



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 Melanie Jackson

Customer name Karl Siebuhr MD

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. Siebuhr told me we had a case coming up, when I asked him about the details he said it was a revision of a previous surgery.

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. Tuesday, October 22, 2024

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, October 15, 2024

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

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

iFuse Torq 11.5mm x 75mm
11575T

Lot number(s)

Lot 9082071

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?

Other problem

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

Describe problem in detail

There was no problem with the implant or the placement of the implant. This was a trauma case, Dr. Siebuhr repaired the anterior pubic rami first with a plate, then placed our iFuse Torq implant posteriorly. The reason for the revision was Dr. Siebuhr didn't like the position of the sacrum after surgery. He said there was a posterior tilt to the posterior wall of his pelvis that he wanted to correct, but to correct it he had to remove the Torq he placed, reposition, and implant Torq again. Plus he also needed to repair the patient's acetabulum, which he hadn't done yet.

Did patient undergo revision surgery to address this problem?

Yes

Revision Procedure

Complete this form as thoroughly as possible for a complaint involving a revision surgery.

Please indicate date of revision procedure

Friday, October 25, 2024

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

After Dr. Siebuhr did the first surgery, he didn't like the position of the posterior wall of the patient's pelvis/sacrum on post-op imaging. He said to correct it, he needed to remove the iFuse implant, reposition and re-implant. He also needed to repair the patients acetabulum.

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:

The revision surgery went very well. He removed iFuse Torq implant without any issues. He then repaired the acetabulum and placed a Synthes threaded lag implant down the pubic bone towards the pubic crest. Then he placed an iFuse Torq 13.5mm revision screw into the S1 body.

To your knowledge, was the patient's issue resolved after surgery?

Yes

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