



## Complaint - Revision - Post Market - Feedback 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.

Select the type of problem you are reporting

Problem with individual device or individual patient

### General Feedback about SI-BONE Product

#### Contact Info

Your name Blake Klipa

Your email blake.klipa@si-bone.com

Your phone number (727) 295-5339

Surgeon's name Peter Ameglio

Contact #1: How did you attempt to contact the surgeon? In person

Was this attempt successful? Yes

#### Complaint Overview

Date you first heard of problem with SI-BONE product. Wednesday, June 1, 2022

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery. Wednesday, November 17, 2021

Which device(s) was/were affected? iFuse-3D

Part number(s), if available

N/a

Lot number(s), if available

N/a

#### Product Complaint or Adverse Event?

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**What is the nature of the problem you are reporting?**

Product complaint that caused or may have caused an adverse event or revision procedure

## Product Complaint Without Adverse Event

Examples include:

- Damaged instrument
- Broken pin
- Bent pin
- Pin advancement but no patient injury
- Problem with packaging

If a damaged part injured a patient, go back and click on "Product complaint that caused or may have caused an adverse event."

## Select Adverse Event Type

Select from the choices below. Your choice guides which section to complete.

If the first 3 do not apply, select "Other".

If a product problem occurred that did NOT cause a patient problem, go back and complete the "Product Complaint Without Adverse Event" section.

**What problem did patient have?**

Pain did not improve or recurred

## Symptomatic Implant Malposition Form

*(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?

For above question, be specific and include all steps of the revision surgery and any complications.

- Was the implant adjusted, removed or added?
- Were the explant holes filled with bone graft?
- Were osteotomes and the/or the removal adapter used?
- Was any non-iFuse hardware installed?

## Pain Did Not Improve or Recurred

**Best description of time course of pain recurrence:**

Pain got better but then recurred

**How long was SI joint pain relieved before recurrence of pain symptoms?**

3 months

**Compared to preoperative level, pain now is**

Less

**CT imaging to evaluate pain recurrence shows:**

CT was done and doctor has shared findings with me

**CT findings (check all that apply)**

No concerns with CT

**Is doctor willing to share CT images with SI-BONE?**

CT done, doctor NOT willing to share

**Imaging type used during initial surgery**

C-arm/fluoro only

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

Yes

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

Blake Klipa

*(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

**Were any additional causes of low back / pelvic pain evident or discovered during workup?**

I don't know

**Were any SI-BONE implants removed or adjusted as a result of this problem?**

No, no implants were adjusted or removed

**Describe revision procedure.**

One implant was added anterior to previous 3 implants.

## **Surgical Wound Problem**

## **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

## Potential Warranty Case

Did patient's situation meet all of the following?

*Did patient undergo a revision procedure that met all of the following:*

1. *The initial procedure involved placement of 3 SI-BONE implants on the affected side*
2. *The revision procedure:*
  - *Was completed within 1 year of the initial procedure*
  - *Was completed at the same hospital or within the same hospital system as the initial procedure*
  - *Was completed during a separate hospitalization from the initial procedure*
3. *The patient followed all physician instructions after the initial procedure*

**Did patient's situation meet warranty criteria shown above?**

Yes, all of the above apply