



Adverse Event Form

TNO:

Initials:

Site Code:

Please complete one Adverse Event Form per event

1. Date of AE:

- -

2. Please tick one event per form:

- Injury to teeth, mouth or throat during anaesthetic
- Urinary retention
- Chest infection
- Nerve or vessel injury due to local anaesthetic (i.e. local blocks)
- Spinal haematoma
- Exacerbation/persistence of knee pain or restriction in range of motion requiring medical intervention
- Deep Infection of the knee joint or the implant
- Wound healing problems
- Fracture, or ligament or tendon damage or rupture
- Implant failure, dislocation, or loosening
- Revision surgery or other corrective surgery
- Thrombosis
- Damage to nerves or vessels in the surgical area
- Persistent muscle soreness or muscle injury
- Bruising
- Other *(Please provide as much detail as possible in the box below)*

Please Note if the event meets the criteria listed below:

- Death
- Life threatening
- Hospitalisation or prolonged hospitalisation
- Disability/ incapacity
- Congenital abnormality/birth defect

This would no longer be classed as an adverse event and needs to be reported as a serious AE, please complete the SAE form

Please note that medical device related AEs or defects should also be reported to Stryker.

3. Please add any further details to the box below or write 'Not Applicable' or N/A

If you are unable to upload this information directly onto the RACER database, please email to RACER@warwick.ac.uk
For queries please call: Tel: 02476 968629

Form completed by (print name): _____

Signature: _____

Date signed: - -