RACER

Robotic Arthroplasty:
A Clinical and cost Effectiveness
Randomised controlled trial

Trial Number ☐☐☐☐☐

Day of Surgery Pack—Learning Effect Study

This pack contains the instructions, Case report forms and study procedures for the Day of surgery. If you have any queries please contact the central study team at:

Racer@warwick.ac.uk

Note: To perform surgery using the MAKO robot surgeons need to be have receive the Certified training provided by Stryker

Forms to be completed included in this pack:

- ☐ Surgery Form
- ☐ MAKO Robot Form

- **Read the instructions in this pack before the Day of surgery so you are prepared.**
- **Ensure that the Surgery form and MAKO form are returned to the RACER Trial office using a return envelope.**

For a printable version of this pack go to: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/current/racer/

GCP Awareness

All Staff with access to Trial paperwork and the Trial Database must be aware of the below GCP principles:

Good Clinical Practice (GCP) - 13 Principles

GCP is an internationally agreed **ethical and scientific quality standard** for designing, conducting, recording and reporting trials that involve the participation of **human subjects**.

Working to GCP principles provides assurance that the **rights, safety and well-being** of trial subjects are protected, we are working ethically and in accordance with the principles that have their origin in the **Declaration of Helsinki**, and that the clinical trial **data is credible.**

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

TRIAL OFFICE USE:

Received:	Initial:	Checked:	Initial:

Learning Effects Study Surgery Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

Name of operating surgeon:

1. PARTICIPANT DETAILS:

A. Participant Initials: ☐☐☐

B. Age: ☐☐ B. Sex: Male ☐ Female ☐

D. Hospital number: ☐☐☐☐☐☐☐☐☐☐

E. BMI: ☐☐.☐ **OR** Height: ☐☐☐ cm Weight: ☐☐☐ kg

F. Which knee is being replaced? Left ☐ Right ☐

G. Most affected knee compartment: Medial ☐ Lateral ☐ Patellofemoral ☐

H. Registering site:

2. PARTICIPANT CONSENT:

*(Please note: your name **must** be on the trial delegation log)*

A. Has consent been verbally re-confirmed today? No ☐ Yes ☐

B. Name of person re-confirming consent:

3. PARTICIPANT ELIGIBILITY:

A. Has eligibility been re-confirmed today? No ☐ Yes ☐

If no, please explain why:

B. Name of person re-confirming eligibility:

4. SURGERY DETAILS:

A. Date of Surgery: d d – m o n – y y y y

B. Surgery Start Time *(Knife to Skin)* H H : M M Surgery End Time *(End of Closure)* H H : M M

C. Type of anaesthesia: General ☐ Regional (spinal) ☐

D. Block used? No ☐ Yes ☐

TRIAL OFFICE USE:

Received:	Initial:	Checked:	Initial:

Learning Effects Study Surgery Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

4. SURGERY DETAILS (cont):

E. Grade of operating surgeon (please choose one option):

Consultant ☐ Non-Consultant Specialist ☐ Post-CCT Trainee ☐

F. Was there a senior supervising surgeon present? No ☐ Yes ☐

If **YES**, name of supervising surgeon: ☐

G. Grade of senior supervising surgeon, if present (please choose one option):

Consultant ☐ Non-Consultant Specialist ☐ Post-CCT Trainee ☐

H. Was the senior supervising surgeon scrubbed? No ☐ Yes ☐

I. Tourniquet used? No ☐ Yes ☐

If **YES**, tourniquet time: ☐ mins

J. Time from incision to closure: ☐ mins

K. Was the patella resurfaced? No ☐ Yes ☐

L. Type of implant:

Posterior stabilised ☐ Posterior Sacrificing ☐ Cruciate Retaining ☐

M. Any complications? No ☐ Yes ☐ *(if yes, please provide details in box below)*

☐

N. Ligament release *(please circle yes or no for all options below)*:

Superficial MCL release **Yes** ☐ **No** ☐

More extensive medial release **Yes** ☐ **No** ☐

Lateral retinacular release ***(For PFJ/patellar tracking)*** **Yes** ☐ **No** ☐

PCL release **Yes** ☐ **No** ☐

Lateral capsule release *(for lateral compartment OA)* **Yes** ☐ **No** ☐

More extensive lateral release **Yes** ☐ **No** ☐

Other *(Please specify below)* **Yes** ☐ **No** ☐

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Learning Effects Study Surgery Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

O. Detail ligament releases:

P. Changes to planned bony cuts:

Q. FEMUR:

Final size:

R. TIBIA:

Final size:

Insert thickness: mm

S. PATELLA:

Final size: mm

Asymmetrical ☐ Symmetrical ☐

*(Please note: your name **must** be on the trial delegation log)*

Name of person who completed form (print name):_____

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

MAKO Robot Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

1a. Pre-op plan:

FEMUR:

Varus/valgus: ☐☐.☐ degrees

Int/ext: ☐☐.☐ degrees

Flexion: ☐☐☐ degrees

Size: ☐

Distal resection:

M: ☐☐.☐ mm

L: ☐☐.☐ mm

Post. Resection:

M: ☐☐.☐ mm

L: ☐☐.☐ mm

Difference between TEA and PCA:

☐☐.☐ degrees

1b. Pre-op plan:

TIBIA:

Varus/valgus: ☐☐.☐ degrees

Int/ext: ☐☐.☐ degrees

Slope/Flexion: ☐☐☐ degrees

Size: ☐

Med. Resection: ☐☐.☐ mm

Lat. Resection: ☐☐.☐ mm

2. Work Flow:

Pre-resection: No ☐ Yes ☐

Measured resection: No ☐ Yes ☐

Gap Balancing: No ☐ Yes ☐

Cut First:

Tibia: No ☐ Yes ☐

Femur: No ☐ Yes ☐

3. Deformity:

Varus/valgus (no stress): ☐☐.☐ degrees

Is varus/valgus correctable prior to ligament release: No ☐ Yes ☐

ROM:

Ext: ☐☐.☐ degrees

Flexion: ☐☐☐ degrees

MAKO Robot Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

4a. Intra-op: Initial Gaps

Ex. Med Gap: ☐☐ mm Ex. Lat Gap: ☐☐ mm

Flexion. Med Gap: ☐☐ mm Flexion Lat Gap: ☐☐ mm

4b. Intra-op:

FEMUR:

Varus/valgus: ☐☐.☐ degrees

Int/Ext: ☐☐.☐ degrees

Flexion: ☐☐☐ degrees

Size: ☐

TIBIA:

Varus/valgus: ☐☐.☐ degrees

Int/Ext: ☐☐.☐ degrees

Slope/Flexion: ☐☐☐ degrees

Size: ☐

4c. Intra-op: Planned Gaps

Ex. Med Gap: ☐☐ mm Ex. Lat Gap: ☐☐ mm

Flexion Med Gap: ☐☐ mm Flexion Lat Gap: ☐☐ mm

5a. Final:

FEMUR:

Varus/valgus: ☐☐.☐ degrees

Int/ext: ☐☐.☐ degrees

Flexion: ☐☐☐ degrees

Size: ☐

Distal resection:

M: ☐☐.☐ mm

L: ☐☐.☐ mm

Post. Resection:

M: ☐☐.☐ mm

L: ☐☐.☐ mm

5b. Final:

TIBIA:

Varus/valgus: ☐☐.☐ degrees

Int/ext: ☐☐.☐ degrees

Slope/Flexion: ☐☐☐ degrees

Size: ☐

Med. Resection: ☐☐.☐ mm

Lat. Resection: ☐☐.☐ mm

Insert thickness: ☐☐ mm

5c. Posterior cruciate ligament excised:

Yes ☐

No ☐

MAKO Robot Form

TNO: ☐☐☐☐☐ Initials: ☐☐☐ Site Code: ☐☐☐

6. Trials:

ROM Ext: ☐☐ degrees

ROM Flexion: ☐☐☐ degrees

Varus/Valgus: ☐☐.☐ degrees

Ex. Med. Gap: ☐☐☐ mm

Ex. Lat. Gap: ☐☐☐ mm

Flx. Med.Gap: ☐☐☐ mm

Flx. Lat. Gap: ☐☐☐ mm

7. Final implant after cementation:

ROM Ext: ☐☐ degrees

ROM Flexion: ☐☐☐ degrees

Varus/Valgus: ☐☐.☐ degrees

8. Please detail any specific comments below:

9. Have the surgery session files been exported from the MAKO Robot onto the removable (external) encrypted device?

Yes* ☐ Date of export: d d – m o n – y y y y

No ☐ If **not possible at the time of surgery**, please ensure the session files remain on the Robot until an export to a external hard drive is possible.

***Please note: The surgery session files MUST be pseudonymised using the standard naming convention of "RACER-K_TNO_SiteCode_Date" prior to being transferred to Warwick.**

*(Please note: your name **must** be on the trial delegation log)*

Name of Surgeon who performed the surgery (print name):_____

Date completed: d d – m o n – y y y y