



# 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** JR Maupin

**Customer name** Brad Duhon

**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:**

Patient was originally implanted with one ifuse 3D and 2 Torq. Patient presented with existing SIJ pain. Dr. Duhon felt the Torq were the issue. He attempted to remove one but couldn't. Removed the 3rd implant and replaced with 11.5 Torq. He then place an additional 10 Torq implant more ventral as all original 3 implants were fairly dorsal.

## 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.** Friday, January 10, 2025

**Date of original surgery (if revision is being reported) or alleged product failure** Wednesday, June 26, 2024

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

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

**Lot number(s)**  
Unknown

## Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact [QA@si-bone.com](mailto: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?**

Poor placement

*(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**

Patient presented with original SIJ pain

## 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.**