

SI-BONE Complaint Reporting Form

Submission Date	2023-08-11 10:35:15
Select the type of problem you are reporting	Problem with individual device or individual patient
Your name	Nate Blair
Your email	nblair@si-bone.com
Your phone number	(260) 704-1245
Surgeon's name	John Williams
Contact #1: How did you attempt to contact the surgeon?	In person
Was this attempt successful?	Yes
Date you first heard of problem with SI-BONE product.	07-20-2023
Which device(s) was/were affected?	iFuse-3D iFuse-TORQ
Part number(s), if available	N/A
Lot number(s), if available	N/A
What is the nature of the problem you are reporting?	Product complaint that caused or may have caused an adverse event or revision procedure
What problem did patient have?	Pain did not improve or recurred
Best description of time course of pain recurrence:	Pain got better but then recurred
How long was SI joint pain relieved before recurrence of pain symptoms?	Patient had close to year of relief
Compared to preoperative level, pain now is	Same
CT imaging to evaluate pain recurrence shows:	CT was done and doctor has shared findings with me
CT findings (check all that apply)	So possible halo effect on sides of implants but not around entire implant
Is doctor willing to share CT images with SI-BONE?	CT done, doctor NOT willing to share
Imaging type used during initial surgery	C-arm/fluoro only
Was initial surgery attended by SI-BONE staff member?	Yes
Name of SI-BONE staff member attending initial surgery	Nate Blair
See summary of IFU steps. Did surgeon complete all steps as shown above?	Yes, all steps were completed accurately
Were any additional causes of low back / pelvic pain evident or discovered during workup?	I don't know

Were any SI-BONE implants removed or adjusted as a result of this problem?

No, no implants were adjusted or removed

Describe revision procedure.

Patient had a bone dowel placed from a posterior/inferior approach within the joint just anterior to the implants. Patient actually had this same thing done in other side and noted great relief.

Did patient's situation meet warranty criteria shown above?

No, not all of the above apply

Comment on warranty

I believe initial procedure was done over a year ago. If our records show the initial procedure was performed within the last year then all criteria is met