Wednesday, August 7, 2024

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 Matt Marlowe

Customer name Travis Dailey

How did you learn about this issue? (select all that apply)? I heard about it from someone else

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

Dr. Dailey was performing a surgery using Granite and the case was covered by his distributor. During the implantation of 10.5 granite, one of the drivers broke (distal tip sheered off). The surgery was completed utilizing the 2nd driver in the tray.

I notified George Deshong and he has looped in engineering and I am sending back the broken instrument. I do think that Dr. Dailey would like communication from the product team as to what caused the breakage.

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. Friday, August 2, 2024

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

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

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

400268

Lot number(s)

(10)31510 or 00810055520763

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 Friday, August 2, 2024

Was the physician able to finish the procedure? Yes, using a different/new 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:

NA

Please describe the details of the event as fully as possible

According to the distributor, all steps were performed accordingly. The patient did have hard bone

(sequential tapping was utilized). During final implantation, the driver broke at the distal tip.

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.