# Complaint Reporting

Friday, February 28, 2025

Use this form to submit information about a complaint related to an SI-BONE product to Quality Affairs.

Contact 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** Shawn Needelman

**Customer name** Glenn Keiper

**How did you learn about this issue? (select all that apply)?** I observed the issue

**Please provide any relevant details about your communication. Full complaint description will be captured on the following page:**

I watched the entire interaction

## 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.** Friday, February 28, 2025

**Date of original surgery (if revision is being reported) or alleged product failure** Friday, February 28, 2025

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

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

7035M-90

**Lot number(s)**

9091711

## Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact 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 occured, 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?**

Surgical wound problem (e.g. hematoma, infection)

# Implant Malposition Form

Use this form if patient an implant malposition was detected.

*(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?

# 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).

**What is the best description of problem?**

Major bleeding

**Please describe event**

Dr. Keiper placed his third implant more interior than we would've liked. Upon placing the implant we believe it breached the anterior pelvic rim. He removed the implant and the patient proceeded to bleed. He spent roughly 2 1/2 hours trying to get the bleeding under control which he finally did after roughly 2200 cc's of blood loss.

**Any other treatment received for problem?**

The patient was transferred from the ASC to the hospital. I was told they were going to perform a CTA but I'm not sure if that occurred.

**Was patient admitted to hospital because of problem?**

Yes, patient was admitted to hospital

**Effect on hospitalization time course**

Hospitalization was prolonged because of event

**Add any further details**

About three hours after the patient arrived at the hospital I received a text from Dr. Keiper telling me:

"The patient is fine. There was no more bleeding and no blood clot."

**Did patient undergo revision surgery to address this problem?**

No

# 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.

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