



# 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](mailto: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 Katie Walla

Customer name Grant Mallory

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:**

Patient still had pain in left si joint after previous granite placement.

## 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, October 18, 2024

Date of original surgery (if revision is being reported) or alleged product failure Thursday, November 23, 2023

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

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

NA

Lot number(s)

NA

## Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact [QA@si-bone.com](mailto: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 occurred, 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?**

6-12 months

**Were any additional causes of pain discovered during workup?**

No other cause determined or suspected

**Describe discovered or suspected other causes of pain**

Pain went away then came back in left si only

**If CT was performed, please email scan to QA@si-bone.com. CT results show:**

No CT was done

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

Yes

**Name of SI-BONE staff member attending initial surgery**

Katie Walla

*(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**

Everything went well, and implants were safely positioned and remained safe after pain came back.

**Did patient have revision surgery as a result of this problem?**

Yes

## **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.

**Please indicate date of revision procedure**

Friday, October 18, 2024

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

Pain came back. Kept granite in, just added torq laterally

**Which step(s) were performed during the revision? Choose all that apply:**

Additional iFuse implant was 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:**

Added 2 torq implants laterally. Kept initial implants in.

**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.**