



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

Contact Info

Your name Sven Güldener

Your email sven.guldener@si-bone.com

Your phone number (172) 860-9111

Surgeon's name Barut

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

Was this attempt successful? Yes

Complaint Overview

Date you first heard of problem with SI-BONE product. Wednesday, September 7, 2022

If problem occurred during placement of an SI-BONE device, enter date placed (initial procedure), not date of revision surgery. Wednesday, September 7, 2022

Which device(s) was/were affected? Instrument

Part number(s), if available

400066

Lot number(s), if available

(10)TI21F003 / (01)00851085007022

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 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

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

Wednesday, September 7, 2022

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 was able to finish procedure with problem 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

During surgery with Dr Barut in Geoffroy Saint Hilaire, we had a problem with the impactor and the soft tissue protector,

While impacting the implant, the impactor got stuck in the soft tissue protector and could not be removed even by force,

While trying to put the same impactor in another soft tissue protector we had the same problem.

We put the PinSleeve after the surgery back into the STP and now its stocked completely. We are not able to remove the PinSleeve from the STP.

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

(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

(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