Wednesday, November 20, 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** Jaclyn Softli

**Customer name** John-David Black

**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. Black notified me of a torq revision from a previous trauma patient and requested the removal set. There would also be other hardware removed during the case.

## 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, November 12, 2024

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

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

100XXLG - 2 of these removed. Unsure of the exact lengths

**Lot number(s)**

n/a

## 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?** 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?** 6-12 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:** No CT was done

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

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

*(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?** Yes, all steps were completed accurately

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

n/a

**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** Wednesday, November 13, 2024

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

The patient was in a car accident a year ago which resulted in a big pelvic trauma case with anterior pelvic instrumentation as well as posterior. The pelvis was in terrible shape and Dr. Black said it was asking a lot for our implants to solve all of her issues. The patient developed more SI pain on the left side as a result of the accident.

**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:**

She had pelvic ring reconstruction as well and Dr. Black removed all of the anterior hardware during this revision as the anterior portion has healed.  Dr. Black removed two of the torq lag implants and replaced them with 13.5 fully threaded implants for better purchase. The lag implants weren't very loose, but the fully threaded would fuse better so he switched them out. He thinks the SI pain was a result of the accident, and not due to our implants being in there previously.

**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.