



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 Nirav Gupta DO

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:

I received a text from Dr. Gupta's surgery scheduler that a case had been scheduled that he would like me to be at. I recognized the patient's name, so I called Dr. Gupta to ask about the situation.

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, June 18, 2024

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, April 24, 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 10mm x 80mm

Lot number(s)
Lot# 9084201

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

In speaking with Dr. Gupta, the patient had an injury after her initial surgery on 4/24/24, and prior to her revision surgery which further fractured the affected site. I don't know the details of the injury, if it was a fall or not, but the patient has poor bone quality. He said he was going to either remove the Torq implant and plate the fracture site, or leave Torq in place and plate around it. When he got into the OR, he ended up backing out the Torq implant and plating the fracture site. Torq wasn't difficult for him to remove, likely because of her poor bone quality, she had almost no osteointegration. Dr. Gupta stated the revision had nothing to do with initially using the Torq implant, that this fracture would have happened regardless because of the injury after surgery, and would have needed to be revised.

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.