STUDY SYNOPSIS

Sponsor:	Medacta International SA Strada Regina CH 6874 Castel San Pietro Switzerland
Study Title:	Prospective, multicentre, single-arm, open, confirmatory trial to assess efficacy and safety of a navigation system providing personalized soft tissue balance data in medially-stabilized total knee arthroplasty.
Short Title / Study ID:	Personalized soft tissue balance in TKA.
Protocol Version and Date:	P02.022.02 version 7.0 dated 04 March 2024.
Trial registration:	The study is registered in a publicly accessible database (ClinicalTrials.gov Identifier: NCT04844879) as well as in the Swiss National Clinical Trial Portal (SNCTP via BASEC)
Study category and rationale:	Risk category C according to HRA (the investigational device is a medical device with no assessment of conformity)
Phase of development:	Confirmatory phase
Study design:	Prospective, multicentre, single-arm, open, confirmatory clinical investigation, designed as a non-inferiority trial with respect to a benchmark.
Background and Rationale:	Total knee arthroplasty (TKA) is a well-established procedure that generally results in the relief of pain, improved physical function, and a high level of patient satisfaction. In order to achieve good clinical outcomes, appropriate soft tissue balancing is recognized as an essential procedure, together with accurate osteotomy and implantation. The NextAR™ TKA system developed by Medacta International SA is a surgical guidance system which measures intra-operatively the effect of prosthesis alignment and positioning on soft tissue balance. Specifically, it provides a visual representation of collateral ligament strain throughout the knee flexion range. Differently from other surgical guidance systems present on the market, collateral ligament strain is measured by detecting bony landmarks of the medial and lateral collateral ligaments and not by measuring joint component gaps. However, to date it is unknown whether this translates to satisfactory clinical and functional outcomes for patients operated with the NextAR™ TKA system.
Objective(s):	<u>Primary objective:</u> 1. To evaluate the efficacy of the NextAR™ TKA system in providing soft tissue balance patterns by comparing the patient-reported functional outcomes with a benchmark. <u>Secondary objectives:</u> 1. To evaluate objective and patient-reported clinical / functional outcomes. 2. To evaluate radiological outcomes. 3. To evaluate the viability of the system in the surgical workflow. 4. To evaluate safety outcomes.

Outcome(s):	Primary outcome: 1. Oxford Knee Score (OKS) at 6 months of follow-up. Secondary outcomes: 1. OKS, Knee Society Score (KSS), Forgotten Joint Score (FJS) and patient satisfaction at 6 months and 12 months of follow-up. 2. Radiological analysis at 2 and 12 months of follow-up. 3. All assessments immediately after / during surgery: - Surgical time (min) - Necessity of soft tissue release to obtain ligament or patellar balance (Y/N) - Time to discharge (days) 4. Device deficiencies and peri- and postoperative adverse events (incl. instrument-related issues and delays experienced during surgery) at all time points.
Inclusion / Exclusion criteria:	Inclusion criteria: 1. Males and females aged over 18 years at time of surgery. 2. Patients who are scheduled to receive Medacta GMK® Sphere system for primary TKA (class III, CE-marked). 3. Patients with functional contralateral knee (i.e. without the need to use walking aids). 4. Patients willing and able to provide written informed consent for participation. 5. Patients willing to comply with the pre and post-operative evaluation schedule. Exclusion criteria: 1. Patients with one or more medical conditions identified as a contraindication defined by the labelling on any Medacta implants used in this study: - Patients presenting with progressive local or systemic infection - Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable. - Severe instability secondary to advanced destruction of condralar structures or loss of integrity of the medial or lateral ligament 2. Patients whose prospects for a recovery to independent mobility would be compromised by known coexistent, medical problems. 3. Patients affected by concomitant spine, hip, ankle or contralateral knee pathologies that can affect walking capacity. 4. Patients unable to understand and take action. 5. Patients with known allergy to the materials used. 6. Patients in which Medacta GMK® Sphere system is used in emergency interventions.
Study Product / Intervention:	NextAR™ TKA system
Control Intervention (if applicable):	Not applicable

Number of Participants with Rationale:	A power analysis for a one sample t-test was performed with G-Power 3.1.9.4. The benchmark data were gathered from an ongoing ODEP study in which the GMK® Sphere is implanted with either standard instrumentation or with patient-specific instrumentation. In that study, the mean Oxford Knee Score (OKS) at 6 months was 37 with standard deviation of 9 (n=482). Considering that the minimal clinically important difference (MCID) for the Oxford Knee Score for TKA has been defined in the literature to be 5 points, we consider that a mean OKS of 32 at 6 months obtained with the NextAR™ TKA system would indicate clinically significant worse functional outcomes. The null hypothesis of the study is H_0 = 37, and the alternative hypothesis is H_a= 32. As the test is to show a discrepancy from the null hypothesis and not specifically a greater or lesser value, a two-tailed test was chosen. By choosing a significance level of 0.05 and power of 0.9, the resulting sample size is n=37, which was rounded up to n=40 patients to account for possible dropouts and patients lost to follow-up. A rejection of the alternative hypothesis (H_a= H_0) would indicate that the NextAR™ TKA system provides comparable functional outcomes than the conventional operation.
Study Duration:	The duration of the project is foreseen for 3.25 years, starting in March 2021 and ending in June 2024. The enrolment of patients is foreseen between March 2021 and June 2023 (27 months).
Investigator(s) and centers:	Prof. Dr. med. Sandro Fucentese Uniklinik Balgrist Forchstrasse 340 8008 Zurich (Switzerland) sandro.fucentese@balgrist.ch +41 76 488 87 45
	PD. Dr. med. Peter Koch Kantonsspital Winterthur Brauerstrasse 15 8401 Winterthur (Switzerland) peter.koch@ksw.ch +41 79 652 23 65
	PD. Dr. med. Peter Koch Privatklinik Lindberg Schickstrasse 11, 8400 Winterthur (Switzerland) peter.koch@gzw.ch +41 52 266 12 12
	PD. Dr. med. Peter Koch Privatklinik Belair Rietstrasse 30, 8200 Schaffhausen (Switzerland) peter.koch@gzw.ch +41 52 266 12 12