 x 45 mm / 7.0 x 40 mm (surgery date: 03-08-2024)

Lot number(s)
Right side: LOT 9044251 / 9060518 / 9054174
Left side: LOT 9081681 / 9086012 / 9086001

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?

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

Patient needed revision surgery in the area of the screw rod system and the Patient also has Bertolotti syndrom.

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

Thursday, July 4, 2024

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

The Patient has Problems with the screw rod system and the surgeon wanted to place iliac screws. Due to the anatomy of the pelvis the iFuse implants are not favorably located.

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 Removal system and the chissle to revise the implants.

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.