



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 Swetlana Juengling

Customer name Matthias Seibl-Leven

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:

Dr Seibl-Leven informed me about the revision by telephone. The first surgery was 2 years ago and the patient was not free of pain. During the X-ray check-up, the misalignment of the first implant and the formation of artefacts on the second and third implants could be seen.

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, October 21, 2024

Date of original surgery (if revision is being reported) or alleged product failure Monday, November 14, 2022

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

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

7.0x45mm
7045-90

Lot number(s)

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?

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 occurred, 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

The first surgery was 2 years ago and the patient was not free of pain. During the X-ray check-up, the misalignment of the first implant and the formation of artefacts on the second and third implants could be seen.

The first implant was removed during the surgery on 11.11.24. It was relatively easy to knock out with the removal instrument. It was therefore loose. The other two implants were then checked. These were firmly in place. No indication of loosening.

Patient is doing very well on the first post-op day. Walking again and relatively pain-free.

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.