



## 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

This is only for non complaint information. Examples: surgeon suggestions, meeting discussions, etc. For complaints, go back and select "Problem..."

### Contact Info

Use this to record your attempts to contact and gather information from the surgeon.

**Your name** Ariana Lavoie

**Your email** alavoie@si-bone.com

**Your phone number** (978) 504-9485

**Surgeon's name** Christian Klare

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

**Was this attempt successful?** Yes

### 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.** Monday, August 21, 2023

**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?

Decide what type of report you are submitting.

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.

**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

Use this form to report an SI-BONE product problem that was NOT associated with a patient 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

Use this form if patient experienced symptomatic implant malposition resulting in nerve irritation.

*(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

Use this form if pain did not improve OR pain improved but then recurred

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

Pain never got better

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

Same

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

CT was done and doctor has shared findings with me

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

Inadequate engagement in sacrum

**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**

Ariana Lavoie

*(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?**

Yes, one or more implants were adjusted or removed

**Describe revision procedure.**

Two implants were added anteriorly to implants from 1st surgery. Most inferior implant from 1st surgery was removed- Dr. Klare thought it was too prominent and lacked enough engagement into the sacrum.

## **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

## Potential Warranty Case

Please help evaluate whether this case could qualify for SI-BONE's warranty policy.

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?**

No, not all of the above apply

### Comment on warranty

Initial surgery done by a different surgeon (Dr. Kurtus Dafford) at another hospital in 2021.