Monday, October 30, 2023

Complaint - Revision - Post Market - Feedback 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.

Select the type of problem you are reporting

Problem with individual device or individual patient

General Feedback about SI-BONE Product

This is only for non complaint information. Examples: surgeon suggestions, meeting discussions, etc. For complaints, go back and select "Problem..."

Contact Info

Use this to record your attempts to contact and gather information from the surgeon.

Your name

Michael Cushing

Your email

michael.cushing@si-bone.com

Your phone number

(714) 366-0380

Surgeon's name

Dimitry Kondrashov

Contact #1: How did you attempt to contact the surgeon?

In person

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

Spoke with Dr. Kondrashov following surgery.

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.

Thursday, October 26, 2023

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery.

Thursday, October 26, 2023

Which device(s) was/were affected?

Instrument

Part number(s), if available

501168

Lot number(s), if available

N/A

Product Complaint or Adverse Event?

Decide what type of report you are submitting.

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.

What is the nature of the problem you are reporting?

Product complaint without a patient problem. (Example: instrument breakage, no impact on patient.)

Product Complaint Without Adverse Event

Use this form to report an SI-BONE product problem that was NOT associated with a patient adverse event.

Examples include:

- Damaged instrument
- Broken pin
- Bent pin
- Pin advancement but no patient injury
- Problem with packaging

If a damaged part injured a patient, go back and click on "Product complaint that caused or may have caused an adverse event."

Date part problem noticed

Monday, October 23, 2023

When was part problem detected?

Part damaged as a results of use

If part in question was used during procedure, was surgeon able to finish the procedure?

Yes, surgeon completed surgery using a different/new part

Was any part of product left in patient? Example: broken pin, metal shavings

No, no part was left in patient

Any further comments or information

We were taking part in a bedrock granite procedure with Dr. Kondrashov at St. Mary's Medical Center. We were using 1.4 guidewire. In which we began by taping 8.5,9.5,10.5 on Large Stryker Power over guidewire. Then we went to put screw in, also using power, however when once we played screw and unscrewed driver, the guidewire was stuck in the screw. Dr. Kondrashov atempted to remove it and once he finally did a piece of the guidewire broke off in the patient. The piece broke off in the joint and Dr. Kondrashov was not happy, saying that this has happened in the past. He in the end was able to remove the broken guidewire from the patient. We completed the procedure but Dr. Kondrashov wanted to make sure that this event was documented. He also me to let Scott Yerbi know what occurred in hopes of getting an answer to this recurring problem.

Select Adverse Event Type

Select from the choices below. Your choice guides which section to complete.

If the first 3 do not apply, select "Other".
If a product problem occurred that did NOT cause a patient problem, go back and complete the "Product Complaint Without Adverse Event" section.

Symptomatic Implant Malposition Form

Use this form if patient experienced symptomatic implant malposition resulting in nerve irritation.

(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?

For above question, be specific and include all steps of the revision surgery and any complications.

- Was the implant adjusted, removed or added?
- Were the explant holes filled with bone graft?
- Were osteotomes and the/or the removal adapter used?
- Was any non-iFuse hardware installed?

Pain Did Not Improve or Recurred

Use this form if pain did not improve OR pain improved but then recurred

(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

Potential Warranty Case

Please help evaluate whether this case could qualify for SI-BONE's warranty policy.

Did patient's situation meet all of the following?
Did patient undergo a revision procedure that met all of the following:

1. *The initial procedure involved placement of 3 SI-BONE implants on the affected side*
2. *The revision procedure:*
   - *Was completed within 1 year of the initial procedure*

Was completed at the same hospital or within the same hospital system as the initial procedure
- *Was completed during a separate hospitalization from the initial procedure*

3. *The patient followed all physician instructions after the initial procedure*

Did patient's situation meet warranty criteria shown above?

No, not all of the above apply

Comment on warranty

There was no revision case.