Friday, November 24, 2023

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 Kyle Blackley

Customer name Christopher Martin

How did you learn about this issue? (select all that apply)?

- From the HCP or associated staff
- I observed the issue
- I heard about it from someone else

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

Was informed day of surgery by RN there was a possible removal of TORQ implants

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, November 22, 2023

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

- iFuse-TORQ

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

80, 55, 45mm implants on each side (bilateral)

Lot number(s)

Unknown

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?

Other problem

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

Describe problem in detail

Patient had been experiencing fever/chills since their initial surgery dating back to some time this past September. The patient was originally treated for a sacral insufficiency fx at the initial surgery with 3 torq implants bilaterally (6 total implants). There was fluid surrounding the implants, and the fracture didn't appear to be healing. The plan was to explant all implants and take cultures. If there was an infection, then they would allow patient to fully recover before bringing patient back to surgery for a L4-Pelvis fusion in the future.

Did patient undergo revision surgery to address this problem? Yes

Revision Procedure

Complete this form as thoroughly as possible for a complaint involving a revision surgery.

Please indicate date of revision procedure Wednesday, November 22, 2023

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

Please see other description

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:

All 6 implants were explanted with very little to no resistance. Dr Martin did not observe any visible signs of infection or sources of the fluid surrounding the implants. Cultures were taken from implants, instruments, and from inside the body. I was not able to recover the implants as they were all sent off for cultures. There were no issues with the removal procedure itself. I learned today (11/24/23) from Dr. Martin that cultures came back positive for infection as the cause for osteomyelitis

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.