Friday, November 22, 2024

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 Grant Boynton

Customer name Daniel Dixon

How did you learn about this issue? (select all that apply)? From the HCP or associated staff

Please provide any relevant details about your communication. Full complaint description will be captured on the following page:

Dr. Dixon called and said this patient had a little bit of pain but not bad and that she was still happy with the surgery. The patient went to an IR Doctor who told her the implant was prominent outside of the ilium. After reading the report from the IR Doctor, the patient decided she wanted the implant out and not to be revised with another Torq Implant.

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. Thursday, November 14, 2024

Date of original surgery (if revision is being reported) or alleged product failure Wednesday, July 10, 2024

Indicate affected device(s) (choose all that apply) iFuse-TORQ

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

Torq Tray 210400

3 guide pins (500373)
1 blunt pin (500374)
1 exchange pin (500375)

3 Torq Implants
10.0 x 60mm (Ref 10060T)
10.0 x 45mm (Ref 10045T)
10.0 x 40mm (Ref 10040T) - this implant was removed

Lot number(s)

10.0 x 60mm (Lot 9088771)
10.0 x 45mm (Lot 9090911)
10.0 x 40mm (Lot 9090801) - this was the implant removed

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? I don't know

(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

This patient came to Dr. Dixon with a little pain after the procedure but said she was still happy with the surgery. She had a visit with an IR Doctor who informed her our most inferior implant was prominent. The patient then requested that Dr. Dixon remove that implant and not revise it.

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 form as thoroughly as possible for a complaint involving a revision surgery.

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