



## 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** Amanda Adams

**Customer name** Raymond Topp

**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:**

Contacted by hospital to inform me there was a removal case with Dr. Topp

### 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.** Thursday, November 9, 2023

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

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

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

REF 11535T

**Lot number(s)**

9060841

### 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?**

Continued, recurrent, or new pain

## 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

**Best description of time course of pain recurrence:**

Pain got better but then recurred

**How long did the patient experience pain relief?**

Less than 6 months

**Were any additional causes of pain discovered during workup?**

I don't know

**If CT was performed, please email scan to QA@si-bone.com. CT results show:**

Inadequate implant engagement in sacrum

**Was initial surgery attended by SI-BONE staff member?**

Yes

**Name of SI-BONE staff member attending initial surgery**

Amanda Adams

*(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?**

No, one or more steps was inaccurately done. (Ignore the fact that patient had malpositioned implant. Focus on whether procedure was correctly executed.)

**Please describe any steps inaccurately performed, or other details of the case**

I do not believe a proper lateral view was obtained on the day of implantation. The inferior implant was placed at the very bottom of the joint and did not fuse.

**Did patient have revision surgery as a result of this problem?**

Yes

## 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**

Tuesday, November 14, 2023

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

The inferior implant was low in the joint and did not fuse.

**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:**

Dr. Topp performed an SI joint injection after the implant was removed.

**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.**