Thursday, November 16, 2023

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 Megan Hinkle

Customer name Alexander Spiessberger

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:

Surgeon reached out to me to let me know that he had a revision case that included loose Granite set screws. (Other hardware was also included).

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, November 10, 2023

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, September 20, 2023

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

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

105090BG (x 2)

Lot number(s)

29961282307-056, 29960672301-078

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

set screw expulsion resulting in rod disengagement.

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 Monday, November 13, 2023

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

The TLIF case shifted position- was removed and an ALIF was performed.
Loose set screws at bilateral left (iFuse Granite x2)- disengaged from rod.
Loose set screw on right (Stryker S2AI) - disengaged from rod.

Which step(s) were performed during the revision? Choose all that apply: Loose set screws were removed, and new set screws were 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:

TLIF cage was removed, ALIF was performed. Patient was repositioned prone to access the loose set screws. The original set screws were removed. The surgeon performed additional insitu rod bending. One of our axial reducers was not reducing the rod so a second axial reducer was used (The first reducer would engage with the tulip, however, when tightened to fully engage the rod it would pop off. The malfunctioning reducer was removed from the tray and sent back to SI-BONE.) The surgeon used 2 new set screws from the Granite tray.

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.