



# 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** Megan Hinkle

**Customer name** Kraig Kristof

**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. Kristofs scheduler messaged me to let me know she was adding the patient on for a revision the next day. I communicated with her and messaged the surgeon to get more information.

## 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, April 30, 2024

**Date of original surgery (if revision is being reported) or alleged product failure** Friday, April 12, 2024

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

**Part number(s) (please list the number of each part involved)(required)**  
7060M-90

**Lot number(s)**  
9081691

## 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**

Megan Hinkle

**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)?**

No, one or more steps not accurately done

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

Due to patient body habitus and c-arm used images were difficult to interpret. We tried several times to get better images and had difficulty. We thought the implants were safe, however, CT showed the implant was too superior.

**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**

Wednesday, May 1, 2024

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

Patient complained of nerve pain and numbness in left leg.

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

iFuse implant was removed

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:**

No issues with instruments or implants. The issue was imaging.

**To your knowledge, was the patient's issue resolved after surgery?**

Unknown

**You may be contacted for further information if your submission is lacking critical details. We appreciate your thoroughness.**