



# 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](mailto: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** Ralf Müller-Issberner

**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:**

first revision of right side was on march 10, 2023 - Dr Müller-Issberner informed me that also the left side is loose, so that he wanted to make another revision

## 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.** Thursday, February 15, 2024

**Date of original surgery (if revision is being reported) or alleged product failure** Wednesday, October 28, 2020

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

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

7040M-90  
7050M-90  
7050M-90

**Lot number(s)**

2717661  
2717681  
2717681

## 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 occurred, 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?**

6-12 months

**Were any additional causes of pain discovered during workup?**

No other cause determined or suspected

**If CT was performed, please email scan to QA@si-bone.com. CT results show:**

Inadequate implant engagement in sacrum

### Additional CT results / details

Revision surgery: Patient, born 1948, 3 iFuse on both sides: all three implants on the left side were loose - initial surgery in October 2020 - complaints only occurred after approx. one year - various treatments were unsuccessful, patient continued to have pain - according to the last CT, Dr. Müller-Issberner indicated a seam around the implants and found that they were loose and therefore had to be removed - the implants were firmly ingrown in the ilium, but totally loose in the sacrum, as the bone condition was anything but firm; with the removal adapter, all three implants could be explanted, so the removal tray was not needed.

**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**

no inaccurately steps

**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**

Friday, March 1, 2024

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

Revision surgery: Patient, born 1948, 3 iFuse on both sides: all three implants on the left side were loose - initial surgery in October 2020 - complaints only occurred after approx. one year - various treatments were unsuccessful, patient continued to have pain - according to the last CT, Dr. Müller-Issberner indicated a seam around the implants and found that they were loose and therefore had to be removed - the implants were firmly ingrown in the ilium, but totally loose in the sacrum, as the bone condition was anything but firm; with the removal adapter, all three implants could be explanted, so the removal tray was not needed. Please describe any steps inaccurately performed, or other details of the case

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

iFuse implant was removed

**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:**

Only the removal adapter was used for explantation

**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.**