Wednesday, November 8, 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 Aaron Watkins

Customer name Christopher Henderson

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:

Patient presented leg pain post op, and x-ray images showed safe implants so Dr. Henderson order a CT to look further into it. One implant was touching a cortical structure so Dr. Henderson deemed taking implant out and replacing with shorter implant. The other two were still safe in the CT.

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. Saturday, November 4, 2023

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, October 24, 2023

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

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

10045T
10040T
10040T
500373
500375

Lot number(s)

9081961
9082111
9076371

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?

Right

Which side shows implant malposition?

Right

Did any SI-BONE staff attend initial surgery?

Yes

Name of SI-BONE staff in attendance at initial surgery Aaron Watkins

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

All implants looked safe on x-ray and both rep/doctor agreed.

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

Monday, November 6, 2023

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

Since x-rays showed safe placement, Dr. Henderson ordered a CT Scan which showed us one implant touching a cortex, did not look like foramen but must've been if the patient was presenting added leg pain post op of the initial surgery of the right side. Patient had left side done and no issues/has relief. Anatomy of the left side appeared different on the CT from the right side as well when comparing both sides.

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:

No issues with instrumentation, Dr. Henderson removed what he thought was the long implant and replaced with a shorter implant in its spot.

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.