



Complaint - Revision - Post Market - Feedback 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.

Select the type of problem you are reporting

Problem with individual device or individual patient

General Feedback about SI-BONE Product

This is only for non complaint information. Examples: surgeon suggestions, meeting discussions, etc. For complaints, go back and select "Problem..."

Contact Info

Use this to record your attempts to contact and gather information from the surgeon.

Your name

Kyle Blackley

Your email

kyle.blackley@si-bone.com

Your phone number

(763) 218-1399

Surgeon's name

David Polly

Contact #1: How did you attempt to contact the surgeon?

In person

Was this attempt successful?

Yes

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, January 3, 2023

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery.

Tuesday, January 3, 2023

Which device(s) was/were affected?

iFuse-TORQ

Part number(s), if available

Driver Sleeve 1

Lot number(s), if available

(01)00855369008521 (10)220509

Product Complaint or Adverse Event?

Decide what type of report you are submitting.

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.

What is the nature of the problem you are reporting?

Product complaint without a patient problem. (Example: instrument breakage, no impact on patient.)

Product Complaint Without Adverse Event

Use this form to report an SI-BONE product problem that was NOT associated with a patient adverse event.

Examples include:

- Damaged instrument
- Broken pin
- Bent pin
- Pin advancement but no patient injury
- Problem with packaging

If a damaged part injured a patient, go back and click on "Product complaint that caused or may have caused an adverse event."

Date part problem noticed

Tuesday, January 3, 2023

When was part problem detected?

Damaged part observed during use

If part in question was used during procedure, was surgeon able to finish the procedure?

Yes, surgeon completed surgery using a different/new part

Was any part of product left in patient? Example: broken pin, metal shavings

No, no part was left in patient

Any further comments or information

TORQ screw would not unscrew from driver sleeve 1 in patient. This was the first TORQ screw in the case so all instruments were clean. The TORQ screw was threaded on to driver sleeve 1 and then slightly loosened to help with unthreading once it was implanted. After the screw was screwed in, the driver sleeve wouldn't disengage from the screw, even with the use of pliers. The screw was eventually completely backed out, and the screw was easily able to unthread from the driver sleeve. Dr Polly put the screw in again without the use of the driver sleeve. I opened a backup TORQ set and they used a new driver sleeve for the 2nd screw, when the screw was halfway implanted, I had Dr Polly unthread the driver sleeve then finish implanting the screw in and that worked great. For the 3rd screw he tried putting in the screw without a driver sleeve and that worked just fine. I tested the faulty driver sleeve today (1/4) and found no issues with it on a demo TORQ screw, and I couldn't visually see anything wrong with it. This particular patient had very hard bone which likely was a major contributor to the

inability to unthread and remove the driver sleeve from the implanted TORQ screw. The faulty driver sleeve will be returned for further analysis. There was no impact to the patient.

Select Adverse Event Type

Select from the choices below. Your choice guides which section to complete.

If the first 3 do not apply, select "Other".

If a product problem occurred that did NOT cause a patient problem, go back and complete the "Product Complaint Without Adverse Event" section.

Symptomatic Implant Malposition Form

Use this form if patient experienced symptomatic implant malposition resulting in nerve irritation.

(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?

For above question, be specific and include all steps of the revision surgery and any complications.

- Was the implant adjusted, removed or added?
- Were the explant holes filled with bone graft?
- Were osteotomes and the/or the removal adapter used?
- Was any non-iFuse hardware installed?

Pain Did Not Improve or Recurred

Use this form if pain did not improve OR pain improved but then recurred

(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

Potential Warranty Case

Please help evaluate whether this case could qualify for SI-BONE's warranty policy.

Did patient's situation meet all of the following?

Did patient undergo a revision procedure that met all of the following:

1. *The initial procedure involved placement of 3 SI-BONE implants on the affected side*
2. *The revision procedure:*
 - *Was completed within 1 year of the initial procedure*
 - *Was completed at the same hospital or within the same hospital system as the initial procedure*
 - *Was completed during a separate hospitalization from the initial procedure*
3. *The patient followed all physician instructions after the initial procedure*

Did patient's situation meet warranty criteria shown above?

No, not all of the above apply