Tuesday, September 24, 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 Luke Harris

Customer name Michael McMains

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. McMains reached out to me during a revision case where Granite set screws had failed. There had been a failure to notify of us about the scheduled revision case. Dr. McMains' PA had notified me approximately 1 month prior to this revision that they were worried that one of Granite's set screws had failed.

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, July 3, 2024

Date of original surgery (if revision is being reported) or alleged product failure Friday, May 24, 2024

Indicate affected device(s) (choose all that apply)

- iFuse Bedrock Granite

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

105090BG

Lot number(s)

29963192305-091

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

S1 screw (Alphatec) and Bedrock Granite failed on one side. S1 screw was completely loose and Bedrock Granite's set screw had popped of tulip head.

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 Thursday, September 5, 2024

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

Pseudoarthosis at L5-S1.

Which step(s) were performed during the revision? Choose all that apply: Bedrock Granite set screw was replaced.

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:

Dr. McMains used a mini open approach to locate S1 screw and Bedrock Granite. He located and removed failed Bedrock Granite set screw. Rod was still in Bedrock Granite tulip head. Dr. McMains inspected tulip head and didn't see signs of cross threading. We gave him a fresh set screw but it failed to fully tighten. Surgeon was afraid tulip head had splayed. He tried to detach tulip head and replace with a new one but was unable too. There was no room to place another pelvic screw due to previously broken S2ai (Alphatec) screw and Bedrock Torq. I then proposed the tapered tip of the rod might be too close to inside of tulip

head and that set-screw tightening might be causing the tulip head to slide distal over tapered portion. He decided to cut main rod after S1 screw and run a short satellite rod from just above S1 screw down to Bedrock Granite. This allowed for tapered tip to be further away from tulip head. The set screw was successfully tightened.

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

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