



## 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](mailto: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** Jared Davis

**Customer name** Everyone Intheworld

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

### Please provide any relevant details about your communication:

TORQ driver sleeve needs an easier back off mechanism when disengaging from the implant once implanted.

### 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, July 1, 2021

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

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

TORQ Driver Sleeves

**Lot number(s)**

TORQ Driver Sleeves

### Product Complaint or Adverse Event?

Decide what type of report you are submitting. Contact [QA@si-bone.com](mailto: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 occurred, go back and click YES to report patient problem.

**When was problem detected?**

Failed during use (part broke, dislodged, etc.)

**Date of surgery or use**

Thursday, July 1, 2021

**Was the physician able to finish the procedure?**

Yes, using the problem part

**Was any part of product left in patient? Example: broken pin, metal shavings**

No, definitely

*(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 (regardless of post-op symptoms)?**

Yes, all steps were completed accurately

**Please describe any step(s) not accurately performed or any notes about the case:**

None

**Please describe the details of the event as fully as possible**

When implanting TORQ the driver sleeve does not disengage from the implant due to the slippery and hard to grab handle.

## 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.**