Monday, October 30, 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 Kendrick Wroe

Customer name Kendrick Wroe

How did you learn about this issue? (select all that apply)? I observed the issue; I heard about it from someone else

Please provide any relevant details about your communication. Full complaint description will be captured on the following page:

TEST ONLY, NOT A COMPLAINT

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. Tuesday, October 17, 2023

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, February 6, 2024

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

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

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Lot number(s)

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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.

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

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

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

Best description of time course of pain recurrence:

Pain got better but then recurred

How long did the patient experience pain relief?

More than 12 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

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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

Additional CT results / details

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Was initial surgery attended by SI-BONE staff member?

Yes

Name of SI-BONE staff member attending initial surgery

Kendrick Wroe

(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

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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).

What is the best description of problem? Major bleeding

Please describe event

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Any other treatment received for problem? IV antibiotics

Additional comments on treatment received

TEST ONLY, NOT A COMPLAINT

Was patient admitted to hospital because of problem? Yes, patient was admitted to hospital

Effect on hospitalization time course Hospitalization was prolonged because of event

Add any further details

TEST ONLY, NOT A COMPLAINT

Did patient undergo revision surgery to address this problem? Yes

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 if patient underwent revision surgery.

Please indicate date of revision procedure Tuesday, October 24, 2023

Please indicate all procedural steps that apply: iFuse implant was repositioned

Provide as much detail on the case as possible:

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Was the patient's issue resolved after surgery?

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You may be contacted for further information if your submission is lacking critical details. We appreciate your thoroughness.