Tuesday, September 5, 2023

Complaint 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.

Contact Info

Use this to record your attempts to contact and gather information from the customer

Your name	dfg dfg
Your email	asd@gmail.com
Your phone number	(123) 123-1231
Customer name	sdf adfg
What method(s) did you use to contact the customer (select all that apply)?	Text
Were you successful?	Yes

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, September 5, 2023
Did the problem occur during use (actual or attempted) in surgery?	No

Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact QA@si-bone.com if you have any questions.

Did the product complaint result in a patient problem?	Yes, potential or actual patient problem (Example: resulted in revision procedure or may have caused a patient adverse event)

Product Complaint Without Patient Problem

Use this form to report an SI-BONE product problem that was NOT associated with a patient adverse event.

Examples include:

- Damaged instrument
- Broken/ bent/ cut pin
- Pin advancement but no patient injury
- Damaged implant
- 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

What problem did patient have? Surgical wound problem (e.g. hematoma, infection)

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?

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).

What is the best description of problem? Deep wound infection (e.g., infection below skin)

Please describe event

dh

Any other treatment received for problem? IV antibiotics

Was patient admitted to hospital because of problem? No, hospitalization was not required

Did patient undergo revision surgery to address this problem? Yes

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

Revision Procedure

Complete this if patient underwent revision surgery.

Please indicate date of revision procedure Monday, September 4, 2023

Please indicate all procedural steps that apply:

- iFuse implant was removed
- Additional iFuse implant was placed
- Non-iFuse implant/instrumentation was placed

Was the patient's issue resolved after surgery?

yes

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? No, not all of the above apply