Thursday, April 11, 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 Kyle Blackley

Customer name Nathan Hendrickson

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:

N/A

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. Friday, April 5, 2024

Date of original surgery (if revision is being reported) or alleged product failure Thursday, December 30, 2021

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

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

11570T, 10040T, 10045T

Lot number(s)

9044081, 9046581, 9043911

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

Revision of loose TORQ implants. I can't say for sure which ones were loose as I didn't go through the preop imaging, but only the 45mm implant came out easy. The 11.5x70 and 10x40 implants were both very difficult to remove via the driver, a trephine was not used on any of the implants, but a good deal of force was required to remove those 2 implants. I had asked Dr. Hendrickson why they loosened and if the implants on the other side (original surgery was bilateral) were loose, and his reply was attributing whatever issue to the patients mental state more so than device issues. During the removal of the 10x40 implant (the first implant removed), we were not able to initially remove it with the driver as the threaded sleeve was blocked from threading into the screw head due to tissue. The screw had screwed out, but we couldn't grab it so we used the extractor to successfully grab the screw and pull it out. The second screw removed was the 11.5x70, and that would not move with the T40 cannulated driver. The tip of the driver broke off inside the screw head so we used the extractor again but the tip of that broke off in the screw head as well. Dr. Hendrickson removed the guide pin from the cannula of the screw and we tried the non cannulated T40 driver from the revision set and that succeeded in screwing out the screw. The last implant he went to remove was the one that easily screwed out. All implants were replaced with 13.5 implants of the same length.

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 Friday, April 5, 2024

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

See description

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:

See description

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.