



## 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

Daniela Sá

Your email

daniela.sa@neurowave.pt

Your phone number

(021) 401-5373

Surgeon's name

Marcel Sincari

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

In person

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

Occurred during surgery.

#### Complaint Overview

Date you first heard of problem with SI-BONE product.

Monday, May 16, 2022

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

Saturday, May 14, 2022

Which device(s) was/were affected?

Instrument

Part number(s), if available

PIN SLEEVE ref. 400065

## Lot number(s), if available

LOT 2084-02

## 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 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

Saturday, May 14, 2022

### When was part problem detected?

Part damaged as a results of 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

The problem occurred after the surgeon used the part. The plastic part broke.

## 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?**

No, not all of the above apply

### Comment on warranty

Not a revision