



# 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** Gavin Cronin

**Your email** gavin.cronin@si-bone.com

**Your phone number** (908) 672-1045

**Surgeon's name** Mark Ruoff

**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.** Tuesday, August 9, 2022

**If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery.** Monday, August 8, 2022

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

**Part number(s), if available**

7065m-90

**Lot number(s), if available**

9046131

## 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?**

Implant malposition causing nerve irritation

## Symptomatic Implant Malposition Form

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

**On which side(s) were SI-BONE implants placed during initial surgery?**

Right

**Which operated side showed postoperative symptoms (i.e., symptoms related to implant malposition)?**

Right

**Did any SI-BONE staff attend initial surgery?**

Yes

**Name of SI-BONE staff in attendance at initial surgery** Gavin Cronin

*(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

**If one or more steps was inaccurately done, describe:**

N/a

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

Yes

**Did the patient have SI joint pain relief following the initial procedure? How long was the pain relief ?** Yes

**Date of revision surgery**

Wednesday, August 10, 2022

**Diagnosis / Reason for the iFuse revision surgery?**

Implant was breaching lateral wall of foramin

**Details of iFuse revision surgery (Treatment):**

Surgeon used adjustment tool to back up implant from lateral wall

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?

**Was the iFuse Removal System Instrument Set (P/N 400132) and chisels used to explant the iFuse Implant(s)?**

No

**Patient's outcome following the iFuse revision surgery: Were the patient's pain complaints resolved?**

Improved pain relief continue intermittent leg pain

## Pain Did Not Improve or Recurred

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

*(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).

## 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?**

Yes, all of the above apply

**Comment on warranty**

No new implants were used