SI-BONE® Complaint Reporting

Thursday, February 8, 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 Swetlana Juengling

Customer name Stefan Enders

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:

The first operation was performed in another hospital 2 years ago. A Diana screw was inserted. This loosened after some time. The screw was then removed and 2 iFuses were inserted.
Patient presented to Prof Dr Enders with pain. Results of CT and Bone szintigraphy show contours of a white rim and indicate loosening.
Prof Enders contacted my by telephone with the idea of removing the implants.
After our conversation, we agreed that we would first check intraoperatively with the help of the removal instrument whether the implants were really loose. If this was not the case, we would insert another implant.
Intraoperatively, we found that the implants were firmly in place. It was therefore decided to insert another 2 iFuse implants.

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. Monday, January 29, 2024

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, February 9, 2022

Indicate affected device(s) (choose all that apply) None

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

None

Lot number(s)

None

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? More than 12 months

Were any additional causes of pain discovered during workup? Yes, alternative diagnoses were discovered or suspected

Describe discovered or suspected other causes of pain

Presumably 2 iFuse were not enough. Patient has a large SI joint. Only 2 implants were not sufficient in the long term.

If CT was performed, please email scan to QA@si-bone.com. CT results show: CT was done, but doctor refuses to comment on results

Was initial surgery attended by SI-BONE staff member? No

(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).

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.

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