Tuesday, December 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

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

Nate Blair

Your email

nblair@si-bone.com

Your phone number

(260) 704-1245

Surgeon's name

Deepak Reddy

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

In person

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

No true complaint. Used 1 3D implant per side at base of construct to pelvis laterally. Patient came back with symptomatic SI on one side so added 2 TORQ implants and patient is doing well

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, December 7, 2022

Which device(s) was/were affected?

iFuse-3D

Part number(s), if available

Don't have

Lot number(s), if available

Don't have

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

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."

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?

Pain did not improve or recurred

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

Best description of time course of pain recurrence:

Pain was diagnosed as implant was used for bedrock as preventative

Compared to preoperative level, pain now is

Worse

CT imaging to evaluate pain recurrence shows:

CT was done and doctor has shared findings with me

CT findings (check all that apply)

Doctor mentioned some halo around distal end of implant

Additional CT results / details

Surgeon described and displayed what he thought was some haloing around distal tip of implant but haloing was on one side of implant and didn't extend the full length

Is doctor willing to share CT images with SI-BONE?

CT done, doctor NOT willing to share

Imaging type used during initial surgery

Robot

Was initial surgery attended by SI-BONE staff member?

Yes

Name of SI-BONE staff member attending initial surgery

Nate Blair

(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

Were any additional causes of low back / pelvic pain evident or discovered during workup?

No other cause determined or suspected

Were any SI-BONE implants removed or adjusted as a result of this problem?

No, no implants were adjusted or removed

Describe revision procedure.

Using Globus robot we placed 2 additional fully threaded TORQ implants around the existing hardware. After successfully placing those implants, he attached threaded removal tool and tried to backslap 3D implant out, but implant did not move at all. He took this as a sign that implant was not loose and left it there.

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

Only 1 implant was used due to it being used in conjunction with pelvic fixation (S2AI) in a lateral bedrock trajectory.