Monday, November 18, 2024

# 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 if you have any questions.

## Contact Info

Use this to record your attempts to contact and gather information from the customer

**Your name** Cameron Cannon

**Customer name** Alan Rechter

**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 Rechter wamted to replace the first previous screw, physician assumed pain was coming from first screw being too long.

## 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.** Wednesday, October 23, 2024

**Date of original surgery (if revision is being reported) or alleged product failure** Monday, September 30, 2024

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

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

11560T

**Lot number(s)**

9082531

## 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?** 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** Brent Pitre

**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**

N/A

**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, October 30, 2024

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

Physician thought his implant was too long and potentially causing nerve impingement

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

- iFuse implant was removed
- The initial implant was removed and a shorter implant size was used

**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:**

Because the physician thought the initial implant was causing nerve impingement and continued pain, The initial screw was revised, and a shorter implant was used.

**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.