Thursday, September 28, 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 Charlene McInroy

Customer name Stefan Kim

How did you learn about this issue? (select all that apply)? I observed the issue

Please provide any relevant details about your communication:

When the scrub tech tried to seat the Granite implant on the Granite driver, she was having trouble seating the distal tip into the implant. I asked to take a closer look at the driver and noticed to distal tip of the driver was damaged. I then asked to see a side by side comparison with the second driver in the tray and confirmed there was an obvious difference. I asked the tech to set that driver aside so I could remove it after the case was complete. I then contacted Frances and CSR to set up a RMA for the return and replacement of the driver. The patient was not affected and there was little to no lost OR time.

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 19, 2023

Indicate affected device(s) (choose all that apply) Instrument(s)

Part number(s) (please list the number of each part involved)(required)

(01)00810055520763

Lot number(s)

400268

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? NO (Ex: damaged instrument)

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/implant
- Broken/ bent/ cut pin
- Pin advancement but no patient injury
- Packaging issue

If patient injury occured, go back and click YES to report patient problem.

When was problem detected?

Problem identified before use (observed issue in packaging or tray)

(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?

Please describe the details of the event as fully as possible

When the scrub tech tried to seat the Granite implant on the Granite driver, she was having trouble seating the distal tip into the implant. I asked to take a closer look at the driver and noticed to distal tip of the driver was damaged. I then asked to see a side by side comparison with the second driver in the tray and confirmed there was an obvious difference. I asked the tech to set that driver aside so I could remove it after the case was complete. I then contacted Frances and CSR to set up a RMA for the return and replacement of the driver. The patient was not affected and there was little to no lost OR time.

Select Adverse Event Type

Implant Malposition Form

Use this form if patient an implant malposition was detected.

(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?

Continued, recurrent, or new pain

Use this form if pain did not improve, pain improved but then returned, or new onset pain

(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

Revision Procedure

Complete this if patient underwent revision surgery.

You may be contacted for further information if your submission is lacking critical details. We appreciate your thoroughness.