Complaint Reporting

Thursday, March 13, 2025

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 Gregory Howes

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:

Notified by surgeon of patient infection at multiple levels, including pelvis. Granite implants had lucency bilaterally.

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, March 13, 2025

Date of original surgery (if revision is being reported) or alleged product failure Thursday, February 8, 2024

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 side S/N 29962972302-070
Right side S/N 29962972302-071
10060T

Lot number(s)

281024
281025
9084161

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?

Surgical wound problem (e.g. hematoma, infection)

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).

What is the best description of problem?

Infection within bone itself (osteomyelitis)

Please describe event

Patient had revision surgery today 03/13/254 deep infection in multiple levels of construct. Granite S2 AI screws were removed for lucency fluency diameter was larger than 13 mm.

TORQ implant seems to have good bone and growth, and the surgeon is not removing that implant.

Any other treatment received for problem?

Oral antibiotics

IV antibiotics

Surgical wound exploration

Was patient admitted to hospital because of problem?

I don't know

Effect on hospitalization time course

Hospitalization was NOT prolonged because of event

Did patient undergo revision surgery to address this problem?

Yes

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.

Please indicate date of revision procedure Thursday, March 13, 2025

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

Deep infection

Which step(s) were performed during the revision? Choose all that apply: iFuse implant was removed

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:

Upon reviewing the CT scan torque implant appears to have good bony in growth. However, both granites bilaterally showed lucency greater than 13 mm on the CT scan. Hardware was removed and no bony in growth can be found on the granite implants. Due to the size of the lucency revising to larger sizing implant was not possible. Surgeon opted to remove granite hardware.

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.