Tuesday, October 25, 2022

Complaint - Revision - Post Market - Feedback Reporting

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.

Complaint Overview
Enter information about surgery that resulted in a problem with any SI-BONE implant, instrument or accessory (e.g., drill bit, pin).

Product Complaint or Adverse Event?
Decide what type of report you are submitting.

Product Complaint Without Adverse Event
Use this form to report an SI-BONE product problem that was NOT associated with a patient adverse event.

Select Adverse Event Type

Symptomatic Implant Malposition Form
Use this form if patient experienced symptomatic implant malposition resulting in nerve irritation.

Pain Did Not Improve or Recurred
Use this form if pain did not improve OR pain improved but then recurred

Surgical Wound Problem
Use this form if patient developed postoperative surgical wound problem (infection, dehiscence).

Other Problem

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

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
Your name	Kyle Blackley
Your email	kyle.blackley@si-bone.com
Your phone number	(763) 218-1399
Surgeon's name	David Polly
Contact #1: How did you attempt to contact the surgeon?	In person
Was this attempt successful?	Yes

Comments about attempts to contact surgeon (optional)

N/A

Date you first heard of problem with SI-BONE product.	Tuesday, October 25, 2022
If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery.	Tuesday, October 25, 2022
Which device(s) was/were affected?	Instrument

Part number(s), if available

501122-0700

Lot number(s), if available

N/A

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.)

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	Tuesday, October 25, 2022

When was part problem detected?	Damaged part observed during 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

As Dr Polly was drilling over a pin with the 7.0 navigated cannulated TORQ drill bit, the drill bit was spinning in place in the patients pelvis due to very hard sclerotic bone. The drill bit eventually advanced to terminal position, but afterwards when Dr Polly removed the drill bit from the pelvis, he noticed some darkened bone on the drill bit indicative of burning from the heat of the drill bit spinning in place. These drill bits aren't all that sharp to begin with so having it spin in place isn't out of the ordinary, but this patient was having a zyga revision, and the prior screw hole from the zyga screw was very sclerotic. Dr Polly selected a trajectory right alongside the prior screw hole, and it was the sclerotic bone from the prior screw hole that caused the drill difficulty advancing. Even though there was some burning of bone from the heat of the drill bit, Dr Polly didn't not seem concerned about any harm to the patient as it was minimal but noticeable. We proceeded to use a backup drill bit for the 2nd TORQ implant. The patient is doing good, there shouldn’t be any noticeable impact to the patient from this event.

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.

(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?

(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?

Use this section ONLY if the patient problem is **NOT**:

- Implant malposition causing nerve irritation
- Pain did not improve or recurred
- Surgical wound problem

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