Monday, May 13, 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 Jennifer Faust

Customer name Mark Lambrechts

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:

I was notified by the hospital OR neuro coordinator of the request to have SI Bone instruments available for the removal of iFuse implants by Dr. Lambrechts.

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, April 23, 2024

Date of original surgery (if revision is being reported) or alleged product failure Tuesday, December 4, 2018

Indicate affected device(s) (choose all that apply) iFuse-3D

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

7055M-90
7045M-90

Lot number(s)

2641481
2654281

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 (Ex: required revision, 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/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.

(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?

Select Adverse Event Type

What problem did patient have?

Continued, recurrent, or new pain

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

Best description of time course of pain recurrence:

Pain never got better

Were any additional causes of pain discovered during workup? I don't know

If CT was performed, please email scan to QA@si-bone.com. CT results show: Inadequate implant engagement in sacrum

Was initial surgery attended by SI-BONE staff member? Yes

Name of SI-BONE staff member attending initial surgery Yale VanDyne

(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?

See summary of IFU steps. Did surgeon complete all steps as shown above? I don't know

Please describe any steps inaccurately performed, or other details of the case

I was not present in the original case. The SI Bone rep that was present during the original surgery is no longer with SI Bone

Did patient have revision surgery as a result of this problem? Yes

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.

Please indicate date of revision procedure Thursday, April 25, 2024

Reason for revision (e.g. nerve impingement, loosening, etc.). Please be as specific as possible:

On-going pain that did not resolve after original surgery. Dr. Lambrechts thought the screws did not have any bony bridging and possibly some hallowing on the CT. Additionally, the most inferior implant was poorly placed and barely crossed the SIJ.

Which step(s) were performed during the revision? Choose all that apply:

Additional iFuse implant was placed

Please further describe the revision procedure (any issues with instrumentation or medical issues?. Be as specific as possible. Failure to provide details will result in continued follow up with you:

Dr. Lambrechts chose to remove both implants instead of adding any more implants or revising the one that was poorly placed. The standard removal instrument in the regular ifuse 3D tray was not adequate enough to remove either implant. He and his resident had to use the removal tray and chisel around the implants. They were challenging to remove but the chisels worked. However, the resident dropped the guide for the chisels on the ground after removing the first implant. We did not have a backup removal tray. Dr. Lambrechts very carefully utilized the chisel blade without a guide to remove the second implants.

To your knowledge, was the patient's issue resolved after surgery?

Unknown

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