



Thursday, August 17, 2023

# 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

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

Samir Aziz

Your email

samir@freedomortho.co.uk

Your phone number

(779) 921-1242

Surgeon's name

Mr. Darren Lui

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

Phone

Was this attempt successful?

Yes

Comments about attempts to contact surgeon (optional)

Successfull

## 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, July 11, 2023

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

Thursday, October 29, 2020

Which device(s) was/were affected?

iFuse-3D

Part number(s), if available

7035M-90

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

N/A

## Product Complaint or Adverse Event?

Decide what type of report you are submitting.

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**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**

Thursday, December 22, 2022

**When was part problem detected?**

No Part Damaged

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

N/A, problem detected OUTSIDE of surgery

**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**

Patient initial primary procedure for right side SIJF on 29.10.202 by Mr. Orpen at BMI Ridgeway  
Both Left & Right sides initially fused  
Revision for both sides followed to remove caudal implant only

Please see history of revision report below submitted 19.10.21;

Female  
Right  
1980/41

Primary SIJ Fusion 29/10/2020  
BMI Ridgeway  
Mr Neil Orpen

Revision of inferior implant (iFuse 3D 7x35mm)  
18/10/2021  
BMI Ridgeway

Mr Orpen

Patient had initial SIJ fusion on the right side in October 2020 and did very well then the surgeon agreed to fuse the left side in January 2021.

The patient complained about pain on left side so that caudal implant was removed on 24/06/2021 which she said relieved her pain.

Patient then complained about pain over right side around 6 weeks later.

The placement of all implants looked correct on CT and lateral, inlet and outlet views and not breaching any foramen or nerve roots and Mr Orpen said therefore " the pain is inexplicable and there seems to be something psychological involved".

Mr Orpen agreed to remove the caudal implant on the right side.

Access through primary incision, retractors applied to gain access.

The removal adaptor was used and threaded onto the implant and removed successfully with the slotted mallet using lateral and AP views.

Mr Orpen didn't use any bone sub in the void but closed as standard.

## 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?**

Yes, all of the above apply

**Comment on warranty**

N/A