# A Multi-Centre Study in Patients Undergoing Total Knee Replacement with Smith+Nephew Porous Total Knee Arthroplasty (TKA) System.

Published: 12-09-2023
Last updated: 05-10-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bone and joint therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53848

**Source**
ToetsingOnline

**Brief title**
POROUS.TKA.SYSTEM.2021.07

### Condition

- Bone and joint therapeutic procedures

**Synonym**
Arthritis, joint inflammation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Smith&Nephew, Inc

**Source(s) of monetary or material Support:** Industry: Smith&Nephew;Inc.

## Intervention

**Keyword:** Arthritis (osteoarthritis, Cementless, inflammatory), Knee Replacement, post-traumatic, Total Knee Arthroplasty

## Outcome measures

### Primary outcome

The primary endpoint for the study is implant survivorship 2 years

post-surgery. Implant survivorship is defined as the cumulative proportion of

knee-implanted components without a revision.

### Secondary outcome

Survivorship of the implant will be assessed at 1-, 2- and 5-year timepoints.

Survivorship of the implant will be defined as the cumulative proportion of all

knee implant components without a revision.

The patient reported outcomes collected at pre-op, 6 weeks, 6 months, 2 years

and 5 years:

• Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR).

• Oxford Knee Score (OKS).

• Forgotten Joint Score (FJS).

Additional secondary endpoints include:

• Radiographic findings (pre-op, 6 weeks, 6 months, 2 years and 5 years)

• Post-op device related re-interventions related to operative knee.

• Survival rate up to 5 years post-op.

2. Safety Endpoints

• All adverse events (AEs) and complications occurring from the time of surgery

until study

termination or study completion including intra-operative adverse events and

complications.

• Device related re-interventions

• Device Deficiencies

3. Other exploratory endpoint(s):

• Operating time from first incision to final skin closure (skin-to-skin time).

• Accuracy of device positioning (difference between planned vs. actual).

# Study description

**Background summary**

Osteoarthritis, also known as degenerative joint disease, is the most common type of arthritis occurring primarily in the weight-bearing joints of the knees, hips, and spine as well as joints exposed to prior injury or repeated stress. It is characterized by the breakdown of the protective cartilage that cushions the ends of bones in joints with diagnosis based on clinical assessment of signs and symptoms along with imaging methods. The symptoms of osteoarthritis such as pain, inflammation, and limited function can be managed and disease progression slowed; however, the damage to the joints cannot be reversed. If left untreated, there is the potential over time for cartilage to wear down completely leading to bone deterioration.

The incidence of joint disease continues to increase, with an estimated 9.3 million adults affected by knee osteoarthritis in the United States (US). The recent upward trend appears to be directly related to the prevalence of certain health factors that may significantly contribute to joint degeneration, specifically, longer life spans, obesity rates, and physical activity levels.

While treatment strategies such as weight reduction, lifestyle changes, physical therapy, or medication may offer temporary relief from the symptoms of knee degeneration, an ever-growing percentage of the affected population may choose to have total knee arthroplasty (TKA). TKA remains the standard of care for subjects experiencing significant losses in quality of life due to advanced osteoarthritic disease.

The optimal mode of fixation in TKA with the majority of surgeons is cemented fixation. Cemented prostheses are regarded as the gold standard for TKA, supported by the long-term clinical success and survivorship analysis from registry-based and clinical studies. Cementless fixation is, however, of interest, as the potential benefits of cementless fixation include promotion of bone growth and therewith fixation on longer term, and shorter operating room time.

The purpose of this study is to evaluate the safety and performance of the cementless Porous TKA System over 5 years in patients undergoing TKA for post-traumatic arthritis, osteoarthritis, or degenerative arthritis. Data from this study will be incorporated into the post-market surveillance body of knowledge on the LEGION and JOURNEY II Porous Systems.

**Study objective**

The primary objective is to assess 2-year survivorship of Total Knee Arthroplasty (TKA) procedures performed using the Smith+Nephew (S+N) Porous Knee System. The secondary objective is to generate safety and performance evidence up to 5 years post-surgery for S+N*s Porous Knee System via the collection of functional outcomes, radiograph findings and safety data.

**Study design**

The POROUS.TKA.SYSTEM.2021.07 study is a premarket, multi-centre, prospective, non-randomized, interventional study with an enrollment phase of approx. 38 months and up to 5 years follow up.

**Intervention**

The Porous TKA System will be used per the current IFU for device type, size, preparation, and recommended implant procedure. Each subject will be implanted with a Porous Tibia Base Plate, a LEGION CR femoral component along with an insert and optional patella.

The implantation of a primary total knee arthroplasty is a surgical procedure supported by a multidisciplinary team (MDT) of healthcare professionals. Variations in practice rightly occur between surgeons, theatre teams, and hospitals. However, the following provides a high-level descriptor of the major

steps relating to the patient journey both in the medical and surgical context.

The surgical procedure may be divided into the pre-operative, intra-operative and post-operative periods.

1. A pre-operative orthopaedic assessment of the joint and its suitability for an implant, and a pre-operative anaesthetic assessment will be performed. Additional pre-operative surgical considerations include radiographic templating.

2. Intra-operatively, the patient will be supine, and some form of a leg holder can keep the knee at 90 degrees or more of flexion during certain parts of the procedure. The surgeon will use the approach that fits the patient and implant requirements, and one they are most comfortable with. The instrument sets to be used are pre-market products, which will be provided as ancillary products. Surgery consists of an arthrotomy and deep exposure, followed by bone cuts of the femur and tibia. Thereafter, soft tissue balancing and confirmation of the final implants through trials, and final implant placement is followed with meticulous wound closure.

Perioperative or immediate post-operative inpatient management (monitoring of early vital signs, analgesia, progressive physiotherapy, general nursing) will be done.

3. Postoperative outpatient care is guided by the surgeon but most heavily reliant on an MDT most prominent of which are physiotherapists.
Surgical follow-up to discharge varies according to each hospital and the commissioning agreements that they have for care.

**Study burden and risks**

The risks related to the surgery are similar to standard of care total knee replacements.

There are risks associated with Porous Total Knee System:
• Wear of polyethylene articulating surfaces if knee prostheses. High rates of wear may shorten useful life of knee system and lead to early revision surgery
• Localised, asymptomatic bone resorption (osteolysis) around components due to foreign body interaction and wear between components
• Loosening, bending, cracking or fracture of implant components as a result of trauma, improper alignment, strenuous activity or long-term use
• Dislocation, subluxation, excessive rotation flexion contracture, decreased range of motion, lengthening or shortening of the leg, looseness of components, unusual stress concentrations and extraneous bone as a result of trauma, improper implant selection or improper implant positioning/fixation
Since the Porous Total Knee System is an investigational device, it is possible that new and so far, unknown risks/discomforts may occur.

Possible risks that may occur as a direct result of this study is related to the additional X-Ray exposure.

The patient has been informed about all of these risks in the informed consent form.

## Contacts

**Public**
Smith&Nephew, Inc

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AF
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

1. Subject needing primary TKA due to degenerative joint disease (primary diagnosis of osteoarthritis), post-traumatic arthritis or inflammatory arthritis.

2. Subject agrees to consent and to follow the prospective study visit schedule

(as defined in the study protocol and informed consent form) by signing the Independent Review Board (IRB)/Independent Ethics Committee (IEC) approved informed consent form.

3. Subject is willing to attend study follow-up visits for up to five (5) years post-surgery.

4. Subject is able to read, understand, and communicate responses to Patient Reported Outcome assessments.

5. Subject is 18-80 years old (inclusive).

## Exclusion criteria

1. Subject received TKA on the contralateral knee as a revision for a previously failed total or unicondylar knee arthroplasty.

2. Subject has a Body Mass Index (BMI) >= 40 at time of surgery.

3. Subject has ipsilateral hip arthritis resulting in flexion contracture.

4. At the time of enrolment, subject has one or more of the following arthroplasties that are not fully healed and well-functioning, as determined by the investigator: Ipsilateral or contralateral primary total hip arthroplasty or hip resurfacing arthroplasty; Contralateral primary total knee or unicondylar
knee arthroplasty.

5. Subject has a condition that may interfere with the TKA survival or outcome (e.g. Paget*s or Charcot*s disease, vascular insufficiency, lupus, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease).

6. Subject has a known allergy to one or more of its components of the study device.

7. Any subject with hardware present in distal femur or proximal tibia.

8. Any subject that meets the definition of a Vulnerable Subject per ISO 14155 Section 3.55.

9. Subject is entered in another drug, biologic, or device study or has been treated with an investigational product in the past 30 days.

10. Subject, in the opinion of the Investigator, has an emotional or

neurological condition that would pre-empt their ability or willingness to participate in the study including mental illness, drug or alcohol abuse.

11. Subject is known to be at risk for lost to follow-up, or failure to return for scheduled visits.

12. Women who are pregnant, nursing, or of child-bearing potential who are not utilizing highly effective birth control measures at the time of screening or the time of surgery or do not engage in a sexual lifestyle that makes pregnancy impossible (e.g. homosexual or are without a sexual partner).

13. Subjects who have participated previously in this clinical trial and who have been withdrawn.

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 27-09-2023 |
| Enrollment: | 30 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Smith+Nephew Porous Total Knee Arthroplasty (TKA) system |
| Registration: | No |

# Ethics review

Approved WMO

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| Date: | 12-09-2023 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 07-03-2024 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 28-03-2024 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 20-06-2024 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | NCT05197036 |
| CCMO | NL81198.000.23 |