Design
Rationale

Next generation robotics and state-of-the-art planning software placed in the hands of skilled surgeons.
Device description

The Smith & Nephew NAVIO™ Surgical System is a surgical planning, navigation, and intra-operative visualization system combined with a hand-held, smart instrument for bone sculpting. The NAVIO Surgical System aids the surgeon in planning and executing a procedure involving bone preparation for unicompartmental knee replacement (UKR), patellofemoral arthroplasty (PFA), and total knee arthroplasty (TKA) procedures.\textsuperscript{1,2}

The system is comprised of computer-assisted surgical instrument control, a commercially available surgical drill, image-free navigation, and planning software with standard navigation technology. The NAVIO Surgical System software consists of a patient and user management module, a surgical planner, and an intraoperative cutting module. The NAVIO Surgical System uses the tracked position of the surgical bur to control its cutting engagement to the bone that is intended to be removed. This cutting control is based on the bur’s proximity to the planned target surface of the bone.\textsuperscript{3}

The camera cart communicates the relative position of the handpiece (cutting tool), the femur, and the tibia (via rigid tracker arrays) to the computer cart, which runs algorithms that control the handpiece. The NAVIO foot pedal is offered as an alternate to the touchscreen monitor to progress through the procedure or when data points are collected, and the Anspach foot pedal controls the Anspach drill.

The NAVIO Surgical System incorporates a detailed user interface that provides procedure setup, tracking status, visual indicators, and real-time cutting progress during the procedure.\textsuperscript{1,2}

The patient’s bone is prepared according to an intraoperative plan that combines soft-tissue and anatomic information with controlled bone removal and predictable long-leg alignment.\textsuperscript{1}

The NAVIO Instrument set consists of a two-level tray that contains all of the required instrumentation for a NAVIO-assisted surgery, such as a robotic-controlled NAVIO handpiece, Anspach power drill, interchangeable guards, tracker arrays, tissue protector, bone tracker hardware and clamps, a Z-retractor and a rasp that has a flat and rounded rasping surface.\textsuperscript{1,2}

The NAVIO TKA application requires one additional instrument set that contains NAVIO reusable cut guides, a Plan Visualization Tool, and JOURNEY™ II, LEGION™, and GENESIS™ II drill guides.

The NAVIO Surgical System devices contain no medicinal substances, tissues, or blood products.
The history of robotics

**Conventional instruments**

Restoration of the neutral mechanical axis to the lower limb via arthroplasty has traditionally used manual instruments to guide placement of the implant and determine where to resect bone in reference to anatomical landmarks. Manual instruments include alignment rods that are intra- or extramedullary that centralize and align the components according to the surgical plan.

Intramedullary and extramedullary alignment guides lack precision, are not tailored to each patient’s individual morphology, and can result in inadvertent deviations from the surgical plan. Inaccurate alignment has been reported to occur in cases where conventional manual instrumentation was used in approximately 30% of TKAs and 40% to 60% of compartment arthroplasties.

Mechanical malalignment >3° has been reported in more than 10% of TKAs equating to higher risk of increased wear, poor function, early loosening, and decreased survivorship.

**Robotics-assisted technologies**

Beyond CAS a robotic component was added approximately 20 years ago for use in knee arthroplasty procedures to perform more precise bone cuts and alignment with the goal to restore normal kinematics. Some early robotic systems were considered to be overly complex, especially when placing fiduciary markers. Systems came at a high cost, surgical times were extensive, and reported safety concerns of autonomous units resulted in some systems being removed from use.

Haptic feedback and autonomous or semi-autonomous controllers allows the surgeon to make the ultimate decision but adds accuracy in implant positioning and soft tissue balancing of the knee, especially for more challenging unicompartmental knee replacement (UKR) procedures.

For total and partial knee replacement, robotic systems help surgeons avoid errors, decrease variability, and establish more natural kinematics. Studies have reported robotics to restore ideal neutral mechanical axis in 97% of TKAs, to achieve better accuracy and increase efficiency of bone resections in all planes than what was achieved by conventional CAS. When used in UKA procedures robotics reported short learning curves, increased accuracy in posterior tibial slope and coronal tibial alignment in comparison to other alignment methods.

**Computer-assisted navigation**

Computer-assisted navigation systems (CAS) are intended to intraoperatively improve alignment, component positioning, and ligament balancing to enhance patient satisfaction, implant survival, and functional outcomes.

In addition to more precise alignment and implant positioning, CAS can improve surgical outcomes including ligament gap measuring throughout range of motion with more accurate balancing of the flexion space which can reduce component rotation errors.

Cons of intraoperative computer assistance include increased operative time, a higher associated cost for navigation equipment, exposure to radiation for imaging (e.g. CT, fluoroscopy), and the system can be difficult to learn.

Robotic systems include passive, semi-active, and active systems with a robotic arm, robotic guided cutting jigs, and robotic milling systems. Robotic-assisted technology requires only a small learning curve.

The NAVIO Surgical System combines key features of a CAS System, handheld robotics, and patient-specific planning.

Visualization of real-time bone sculpting with minimal bone loss due to inaccuracies and dynamic ligament balancing, improved radiographic outcomes, and reduced mechanical axis malalignment.

Studies have demonstrated that the minimal learning curve of robotic technology quickly enables less experienced surgeons to achieve reproducible and accurate alignment and successful clinical outcomes equivalent to those obtained by surgeons with vast experience. Operative times using robotic assistance after a few initial cases are expected to decrease without impact on surgical efficiency.
The history of robotics (continued)

Summary
- Based on meta-analysis computer navigation has been shown to obtain more accurate mechanical alignment with fewer outliers, better short term functional outcomes, and fewer complaints than conventional instruments in TKA and UKA.\textsuperscript{22,23}
- Robotic navigation systems have also demonstrated similar ability to consistently restore mechanical alignment more precisely than conventional instruments but with the added benefit of providing perioperative feedback to the surgeon. Meta-analysis has reported computer navigation including robotic systems to provide more accurate alignment (i.e., mechanical axis, coronal femoral, femoral flexion, tibial slope, and femoral component rotation) over CONV.\textsuperscript{6,23,24}

The next generation of robotics: NAVIO Surgical System

Confidence of handheld robotics
The NAVIO handpiece accurately removes bone identified by the surgeon approved, patient-specific plan.\textsuperscript{25}

The surgical plan is enforced with two types of robotic control modes, Exposure Control and Speed Control. The surgeon can alternate between these two cutting control modes or can disable both control modes and operate the NAVIO Surgical System as a standard navigated drill.

Exposure Control
Exposure Control adjusts the bur’s exposure with respect to a guard. If the surgeon encroaches on a portion of bone that is not to be cut, the NAVIO Surgical System retracts the spinning bur behind the guard, disabling cutting. The NAVIO Surgical System software adjusts the depth of the cut by adjusting the exposure of the bur outside of the guard.

During Exposure Control, the bur spins at full power (80,000 rpm), regardless of exposure level.

Speed Control
Speed Control regulates the speed of the bur, from 0 to 80,000 rpm, depending on its position. The control mode limits the speed of the spinning bur or disables bur motion entirely if the target surface has been reached. Bur motion is also disabled if the bur is moved outside of planned cutting boundaries.
Partial knees
Bone removal is completed exclusively using the cutting modes of the robotics-assisted handheld bur.

Total knees
The NAVIO™ Surgical System uses a hybrid approach for complete bone preparation, with the combined use of burs and saws. The robotic-assisted bur is used to prepare the femur and tibia bone surfaces to receive NAVIO specific cut guides which guide a surgical saw in bone removal.

Workflow for femur bone preparation using cut guides

Workflow for tibia bone preparation (Left: tibia cut guide; Right: twin peg tibia cut guide)

The NAVIO TKA application also has a Bur All feature.
- Bur All allows the surgeon to forgo the use of cut guides and prepares the bone surface using the robotic-assisted bur. Bur All is the same method of bone removal as the UKR and PFA applications.
- The Bur All feature also provides a way to refine the bone model and make additional fine cuts if adjustments need to be made
  - Modification of bone cuts for varus/valgus, slope, and resection level can be made in 0.5mm and 0.5° increments

Refine tibia

Bur All for the tibia
Image-free navigation

Flat markers
- Single-use, sterile disposable infrared reflective disks used as part of the NAVIO® system to provide optical tracking performance
- The NAVIO system’s infrared tracking camera is used to determine the position of the point probe and the surgical bur tip, and track their movement by scanning the position of reflective trackers relative to the position of trackers mounted on the patient’s femur and tibia.

Tracking array
NAVIO uses a two-pin bicortical fixation system to fix tracking arrays to the femur and tibia. Flat Markers are secured to the tracking arrays to relay position information to the computer cart with the assistance of the infrared camera.

Infrared camera
The mobile infrared tracking camera is used to determine the position of the point probe and the surgical bur tip and track their movement by scanning the position of reflective trackers relative to the position of trackers mounted on the patient’s femur and tibia.
NAVIO™ Cart

The mobile cart contains the touchscreen monitor, electronic control system, electrical system integration unit, computer, and uninterruptible power supply (UPS). The cart provides storage for the power cord, Anspach® drill foot control, and the NAVIO system foot control.

- **Surgeon controlled with foot pedal or through the touch screen**
  - Touch screen monitor
    - The touchscreen monitor is the primary user interface for the NAVIO system
  - Foot control pedals
    - **Anspach® Drill Foot Control**
      The Anspach drill foot control is used to control the Anspach drill during surgery, however the speed of the drill is controlled by the NAVIO Surgical System
    - **NAVIO System Foot Control**
      The NAVIO system foot control is used as an alternative to the touchscreen monitor when data points are being collected to define landmarks, shape bone, and position the implant prior to surgery

- **Portability**
  - Easily move the cart from OR to OR or facility to facility, providing flexibility and efficiencies
  - Featuring simple calibration and a footprint designed for use in the surgery center or hospital, NAVIO can easily support the demand for efficiency needed by orthopaedic programs

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**Small footprint**

Left knee OR setup

Right knee OR setup
NAVIO™ Instrument Kit
The NAVIO instrument kit consists of a two-level tray that contains required instrumentation for total knee, unicompartmental knee, and patellofemoral joint replacement surgery using the NAVIO Surgical System.

NAVIO Total Knee Instrument Kit
The NAVIO total knee instrument kit is a single-level tray that contains required instrumentation for total knee replacement using the NAVIO Surgical System. NAVIO-specific drill guides pair with existing AP cut blocks from the JOURNEY™ II, GENESIS™ II, and LEGION™ manual instrument sets.

Trays
State-of-the-art planning software

CT-free registration
A 3D model of the patient’s cartilage and bone is captured through direct surface mapping
The NAVIO® Surgical System does this without requiring a CT scan and allows surgeons, staff and patients the experience of a patient-specific plan without the extra steps associated preoperative imaging that can increase cost or delay surgery

Total and unicompartmental knees
• Limb alignment and soft tissue laxity are collected to assist the surgeon during implant component placement

Surgeon controlled, patient-specific planning
Component placement is planned virtually using cross-section and three dimensional surface views

Total and unicompartmental knees:
• Registration information allows the surgeon to virtually place implant components and predict postoperative joint laxity at the time of surgery without being locked into a plan before verifying the severity of the disease

• Planned implant position is combined with ligament laxity information under varus/valgus stress through full range of motion to calculate postoperative joint balance
**Bone preparation**

Patented NAVIO™ handheld burring technology removes only the bone determined by the surgeon plan.

- Bone removal is seen on the NAVIO screen in real-time allowing the surgeon to continually assess patient anatomy against the plan.

In total knee replacement, a Plane Visualization Tool confirms the plane of the cut, depth of the bone resection, and rotation of the components are consistent with the surgeon’s plan.

**Confirmation**

Total knee replacement and unicompartmental knee replacement

- Postoperative range of motion is evaluated by collecting alignment data while moving the leg through flexion/extension

- Varus/valgus balance is assessed to confirm the achieved long-leg alignment
Multiple implant support

NAVIO® provides the accuracy from robotics-assistance as well as the flexibility of multiple pioneering implant designs for partial and total knees to accommodate surgeon and patient needs.

Surgeons must assess patients as they are and utilize the best tools at their disposal to treat them.

NAVIO supports the JOURNEY® II Total Knee System. The anatomical shape of JOURNEY II TKA is designed to reproduce normal knee kinematics and thereby delivers improved functional outcomes and high patient satisfaction26–31.

Components made with OXINIUM® alloy, an advanced material shown to be 4,900 times more resistant to abrasion32, more than twice as hard33, and has a coefficient of friction that is up to half that of CoCr34.

Supports STRIDE UNI, designed to be optimized for robotics

Offers a selection of implant options with a strong clinical heritage including ZUK UNI35, GENESIS® II36 and LEGION® Primary37-39

*NAVIO with JOURNEY II XR not available for commercial use until 2018
Supporting healthcare professionals for over 150 years

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References: