



# 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** Michael Cushing

**Customer name** Kirkham Wood

**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:**

Dr. Wood had completed the lateral 3D procedure on the Friday prior. We got a call over the weekend that the patient was having some neurological pain due to a malpositioned implant.

## 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.** Saturday, June 15, 2024

**Date of original surgery (if revision is being reported) or alleged product failure** Friday, June 14, 2024

**Indicate affected device(s) (choose all that apply)** iFuse-3D

**Part number(s) (please list the number of each part involved)(required)**  
n/a

**Lot number(s)**  
10040T

## 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?**

Implant malposition (e.g. causing nerve irritation)

## Implant Malposition Form

Use this form if patient an implant malposition was detected.

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

Left

**Which side shows implant malposition?**

Left

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

Yes

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

Susan Law

**Imaging type used during initial surgery**

C-arm/fluoro only

*(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 (regardless of post-op symptoms)?**

Yes, all steps were completed accurately

**Please describe procedure steps not done properly or other pertinent information**

One of the implants was placed far too anterior and was causing the patient nerve pain.

**Did patient have revision surgery?**

Yes

## 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).

## 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**

Monday, June 17, 2024

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

One of the implants was placed far too anterior and was causing the patient nerve pain. We removed the 3D implant and replaced with a torq screw in a better position.

**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:**

One of the implants was placed far too anterior and was causing the patient nerve pain. We removed the 3D implant and replaced with a torq screw in a better position.

**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.**