



## 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](mailto: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

#### Contact Info

Your name Mahua Ghoshal

Your email mahua.ghoshal@si-bone.com

Your phone number (000) 000-0000

Surgeon's name Dr. XX YY

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

Was this attempt successful? Yes

Comments about attempts to contact surgeon (optional)

Test- microsoft edge

#### Complaint Overview

Date you first heard of problem with SI-BONE product. Wednesday, March 2, 2022

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery. Thursday, March 24, 2022

Which device(s) was/were affected? iFuse-TORQ

Part number(s), if available  
P/Nxyx

**Lot number(s), if available**

o1234

## Product Complaint or Adverse Event?

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.

**What is the nature of the problem you are reporting?**

Product complaint that caused or may have caused an adverse event

## Product Complaint Without 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."

## 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.

**What problem did patient have?**

Implant malposition causing nerve irritation

## Symptomatic Implant Malposition Form

**On which side(s) were SI-BONE implants placed during initial surgery?**

Left

**Which operated side showed postoperative symptoms (i.e., symptoms related to implant malposition)?**

Left

**Did any SI-BONE staff attend initial surgery?**

Yes

**Name of SI-BONE staff in attendance at initial surgery** xy zz

*(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

**If one or more steps was inaccurately done, describe:**

n/A

**Were any SI-BONE implants removed or adjusted as a result of this problem?**

Yes

**Did the patient have SI joint pain relief following the initial procedure? How long was the pain relief ?**

yes

**Date of revision surgery**

Wednesday, March 16, 2022

**Diagnosis / Reason for the iFuse revision surgery?**

xyz

**Details of iFuse revision surgery (Treatment):**

iz

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?

**Was the iFuse Removal System Instrument Set (P/N 400132) and chisels used to explant the iFuse Implant(s)?**

Yes

**Patient's outcome following the iFuse revision surgery: Were the patient's pain complaints resolved?**

n/a

## Pain Did Not Improve or 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

## 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

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?**

Yes, all of the above apply

**Comment on warranty**

n/a