Thursday, January 23, 2025

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 Nate Wright

Customer name Jason Kelly

How did you learn about this issue? (select all that apply)? I observed the issue

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

This was a first Granite case for Dr. Kelly. After he implanted a 9.5 granite, the implant backed out when he was trying to disconnect the driver. We replaced the implant with a 10.5 granite.

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 22, 2025

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, January 22, 2025

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

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

NA
Granite Locking Driver

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? NO (Ex: damaged instrument)

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.

When was problem detected? Failed during use (part broke, dislodged, etc.)

Date of surgery or use Wednesday, January 22, 2025

Was the physician able to finish the procedure? Yes, using the problem part

Was any part of product left in patient? Example: broken pin, metal shavings No, definitely

(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 (regardless of post-op symptoms)? Yes, all steps were completed accurately

Please describe any step(s) not accurately performed or any notes about the case:

All steps were followed and accurately performed.

Please describe the details of the event as fully as possible

Overall Case went well. We used Medtronic Navigation. Dr. Kelly Started with the Midas and went to a depth of roughly 25mm. He then went straight to the 8.5 granite tap navigated with the T-handle. We then used the SI Bone power ease adaptor and he used Medtronic power to implant a 9.5 X45 Granite Implant. The implant went in well and he liked how it was seated. I instructed him how to release the driver, by pulling back the gold locking tab and twist left at that same location. As he was turning left he said “is the tower supposed to be spinning”. I said no and he continued to turn left and he backed the implant out

accidentally. He asked how that happened and I said I don't know but lets look at it on the back table. I had the scrub tech hold the tower firm and turn left at the locking tab. It took some force but he was able to pop it loose.

Select Adverse Event Type

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

Revision Procedure

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

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