Complaint Reporting

Monday, June 17, 2024

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 Steffen Pölzl

Customer name Julius Dengler

How did you learn about this issue? (select all that apply)? From the HCP or associated staff

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

received a telephone call end of may where they asked for the revision set

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. Tuesday, May 28, 2024

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, January 10, 2023

Indicate affected device(s) (choose all that apply) iFuse-3D

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

1x 7x60
1x 7x 50
1x 7x45

Lot number(s)

2659071
9047991
9046091

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?

Continued, recurrent, or new pain

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

Best description of time course of pain recurrence: Pain got better but then recurred

How long did the patient experience pain relief? Less than 6 months

Were any additional causes of pain discovered during workup? I don't know

If CT was performed, please email scan to QA@si-bone.com. CT results show: Inadequate implant engagement in sacrum

Was initial surgery attended by SI-BONE staff member? Yes

Name of SI-BONE staff member attending initial surgery Steffen Pölzl

(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

Please describe any steps inaccurately performed, or other details of the case

everything was correct

Did patient have revision surgery as a result of this problem? Yes

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

Revision Procedure

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

Please indicate date of revision procedure

Thursday, November 2, 2023

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

one iFuse was removed - a new one was placed

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:

Prof Dengler did the revision alone - they told me, that they didn't had any difficulties, but the implant was very difficult to get out

In the revision surgery last week Prof Dengler told me that the patient has psychological problems and wanted all implants to be removed;
It was very very stressful to remove the implants - they were all very well ingrown.
So the problem was not the implants, but lies in the patient's head...

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

No

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