SI-BONE® Complaint Reporting

Monday, May 13, 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 Mostafa Beizai

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 head of the surgical department informed me about the upcoming surgery. I contacted Dr Beizai and made an appointment to discuss the case in advance. Dr Beizai showed me the latest X-ray and CT images. These showed no abnormalities or reasons for removing the implants. Dr Beizai explained to me that he had already had a total of 4 discussions with the patient to explain to her that there was no medical need to remove the implants. The patient would still like to have them removed at her own request as she has a feeling of a foreign body.

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. Friday, April 12, 2024

Date of original surgery (if revision is being reported) or alleged product failure Monday, August 28, 2023

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

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

7050M-90/100
7060M-90/100

Lot number(s)

9060462
2691911

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? NO (Ex: damaged instrument)

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.

When was problem detected? I don't know

(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?

Please describe the details of the event as fully as possible

Dr Beizai showed me the latest X-ray and CT images. These showed no abnormalities or reasons for removing the implants. Dr Beizai explained to me that he had already had a total of 4 discussions with the patient to explain to her that there was no medical need to remove the implants. The patient would still like to have them removed at her own request as she has a feeling of a foreign body.
Removal surgery went smoothly. After preparation and release of the distal implant ends, the implants could be removed without any problems. The images of the removed implants showed very good bone tissue ingrowth in the implant area.

Select Adverse Event Type

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).

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.