Thursday, June 2, 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 General feedback about an SI-BONE product

General Feedback about SI-BONE Product

Your name Megan Hinkle

Your email megan.hinkle@si-bone.com

Your phone number (419) 619-1366

Person who provided feedback Megan Hinkle

Date you received feedback about SI-BONE product Monday, May 2, 2022

Provide details of feedback/ post market information.

Revision case performed. Initial procedure performed with 2 iFuse 3D implants. (Superior 50mm, inferior 40mm) Patient felt good after the procedure, felt a "pop" during PT followed by pain. Inferior implant was too short and not placed deep enough in the sacrum based upon post op CT scans. Surgeon then removed the inferior implant, replaced it with a 10.75 x 55 mm implant and added a iFuse 3D-45mm implant anteriorly between the 2 implants.

Contact Info

Your name Megan Hinkle

Your email megan.hinkle@si-bone.com

Your phone number (419) 619-1366

Surgeon's name Kraig Kristof

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

Was this attempt successful? Yes

Comments about attempts to contact surgeon (optional)

Surgeon and scheduler informed me about the upcoming case. We discussed a plan prior to the procedure.

Complaint Overview

Date you first heard of problem with SI-BONE product. Monday, April 4, 2022

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

Part number(s), if available

7040M-90

Lot number(s), if available

2765041

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

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.

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

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*