Complaint Reporting

Thursday, May 9, 2024

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 Jennifer Faust

Customer name Camilo Molina

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:

Dr. Molina could not advance an 11.5 screw he used to upsize a loose 10.5 Stryker S2AI screw and broke a Granite nav lock driver trying to do so.

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 2, 2024

Date of original surgery (if revision is being reported) or alleged product failure Thursday, May 2, 2024

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)

Driver 400429
Granite 11.5 x 90 - lot 29961992202 exp 2027-07-18

Lot number(s)

Granite 11.5 x 90 - lot 29961992202 exp 2027-07-18

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 Thursday, May 2, 2024

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 Yes, 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:

N/A

Please describe the details of the event as fully as possible

Dr. Molina chose to up-size a loose 10.5 Stryker S2AI screw with a Granite 11.5. He did not think he needed to tap because there was already the hole from the loose 10.5 screw. We did not have an 11.5 Granite tap available if he wanted to tap line-to-line. The screw would not advance to terminal depth and the tip of the driver broke. Dr. Molina tried to remove the screw with vice which did not work. He removed the tulip head, used a metal cutting burr to pilot a hole and tried using a male Shukla bit to remove the granite implant. That also failed. The force ended up breaking the Shukla bit. Dr. Molina had no other

choice but to use the burr to cut off what was still too proud on the screw and left the remainder of the screw implanted in the patient.

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.