Saturday, August 13, 2022

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

Contact Info

Your name
Dan Cooney

Your email
daniel.cooney@si-bone.com

Your phone number
(631) 987-5888

Surgeon's name
Patrick Senatus

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

Was this attempt successful?
Yes

Comments about attempts to contact surgeon (optional)
I was present in the OR when event happened

Complaint Overview

Date you first heard of problem with SI-BONE product.
Wednesday, August 3, 2022

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery.
Wednesday, August 3, 2022

Which device(s) was/were affected?
iFuse-3D

Part number(s), if available
n/a

Lot number(s), if available

n/a

Product Complaint or Adverse Event?

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 that caused or may have caused an adverse event or revision procedure

Product Complaint Without 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."

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.

What problem did patient have?

Surgical wound problem

Symptomatic Implant Malposition Form

(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

(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

What is the best description of problem?

Major bleeding

Please describe event

After initial incision was made, all usual steps were followed. As surgeon drilled, bleeding occurred, resulting in a decrease in blood pressure. This necessitated the use of pressors and IV fluids to stabilize patient. Bleeding was controlled by Dr. Senatus with GelFoam wound packing and direct pressure. This event did not happen as a result of a device or equipment issue. Dr. Senatus believes it was likely a vascular anomaly. Surgery was aborted and no implants were placed. 1 implant was wasted, as it was opened to be placed.

Were any SI-BONE implants removed in response to this problem?

No implants removed

Any other treatment received for problem?

IV fluids, wound packing, pressers

Was patient admitted to hospital because of problem?

Yes, patient was admitted to hospital

Effect on hospitalization time course

Hospitalization was NOT prolonged because of event

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

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