

# The Medacta GMK SpheriKA Post-Marketing Surveillance Study

NCT05459948

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**Status** RECRUITING  
**Sponsor** Medacta International SA  
**Enrollment** 281 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Patients willing to sign the informed consent.
- Patients able to comply with follow-up requirements, including postoperative weight-bearing restrictions and self-evaluations.
- Patients 18 - 80 years of age at the time of surgery.
- Patients requiring a primary total knee replacement (on label use).
- Patients with intact collateral ligaments.

### Exclusion (10)

- Patients with inflammatory arthritis.
- Morbidly obese patients, with a body mass index (BMI)  $\geq 40$ .
- Patients with a history of total or unicompartmental reconstruction of the affected joint.
- Patients that have had a high tibial osteotomy or femoral osteotomy.
- Patients with neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device.

... and 5 more (see full listing online)

## Locations (4 total)

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Centre de l'Arthrose, Mérignac, France  
Clinique de l'Union, Saint-Jean, France  
Humanitas Castelli, Bergamo, Italy  
... and 1 more locations