Complaint Reporting

Tuesday, February 4, 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 Luke Harris

Customer name David Stockwell

How did you learn about this issue? (select all that apply)? From the HCP or associated staff; I observed the issue

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

Dr. Stockwell informed me that a patient that we had previously placed Granite in needed 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. Tuesday, December 31, 2024

Date of original surgery (if revision is being reported) or alleged product failure Friday, May 19, 2023

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

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

105060BG

Lot number(s)

29961812202

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

The initial surgery was a revision of a spinopelvic fusion construct where all 4 Medtronic ballast screws had failed. Broken screw shanks were left in ilium which limited room for placement of new granite/ballast screws. With the use of navigation, the surgeon was able to place bilaterally one granite and one ballast s2ai screw.

The patient was non-compliant according to surgeon. The granite and ballast screw failed on one side almost a year later. The opposite granite and ballast screw were fine.

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 Wednesday, January 22, 2025

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

Granite screw and Ballast screw were loose on one side.

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

iFuse implant was removed

Additional iFuse implant was placed

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 loose Granite and ballast screw were removed. A screw extraction set was used to remove the old broken screw shanks.

A single longer 10.5mm Granite implant was place in s2ai position in a new trajectory.

Another granite implant was place in modified iliac screw position.

To your knowledge, was the patient's issue resolved after surgery? Yes

You may be contacted for further information if your submission is lacking critical details. We appreciate your thoroughness.