Thursday, July 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 Michael Cushing

Customer name Kirkham Wood

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. Wood informed us that the patient had the IFUSE 3D procedure done by another surgeon and was not receiving good outcomes. Therefore he decided to remove all 3 of the 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. Friday, June 21, 2024

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, September 6, 2022

Indicate affected device(s) (choose all that apply) iFuse-3D

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

n/a

Lot number(s)

7050-90, 7040-90, 7045-90

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?

Left

Which side shows implant malposition?

Left

Did any SI-BONE staff attend initial surgery?

Yes

Name of SI-BONE staff in attendance at initial surgery

Katie Moroni

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)? I don't know

Please describe procedure steps not done properly or other pertinent information

Implants were not positioned accordingly. One of the implants being placed too posterior. Patient wasn't getting lasting pain relief and could not have been a candidate for an SI Joint Fusion in the first place.

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 Friday, June 28, 2024

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

Patient was not getting relief from the implants. Wanted them removed.

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:

No issue with removing the 3D implants.

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.