PRISM

Summary of Clinical Evidence

CORI◊ Surgical System clinical evidence

January 2026

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Smith+Nephew

CORI◊ Surgical System: Personalised knee and hip arthroplasty

CORI Surgical System uses RI.KNEE◊ ROBOTICS software for knee arthroplasty and RI.HIP◊ NAVIGATION for hip arthroplasty. The NAVIO◊ Surgical System is the predecessor to the CORI Surgical System. Because both surgical systems share the same core functionality, clinical evidence generated with NAVIO is relevant to the clinical profile of CORI. Throughout this document, evidence relating to NAVIO Surgical System – or studies evaluating both systems – is referred to as evidence for Smith+Nephew handheld robotics.

Versatility with CORI Surgical System

- Enables personalisation across **unicondylar, total and revision knee arthroplasty, and total hip arthroplasty procedures**
- Accommodates a broad range of cases through **image-free or image-based pre-operative planning**
- More **compact footprint** than Mako™ (Stryker) and ROSA® Robotics (Zimmer Biomet),[1] making it easy to transport between operating rooms

CORI Surgical System is redefining revision TKA: From canal-based to anatomical joint line-based reconstruction

- The **first robotics platform indicated for use in revision** knee arthroplasty in the US and Europe[2]
- **Enabling surgeons to prioritise joint-line reconstruction** in revision TKA rather than being constrained by diaphyseal anatomy when using conventional methods[2]

Enabling consistent gap balancing with CORI Digital Tensioner

- An objective tool to support **consistent and repeatable** gap balancing and alignment in TKA[3,4]

56
publications*

>49,000
total patients studied†

10 randomised controlled trials (RCTs)‡

1 systematic literature review (SLR) and meta-analysis

3 prospective comparative

2 registry analyses

24 retrospective comparative

10 case series/single-arm cohort

3 cost/efficiency analyses

1 modelling study

Publication counts may be higher than study counts, as individual study cohorts may have resulted in more than one publication.

*As of August 2025; †Overall cases analysed in publications (Smith+Nephew RA TKA plus comparators), numbers adjusted to account for publications that report the same cohort of patients and case numbers have not been included for cost analyses or meta-analyses. ‡One used a quasi-RCT design (Migliorini F, et al. *Orthopädie.* 2026;55:48–54.)

Personalised TKA with RI.KNEE◊ on CORI◊ Surgical System

CORI Surgical System enables surgeons to execute personalised alignment TKA, including functional and kinematic alignment. Both the anatomically designed JOURNEY◊ II TKA and the LEGION◊ Total Knee System, which offers both cementless and cemented options, can be accurately positioned using CORI◊ Surgical System.[5,11] Soft tissue tension can then be assessed in real time.

Access TKA studies by clicking or scanning the QR code:

29 publications

In RCTs, Smith+Nephew handheld robotic-assisted (RA) functional alignment TKA has outperformed conventional TKA (cTKA) for accuracy of implant and limb alignment, soft-tissue preservation, natural joint feeling and patient satisfaction, with no clinically relevant differences in procedure time.*[5,6] Real-world analyses have demonstrated OR efficiencies related to reduced instrument requirements[7] and reduced 90-day episode of care costs versus cTKA.[8]

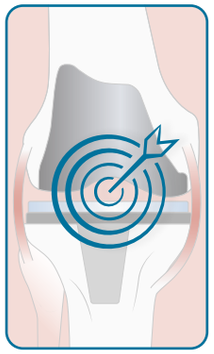
Compared with cTKA, Smith+Nephew RA TKA has been shown to result in:

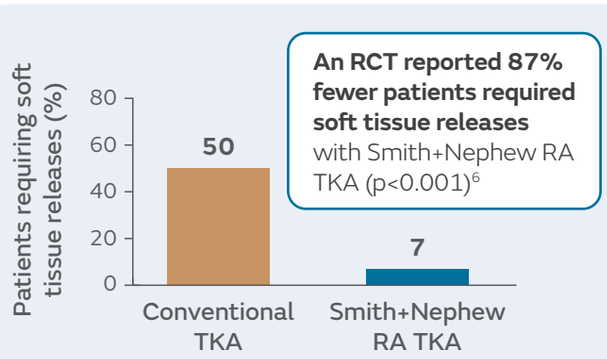
Intra-operative and immediately post-op

More accurate bone resection and improved soft tissue preservation[5,6,9–13]

Improved accuracy of limb and implant alignment has been demonstrated in five RCTs†[5,9–12]

RCTs have also shown significantly **improved gap balancing‡[6] and reduced local trauma§[13]**





An RCT reported 87% fewer patients required soft tissue releases with Smith+Nephew RA TKA (p<0.001)[6]

Post-operative

Improved natural joint feeling and patient-reported satisfaction at 1 year[6]

At 1 year, an RCT has shown significantly[6]

- **More natural joint feeling** (better 12-item Forgotten Joint Score)[6]
- **Improved patient-reported function, pain, satisfaction and health-related quality of life¶[6]**

(p≤0.029 for all)

Health economic

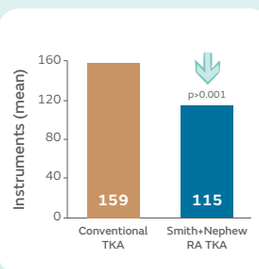
OR efficiencies and reduced costs, without a meaningful increase in procedure time[6–8,11,13]

RCTs have reported **no clinically relevant difference in procedure time** after an initial learning curve‖[6,11,13]

OR efficiencies

In a real-world study of 9 centres:

On average, **45 fewer instruments** used per TKA, resulting in an estimated **cost saving of $286 per procedure** (p<0.001)[7]



Cost analysis

An analysis of >1000 propensity-matched patients from the Premier PINC AI™ Healthcare Database reported:

Lower 90-day episode of care costs ($14,725 vs $15,670; p<0.0001)**[8]

*Surgery duration in Bollars (2025)[6] was 76 minutes in the Smith+Nephew RA TKA group and 73 minutes in the conventional TKA group (p=0.001), authors did not consider the 3 minutes difference to be clinically relevant. †p≤0.038 for all. ‡Improved gap balancing defined as fewer patients required soft tissue releases and inserts >10mm thick (p≤0.004). §Lower inflammatory marker c-reactive protein at post-op days 1 and 5; p≤0.0003 in a quasi-RCT. ¶OKS, KSS [function and satisfaction], EQ-5D index score, VAS pain and satisfaction. ‖Two RCTs have found no clinically relevant difference in procedure time (1.6–3mins between groups; p≤0.04). **Most patients (80%) in the analysis had a TKA and 20% had a UKA.

Abbreviations: cTKA = conventional TKA, OR = operating room, RA TKA = robotic-assisted TKA, RCT = randomised controlled trial, TKA = total knee arthroplasty.

Accurate UKA with RI.KNEE◊ on CORI◊ Surgical System

Despite the benefits of UKA over TKA and that considerable numbers (25–47%)[14] of TKA patients are eligible for the procedure, only 8–15% of all knee arthroplasties are UKA.[15] Low utilisation is partly due to surgical complexity and reduced threshold for revision,[16] which it may be possible to overcome using robotic-assistance to help correctly position the implant.[16–19] CORI Surgical System assists with implantation of JOURNEY◊ II UK with OXINIUM◊ Technology, which has shown excellent early survivorship*[20,21] and has a 5A ODEP rating.[22]

Access UKA studies by clicking or scanning the QR code:

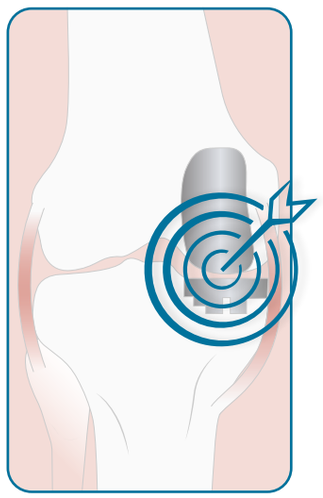
18 publications

Clinical studies have shown implant placement and knee alignment is more accurate with Smith+Nephew robotic-assisted (RA) UKA than conventional UKA (cUKA),[16–19] irrespective of surgeon experience.†[23] The accuracy afforded by robotic-assistance is thought to contribute to the significantly lower revision risk with RA UKA versus cUKA.[24,25] Increasing UKA utilisation results in several patient benefits which have been linked to improved cost efficiency versus TKA, including quicker discharge.[26]

Versus cUKA, Smith+Nephew RA UKA has resulted in:

Intra-operative

Improved accuracy,[16–19] irrespective of surgeon experience†[23]



Improved accuracy of implant placement and knee alignment,[16–19] irrespective of individual surgeon experience with cUKA†[23]

Post-operative

Improved survivorship and patient-reported outcomes (PROMs) with fewer bed days[24,25,27–31]

Versus cUKA, RA UKA has resulted in:

Up to **58%** **lower revision risk** (two independent meta-analyses)[24,25]

Versus cUKA, Smith+Nephew RA UKA:

100% **survivorship** with JOURNEY II UK in the NJR at 1 year‡[27] n=122

Significantly **earlier discharge** from hospital and physical therapy[28] and higher PROMs§ (p≤0.02)[29–31]

Health economic

Increasing UKA utilisation may lower episode of care costs

Increasing UKA utilisation results in several benefits which have been linked to improved cost efficiency versus TKA:

Lower early complication rates

Lower risk of early complications including cardiac events, venous thromboembolism and deep infections[32]

Shorter length of stay and lower costs

Typically, UKA procedures are lower cost[33] and patients are discharged >1 day earlier[32]

Quicker recovery

Patients may regain knee function, and return to sports and work sooner[32]

Using CORI Surgical System to implant JOURNEY II UK may only require a **single tray** (versus 2–3 with cUKA)[34]

*Up to 99.6% survivorship at 2 years; †Study conducted on dry bone models; ‡The data used for this analysis was obtained from the National Joint Registry ("NJR"), part of the HQIP, the NJR and/or its contractor, NEC Software Solutions (UK) Limited ("NEC") take no responsibility (except as prohibited by law) for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation including any duty of care to third party readers of the data analysis. §KOOS-JR at 6 months post-UKA (p=0.037)[30] and IKSS-O (p<0.05)[29] and KSS-F (p=0.01)[31] at ≥1-year post-UKA.

Abbreviations: cUKA = conventional UKA, RA UKA = robotic-assisted unicompartmental knee arthroplasty, ODEP = Orthopaedic Data Evaluation Panel, QALY = Quality-Adjusted Life Year, TKA = total knee arthroplasty, UKA = unicompartmental knee arthroplasty.

Redefined revision TKA with RI.KNEE◊ on CORI◊ Surgical System: Restoring the anatomical joint line

CORI Surgical System enables real-time visualisation of anatomical landmarks to help with augment planning and to allow old and new joint line parameters to be established. To ease transitions from primary to revision, LEGION◊ Primary and Revision Knee Systems share the same bone conserving* femoral resections[35] and include a full continuum of revision dedicated instrumentation.

Access revision TKA studies by clicking or scanning the QR code:

2 publications

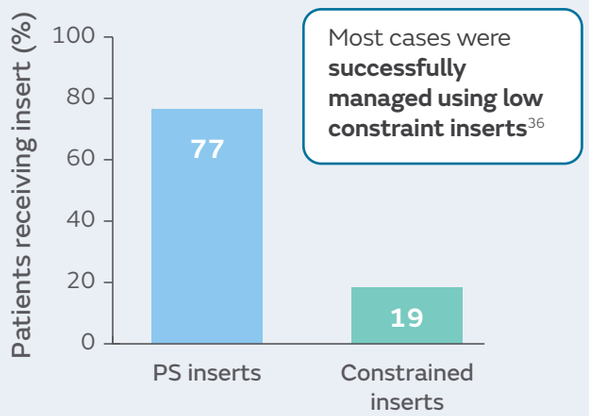
As the first robotics platform indicated for use in revision TKA (rTKA), CORI Surgical System has enabled a shift toward reconstructing the joint based on native anatomy, rather than conforming to the geometry of the diaphyseal canal.[2] This approach facilitates precise restoration of joint line height and orientation.[2] A clinical study of CORI Surgical System with LEGION Revision Knee System reported 93% of rTKA patients' joint line was restored to that of the contralateral knee.[36]

Intra-operative

Achieving joint line restoration

In a retrospective case series of CORI Surgical System with LEGION RK System for 115 rTKA patients:[36]

93% **achieved joint line restoration†** (across a **wide range of cases**)[36]



Post-operative

Early evidence suggests improved PROMs‡ and high home discharge rates

In a retrospective case series of CORI Surgical System with LEGION RK System for 115 rTKA patients:[36]

Significantly **improved pain and PROMIS depression scores** (versus pre-op scores at 90 days post-op; p≤0.013)[36]

Low readmissions at 30 (1%) and 90 days (3%) post-op[36]

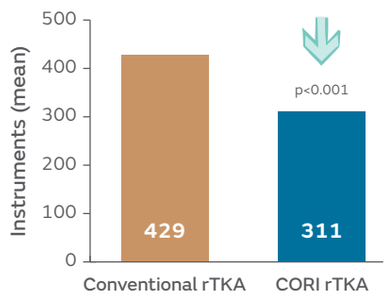
87% patients discharged home[36]

Health economic

OR efficiencies and reduced costs versus conventional rTKA

In a real-world study of CORI Surgical System in 9 centres:

On average, **118 fewer instruments** used per rTKA, resulting in an estimated **cost saving of $753 per procedure** (p<0.001)[7]



*Bone conserving versus Insall-Burstein™ II, PFC™ Sigma™, Optitrak™, and Nex-Gen™ Legacy™; †Within 5mm of the native contralateral knee; ‡at 30 and 90 days post-op, versus pre-op scores.
Abbreviations: PS = Posterior Stabilised; rTKA = revision total knee arthroplasty.

Personalised THA with RI.HIP◊ on CORI◊ Surgical System

Although THA is a highly successful surgery, dislocation remains a leading cause of revision and is often caused by impingement.[37] Implant malpositioning and reduced spinopelvic mobility have been shown to increase impingement risk and dislocation,[38-39] highlighting the importance of accounting for spinopelvic mobility and optimal implant positioning for THA success.

Access THA studies by clicking or scanning the QR code:

7 publications

CORIOGRAPH◊ Pre-Op Planning and Modeling services enables personalised pre-operative planning based on patient spinopelvic mobility in the context of activities of daily living (ADLs) to help minimise impingement risk.[40] Clinical studies have shown, versus conventional THA, navigated THA with RI.HIP supports optimal implant placement[41] and significantly improves impingement-free range of motion[42–44] and revision risk at 10 years.[45]

Pre-operative

CORIOGRAPH Pre-Op Planning and Modelling services for hips

Personalised THA pre-op planning that operates with 2D (X-ray) and/or 3D (CT) images

Advanced modeling capabilities that go beyond the mechanics of range of motion to **offer 12 ADLs**

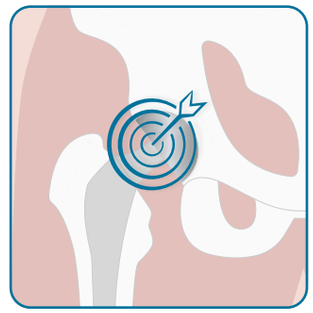
Allows pre-operative **assessment of spinopelvic condition with ADLs** to help mitigate impingement risk[40]

Versus conventional THA, RI.HIP THA has resulted in:

Intra-operative

Optimised implant placement and accuracy

Significantly **reduced deviation from target** component positioning ($p<0.001$)[41]



Post-operative

Improved impingement-free ROM, revision risk and patient satisfaction

When used with Smith+Nephew acetabular components:

Significantly **improved impingement-free ROM** ($p\leq0.05$)[42–44]

Significantly **lower revision risk at 10 years** (1.06 vs 3.88%; $p=0.005$)[45]

Significantly **higher patient satisfaction** ($p=0.003$)[45]

Abbreviations: ADLs = activities of daily living, ROM = range of motion, THA = total hip arthroplasty.

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