



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 Rachel Strauss

Customer name Samuel Smith

**How did you learn about this issue?
(select all that apply)?**

From the HCP or associated staff

I observed the issue

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

Dr. Samuel Smith revision case on 5/14/24. Patient had primary SIJ fusion performed by Dr. Benz in 2022. Patient reported continued pain & received relief with SIJ injections. 2 out of 3 implants appeared haloed on imaging, specifically on the iliac side. Dr. Smith opted to only remove one of the haloed implants and replaced it with a 13.5mm TORQ implant.

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. Wednesday, May 8, 2024

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, May 14, 2024

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

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

N/A

Lot number(s)

N/A

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 never got better

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:

Dark areas around implant without a rind of bone

Additional CT results / details

2 out of 3 implants appeared haloed on imaging, specifically the iliac side

Was initial surgery attended by SI-BONE staff member?

Yes

(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?

I don't know

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

n/a

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

Tuesday, May 14, 2024

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

continued pain & received relief from SIJ injections, implant loosening on imaging (halo)

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:

Some difficulty lining the guide up on the implant in the proper orientation due to bone growth & difficulty with one side in particular when chiseling it out (hard bone, took a lot of force). 2 of 3 implants appeared haloed on imaging but Dr. Smith opted to only remove one. The implant that was removed was replaced with a 13.5 TORQ implant (placed in the void left when the implant was removed-- therefore same position and trajectory). Both navigation and C-arm were used.

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.