



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 Susan Law

Customer name Sigurd Berven

**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:

Patient diabetic and obese, had a bad abscesses/puss pocket on right side. Right lower lumbar removed partial rod/ pedicle screws, granite s2ai and iliac. Wash out and replaced pedicle screws only no pelvic screws.

Removed set screw and threaded granite nav driver to remove granite screw that took a good amount of torq to break the ingrowth at the tip.

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, May 16, 2024

Date of original surgery (if revision is being reported) or alleged product failure Thursday, November 2, 2023

Indicate affected device(s) (choose all that apply) iFuse Bedrock Granite

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

105080BG x 1 qty
SN 29900752304-101

Lot number(s)

105080BG x 1 qty
SN 29900752304-101

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?

Surgical wound problem (e.g. hematoma, infection)

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).

What is the best description of problem?

Deep wound infection (e.g., infection below skin)

Please describe event

Pussing, skin breakdown (patient diabetic and obese)

Any other treatment received for problem?

IV antibiotics

Surgical wound exploration

Wash out

Was patient admitted to hospital because of problem?

Yes, patient was admitted to hospital

Effect on hospitalization time course

Hospitalization was NOT prolonged because of event

Did patient undergo revision surgery to address this problem?

Yes

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

Thursday, May 16, 2024

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

Infection

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:

No instrument issues

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.