Tuesday, September 3, 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 Ariana Lavoie

Customer name Simon Chao

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:

Surgeon wanted to remove the top implant

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, August 14, 2024

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, June 19, 2024

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

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

please see RPO

Lot number(s)

please see RPO

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:

New pain, different from pre-op

How long did the patient experience pain relief? Less than 6 months

Were any additional causes of pain discovered during workup? Yes, alternative diagnoses were discovered or suspected

Describe discovered or suspected other causes of pain

Patient went back for L4-S1 at same time as removal. Surgeon thought implant might be involved so opted to remove.

If CT was performed, please email scan to QA@si-bone.com. CT results show: CT was done, but doctor refuses to comment on results

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

Name of SI-BONE staff member attending initial surgery Ariana Lavoie

(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, August 28, 2024

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

L5 symptoms that may or may not be related

Which step(s) were performed during the revision? Choose all that apply:

- iFuse implant was removed
- Non-iFuse implant/instrumentation 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:

surgeon removed the washer and the implant without issue, then proceeded with L5-S1 procedure.

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.