SI-BONE Complaint Reporting Form

Submission Date	2024-10-07 16:02:17
Your name	Megan Hinkle
Customer name	Dustin Donnelly
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:	While placing a TORQ implant in the bedrock technique the threads of the driver sleeve 1 broke off in the TORQ implant.
Date you first heard of problem with SI-BONE product.	10-07-2024
Date of original surgery (if revision is being reported) or alleged product failure	10-07-2024
Indicate affected device(s) (choose all that apply)	Instrument(s)
Part number(s) (please list the number of each part involved)(required)	400248
Lot number(s)	NA
Did the product complaint result in a patient problem?	NO (Ex: damaged instrument)
When was problem detected?	Failed during use (part broke, dislodged, etc.)
Date of surgery or use	10-07-2024
Was the physician able to finish the procedure?	Yes, using a different/new part
Was any part of product left in patient? Example: broken pin, metal shavings	Possibly
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:	N/A
Please describe the details of the event as fully as possible	TORQ implant was threaded onto driver sleeve 1 by the surgical tech. While placing the implant in the patient the threads of driver sleeve 1 broke off in the implants. The threads were removed using a curette and both parts of the instrument are being sent to corporate for evaluation.