Wednesday, January 22, 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 Matthew Mendel

Customer name Vaibhav Patel

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 informed me that he would need to revise a surgery that was completed approximately one year and five months ago. The reason for the revision was that there was lucency around the granite implants on the right and, left side and some lucency around part of the TORQ implant on the right side. The patient S1 hardware on the right side from De Puy had also broken and our granite tulip head on the left side had splayed open and popped the set screw off.

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. Sunday, January 19, 2025

Date of original surgery (if revision is being reported) or alleged product failure Monday, August 7, 2023

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

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

Left Granite 105070BG
Right granite 105070 BG
Right TORQ 10070T

Lot number(s)

Left granite 29960442303
Right Granite 29980442303
Right Torq 9076381

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?

Continued, recurrent, or new pain

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

Best description of time course of pain recurrence: Pain got better but then recurred

How long did the patient experience pain relief? More than 12 months

Were any additional causes of pain discovered during workup? I don't know

Describe discovered or suspected other causes of pain

Patient also had translation of vertebral cage that destabilized the lumbar spine. The doctor corrected this by performing a single level ALIF.

If CT was performed, please email scan to QA@si-bone.com. CT results show: Dark areas around implant WITH boney rind

Additional CT results / details

CT scan showed obvious lucency around right and left granite implants. Left TORQ implant had solid bony growth. The surgeon attempted to remove that implant as well, but was unsuccessful due to fusion. The right TORQ implant had some bony in growth, but the surgeon felt it was not sufficient and would not improve. That implant was removed.

Was initial surgery attended by SI-BONE staff member? Yes

Name of SI-BONE staff member attending initial surgery Mark Futrell

(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? Yes, all steps were completed accurately

Please describe any steps inaccurately performed, or other details of the case

No additional details

Did patient have revision surgery as a result of this problem? I don't know

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.