Thursday, June 2, 2022

# 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** | Paul Sosman |
| **Your email** | paul.sosman@si-bone.com |
| **Your phone number** | (908) 577-7808 |
| **Surgeon's name** | Patrick Senatus |
| **Contact #1: How did you attempt to contact the surgeon?** | In person |
| **Was this attempt successful?** | No |
| **Contact #2: How did you attempt to contact the surgeon?** | In person |
| **Was this attempt successful?** | No |
| **Contact #3: How did you attempt to contact the surgeon?** | Phone |
| **Was this attempt successful?** | No |

## Complaint Overview

| | |
|---|---|
| **Date you first heard of problem with SI-BONE product.** | Wednesday, May 18, 2022 |
| **Which device(s) was/were affected?** | iFuse-3D |

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

Not available

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

Not available

# 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, May 18, 2022

**When was part problem detected?**

Revision to remove implants that were implanted years before

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

I don't know

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

No, no part was left in 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

*(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