



## 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** Robyn Capo

**Customer name** Steven Strange

**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:**

Dr Strange opened a package and it exploded

### 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, October 27, 2023

**Date of original surgery (if revision is being reported) or alleged product failure** Friday, October 27, 2023

**Indicate affected device(s) (choose all that apply)**  Instrument(s)

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

456789

**Lot number(s)**

123456

### 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?**  NO (Ex: damaged instrument)

## 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.

### When was problem detected?

Problem identified before use (observed issue in packaging or tray)

*(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?

### Please describe the details of the event as fully as possible

Opened the package, went boom

## Select Adverse Event Type

### 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).

## **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 if patient underwent revision surgery.

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