Tuesday, December 19, 2023

Complaint 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.

Contact Info

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

Your name Morgan Menard Pailler

Customer name Antoine Bourgoin

How did you learn about this issue? (select all that apply)? I heard about it from someone else

Please provide any relevant details about your communication. Full complaint description will be captured on the following page:

The surgeon wanted to remove implant because of suspected infection after scintigraphy and Petscan.

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. Sunday, December 10, 2023

Date of original surgery (if revision is being reported) or alleged product failure Thursday, September 19, 2019

Indicate affected device(s) (choose all that apply) iFuse (original)

Part number(s) (please list the number of each part involved)(required)

7060-100
7040-100
7040-100

Lot number(s)

7060-100: 494397-R
7040-100: 494529
7040-100: 494529

Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact QA@si-bone.com if you have any questions.

Did the product complaint result in a patient problem?

YES, potential or actual (Ex: required revision, patient adverse event)

Product Complaint Without Patient Problem

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

Examples include:

- Damaged instrument/implant
- Broken/ bent/ cut pin
- Pin advancement but no patient injury
- Packaging issue

If patient injury occured, go back and click YES to report patient problem.

(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?

Select Adverse Event Type

What problem did patient have?

Surgical wound problem (e.g. hematoma, infection)

Implant Malposition Form

Use this form if patient an implant malposition was detected.

(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?

Continued, recurrent, or new pain

Use this form if pain did not improve, pain improved but then returned, or new onset pain

(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).

What is the best description of problem?

Deep wound infection (e.g., infection below skin)

Please describe event

difficult to know, because the result of the microbiology were unknown

Any other treatment received for problem?

Oral antibiotics

Was patient admitted to hospital because of problem?

No, hospitalization was not required

Did patient undergo revision surgery to address this problem?

Yes

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

Revision Procedure

Complete this form as thoroughly as possible for a complaint involving a revision surgery.

Please indicate date of revision procedure

Thursday, December 14, 2023

Reason for revision (e.g. nerve impingement, loosening, etc.). Please be as specific as possible:

the pain reappeared after a year, the patient was operated on again with a cage in the lower part of the joint and 2 years later he was still in pain and another surgeon decided to remove all the material and do a posterior approach with S1 screw and Bedrock iFuse.

Which step(s) were performed during the revision? Choose all that apply:

iFuse implant was removed

Additional iFuse implant was placed

Please further describe the revision procedure (any issues with instrumentation or medical issues?. Be as specific as possible. Failure to provide details will result in continued follow up with you:

the implants were very complicated to remove, the osteointegration was very strong. The scissors were used several times but the implants were still very difficult to remove. 3 hours to remove the 3 implants. The length of the scissors was too short, and one was bent and stuck in the guide.

To your knowledge, was the patient's issue resolved after surgery?

Unknown

You may be contacted for further information if your submission is lacking critical details. We appreciate your thoroughness.