

CORI Surgical System

Category:

Best Medical Technology

Company Name:

Smith & Nephew, Inc.

Product/Solution Name:

CORI Surgical System

Compound/Tech Name:

Surgical Robotics

Trade Name:

CORI Surgical System

Corporate Name:

CORI Surgical System

Date of Approval:

2020-02-14

Indications:

Partial, Total and Revision Knee Arthroplasty, Total Hip Arthroplasty

Therapeutic Areas:

Orthopedics

General Information File Document upload:

[Smith Nephew COR2443240Gallienawardssubmission.pdf](#)

Background information and need for drug / device:

The hip and knee arthroplasty business is approximately a \$17B market. Robotics is

becoming the standard of care solution that is utilized to enhance orthopedic procedures. Despite being overwhelmingly successful procedures, knee and hip arthroplasty still have opportunities for improvement. Over 20% of patients undergoing knee replacement are dissatisfied with their surgery. In total knee arthroplasty (TKA), the precise positioning and alignment of knee implants are critical for long-term success. However, achieving optimal alignment manually can be challenging due to the knee joint's complex anatomy, including ligaments, bones, and soft tissues. Similarly, in the hip arthroplasty space, around 3-4% of patients experience impingement that can lead to dislocation within the first two years and revision rates range from 5-20%. Robotics has the potential to address these needs by providing:

1. Customized Planning: Robotic systems can use preoperative imaging or intraoperative anatomical model generation to create personalized surgical plans based on individual anatomy to ensure accurate implant positioning.
2. Intraoperative Guidance: During surgery, robots assist surgeons in making precise bone cuts and positioning implants accurately. The real-time feedback helps achieve better alignment and reduces complications.
3. Reducing Soft Tissue Trauma and Blood Loss: Minimizing trauma to surrounding soft tissues is essential. Robotic-assisted approaches allow for smaller incisions, resulting in faster recovery and less postoperative pain. Robotic systems also avoid violation of the intramedullary canal, a method used in traditional knee arthroplasty to align the components, but can result in excessive blood loss.

In total hip arthroplasty (THA), achieving optimal implant placement while preserving bone integrity is crucial in hip replacement surgery. Specifically, component positioning is critical to achieving long term success:

1. Acetabular Cup Positioning: Accurate placement of the hip socket component is essential to prevent dislocation. Robotic and navigation systems can guide surgeons to achieve precise positioning.
2. Femoral Component Alignment: Ensuring proper alignment and leg length equality is critical. Robotic and navigation systems can help ensure and achieve accurate implant placement.

Background File Document upload:

1 True dislocation rate of total hip 2020.pdf

2 Revision rates 2010.pdf

History of the development of the solution/product:

How unique and differentiated this system is compared to others. Instead of an arm based robotic solution, the CORI Surgical System is a handheld precision robotics tool that optimizes orthopedic procedures for knee and hip arthroplasty. The CORI Surgical System is also the world's only image-agnostic robotics platform that enables surgeons to use the right imaging for the right patient to personalize surgery. Recognized by the Design Management Institute*, the CORI Surgical System is the 2nd generation robotics system from Smith+Nephew, enhanced from the first generation NAVIO Surgical System. The CORI Surgical System is technically differentiated from every other orthopedic robotic system with the following features:

1. Pre-Operative Planning:

- CORIOGRAPH is Smith+Nephew's pre-operative planning and modeling service designed for orthopedic surgeries, including hip and knee replacements.
- CORIOGRAPH enables surgeons to visualize patient-specific anatomical details and assess conditions such as spinopelvic alignment for hips.
- With advanced modeling capabilities and X-ray and/or CT imaging compatibility, it provides personalized care plans tailored to patient needs.

2. Advanced Tracking System:

- CORI incorporates an Advanced Tracking System (ATRACSYS), specifically designed for robotic surgery. Compared to first generation of robotics systems, CORI offers a 458% faster refresh rate¹. This improvement ensures more precise intraoperative tracking, enhancing the system's accuracy during bone preparation and implant placement.

3. Cutting Technology:

- CORI's cutting technology has been significantly upgraded. It can handle twice the cutting volume compared to first generation robotics systems². This advancement streamlines bone resection, leading to more efficient procedures. CORI also enables smart saw solutions with minimally invasive pinning solutions to provide further OR efficiencies for knee replacement surgeries.
- The increased cutting capacity allows for precise bone shaping, essential for achieving optimal implant fit and alignment.

4. Ergonomics and Portability:

- CORI is designed to be small and portable, making it suitable for various clinical settings, including ambulatory surgery centers (ASCs) and outpatient facilities².
- Its compact footprint ensures flexibility in surgical environments, allowing for seamless integration into existing workflows.

5. Expanded Indications:

- CORI is indicated for unicompartmental (UKA) and total knee arthroplasty (TKA), and has recently expanded its capabilities to include revision knee arthroplasty³. It is the first system indicated for robotic-assisted revision knee surgery in the US.
- The ability to address complex cases and revision scenarios broadens CORI's clinical

utility.

6. Workflow Enhancements:

- CORI incorporates the RI.KNEE Robotics software, designed to enhance surgeons' workflow. It increases productivity, usability, and reduces the learning curve 1.
- The streamlined interface allows for efficient planning, precise bone cuts, and implant positioning.

7. Total Hip Arthroplasty Compatibility:

- CORI is not limited to knee procedures alone. It is also compatible with implants and approaches for total hip arthroplasty 4.
- Surgeons can leverage the system's capabilities for both knee and hip joint reconstructions.

8. Clinical Outcomes:

- Despite differences in operative time (CORI vs. Navio), studies have shown that both systems achieve highly accurate femoral component rotational alignment.
- Radiographic scores and blood loss are comparable between CORI and Navio, emphasizing the system's reliability and precision.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

How unique and differentiated this system is compared to others. Instead of an arm based robotic solution, the CORI Surgical System is a handheld precision robotics tool that optimizes orthopedic procedures for knee and hip arthroplasty. The CORI Surgical System is also the world's only image-agnostic robotics platform that enables surgeons to use the right imaging for the right patient to personalize surgery. Recognized by the Design Management Institute*, the CORI Surgical System is the 2nd generation robotics system from Smith+Nephew, enhanced from the first generation NAVIO Surgical System. The CORI Surgical System is technically differentiated from every other orthopedic robotic system with the following features:

1. Pre-Operative Planning:

- CORIOGRAPH is Smith+Nephew's pre-operative planning and modeling service designed for orthopedic surgeries, including hip and knee replacements.
- CORIOGRAPH enables surgeons to visualize patient-specific anatomical details and assess conditions such as spinopelvic alignment for hips.
- With advanced modeling capabilities and X-ray and/or CT imaging compatibility, it

provides personalized care plans tailored to patient needs.

2. Advanced Tracking System:

-CORI incorporates an Advanced Tracking System (ATRACSYS), specifically designed for robotic surgery. Compared to first generation of robotics systems, CORI offers a 458% faster refresh rate¹. This improvement ensures more precise intraoperative tracking, enhancing the system's accuracy during bone preparation and implant placement.

3. Cutting Technology:

-CORI's cutting technology has been significantly upgraded. It can handle twice the cutting volume compared to first generation robotics systems². This advancement streamlines bone resection, leading to more efficient procedures. CORI also enables smart saw solutions with minimally invasive pinning solutions to provide further OR efficiencies for knee replacement surgeries.

-The increased cutting capacity allows for precise bone shaping, essential for achieving optimal implant fit and alignment.

4. Ergonomics and Portability:

-CORI is designed to be small and portable, making it suitable for various clinical settings, including ambulatory surgery centers (ASCs) and outpatient facilities².

-Its compact footprint ensures flexibility in surgical environments, allowing for seamless integration into existing workflows.

5. Expanded Indications:

-CORI is indicated for unicompartmental (UKA) and total knee arthroplasty (TKA), and has recently expanded its capabilities to include revision knee arthroplasty³. It is the first system indicated for robotic-assisted revision knee surgery in the US.

-The ability to address complex cases and revision scenarios broadens CORI's clinical utility.

6. Workflow Enhancements:

-CORI incorporates the RI.KNEE Robotics software, designed to enhance surgeons' workflow. It increases productivity, usability, and reduces the learning curve¹.

-The streamlined interface allows for efficient planning, precise bone cuts, and implant positioning.

7. Total Hip Arthroplasty Compatibility:

-CORI is not limited to knee procedures alone. It is also compatible with implants and approaches for total hip arthroplasty⁴.

-Surgeons can leverage the system's capabilities for both knee and hip joint reconstructions.

8. Clinical Outcomes:

-Despite differences in operative time (CORI vs. Navio), studies have shown that both

systems achieve highly accurate femoral component rotational alignment.
-Radiographic scores and blood loss are comparable between CORI and Navio, emphasizing the system's reliability and precision.

Innovation File Document upload:

[4 Eerens et al 2022.pdf](#)
[3 Matsumoto et al 2023.pdf](#)
[5 Khan et al 2021.pdf](#)
[6 Vaidya et al 2020.pdf](#)
[8 Davis et al 2021.pdf](#)
[7 Canetti et al 2018.pdf](#)

Please provide appropriate references (PubMed, Abstract, Website):

See attached.

References File Document upload:

[1 True dislocation rate of total hip 2020.pdf](#)
[2 Revision rates 2010.pdf](#)
[4 Eerens et al 2022.pdf](#)
[3 Matsumoto et al 2023.pdf](#)
[5 Khan et al 2021.pdf](#)
[6 Vaidya et al 2020.pdf](#)
[8 Davis et al 2021.pdf](#)
[7 Canetti et al 2018.pdf](#)
[10 Savov et al 2021.pdf](#)
[9 Mergenthaler et al 2020.pdf](#)