FixDT
UK Fixation of Distal Tibia Fractures

Serious Adverse Event Form

Please report any SAEs which occur following initial discharge

Please fax immediately to the FixDT Coordinating Centre on [redacted]

Centre ID: ☐☐☐ **Participant ID:** ☐☐☐☐ **Participant Initials:** ☐☐☐ **Date of Birth:** ☐☐-☐☐☐-☐☐☐☐ **Initial or Follow Up?** **Initial:** ☐ **Follow Up:** ☐

1. EVENT TYPE:

	Yes	No
i. Death	☐	☐
ii. Life-threatening	☐	☐
iii. Hospitalisation or prolongation of existing hospitalisation	☐	☐
iv. Persistent or significant disability/incapacity	☐	☐
v. Required medical intervention to prevent one of the above	☐	☐
vi. Otherwise considered medically significant	☐	☐

2. EVENT DETAILS:

i. Date event deemed serious: ☐☐-☐☐☐-☐☐☐☐

ii. Details of Event:
Please include all **relevant** details of the event, any tests performed and associated results:

3. CAUSALITY: **In the opinion of the Principal Investigator was the event related to the trial**

Related: ☐ Unrelated: ☐

4. EXPECTEDNESS:

Expected: ☐ Unexpected: ☐

5. OUTCOME OF EVENT:

Resolved ☐ On-going ☐

Principal Investigator Signature: _____

Date signed: ☐☐-☐☐☐-☐☐☐☐

Office use only:

Is the event related to the intervention? → No ☐

↓ Yes ☐

Is it Unexpected? → No ☐

↓ Yes ☐

Date report sent to MREC/Sponsor (within 15 days of FixDT team receiving report) ☐☐-☐☐☐-☐☐☐☐

Chief Investigator Signature: _____

Date signed: ☐☐-☐☐☐-☐☐☐☐

SAE reference number: ☐☐☐☐-☐☐