TRIAL OFFICE USE:

Received:	Initial:	Checked:	Initial:

Serious Adverse Event Form—Follow-up

Participant Trial Number: ☐☐☐☐☐ **Participant Initials:** ☐☐☐

Randomising Site:

SAE Reference No.
For trial office use only

Please email immediately to the RACER Coordinating Centre to wctuqa@warwick.ac.uk

1. THIS REPORT RELATES TO THE ADVERSE EVENT DEEMED SERIOUS ON: d d – m o n – y y y y

(Date must match to that stated in Section 2 of Initial Report)

2. FURTHER DETAILS OF EVENT:

1. Have there been any additional serious adverse event symptoms or worsening in grade of the event symptoms reported on the initial report?

Yes ☐ **No** ☐ → *Please continue to next page.*

Please complete section below with any new or updated information.

Please include all relevant further details of the event, any additional tests performed, updated results and treatment:

(Please continue on SAE Continuation Form as necessary)

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3. CAUSALITY:

1. Was the event related to administration of the study procedures i.e. the anaesthetic, operation or post-operative care?

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

2. Was the event related to the robot? ***WCTU will ALSO contact STRYKER about any robot related SAEs***

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

4. OUTCOME OF EVENT: *(please select one only)*

1. Resolved—no sequelae ☐ → **Date of resolution:** d d – m o n – y y y y

2. Resolved—with sequelae ☐ → **Details of sequelae:** _____ **Date of resolution:** d d – m o n – y y y y

3. Unresolved ☐ → **Please complete the SAE Follow-up Form as appropriate**

4. Death ☐ → **Please complete Notification of Death form**

5. Unresolved at time of death/withdrawal ☐ → **Please complete Notification of Death/Withdrawal Form as appropriate**

Clinician assessing causality (print name): _____

*(Please note: your name **must** be on the trial delegation log with responsibility code J)*

Signature: _____ **Date signed:** d d – m o n – y y y y

Form completed by (print name): _____

*(Please note: your name **must** be on the trial delegation log with responsibility code K)*

Signature: _____ **Date signed:** d d – m o n – y y y y

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Received:	*Initial:*	*Checked:*	*Initial:*

Completion Guidelines for RACER Serious Adverse Event Form—Follow-up report

Form dates: Use format: 0 6 - J U N - 1 9 5 6

Further details of event: Please add any additional **relevant** information that has come to light since the initial report

Was the event related to administration of the study procedures i.e. the anaesthetic, operation, or post-operative care?

Unrelated:	There is no evidence of any causal relationship
Unlikely:	There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the participant's clinical condition, other concomitant medications).
Possibly:	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant medications).
Probably:	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely:	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

If an SAE Continuation Form is required, it must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinical member of staff responsible for assessing causality; the signatures must appear on your Site Signature and Delegation Log.