Monday, November 25, 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 Melanie Jackson

Customer name James McFadden MD

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. McFadden text me on 11/13/24 that he was revising a previous case we had the following day and asked me to be there.

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 13, 2024

Date of original surgery (if revision is being reported) or alleged product failure Thursday, October 24, 2024

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

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

iFuse Torq 10mm x 70mm

Lot number(s)

9088932

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

Melanie Jackson

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 steps of the surgery were completed accurately.

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

Thursday, November 14, 2024

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

The patient was experiencing some radicular pain post-op so Dr. McFadden ordered a CT scan. The c-arm images during the surgery were all good images, the implant looked safe and not impinging at all on the S1 or S2 foramen. However, the CT showed that the threads of the implant were encroaching on the foramen, so he decided to schedule a revision surgery.

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:

The revision surgery was quick with no issues. Dr. McFadden found the head of the implant, put a blunt pin down the cannula, inserted the driver and backed out the implant. He removed it and did not replace the implant or reposition it.

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.