Surgical Technique Guide for Knee Arthroplasty
The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the NAVIO® Surgical System, including its indications for use, contraindications, and product safety information, please refer to the product’s label and the Instructions for Use packaged with the product.
Introducing NAVIO™

The NAVIO™ Surgical System is an intraoperative visualization and surgical planning system, combined with a handheld, smart instrument for bone sculpting.

NAVIO assists the surgeon in image-free registration of patient anatomy and joint space to aid in planning of prosthesis components. Using a robotic-assisted bur, the surgeon can execute a procedure for unicompartmental (UKR), patellofemoral (PFA), and total knee (TKA) arthroplasty procedures. The handheld robotic tool limits the amount of bone to be removed, by enforcing a virtual boundary as per the patient plan, and mechanically controlling bur exposure or speed.

The NAVIO Surgical System is designed to aid surgeons in key factors for knee arthroplasty:

- component positioning,
- ligament balancing, and
- bone preparation

**NAVIO’s Key Features**

<table>
<thead>
<tr>
<th>Familiar workflows</th>
<th>NAVIO integrates into familiar surgical workflows for partial knee, total knee, and bi-cruciate retaining knee procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image-free system</td>
<td>With the image-free system, no preoperative imaging is required.</td>
</tr>
<tr>
<td>Dynamic ligament balancing throughout the procedure</td>
<td>This NAVIO feature enables the surgeon to assess soft tissue and balance the knee throughout the full range of motion (ROM).</td>
</tr>
<tr>
<td>Patient-specific plan</td>
<td>A plan is created using software that provides a unique, intra-operative 3D model based on the patient’s anatomy.</td>
</tr>
</tbody>
</table>
| Two control modes (exposure & speed) | NAVIO’s precision freehand sculpting technology tracks the position of the handpiece and bur relative to the surgical plan, and adjusts the exposure or speed of bur to control cutting  
  - Exposure Control continually adjusts exposure of the bur beyond a static guard to modulate cutting.  
  - Speed Control continually varies speed of a fully exposed bur to modulate cutting. |
Using this Guide

This document is intended to provide guidance on the recommended surgical technique for using the NAVIO™ Surgical System with Smith & Nephew Knee Systems.

Smith & Nephew recommends that you review this guide prior to performing knee arthroplasty utilizing the NAVIO Surgical System.

This guide should be used in conjunction with, not replacing, the information contained within the NAVIO™ Surgical System User’s Manual that accompanied the purchase of the NAVIO Surgical System.

NOTE: Screenshots used in this guide are examples used for reference only. Actual screens may vary.

WARNINGS!

• The NAVIO Surgical System is a surgical tool designed to assist the surgeon; it is not a substitute for the surgeon's experience and skill. The surgeon retains all responsibility for the planning and the conduct of the surgery during which the NAVIO™ Surgical System is being used.

• Consult the applicable knee system labeling for its full-intended use, indications for use, contraindications, and recommendations for implant sizing compatibility.

Intended Use

The NAVIO Surgical System is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

Indications for Use

The NAVIO Surgical System is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be determined.

These procedures include unicondylar knee replacement (UKR), patellofemoral arthroplasty (PFA), and total knee arthroplasty (TKA). The NAVIO Surgical System is indicated for use with cemented implants only.

Contraindications

The NAVIO Surgical System is not intended to be used on children, pregnant women, patients who have mental or neuromuscular disorders that do not allow control of the knee joint, morbidly obese patients, or any other patients contraindicated for UKR, PFA, or TKA.

Smith & Nephew Knee Systems

NOTE: Not all implants are available in all markets.

Environments of Use

The NAVIO Surgical System is intended to be used by trained medical professionals in a hospital or clinical setting equivalent to an orthopedic surgical suite. The components of the NAVIO Instrument kit and of the NAVIO Total Knee Instrument Kit will be used in a sterile environment and must be sterilized prior to use. The NAVIO camera cart and system cart must be cleaned and appropriately draped to maintain the integrity of the sterile field.

NOTE: Please reference the implant manufacturer’s instructions for use and recommendations for the compatibility of implant system combinations.
Getting to Know the NAVIO° Surgical System

The NAVIO Surgical System is a surgical planning, navigation, and intraoperative visualization system, combined with a handheld smart instrument for bone sculpting.

The camera cart communicates the relative position of the handpiece, the femur, and the tibia (via rigid tracker arrays) to the computer cart (Figure 1).

The NAVIO Surgical System’s application uses data gathered at the beginning of the surgical procedure (registration phase) to generate a computer model of the knee surface. This model is used to guide the surgeon in planning implant component position, based on anatomy and soft tissue data. Once the surgeon confirms the surgical plan, the surgeon utilizes a robotic-assisted handheld tool to prepare the bony surface for optimal placement of the implant components in the planned position.

The NAVIO Surgical System’s application can be broken up into the following stages, described in this document:

1. Setting Up for Operation
2. Registration
3. Implant Planning
4. Bone Cutting
5. Trial Reduction
6. NAVIO Case Review

NOTE: This surgical technique guide is separated into the same stages, for clarity.
Setting Up for Operation

Operative setup includes:

1. Exposing the Knee
2. Placing Bone Tracking Hardware
3. Placing the Tracker Arrays
4. Confirming Array Visibility
5. Placing Checkpoint Pins

Exposing the Knee

The NAVIO™ Surgical System is compatible with the typical exposure recommendations for knee arthroplasty.

**NOTE:** Consult the *implant manufacturer’s instructions for use* and product documentation for specified exposure recommendations.

Upon making the incision,

- Carefully debride and inspect the joint.
- Remove prominent spurs or osteophytes, which could inhibit the leg motion, with an osteotome or rongeur.
- Remove intracondylar, medial, and lateral osteophytes to avoid impingement with the tibial spine or cruciate ligaments, as well as peripheral osteophytes that may interfere with the collateral ligaments and capsule. It is crucial that all osteophytes are removed from the entire medial edge of both the femur and tibia, in order to assess joint stability reliably.
- Inspect the joint, and if required, resect the deep meniscotibial layer of the medial capsule to provide access to any tibial osteophytes. Exposure also can be improved with excision of patellar osteophytes.

For a cruciate retaining (CR) or a posterior stabilized (PS/BCS) knee surgery,

- Resect the ACL, or ACL and PCL, respectively, before proceeding with patient registration using the NAVIO Surgical System.

**NOTE:** Perform final debridement before component implantation.
Placing Bone Tracking Hardware

Rigid fixation of the femur and tibia tracking frames to the bone is critical for a successful NAVIO robotics-assisted surgery.

The NAVIO™ Surgical System utilizes a two-pin bi-cortical fixation system. This fixation system is installed using bone pins, a tissue protector, and tracker clamps. Once fixed to the bone, the tracking frames are oriented towards the optical tracking camera so that the tracking markers are in view.

**WARNING!**

A full conventional surgical instrumentation tray for the chosen implant should be available during every system use to implant manually the prosthesis in the event of system failure.

**NOTES:**

- There are two methods of tracker array attachment: attachment with the use of the tissue protector and attachment without the use of the tissue protector.
- If performing a bi-compartmental knee replacement where a patellofemoral prosthesis and a unicondylar prosthesis will be placed, ensure that the placement of the femoral bone hardware is far enough proximally on the femur bone, so as not to interfere with the camera’s visibility of the handpiece during either procedure.

The NAVIO Surgical System fixation system is comprised of the tools pictured in Figure 2. These tools allow for the tracking arrays (Figure 3) to be fixed to the bone and for the tracking markers to be oriented towards the optical tracking camera.

**CAUTION**

If using a surgical drill to place bone pins, do not clamp onto the threads of the pin; threads could become damaged, leading to poor tracker attachment.

**WARNINGS!**

- Be sure to place bone pins properly to avoid hitting critical anatomy.
- The bone pins must engage both cortical surfaces (Figure 4). If the bone pins fail to engage both cortical surfaces, then the tracker array may be unstable and lead to the collection of inaccurate anatomical data. If the bone pin perforates the outside of the bone significantly, there is an increased risk of patient injury.
- Do not reposition the bone pins once they have been installed in the patient’s bone.
Attaching Tracking Markers
In preparation for placing the bone tracking hardware and arrays, the scrub technician attaches the tracking markers (Figure 5) to the femur (Figure 6) and tibia tracker arrays, as well as to the handpiece tracker and point probe. Use four tracking markers for each tracker array, and four for the point probe.

Instructions

Wearing clean, sterile gloves,

1. Gently snap a tracking marker onto each prong of the tracker arrays and the point probe.

2. Support the tracker array behind the marker attachment point. Avoid transferring force to the entire tracker array. Ensure that each tracking marker is seated fully on each prong.

Cleaning or Replacing Tracking Markers
If markers are not visible in the Camera Orientation Adjustment screen, or there is flickering of the component visibility indicator, the markers may need to be cleaned or replaced.

Instructions

To clean the tracking marker,

• Using a sterile rag, towel, or gauze, gently wipe the front of the tracker array (the portion facing the camera) to remove any debris.

To replace the tracking marker,

• When removing the tracking markers for replacement, support the tracker array with your hand, and gently unseat the marker from its prong. Support the tracker array behind the marker attachment point. Avoid transferring force to the entire tracker array. Ensure that each tracking marker is seated fully on each prong.

After cleaning or replacing markers, to ensure that tracking frames have not moved,

• Verify checkpoint locations.

If tracking markers on the handpiece need to be cleaned or replaced,

• Recalibrate the handpiece prior to cutting bone.

• Support the tracker array behind the marker attachment point. Avoid transferring force to the entire tracker array. Ensure that each tracking marker is seated fully on each prong.
### Placing the Tracker Arrays

#### Inserting the Bone Pins with Use of the Tissue Protector

**Instructions**

<table>
<thead>
<tr>
<th>Tibia</th>
<th>Femur</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Position the tissue protector one hands breadth inferior of the tibia tubercle, slightly medial to the tibial crest, ensuring the tissue protector is perpendicular to the flat (medial) surface of the tibial shaft.</td>
<td><strong>1.</strong> Position the tissue protector one hands breadth superior of the patella in the anterior portion of the femoral shaft, centered mediodlaterally.</td>
</tr>
<tr>
<td><strong>WARNING!</strong> Be sure to place the proximal bone pin one hands breadth inferior of the tibia tubercle to prevent interference with the final implant.</td>
<td><strong>WARNING!</strong> The tissue protector guides spacing between pins; it does not guide pin insertion depth. Bottoming out the pin driver on the tissue protector may cause threads to strip leading to pin instability. (Figure 9).</td>
</tr>
<tr>
<td><strong>2.</strong> Firmly press down on the tissue protector to mark the skin. (Figures 7 and 8).</td>
<td><strong>2.</strong> Drill the first bone pin through the tissue protector, perpendicular to the surface of the bone, taking care to only engage, and not perforate, the opposing cortex. <strong>WARNING!</strong> The tissue protector guides spacing between pins; it does not guide pin insertion depth. Bottoming out the pin driver on the tissue protector may cause threads to strip leading to pin instability. (Figure 9).</td>
</tr>
<tr>
<td><strong>3.</strong> Pierce the skin, using a stab incision, down to the bone, in both locations.</td>
<td><strong>3.</strong> Drill the second bone pin into the bone slowly, perpendicular to the bony surface, taking care to only engage, and not perforate, the opposing cortex (Figure 9). <strong>NOTE:</strong> The tissue protector is not a depth guide. <strong>WARNING!</strong> The tissue protector guides spacing between pins; it does not guide pin insertion depth. Bottoming out the pin driver on the tissue protector may cause threads to strip leading to pin instability. (Figure 9).</td>
</tr>
<tr>
<td><strong>4.</strong> Clear the soft tissue at the incisions, and place the tissue protector into the incisions, to prevent the bone pin from engaging with soft-tissue.</td>
<td><strong>4.</strong> <strong>NOTE:</strong> When placing the pins, be sure they are placed perpendicular to the bone surface to prevent skiving.</td>
</tr>
<tr>
<td><strong>Using the bone pin driver and a surgical drill:</strong></td>
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</tr>
<tr>
<td><strong>5.</strong> Drill the first bone pin through the tissue protector, perpendicular to the surface of the bone, taking care to only engage, and not perforate, the opposing cortex.</td>
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</tr>
<tr>
<td><strong>7.</strong> Remove the tissue protector by pulling it up and over the bone pins.</td>
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</tr>
<tr>
<td><strong>8.</strong> Proceed to <a href="#">Attaching the Tracker Arrays</a>.</td>
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</tr>
</tbody>
</table>

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**Figure 7.** Tibia placement

**Figure 8.** Femur placement

**Figure 9.** The knee should be flexed when drilling bone pins.
Inserting the Bone Pins without Use of the Tissue Protector

**WARNING!**
Properly explore the area to verify that critical anatomy is not involved if placing bone pins without the tissue protector.

**Instructions**

<table>
<thead>
<tr>
<th>Tibia</th>
<th>Femur</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Slide the bone pins into the tracker clamp, as it will hold the bone pins in the proper alignment.</td>
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</tr>
<tr>
<td>2. Ensure that the tracker frame is not in the tracker clamp, and that the clamp is not tightened at this stage. Hold the clamp when drilling pins into the bone.</td>
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</tr>
<tr>
<td>3. Mark the position on the tibia one hand’s breadth inferior to the tibial tubercle, on the medial side of the tibial crest.</td>
<td>3. Mark the position on the femur one hand’s breadth superior to the patella in the center of the femur.</td>
</tr>
<tr>
<td>4. Pierce the skin, using a stab incision, down to the bone, in both locations.</td>
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</tr>
<tr>
<td>5. Clear soft tissue at pin site, to prevent bone pin from engaging with soft-tissue. <strong>NOTE:</strong> When placing the pins, be sure they are placed perpendicular to the bone surface to prevent skiving.</td>
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</tr>
<tr>
<td>6. Percutaneously place the first bone pin one hand’s breadth inferior to the tibial tubercle, on the medial side of the tibial crest.</td>
<td>6. Percutaneously place the first bone pin one hand’s breadth superior to the patella in the center of the femur.</td>
</tr>
<tr>
<td>7. Using the bone pin driver and a surgical drill, slowly drill the bone pins into each bone, perpendicular to the bony surface, taking care to engage the opposing cortex and stop.</td>
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</tr>
<tr>
<td>8. Check each pin to ensure that it has engaged the second cortex. Fine adjustments are made using the T-handle wrench.</td>
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</tr>
</tbody>
</table>

**Attaching the Tracker Arrays**

**Instructions**

1. Slide the tracker array clamp (with the clamp hardware oriented towards the camera) over the two bone pins, until the bottom of the clamp is within 1 cm of the patient’s skin, taking care not to place the clamp touching the skin or covering the exposed threads of the bone pins. (Figure 10).

   **NOTE:** Position the bone clamp below black laser marks on bone pins.

2. Place the smaller side of the tracker array closest to the operative site.

3. Orient the markers towards the camera and slide the array away from the incision site. Be sure to slide the tracker array as far away from the surgical site as possible, to allow for maximum working volume during the procedure.

4. The tracker arrays have flats and corners. Position the tracker array on the flat side inside the tracker clamp.

5. Secure the tracker array into the tracker array clamp along the length of the bar on the array.

6. Press Adjust Camera to move to the Camera Orientation Adjustment screen.

7. Ensure that the tracker array can be seen in all points of flexion and extension before tightening with the T-handle wrench.

   **NOTE:** When tightening the array make sure to tighten the clamp on the flat side, not on the corners (Figure 11).

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*Figure 10. Femur and tibia tracking array positions*

*Figure 11. Tightening the tracker array clamp assembly*
Confirming Array Visibility

Confirm that the position of the camera cart and tracker arrays allow for full, uninterrupted visibility throughout the registration and cutting processes (Figure 12).

**WARNING!**
Do not bump or move tracker arrays once you have begun collecting anatomical data. If the tracker array is bumped, it may damage the patient’s bone and invalidate collected data.

Instructions

1. Advance to the Camera Orientation Adjustment screen (Figure 13) in the surgical system's onscreen workflow and confirm visibility of the Femur (F) and Tibia (T) tracker arrays in the three positions, described in steps 2-4.

   Both (F) and (T) icons should be located in the lower third in the field of view area, and in the farther right third of the near-to-far range.

2. With the leg in deep flexion, ensure that the (F) is visible in the camera’s field of view.
3. With the leg in approximately 20° of flexion, ensure that the (F) is visible while rotating the leg at the hip.
4. With the leg in full extension, ensure that the (T) is visible in the camera’s field of view.

Placing Checkpoint Pins

Checkpoint pins should be placed in both the femur and the tibia (Figure 14), in positions where they will not be disturbed during bone removal. These points are referenced using the point probe at defined stages throughout the procedure to determine if either tracker array has moved.

The recommended position for the femoral checkpoint pin is in the medial or lateral femoral metaphysis. The recommended position for the tibial checkpoint pin is within the incision distal to the anticipated tibia cut.

**WARNING!**
Ensure that the checkpoint pins are placed away from the bone to be removed, to avoid cutting through or dislocating the checkpoint pins.
Registration

The NAVIO™ Surgical System’s image-free registration process utilizes standard image-free principles to construct a virtual representation of a patient’s anatomy and kinematics.

NOTES: The NAVIO registration steps are generally sequential, with certain stages being accessible for recollection if needed. Some registration stages from below may not be applicable for all NAVIO procedures.

Any registration point or collection also may be recollected in sequence, by moving backwards through the workflow stages.

Collecting Landmark Points

Landmark points are used as visual references during Implant Planning. Specific landmark points are prompted for collection based on the NAVIO application. The detailed utility and workflow for collection of these points are described in the NAVIO Surgical System User’s Manual.

Defining the Mechanical Axis

The mechanical axis of the knee is calculated by the NAVIO system by the surgeon-defined ankle center, knee centers, and hip center, as instructed below.

Defining the Ankle Center

• Using the point probe, input the locations of the medial and lateral malleoli points (Figure 15).

These landmarks help define the center of the ankle for the patient. The ankle center definition is then used to define the long leg axis, as well as the tibial mechanical axis for the patient.

Defining the Knee Centers

• Collect the center of the knee for tibia and femur (Figure 16), which will determine the weight bearing mechanical axis in conjunction with the ankle center and/or hip center.

Figure 15. Collect the medial and lateral malleoli points to calculate the ankle center

Figure 16. Defining the knee centers
Defining the Hip Center

NAVIO’s Hip Center Calculation stage defines the center of the femoral head. Circular movements of the femur tracker allows the system to find the hip center as a center point of rotation. Pelvic movement during this collection can be a source of error for this definition. The hip center is used to determine the long leg axis of the patient, as well as the femoral mechanical axis.

- Prior to beginning collection, the leg should start at approximately 20° - 40° of knee flexion and 20° of abduction, in order to provide enough room to rotate the leg.
- Slowly rotate the leg at the hip until all sectors of the graphic have changed to green (Figure 17).

Defining Neutral Position and the Kinematic Axis

Instructions

Neutral Position

- Place the leg in full extension, applying slight axial pressure to the knee, simulating a weight bearing condition (Figure 18).

This collection is utilized in determining the patient's preoperative varus/valgus deformity, and extension that the knee is able to achieve.

Flexion Range Collection

The next step will record normal flexion motion, as well as calculate the femoral kinematic rotational axis.

- Slowly move the leg through a normal (unstressed), complete range-of-motion, applying a slight axial force to the joint to keep the femur and tibia in contact (Figure 19).

Flexion range in this state is recorded and available for review.

**NOTE:** Collect the patient's entire flexion range when completing a TKA operation.

**UKR**

The kinematic axis will determine rotational axis of the femur and tibia

**TKA**

The kinematic axis is an initial definition of the medial-lateral axis of the knee. This kinematic axis is only used for the general orientation of a virtual bone for the image-free mapping stage.
Collecting Ligament Tension

Ligament tension collection is an option for UKR and TKA (Figures 20-21). This collection informs how much gap (laxity) will be built into the joint, based on the position of the implants, set in the Planning stage.

For more detailed information, see Performing Gap Planning.

NOTES:

• Collect as many sectors in this stage with consistent pressure on the ligaments for best interpretation of gaps during the implant and gap planning stages.

• Apply uniform stress to the operative collateral ligament(s) (e.g. valgus stress to the medial collateral ligament (MCL) when performing a medial UKR procedure, or varus and valgus stress to the MCL and lateral collateral ligament (LCL) for a total knee procedure) and collect the data throughout the flexion (Figure 20)

• For UKR, a collection in extension, mid-flexion and deep flexion (beyond 90°) is required to proceed. Ensure there is consistent tension throughout collected ranges, and do not over-tension ligaments and force alignment into the diseased compartment of the knee.

Figure 20. Ligament tension collection in uni knee replacement

Figure 21. Ligament tension collection in total knee replacement
Performing Surface Mapping

NAVIÖ's Free Collection stages offer a visualization of the previously collected femoral and tibial mechanical axis and rotational axis (blue lines), as well as discrete femur/tibia anatomic points (yellow dots) in UKR and PFA. (Figures 22-23).

It is recommended to digitize as much bone surface as possible to fit implant components best in the planning stage, and benefit from the understanding of the femur anatomy.

Surgery Specific Collection

To aid in planning TKA, ensure thorough surface collection of the exposed femur anterior cortex. For all procedures, be sure to collect exposed articular surfaces of the joint.

Collect free points on the femur throughout the trochlear groove and anterior femoral cortex regions of the bone for PFA procedure.

Collecting Femur Free Points

<table>
<thead>
<tr>
<th>Femur Free Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Move the point probe over the entire surface while holding down the footpedal, to digitize the femoral condyle(s), and other regions of interest.</td>
</tr>
<tr>
<td>• Use both hands to ensure constant contact of the point probe with the bone surface. Start by outlining the surface you want to digitize, and then fill in the entire surface.</td>
</tr>
<tr>
<td>• Ensure there is enough coverage specifically beyond the edges of the condyle in order to best assess the fit of the components in planning.</td>
</tr>
</tbody>
</table>

In order to best fit the component,

• Ensure coverage beyond the anterior notch point, specifically at the proximal portion of the anterior femur implant position, and beyond the edges of the condyle.
• Flex the leg to map the posterior portion for unicompartmental and total knee replacement.

For UKR and PFA,

• Manipulate the touchscreen to view the collected virtual bone surface in 3D (three dimensions).
Collecting Tibia Free Points

During Tibia Free Collection, ensure thorough surface collection of all exposed articular surfaces of the joint and on the anterior or and medial edges to the depth of planned resection.

### Tibia Free Collection

- Move the point probe over the entire surface while holding down the footpedal, to digitize the tibial plateaus.

- Use both hands to ensure constant contact of the point probe with the bone surface. Start by outlining the surface you want to digitize, and then fill in the entire surface.

- Ensure there is enough coverage specifically beyond the edges of the plateaus in order to best assess the fit of the components in planning.

- Flex the leg to map the posterior portion for unicompartmental and total knee replacement.

- Define anterior and medial/lateral edges of the plateau as far posterior as is accessible. Fill in the surface, moving anterior to posterior as space allows.

- Externally rotate the tibia, apply valgus stress, or hyperflex to access additional portions of the articulating anatomy.

- Collect points approximately 15 to 20 mm down the anterior and medial side of the tibia, so that overhang can be identified during the Implant Planning stage, and for TKA, the tibia cut guide can be visualized on the patient’s anatomy, for placement without interference.

- Compare ML axis to rotational landmarks visible on the virtual bone surface.

For UKR and PFA,

- Manipulate the touchscreen to view the collected virtual bone surface in 3D (three dimensions).

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**For the JOURNEY II XR implant only:**

- Map the anterior, lateral and medial surface of the tibia separately in order to create a “boundary” around the ACL.

- Map around the edge of the tibial plateau to ensure coverage on anterior, medial, and lateral sides as much as the incision allows.

- Map the medial plateau up to the eminence ridge, marking the boundary for the implant placement.

- Map the anterior portion of the eminence up to the ACL footprint, stopping at the boundary for the implant placement.

- Only map the bone surfaces that are to be resurfaced for the JOURNEY II XR implant.

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**Figure 23.** The software presents a virtual representation of the bone surface of the tibial operative condyle, generated from the collected free points. Manipulate the visualization to view in 3D.
Defining Special Points for TKA in Free Collection

In the free collection stage in TKA, the NAVIO system provides the option to collect additional points in a distinct color. The points are visible in the planning stage for any additional planning guidance that the user may need. They can be toggled to be displayed, or hidden in both the collection and the planning stages.

For the JOURNEY II XR implant only:

These points may be used for outlining the ACL to assist in planning the position of the eminence.

Defining the Axes

Femur Axis Definition

<table>
<thead>
<tr>
<th>TKA</th>
<th>The femur rotational axis is defined by NAVIO, or, the user has the option to define the patient’s AP axis as a surgical preference.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAVIO-Defined Axis</td>
<td>If you choose to use the rotational reference defined by NAVIO, NAVIO will determine the anatomical posterior condylar axis (PCA) based on the free collection mesh. NAVIO finds the most posterior medial and lateral points based on the free collection, and builds the PCA axis from the same.</td>
</tr>
<tr>
<td>User-Defined AP Axis</td>
<td>In the Femur Axis Definition stage, which follows Femur Free Collection, you can visualize the NAVIO-defined posterior condylar axis (PCA), as well as a live representation of the transepicondylar axis (TEA), and the AP axes altogether on the free collection mesh. The surgeon has the ability to fine-tune the preferred axis in this stage.</td>
</tr>
</tbody>
</table>

NOTES: The Femur Axis Definition stage is set as a required collection for patients with deformities greater than 3° of valgus or 7° of varus.

These rotational references are used during Implant Planning for component placement onto the patient anatomy.

| UKR | The femur rotational axis is derived from the kinematic axis, as defined during the kinematic range of motion. |
| PFA | The femur rotational axis is defined by the collection of the AP axis. |
The tibia rotational axis is derived from the kinematic axis that is defined during the kinematic range of motion.

The tibial rotational axis is derived from the femoral AP axis in Neutral Position (Figure 24).

The *Tibia Axis Definition* stage is accessible from multiple states in the workflow.

Similar to the *Femur Free Collection* stage, if upon entering the *Tibia Free Collection* stage, you feel that the rotational axis is not properly aligned, you may access the Tibia Axis Definition screen by selecting the Tibia Axis Definition icon in the upper right corner.

**Understanding NAVIO's Initial Sizing and Placement of the Implant**

**WARNING!:** Consult specific implant manufacturer instructions for information regarding implant sizing compatibility.

**NAVIO's Sizing of the Femur**

**UKR** NAVIO determines the initial size of the femur component by evaluating the tidemark point along with the posterior point.

**PFA** NAVIO always defaults to the smallest implant size.

**TKA** NAVIO determines the initial component size from the free collection mesh, based on the AP size of the bone.

NAVIO selects the smallest size which does not notch anteriorly when the component is initially fit to the posterior bone as the initial size.

**NOTE:** For TKA, initial sizing and placement of the femur component is dependent on the surface mapping definition, especially on the distal and posterior portions.

Optimal surface definition in these regions is critical for the software to best estimate a good starting position for the femur implant.

**NAVIO's Sizing of the Tibia**

**UKR** NAVIO determines the initial size of the tibia component by evaluating the medial (or lateral) landmark along with the eminence ridge collection.

**TKA** NAVIO determines the initial size of the tibia component from the free collection mesh. The mediolateral width of the bone is assessed at the level of resection. The closest tibia component size is set as the initial prosthesis for planning.
### UKR

<table>
<thead>
<tr>
<th>Superior-Inferior Positioning:</th>
<th>The distal portion of the implant aligns with the surgeon-defined distal femoral landmark point.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mediolateral Positioning:</td>
<td>The distal point is used to centralize the femur component on the operative condyle.</td>
</tr>
<tr>
<td>Anterior-Posterior Positioning:</td>
<td>The most posterior aspect of the implant aligns with the surgeon-defined posterior landmark point.</td>
</tr>
<tr>
<td>Alignment, Flexion and Rotation:</td>
<td>The distal resection defaults to a cut perpendicular to the mechanical axis.</td>
</tr>
<tr>
<td></td>
<td>The flexion of the femur component defaults to the implant manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td>Rotation of the component is set to 0° with reference to the kinematic axis of the knee.</td>
</tr>
</tbody>
</table>

### TKA

<table>
<thead>
<tr>
<th>Superior-Inferior Positioning:</th>
<th>The most distal portion of the component matches to the most distal portion of the free collection mesh, either the medial or lateral side.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOTE:</td>
<td>The superior-inferior and anterior-posterior positioning of the femur implant component also is dependent on the selected resection depth of the tibia.</td>
</tr>
<tr>
<td>Mediolateral Positioning:</td>
<td>The component is centralized mediolaterally on the distal cut surface of the femur.</td>
</tr>
<tr>
<td>Anterior-Posterior Positioning:</td>
<td>The most posterior points of the implant are set to match the most posterior points found on the free collection mesh, medially and laterally. The femur component starts at 3° of flexion to the mechanical axis.</td>
</tr>
<tr>
<td>Alignment, Flexion and Rotation:</td>
<td>The rotation of the femur component is set to the implant manufacturer’s recommendation by considering the free collection mesh of the patient’s anatomy, unless the user has performed AP axis definition.</td>
</tr>
<tr>
<td></td>
<td>If the surgeon has defined the AP axis, the implant component rotation is set perpendicular to the AP axis. When changing rotation, note the point of rotation is about the posterior medial condyle.</td>
</tr>
<tr>
<td></td>
<td>The Femur Axis Definition stage is accessible from multiple states in the workflow.</td>
</tr>
</tbody>
</table>

On the **Femur Free Collection** screen, accessible from the Planning screens, press the Femur Axis Definition icon in the upper right corner. The **Femur Axis Definition** screen displays. Use the point probe to rotate the grid to align the AP axis to the desired location.
# NAVIO's Positioning of the Tibia

| UKR | Superior-Inferior Positioning: The depth of cut is always set to 5 mm from the low point collected.  
|     | Mediolateral Positioning: The medial (or lateral) border of the implant matches the surgeon-defined medial (or lateral) tibia landmark point.  
|     | Anterior-Posterior Positioning: The most anterior aspect of the implant is aligned with the surgeon-defined anterior landmark point on the tibia.  
|     | Alignment, Slope, and Rotation: The proximal tibia cut default to 0° varus/valgus. The slope for a partial knee tibia always defaults to 5° from the defined mechanical axis of the tibia.  
|     | The rotation of the tibia component is set to match the surgeon-defined eminence ridge collection. |
| TKA | Superior-Inferior Positioning: The tibia resection depth is set by the surgeon, based on the selected surgeon preference. If Implant Default is chosen as the surgeon preference, the lateral implant surface is set to match the lateral landmark point NAVIO defines from the mesh.  
|     | Mediolateral Positioning: The tibia implant is centralized on the knee center point.  
|     | Alignment, Slope, and Rotation: The proximal tibia cut is set perpendicular to the mechanical axis.  
|     | The slope of the tibia component is set 3° to the mechanical axis.  
|     | The initial rotation of the component is set to 0° in relation to the tibia rotational axis. |
Implant Planning

The *Implant Placement* stage presents a virtual representation of the patient’s femoral and tibial anatomy.

- If both PFA and UKR procedures will be performed, Smith & Nephew recommends completing either the entire Unicondylar procedure (UKR) or the Patellofemoral procedure (PFA) individually. This is to ensure that enough bone is available for the PFA implant.

For detailed information on the options available for planning visualization, reference the *NAVIO™ Surgical System User’s Manual*.

**Using the Navio Planning Screens**

The Prosthesis Placement/Implant Planning screens display four primary viewscreens used to manipulate the implant component. The screen depicts sagittal, coronal, and transverse views, as well as an arbitrary view, to plan the femur and tibia implants on the defined anatomy. The functionality of the buttons and widgets on these screens (Figures 25-27) is described in Tables 1-3.

<table>
<thead>
<tr>
<th>Symbol on Active View</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Superior (Position Control)</td>
</tr>
<tr>
<td>I</td>
<td>Inferior (Position Control)</td>
</tr>
<tr>
<td>M</td>
<td>Medial (Position Control)</td>
</tr>
<tr>
<td>L</td>
<td>Lateral (Position Control)</td>
</tr>
<tr>
<td>P</td>
<td>Posterior (Position Control)</td>
</tr>
<tr>
<td>A</td>
<td>Anterior (Position Control)</td>
</tr>
<tr>
<td>▲</td>
<td>Move up</td>
</tr>
<tr>
<td>▼</td>
<td>Move down</td>
</tr>
<tr>
<td>▲</td>
<td>Move to the left</td>
</tr>
<tr>
<td>▼</td>
<td>Move to the right</td>
</tr>
<tr>
<td>◀</td>
<td>Rotate clockwise</td>
</tr>
<tr>
<td>◀</td>
<td>Rotate counterclockwise</td>
</tr>
<tr>
<td>⬆</td>
<td>Maximize view to full screen</td>
</tr>
<tr>
<td>⬇</td>
<td>Minimize view to full screen</td>
</tr>
<tr>
<td>☰</td>
<td>Increase magnification</td>
</tr>
<tr>
<td>☸</td>
<td>Decrease magnification</td>
</tr>
<tr>
<td>✅</td>
<td>Selected plane of reference</td>
</tr>
</tbody>
</table>

**Table 1.** Active view button description

Figure 25. Implant Planning screen, depicting UKR femur planning

Figure 26. Implant Planning screen, depicting PFA planning

Figure 27. Implant Planning screen, depicting TKA combined planning
<table>
<thead>
<tr>
<th>Implant Planning Widgets</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left Side Screen Panel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>To:</strong></td>
<td><strong>• Press</strong></td>
<td></td>
</tr>
<tr>
<td>verify checkpoints,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>switch from the solid surface to cross section view,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>toggle resection depths on and off,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>change the view of the bone model,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>maximize the active view,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>toggle between discrete and continuous gap graphs (if Gap Assessment is completed),</td>
<td></td>
<td></td>
</tr>
<tr>
<td>evaluate joint space at any point in planning,</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Table 2. Implant Planning widgets – left side screen panel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>To:</strong></td>
<td><strong>• Press</strong></td>
</tr>
<tr>
<td>access case information throughout the procedure,</td>
<td>(TKA)</td>
<td></td>
</tr>
<tr>
<td>view instructions specific to the state,</td>
<td>(UKR/PFA)</td>
<td></td>
</tr>
<tr>
<td>change the implant design intraoperatively,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>switch from the solid surface to cross section view,</td>
<td>(UKR/PFA)</td>
<td></td>
</tr>
<tr>
<td>adjust the implant or poly size,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>access the Other Options Menu,</td>
<td>(TKA)</td>
<td></td>
</tr>
<tr>
<td>take a screenshot,</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Table 3. Implant Planning widgets – right side screen panel</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Unicompartmental Knee Planning

Placing the Femoral Component

The NAVIO™ Surgical System software provides a starting size and initial placement of the femoral component (Figure 28) utilizing the femur landmark points collected during the Registration stage.

From the initial placement, you have the ability to adjust the size and placement of the component.

NOTES: If the current virtualization of the femoral condyle is not sufficient at any point during Implant Planning,

- Press the Collect Femur/Tibia Points button in the lower portion of the screen.
- Collect additional points in Femur Free Collection in the deficient areas. Continuing forward from this screen will bring you right back to the Implant Placement stage.

When localizing the femoral component on the digitized surface, the following instructions provide key metrics to review.

Instructions

1. Activate the desired plane of view by pressing it.

2. Slide a finger vertically on the viewscreen to navigate through cross sectional views.

In the sagittal plane of view:

1. Confirm that the size provides full coverage from the based on the free collection mesh.

2. Adjust component flexion (use the Rotation arrows in the viewscreen) to achieve desired anterior transition within the virtual condylar surface (Figure 29).

The supported implants are designed to be implanted at the degrees of flexion show in the table on the following page.

Instructions

In the transverse plane of view:

For condyles that are wider than the implant, the prosthesis should be biased laterally (or medially) to optimize tracking on the tibial component.

1. Ensure the component is localized properly on the condyle.

2. Confirm that the component is not overhanging medially or laterally.

This will be evident by the dark gray of the virtual implant appears to be breaking through the virtual bone surface.

If required, you can apply external rotation to the component using the Rotation arrows in the active viewscreen. The software will indicate how much rotation you are applying.
<table>
<thead>
<tr>
<th>Implant</th>
<th>Degrees of Flexion</th>
<th>Flexion Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>JOURNEY™ UNI</td>
<td>45°</td>
<td>Angle between the posterior femoral implant post and the femur mechanical axis.</td>
</tr>
<tr>
<td>JOURNEY™ II UK</td>
<td>0°</td>
<td>Angle of the distal cut to the femur mechanical axis</td>
</tr>
<tr>
<td>STRIDE™</td>
<td>25°</td>
<td>Angle of the post holes to the femur mechanical axis</td>
</tr>
<tr>
<td>ZUK™</td>
<td>25°</td>
<td>Angle between the posterior femoral implant post and the femur mechanical axis.</td>
</tr>
</tbody>
</table>

**NOTE:** To plan the ZUK implant in a manner similar to the manual instrumentation, plan the posterior femoral component flush with the native cartilage and then move the component anteriorly 2 mm.

Four clicks is approximately equivalent to 2 mm on the planning screens. At this stage, confirm that the anterior portion of the femoral component is in the desired position in relation to the Tidemark point.

---

**Placing the Tibial Component**

The NAVIO™ Surgical System software will provide a starting size and initial placement of the tibial component.

From the **initial placement**, you have the ability to adjust the size and placement of the component.

Identifying the posterior aspect of the tibia may be difficult in a tight knee (Figure 30). If applicable, use a lateral radiograph to help determine the size of the tibial component prior to conducting a UKR procedure.

When localizing the tibial component on the digitized surface, the following instructions provide key metrics to review.

**Instructions**

**In the transverse plane of view:**

1. Confirm the size of the implant component. Adjust sizing as necessary, paying close attention to avoid medial/lateral and anterior overhang.

   To adjust this rotation,

   2. Press the arrows in the transverse plane of view, to fit the natural anatomic curvature best at the level of bone resection.

**In the sagittal plane of view:**

1. Confirm the posterior slope. The tibial component will default to the thinnest bearing.

   To adjust thickness,

   2. Change the component using the TIBIA Thickness arrows in the control panel on the right side of the screen.

![Figure 30. Confirm posterior slope is appropriate for patient (upper right)]
**Patellofemoral Knee Planning**

The NAVIO™ Surgical System software provides an initial placement of the PFA component, utilizing the anterior cortex and knee center landmark points collected during the Registration stage.

From the initial placement, you have the ability to adjust the size and placement of the component.

When localizing the component on the digitized surface, the following instructions provide key metrics to review.

**Instructions**

<table>
<thead>
<tr>
<th>1. Confirm the rotation of the femoral component matches native anatomy, where possible.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The distal triangle (distal tip) of the implant is suitably flush with the bone and the trochlea of the implant should reflect the anatomic trochlea.</td>
</tr>
</tbody>
</table>

| 2. Confirm that the implant fixation post (top of intercondylar notch) is suitably below the bone surface (Figure 31). The trochlea of the implant should reflect the anatomic trochlea (i.e., the axis of Whiteside's line). |

| 3. Confirm that the transitions between the distal/inferior implant walls and the femoral condyles are as level as possible (i.e., that there is no downward or upward transition step). |
| This enables the patella to run smoothly over this part of the joint (Figure 31). |
| **NOTE:** It is better to err towards having the implant slightly recessed, rather than protrude into the transition zone. |

| 4. Confirm that the anterior implant cut is tangential to the anterior cortex, in order to prevent notching or over-stuffing of the anterior joint. |

*Figure 31. The implant position in Cut Surface view*
Total Knee Planning

Placing the Femoral Component
The NAVIO® Surgical System software provides a starting size and initial placement of the femoral component, utilizing the femur free collection points collected during the Registration stage.

From the initial placement, you have the ability to adjust the size and placement of the component.

NOTE: Prior to planning, ensure sufficient high confidence mesh coverage in areas of clinical importance including (for the TKA application) the femur anterior cortex, distal condyles, and posterior condyles.

When localizing the femoral component on the digitized surface, the following instructions provide key metrics to review.

Instructions

**In the transverse plane of view:**

1. Confirm that the component size provides adequate coverage on the digitized femur bone surface.

2. Utilize the solid viewscreens, as well as the cross-section views, to ensure that the implant component has adequate resection depths in both the distal, as well as posterior, sections of the bone.

The resection depths are calculated by NAVIO by evaluating the most distal and posterior points found in the bright yellow mesh to the level of implant resection.

**In the sagittal plane of view:**

- Verify that the implant component is not overhanging or notching anteriorly into the digitized bone surface.

**In the coronal plane of view:**

- Confirm that the implant component has adequate resection depths in both the distal as well as posterior sections of the bone.

- Ensure that all visualizations are referenced from the actual mapped surface (bright yellow mesh) and not model approximations. Ensure that there is sufficient coverage of the proximal portion of the anterior femur implant position on the bone (bright yellow mesh).

NOTE: Refer to the applicable Total Knee System Surgical Technique for recommended implant component rotational constraints, bone resection, and alignment of component on the bone surface.

Placing the Tibial Component

The NAVIO Surgical System software will provide a starting size and initial placement of the tibial component utilizing the tibia free collection points collected during the Registration stage.

From the initial placement, you have the ability to adjust the size and placement of the component. The tibial component defaults to the thinnest bearing option. The polyethylene thickness can be adjusted using the thickness arrows on the right side of the screen.

Using the position control arrows active in the coronal plane of view, you may increase or decrease the resection depth. The resection depth displayed on the viewscreen is based on the collected surface during the Tibia Free Collection stage.

When localizing the tibial component on the digitized surface, the following instructions provide key metrics to review.

Instructions

**In the transverse plane of view:**

1. Press the Tibia Size arrows on the right side of the screen to confirm the size of the implant component.

2. Use the rotation arrows to adjust the implant rotation.

**In the sagittal plane of view:**

- Confirm the posterior slope of the component.

The software displays the posterior slope within this viewscreen, which reflects the slope of the tibial implant component with respect to the mechanical axis defined during the Registration stage.

**In the coronal plane of view:**

- Confirm the resection depths of the medial and lateral plateaus for the tibial implant.

NOTE: For TKA implants, the rotation and ML placement of the tibial component is not constrained by the NAVIO® cut guides. The final implant rotation and the placement is performed with manual instrumentation.
For the JOURNEY II XR implant only:

For a JOURNEY™ II XR implant, the NAVIO® Surgical System prepares the bone with respect to the rotation set during the Implant Planning stage, in order to preserve the eminence as executed with manual instruments.

1. Position the tibia implant such that sagittal cuts do not encroach upon the ACL footprint. Use the special points collected in planning to accomplish this.

2. Use the Solid Surface implant view to confirm implant placement visually, and adjust the size based on the virtual bone surface in order to not violate the ACL footprint.

3. Use Special Point to ensure that the unmapped ACL footprint falls within the intercondylar space of the tibia implant.
Performing Gap Planning

NAVIO’s **Gap Planning** stage provides you with the ability to balance soft tissue laxity (gap) throughout the patient’s range of motion.

The soft-tissue gap planning is predicated on the stressed range of motion input from the **Registration** stage. During the Stressed ROM (range of motion) stage, the applied valgus stress (for a medial UKR), or varus stress (for a lateral UKR) to the operative-side collateral ligament, or the completion of both stressed evaluation (TKA) determines the compartment ligament laxity plot.

Planning for gaps takes place in UKR and TKA. Like **Implant Planning**, **Gap Planning** screens (Figures 32-33) display four primary interactive viewscreens used to manipulate the implant component, depicting sagittal, coronal, and transverse views to plan the femur and tibia implants on the defined anatomy. Use these views to translate and rotate the components with respect to the virtualized joint of the patient. Beneath those viewscreens is a graph from 0° through 120° of flexion. The x-axis represents the flexion (degrees). The y-axis represents millimeters of either the relative gap/laxity (+) or the overlap/tightness (-).

**NOTE:** Avoid overlap, which may over-stuff the joint and load the contralateral compartment.

Performing UKR Gap Planning

The functionality of the buttons on the **Gap Planning** screen (Figure 34), that are not described in Tables 2 and 3 but appear on the UKR Gap Planning screen, is described in Table 5.

<table>
<thead>
<tr>
<th><strong>UKR Gap Planning Widgets Left Side Screen Panel</strong></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Green Dots/Free Collection" /></td>
<td>The Green Dots/Free Collection button is used to show or hide the cloud of discrete green points collected during <strong>Free Collection</strong> stages. It is generally helpful to hide the green points in order to view the virtual bone surface unobstructed.</td>
</tr>
<tr>
<td><img src="image" alt="Atlas Mesh" /></td>
<td>Press the Atlas Mesh toggle button to show/hide the mesh.</td>
</tr>
<tr>
<td><img src="image" alt="Ligament" /></td>
<td>Press the Ligament button to the left of the flexion gap graph to switch the focus of the graph from the orange line to the blue line. The blue line represents the unstressed ROM collected during the <strong>Registration</strong> stage. By displaying both of these lines on top of one another on the graph, you can identify how much laxity was mapped into the joint through the Stressed ROM Collection visually. If the orange line meets the blue line, then this indicates you were unable to apply ligament stress to the knee at this section of flexion.</td>
</tr>
</tbody>
</table>

**Table 5.** UKR Gap Planning left side screen panel widget description
Figure 34. UKR Gap Planning screen depicting adjusting the tibial depth resection will increase or decrease the gap from extension to flexion.

**NOTE:** It is important to balance the graph with the orange Stressed ROM collection line, not the blue Unstressed ROM collection line.

- The goal is to balance the soft tissue gap throughout flexion, Ideally aiming for a relatively flat line with approximately 1 to 2 mm of gap/laxity.
- Run a finger over the flexion graph at bottom of screen to visualize the theoretical articulation of the femur and tibia implant components throughout the ROM in the viewscreens.

Orange and purple data sets represent medial and lateral joint space, respectively. If the data set is above the x-axis, this represents predicted gap in the joint space. If the data set is below the x-axis, this represents predicted overlap of the joint space.

Table 6 provides suggested ligament balancing manipulations.

<table>
<thead>
<tr>
<th>Ligament Balancing Scenario</th>
<th>Manipulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance is tight throughout flexion.</td>
<td>Move tibial component inferior and/or reduce thickness.</td>
</tr>
<tr>
<td>Balance is loose throughout flexion.</td>
<td>Move tibial component superior and/or increase thickness.</td>
</tr>
<tr>
<td>Balance is tight in extension and loose in flexion.</td>
<td>Move the femoral component posterior, or reduce femoral component flexion.</td>
</tr>
<tr>
<td>Balance is tight in flexion and loose in extension.</td>
<td>Consider upsizing the femoral component, then, verify bone coverage.</td>
</tr>
<tr>
<td>Balance is tight in flexion and loose in extension.</td>
<td>Move femoral component anterior and superior. Consider downsizing femoral</td>
</tr>
</tbody>
</table>

Table 6. Planning Final UNI Gap - Ligament Balancing Manipulations
### Adjusting the Component M-L Position (UKR)

This stage provides you with the ability to manipulate the M-L position of the component (Figure 35). Contact points should indicate that implants are loaded centrally, and that no significant edge loading occurs during knee flexion.

**Instructions**

1. Use the position controls, in conjunction with the planes of view, to adjust the components’ mediolateral position. Contact points should indicate that implants are loaded centrally, and that no significant edge loading occurs during knee flexion.

   Adjustment of contact points may be made by translational or rotation manipulations to the components, including adjustments to the component’s varus/valgus position.

2. Ensure that adjusting the mediolateral position does not compromise the contact between the implant and the respective bone.

   It is important to ensure that fine-tuned adjustments of the flexion gap graph do not move the implant out of position. If necessary, navigate back through the workflow to the Prosthesis Placement screens to adjust general sizing and placement.

3. Activate a virtualization of the femur and tibia components by dragging a finger across the flexion gap graph. This shows the articulation of the two components.

4. Manipulate the position and orientation of the implant components so that the resulting flexion gap graph is flat, generally, and so that it is positioned 1 to 2 mm above the zero line in early to mid-flexion.

   In deeper flexion (> 90°), the resulting gap should be increased slightly.

5. Rotate the femoral component to view the backside in order to confirm that the implant resection is appropriate.

---

**Figure 35.** The final flexion gap graph should reflect an appropriate level of laxity in the joint throughout flexion.
Performing Total Knee Gap Planning

The Planning stage of the TKA workflow allows you to adjust the implant plan based on predicted gap information collected in the Gap Assessment stage (Figure 36).

If ligament balancing was a selected workflow preference, the NAVIO system takes the user from the Implant Planning stage to the Gap Assessment stage. The surgeon is expected to tension both the medial and lateral collateral ligaments consistently throughout the range of motion in the Gap Assessment stage. This joint space information is used by NAVIO to predict gaps based on the planned component positions.

The gap graphs display the gap or overlap between the femur and the tibia implant components. You can use the implant position controls to change the position in order to manipulate the gap between the two.

Using the Gap Graph toggle button on the left side of the screen, you can select between two views of the gap graphs. These are the extension/flexion view or the full range of motion (ROM) view.

Viewing Extension/Flexion

The Flexion and Extension Gap view displays two discrete points; one for the medial compartment and one for the lateral compartment; values are displayed in millimeters of gap or overlap. For extension, the discrete points represent the values collected in each compartment during Gap Assessment that were closest to 0°. For flexion, the discrete points represent the values collected in each compartment during the Gap Assessment stage that were closest to 90°.

Viewing Full ROM

The medial compartment and lateral compartment gaps are plotted throughout the flexion range collected in the Gap Assessment stage. This graph is translated to the Implant Planning screen to assist with gap balancing throughout the range of motion.

The x-axis indicates the range of motion throughout flexion in degrees, and the y-axis indicates gap (+) or overlap (-) in millimeters. The vertical blue line indicates the angle at which the patient's neutral position was collected.

You should plan for compartment gap spaces that match the implant design's rationale.

The goal of this stage is to have balanced extension and flexion gaps, in medial and lateral compartments, respectively. The extension gap will likely look unbalanced when comparing the medial and lateral space if no ligament release has been performed for a deformed knee.

You may choose to perform anterior cruciate ligament (ACL) release for CR procedure, or ACL and posterior cruciate ligament (PCL) release for a BCS or PS procedure if they are not already resected. Collateral ligament release(s) may be performed, and laxity information may be re-collected.

- Press the Collect Joint Laxity button to depict what the joint space actually will look like in extension and flexion.

NOTE: If you choose to perform ligament release after bone preparation, focus on the gap of the looser condyle in extension. Post implant placement, ligament release would open up the tighter compartment.

Final Gap Planning Manipulations during TKA

Adjustments to femoral component rotation should be carefully considered relative to prior parameters such as fit to the bone and anterior notching.

Confirm that the implant resection is appropriate for the femur and tibia in extension as well as flexion. Confirm the anterior transition of the femur implant to avoid notching and confirm tibia slope for gap balancing.

Adjustments to femoral flexion should be considered carefully against prior considerations regarding anterior fit and alignment to the intramedullary (IM) axis.
The final gap graph should reflect an appropriate level of laxity in the joint in a tensioned state.

<table>
<thead>
<tr>
<th>Ligament Balancing Scenario</th>
<th>Manipulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance is tight in extension and flexion.</td>
<td>Move tibial component inferior and/or reduce thickness.</td>
</tr>
<tr>
<td>Balance is loose in extension and flexion.</td>
<td>Move tibial component superior and/or increase thickness.</td>
</tr>
<tr>
<td>Balance is tight in extension and loose in flexion.</td>
<td>Move femoral component superior. Increase the femoral component size - or-- Reduce femoral component flexion.</td>
</tr>
<tr>
<td>Balance is tight in flexion and loose in extension.</td>
<td>Downsize the femoral component, or move it anterior.</td>
</tr>
<tr>
<td>NOTE: The femur implants are anterior referenced. Upsizing or downsizing the components does not change the anterior cut from the plan, unless the user moves the component.</td>
<td></td>
</tr>
<tr>
<td>NOTE: Exercise caution when anteriorizing or posteriorizing the femur component as it would affect the anterior transition of the component on bone, and evaluate for notching.</td>
<td></td>
</tr>
<tr>
<td>Move the femur component inferior to tighten the extension gap.</td>
<td>-or-- Increase posterior slope of tibial component.</td>
</tr>
<tr>
<td>Balance is loose in the medial compartment in flexion.</td>
<td>Internally rotate the femur implant to balance gap in the medial and lateral compartments</td>
</tr>
<tr>
<td>Balance is tight in the medial compartment in flexion.</td>
<td>Externally rotate the femur implant to balance gap in medial and lateral compartments</td>
</tr>
<tr>
<td>Balance is loose in the lateral compartment in extension.</td>
<td>Plan with the lateral gap (if not performing medial collateral ligament release at this stage) in order to balance the medial and lateral gap in extension.</td>
</tr>
<tr>
<td>Move the femur component inferior in extension, to tighten the gap presented.</td>
<td></td>
</tr>
<tr>
<td>Balance is tight in the lateral compartment in extension.</td>
<td>Plan with the lateral gap (if not performing lateral collateral ligament release at this stage). Move the femur component superior in extension, to loosen the extension space.</td>
</tr>
<tr>
<td>The medial and lateral compartments are not balanced in extension</td>
<td>The component default rotation in varus/valgus is 0° to ensure a perpendicular distal cut with respect to the femur mechanical axis.</td>
</tr>
<tr>
<td></td>
<td>To balance the medial and lateral space in extension, re-collect ligament stress in extension, after performing medial-collateral ligament release.</td>
</tr>
</tbody>
</table>

Table 6. Planning Final TKA Gap- Ligament Balancing Manipulations
Preparing for Bone Cutting – TKA Cut Guide Placement

Using a NAVIO Cut Guide for TKA

Prior to the Bone Cutting stage in TKA, you are presented with the Cut Guide Placement screen. The default cut guide can be changed using the button containing the manufacturer name and implant name in the upper right of the screen (Figure 37).

The cross section view on the left side of the screen depicts a transverse cross section, and functions similarly to the Implant Planning screens.

There are three methods for performing bone removal on the femur:
- NAVIO Femur Cut Guide
- Distal Burring
- Bur All

Each of these methods presents a different view in the stage. For complete descriptions of each bone removal method, please see the respective sections in the Bone Cutting stage of this technique.

Placing the NAVIO Femur Cut Guide

Instructions

1. Ensure that the cut guide will not interfere with patient soft tissue by assessing the incision.
2. Ensure that all four locking features on the femur distal cut guide assembly (consisting of the distal cut guide and femur stabilizer) have purchase into the bone surface.
3. Choose an appropriate cut guide option by selecting from Small, Medium, or Large on the top of the screen.
4. Use the cross section view to ensure that the anterior locking features of the cut guide have purchase into the bone surface and are centralized close to the anterior crests of the femur bone surface. Confirm that the distal lock features also are embedded into the bone surface.

Distal Burring – AP Cut Guide Placement

The NAVIO Surgical System supports a hybrid approach for complete bone preparation of the femur, with the combined use of burs and saws.

The distal femoral cut is completed with the bur, and the AP cut guide can then be fixed to the bone to complete the component cuts.

In the Cut Guide Placement stage, the screen will display the implant AP cut guide on the bone surface.

For this bone preparation method, ensure the AP cut guide is centralized on the bone (M-L). The AP position and rotation of the cut guide is set by the NAVIO implant plan.
Using Bur All

If you select this cutting method in the Cut Guide Selection stage, the digitized virtual bone model does not display a cut guide on screen.

Placing the NAVIO Tibia Cut Guide

The Cut Guide Placement screen allows you to move and rotate the cut guide in the cut plane.

Instructions

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Choose an appropriate cut guide option by selecting from Twin Peg, Small, or Medium on the top of the screen.</td>
</tr>
<tr>
<td>2.</td>
<td>Confirm that the cut slot portion of the cut guide is not impinging on the bone surface by referencing both the cross section view, and the 3D view. Take care to evaluate cut guide placement so that it does not interfere with patient soft tissue.</td>
</tr>
<tr>
<td>3.</td>
<td>Use the cross section view to ensure that the locking features of the tibia cut guide have sufficient purchase into the bone surface, and do not interfere with soft tissue.</td>
</tr>
<tr>
<td>4.</td>
<td>For the Small and Medium cut guides, pay close attention to the angled posterior locking features, ensuring that they are both buried deep into the bone surface.</td>
</tr>
</tbody>
</table>

NOTE:

For the JOURNEY II XR implant only:

For the JOURNEY™ II XR implant, the NAVIO™ Surgical System does not support tibia cut guides.

It may be helpful to position the cut guide further away from the medial (or more severely diseased) condyle so that the medial posterior locking feature is buried into the intercondylar eminence to achieve sufficient purchase into the bone.
Bone Cutting

During bone preparation, you execute the surgical plan as generated from the *Implant Planning* stage.

**NOTE:** To adjust the plan at any time during the cutting process, select the Back to Planning button. After making the adjustments, you may move forward again to the *Bone Removal* stage to continue bone preparation.

This section reviews methods of bone preparation for the femur and tibia.

**Setting Up Equipment**

The handpiece and drill cables should rest on the operating room table within the sterile field. Take care not to drop them below the table. Resting the cables on the table below the trackers and running up to the handpiece by the patient’s foot will help keep the cables from interfering with the visibility of the bone tracker arrays.

During cutting, if the camera loses sight of either of the bone tracker arrays, check that the cables have not obscured any of the tracking markers.

**Setting Up the Irrigation System**

The irrigation system needs to prime for approximately 20 seconds prior to active irrigation (Figure 38).

To prime the fluid,

- Put the system into Bur Cut Guide mode and depress the black Anspach® footpedal.

  This will run the integrated peristaltic pump on the side of the NAVIO™ system cart.

**Checking the Handpiece**

Ensure that the NAVIO handpiece has been assembled properly.

**Instructions**

1. Tug on the Anspach drill cylinder inserted into the back of the handpiece. If it comes loose, reattach the two properly for use.

To provide support,

2. Your dominant hand should be placed on the body of the tool, with the opposing hand placed near the tip (Figure 39).
In order to initiate the bur for bone removal,

- Fully depress the Anspach footpedal. During Exposure Control mode, the bur will spin at approximately full power (80,000 RPM), regardless of exposure level. During Speed Control mode, the system will adjust the speed of the bur (0 to 80,000 RPM), depending on its proximity to the planned target surface, as defined in the Implant Planning stage.

The cutting control modes do not limit cutting beyond the protected-bone surfaces. Therefore, posterior to the cut plan and medial (lateral) to the cut plan, burring should be done with care.

**Using the Bone Removal Screens**

**WARNINGS!**

- Operate the Anspach® surgical drill with adequate irrigation. Failure to do so may result in damage to the bone surface, bone necrosis, or damage to the surgical bur or drill motor.

- The NAVIO® Surgical System does not prohibit cutting of soft tissue, which may be in the surgical area. Always use retractors to protect ligaments and other capsular structures. Use steady movement to minimize potential for ligament damage.

- The cutting control modes do not limit cutting beyond the protected-bone surfaces. Therefore, posterior to the cut plan and medial (lateral) to the cut plan, burring should be done with care.

- Move the bur slowly during bone removal and avoid touching anything other than the target bone.

- The system does not prevent overcuts of the tibia when preparing the femur and vice-versa.

- Always use the bur control/selection screen when changing burs.

- The system will not stop cutting once the target surface is reached if control modes are disabled.

- Ensure that you are following the workflow for femur and tibia bone preparation specifically. Using the cut reference blocks in the incorrect order, or not using the stabilizer block while making the distal femur cut, may result in improper implant placement or ligament stress.

Figure 40 shows a typical Bone Removal screen. Screen features are defined in Table 7. Left and right side screen panel widgets are defined in Tables 8 and 9.
<table>
<thead>
<tr>
<th>Screen Feature</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td>The Tool's Eye View section displays “what the tool sees,” similar to a scope view, and it is continuously active.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Image" /></td>
<td>This icon indicates that the drill control mode is set to Exposure. Click on the button to open the Bur and Control Selection screen to change the control mode (Speed, Exposure, or OFF). Press OK to return to the Bone Removal Femur/Tibia screen.</td>
</tr>
<tr>
<td><img src="image3.png" alt="Image" /></td>
<td>This icon indicates that the drill control mode is set to Speed. When the button is red, the bur is not rotating; when the button is green, the bur is rotating. Click on the button to open the Bur and Control Selection screen to change the control mode (Speed, Exposure, or OFF). Press OK to return to the Bone Removal -Femur/Tibia screen.</td>
</tr>
<tr>
<td><img src="image4.png" alt="Image" /></td>
<td>This icon indicates that the drill control mode is set to OFF. Click on the button to open the Bur and Control Selection screen to change the control mode (Speed, Exposure, or OFF). Press OK to return to the Bone Removal -Femur/Tibia screen.</td>
</tr>
<tr>
<td><img src="image5.png" alt="Image" /></td>
<td>Tracker Array Status show tracker array visibility to the camera (green) or obstructed (black). Check this status indicator if the system is not cutting, as it will prevent bone cutting when an array important to the action is obstructed from view. To confirm tracker array visibility within the camera's field of view, press this icon to present a Field of View screen.</td>
</tr>
<tr>
<td><img src="image6.png" alt="Image" /></td>
<td>Press this button to rotate the bone model manually. Drag the bone model to control the rotation.</td>
</tr>
<tr>
<td><img src="image7.png" alt="Image" /></td>
<td>Press this button control the magnification of the bone model manually. Drag the bone model to control the degree of magnification.</td>
</tr>
<tr>
<td><img src="image8.png" alt="Image" /></td>
<td>Press this button to move the bone model manually. Drag the bone model to move it up, down, left, or right.</td>
</tr>
<tr>
<td><img src="image9.png" alt="Image" /></td>
<td>Press this button to restore the view to the position initially displayed. However, if you reposition the bone model and then leave the screen, the system will mark the current position of the bone model as the new restore point.</td>
</tr>
</tbody>
</table>

The Cutting Mode (Bur Cut Guide, Visualize Cut, Refine, Bur All, or Femur/Tibia) selected highlights the current mode that you are using, and can be used to navigate to other modes.

Pressing Go Back returns you to the Checkpoint Verification stage.

Pressing Bur Cut Guide displays a loaded model generated from the selected cut guide block post model and the bone mesh.

Pressing Visualize Cut displays the bone model with the bone to be removed by the planned saw cuts also removed from the model.

Pressing Refine displays the Bone Refining stage; a model generated from the selected implant block model and the bone mesh (which should support removal of all bone to fit the trial).

Pressing Bur All enters the bur all mode, which starts the tool and allows you to perform controlled cutting using the bur all workpiece, which is generated during the refine step.

Pressing the Tibia button transitions to the Tibia Bone Removal state.

**Table 7. Bone Removal screens – features defined**
### Bone Removal Widgets

**Left Side Screen Panel**

<table>
<thead>
<tr>
<th>To:</th>
<th>• Press</th>
</tr>
</thead>
<tbody>
<tr>
<td>verify checkpoints,</td>
<td><img src="image1.png" alt="icon" /></td>
</tr>
<tr>
<td>update the system about a change you made to the selected bur size,</td>
<td><img src="image2.png" alt="icon" /></td>
</tr>
<tr>
<td>to return to the Gap Planning stage, where you can adjust the</td>
<td><img src="image3.png" alt="icon" /></td>
</tr>
<tr>
<td>implant placement plan,</td>
<td><img src="image4.png" alt="icon" /></td>
</tr>
<tr>
<td>remove the magenta layer of the bone mode, (TKA)</td>
<td><img src="image5.png" alt="icon" /></td>
</tr>
</tbody>
</table>

*Table 8. Bone Removal Widgets – left side screen panel*

**Right Side Screen Panel**

<table>
<thead>
<tr>
<th>To:</th>
<th>• Press</th>
</tr>
</thead>
<tbody>
<tr>
<td>toggle between bird’s-eye view (default view) and tool’s eye view,</td>
<td><img src="image6.png" alt="icon" /></td>
</tr>
<tr>
<td>show or hide the crosshair view,</td>
<td><img src="image7.png" alt="icon" /></td>
</tr>
<tr>
<td>activate and view a virtual cut guide,</td>
<td><img src="image8.png" alt="icon" /></td>
</tr>
<tr>
<td>activate and view a virtual implant,</td>
<td><img src="image9.png" alt="icon" /></td>
</tr>
<tr>
<td><em>This is useful to confirm progress to the cut plan, and to check for overhang of implant on bone.</em></td>
<td><img src="image10.png" alt="icon" /></td>
</tr>
<tr>
<td>take a screenshot,</td>
<td><img src="image11.png" alt="icon" /></td>
</tr>
</tbody>
</table>

*Table 9. Bone Removal Widgets – right side screen panel*
Performing Bone Model Refinement

*Refine Mode* is accessible in all applications, where the bur tip or the guard of the handpiece (in exposure mode) can be used to update the virtual bone model, to depict the current state of the bone surface (Figure 41).

**NOTE:** Only the visual model is being updated in *Refine Mode*. This stage cleans up the visualization of the model to ensure that any bone that was modeled beyond the patient's articulating bone surface is erased, so that it does not obstruct your view.

Preparing for Bulk Bone Removal

**NOTE:** A self-retaining retractor, like the Gelpie retractor (Figure 42), has proven useful at keeping the incision open and bone exposed during cutting. This allows your assistant to focus on other retractions or tasks.

For easily accessible areas unrestricted by boney anatomy, (i.e., UKR, distal burring, and bur all techniques for TKA and bi-cruciate knee replacement) utilizing exposure control mode with the bur working perpendicular to the cutting surface is recommended. For regions that have limited access such as posterior femur and tibia, utilization of speed control mode is a more efficient preparation method.

Instructions

1. It is recommended to complete all burring for cut guide placement of the femur and tibia prior to completing any bulk bone removal with the saw.

   This reduces the probability of tracker movement affecting system accuracy when completing saw cuts.

To remove bulk bone,

2. A slow, methodic "plunge and drag motion" through to the cortical layer, will remove bone with the greatest efficiency.

   The bur will stay protruded only until it has reached the target surface and the bur exposure will be actively adjusted so that cutting beyond the target surface is minimized.

3. Widen the cut, moving at a deliberate pace. Trace around the outer edge of the implant cut plan.

4. Make left-right or up-down passes to remove the remaining middle bone.

   Avoid quick passes, or "feathering", the tool over the surface. Methodical motion will remove bone with the greatest efficiency.

5. Move from the anterior down to the distal part of the condyle. Continue to cut down to the posterior until you cannot access any more femur area. Increase flexion to maximize access while moving down the condyle.

6. When burring bone near and around the collateral capsular structure (medial collateral ligament, MCL, or lateral collateral ligament, LCL) ensure that a retractor is used to prevent the bur from cutting the ligament (Figure 41).
Preparing Bone in UKR & PFA

The NAVIO™ Surgical System provides guidance for bulk bone removal and fixation preparation based on the planned implant position. The table below indicates the compatible bur sizes, use and control mode for each supported partial knee (UKR, PFA) implant.

<table>
<thead>
<tr>
<th>UKA</th>
<th>Implant</th>
<th>Bur</th>
<th>Control Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>JOURNEY UNI</td>
<td>6mm Spherical Bur</td>
<td>Exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5mm Spherical Bur (post hole - femur)</td>
<td>Speed</td>
</tr>
<tr>
<td></td>
<td>STRIDE</td>
<td>6mm Spherical Bur</td>
<td>Exposure</td>
</tr>
<tr>
<td></td>
<td>ZUK</td>
<td>6mm Spherical Bur</td>
<td>Exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6mm Spherical Bur (post hole)</td>
<td>Speed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2mm Spherical Bur (keel)</td>
<td>No Control Mode / Manual</td>
</tr>
<tr>
<td></td>
<td>JOURNEY II UK</td>
<td>5mm Cylindrical Bur</td>
<td>Exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5mm Cylindrical Bur (post hole)</td>
<td>Speed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2mm Spherical Bur (keel)</td>
<td>No Control Mode / Manual</td>
</tr>
<tr>
<td>PFA</td>
<td>JOURNEY PFJ</td>
<td>6mm Spherical Bur</td>
<td>Speed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3mm Spherical Bur (post hole)</td>
<td>Speed</td>
</tr>
</tbody>
</table>

1 For the JOURNEY UNI Tibia, fixation features (pegs & keel) are to be prepared with manual instrumentation. Reference the applicable implant surgical technique for guidance.

Table 10: Compatible bur sizes and control modes by implant

UKR

Based on the geometry of the components, a rasp may be needed to make fine adjustments to preparations completed with the NAVIO handpiece. If applicable for the UKA tibial component, utilize the included rasp (or similar) to square the tibial corner between the vertical and horizontal cuts along the spine. Once squared-off, the tibial component will seat properly on the finished cuts.

NOTE: If manual instrumentation (e.g. saws, rasps) is used for bone preparation at any time, make sure to switch to the refine mode, and update the affected bone model.

For trialing and implant fixation, refer to the implant specific technique guide.

PFA

When planning and executing the cuts for a JOURNEY PFJ procedure, keep in mind the geometry and fit of the implant design.

NOTE: The PFA trochlear groove has a tight radius, which provides for smooth transition zones between the implant and the femoral condyles. Therefore, some minimal green color may remain near the troclear groove when preparing the bone using speed control mode.
Preparing the Bone in TKA

The handpiece is used to prepare fixation features on the surface of the patient bone that lock the cut guides in place, in accordance with the implant placement plan, for final bone preparation using recommended saws.

Fine cuts may be made after bulk bone removal using the handpiece.

**NOTE:** For TKA systems, the recommended saw blade thickness is 1.35mm.

Preparing the Femur

**Instructions**

<table>
<thead>
<tr>
<th>Use the handpiece either to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prepare the cylindrical fixation features of the NAVIO femur cut guide in the bone, or</td>
</tr>
<tr>
<td>2. Bur the distal surface of the femur.</td>
</tr>
</tbody>
</table>

Using the NAVIO TKA Femur Cut Guide

Confirm the location of the fixation features of the cut guide in the Cut Guide Placement stage.

**NOTE:** All Navio TKA cut guides are designed to be secured with 1/8” diameter S&N Speed Pins.

**WARNING!**

Before placing any TKA cut guides, clear burred surfaces of any residual debris using irrigation, suction and/or hand tools.

**Instructions**

1. Once the locking features are prepared, clear the surface of any residual debris using irrigation, suction, and hand tools.

To remove bulk bone,

2. Place the femur distal cut guide on the anterior features that have been prepared on the bone and lock its position using the femur stabilizer.

The femur stabilizer fits into the distal features prepared on the bone.

**NOTE:** The cut guide attaches to the bone using a press fit

3. On assembly, tighten the thumb screw on the femur stabilizer, to ensure that the stabilizer is flush with the distal cut guide when assembled. Tap on the cut guide assembly to ensure that the distal cut guide is secured in place.

4. Using Visualize Cut mode, ensure that the cut guide is appropriately located on the bone, per the user plan. Secure the distal cut guide on the bone surface using ⅛” diameter non-rimmed speed pins provided in the Smith & Nephew implant system trays. Stabilize the distal cut guide by placing one or more pins in the oblique pin holes provided.

5. Detach the femur stabilizer from the distal cut guide. Based on the implant size plan, assemble the applicable femur drill guide, with the femur cut adapter.

6. Attach this assembly to the distal cut guide, and drill through the appropriate holes in the guide, based on the femur implant sizing plan.

7. Remove the femur cut adapter and the distal cut guide.

8. In the drilled holes, insert the applicable AP cutting block, as per the implant family and size planned, and pin it in position, as described in the applicable Smith & Nephew TKA System Surgical Technique.

---

For the JOURNEY II implant only:

For the JOURNEY™ II implants only, ensure that the dial on the block is set to the zero mark, and tighten the dial using the Smith & Nephew JOURNEY 3.5 mm hex driver. See placing the AP Cut Guide, below.

---

Distal Burring

Use the Distal Femur Punch with the Quick Connect Handle.

A 5mm cylindrical bur is recommended to prepare:

- The distal femoral cut on the patient’s bone, and
- Two pilot holes to guide the placement of the AP cut guide.

**WARNINGS!**

- Align the placement features of the TKA distal punch tool with the burred holes.
- Take care to keep hands clear of the pinch points on the distal femur punch.

An implant specific distal femur punch may then be used to aid in preparing the femur for placement of the AP cut block.
There are two available implant-specific configurations for the distal punch: the 45mm for LEGION, GENESIS® II, and ANTHEM™ and the 38mm punch for JOURNEY® II.

- Secure the punch in the pilot holes prepared with the 5mm bur.
- Press down to punch the pins into the bone.

**NOTE:** If required, use the slap-hammer to remove the punch from the femur.

- Alternatively, a 2mm bur can be used under Speed Control to prepare the final holes for AP cut guide fixation.

### For the JOURNEY II implant only:

For the JOURNEY® II implants only, ensure that the dial on the block is set to the zero mark, and tighten the dial using the Smith & Nephew JOURNEY 3.5 mm hex driver. See placing the AP Cut Guide, below.

### Completing Preparations

Use the recommended saw blades to complete the anterior, posterior, and chamfer cuts.

After bulk bone removal, you can use the handpiece to make fine cuts.

### Preparing the Tibia

Use the handpiece and bur to prepare the fixation features of the tibia cut guides.

**NOTE:** Ensure the physician's assistant has various ligament protecting retractors readily available for use. The cut guide attaches to the bone using a press fit.

### Instructions

1. Place the tibia cut guide on the prepared bone features (Figure 42).

   Using **Visualize Cut** mode,

2. Ensure that the cut guide is placed according to the plan. Secure the cut guide on the bone surface using 1/8” diameter non-rimmed speed pins provided in the Smith & Nephew implant system trays.

3. Using the recommended saw blade, perform the tibia cut through the cut guide

### For the JOURNEY II XR implant only:

The *Initial Cut* stage does not apply to XR.

It is recommended to use speed control mode for burring the tibia.

1. Use a tunneling technique, starting from the anterior and working to the posterior.

2. "Undermine" cartilage close to the eminence ridge to avoid having the bur skip on the bone and inadvertently hitting the ACL.

   **NOTE:** Do not prepare the tibia implant component fixation features (keel) with the bur on the NAVIO handpiece; they must be prepared with manual instrumentation.

3. When burring the tibia, prepare the medial and lateral plateaus, while preserving the anterior bridge.

   With the anterior bridge in tact,

Figure 43 depicts the workflow for tibia bone preparation. At any point during the preparation, you can use the Back to Planning button to return to the Planning screens, in order to adjust the implant placement plan.

**Visualizing the Cut**

The *Visualize Cut* screen displays the bone model with the bone already removed from the planned saw cuts. The screen also displays a semi-transparent model of the plane visualization tool. This enables you to visualize how the actual cut will compare to the planned cut.

The plane visualization tool attaches to the handpiece, similar to the speed control guard; you can use this tool to visualize all the cut planes at any stage during bone removal.

Use this tool to ensure that the cut guide is placed in its intended position by passing the plane tool through the cut slot (Figure 44). This can be used to compare the plane of cut, with the plan created for bone removal. This helps ensure that the rotation of the component and depth of the cuts are consistent with the plan. This tool also can be used after bone removal to visualize the actual cut prepared.

The cut can be visualized in all three anatomic planes. Counterclockwise from the upper right, these views are the sagittal, coronal, and transverse. The lower right view display an arbitrary view that can be manipulated to change its orientation.

These views are activated by placing the plane visualization tool close to the cut plane you wish to view. A solid line appears which represents the cross-section of the plane visualization tool relative to the bone. A dotted line will appear for either the distal cut plane, anterior cut plane, or the proximal cut plane in case of the tibia.

The angle between these lines is calculated as an angle error, depicted in tenths of degrees. The distance calculated between the planned surface and plane visualization tool is represented as distance error, shown in tenths of millimeters. When you are evaluating the distal cut or the anterior cut, both the angle error and the distance error are displayed.

**Figure 43.** Workflow for tibia bone preparation. (Left images show the tibia cut guide; Right images show the twin peg tibia cut guide).

**Figure 44.** Visualize cut after bone removal.
Performing Trial Reduction & Postoperative Assessments

Confirming Sizing

Instructions

1. After completing all of the bone cuts and adjustments to the final surfaces, thoroughly clean and dry the cur bone surface.

2. Once bone surface preparation is complete, perform a trial reduction with the appropriate size femoral and tibial trial components, as described in the applicable Total Knee System Surgical Technique.

   If the joint is too tight, reduce the size of the bearing component to a thinner component, or resect more tibial bone.

**For the JOURNEY II XR implant only:**

Always trial with the anterior bridge in place to avoid tibia eminence fracture. Switch to a CR implant for the JOURNEY™ II XR implant, if the ACL is compromised.

Trialing a PFA Implant

It is necessary to trial a patellofemoral implant prior to finalizing the procedure.

Instructions

1. Re-cut and re-plan for an undercut.

   Alternately, if you are not satisfied with the implant to bone transition, for looseness:

   2. Apply bone cement to correct for an overcut.

Performing Dynamic Postop Assessments

The *Collect Postop Baseline* screen (Figure 45) records normal flexion motion, post-operatively.

Instructions

1. Press and hold the right footpedal.

2. Slowly move the leg through a normal (unstressed) range of motion to maximum flexion.

   Collect as many green bar sectors as possible. Not all sectors need to be collected, however, you will need to collect at least one in flexion (greater than 50°) and one in extension (less than 50°).

   **NOTE:** If you choose to change the thickness of the poly during trialing, remember to return to Postop Baseline Collection and re-collect this data set. For TKA, the patient’s Achieved Alignment is calculated in this state. NAVIO records the varus/valgus alignment of the joint at the collection closest to 0°.
Assessing Postoperative Gaps

The Postop Gap Assessment screen (Figures 46-47) allow you to assess the post-op achieved gaps in the medial (orange) and lateral (purple) compartments.

Apply constant varus and/or valgus stress to the collateral ligaments and collect the data throughout flexion. The orange graph displays the medial compartment and the purple graph displays the lateral compartment. The current line plot on the graphs display the planned stressed ROM from the Gap Assessment stage.

As you collect the data, the graph will update with the 'live' gaps in the medial and lateral compartments. You can collect these points either continuously or discretely.

Assessing Postop Gap for a TKA Procedure

If you have collected a stressed range of motion and complete the Gap Assessment stage, a feature to assess postoperative gaps, as compared to the planned gaps, becomes active.

To evaluate the achieved gaps as compared to the planned gaps, planned gaps may be toggled 'on'

• Press the Show/Hide Planned Gaps Widget.

Figure 46. UKR Postop Stressed Gap Assessment screen

Figure 47. TKA Postop Stressed Gap Assessment screen
Reviewing the NAVIO TKA Case

Upon completion of a TKA case, the NAVIO™ Surgical System provides you the opportunity to confirm and/or update information relating to the implant components placed during the procedure (Figure 49). This screen also may be displayed at any time by pressing the info button ( ). The case may be reviewed, and the implant design and femur/tibia size and thickness may be modified.

**Figure 49. NAVIO Case Review screen**

**Instructions**

To change the implant design,
1. Press the field next to Implant Design.
   - A list of available implants is displayed in a pop-up screen.
2. Press to select the name of the implant.
   - The pop-up screen closes and the Implant Design name is changed to the newly selected one.

To change the size of the femur/tibia,
3. Press the left arrow to make smaller, or press the right arrow to enlarge.

To change the thickness of the implant,
4. Press the left arrow to make smaller, or press the right arrow to enlarge.

To close the Case Review screen,
- Press the info button ( ).
Cementing and Closing

WARNINGS!
• Always inspect for fragments and thoroughly irrigate the surgical site prior to placing final implants and closing the incision.
• Prior to closing the patient’s incision, be sure to remove both the femoral and tibial bone checkpoint pins.
• When removing checkpoints pull in a perpendicular manner away from the bone. Do not pry or bend the checkpoint when removing.

Instructions:
• Finish the implantation of the final components, as recommended in the applicable implant *Surgical Technique*, using appropriate instruments and tools.
Recovery Procedure Guidelines

If a NAVIO™ Surgical System failure occurs at any point during the surgical case, the following table provides guidelines for recovering to a fully manual procedure.

A failure can consist of, but is not limited to, a system software crash, unrecoverable hardware failure, handpiece failure with no backup available, tracker array failure or loss of contact with bone that is unrecoverable, etc.

You should consult and be familiar with the applicable Surgical Technique document that accompanied the purchase of the implant.

**WARNINGS!**
- Remove the checkpoint pins when converting from a NAVIO procedure to a manual case.
- A full conventional surgical instrumentation tray for the chosen implant should be available during every system use to implant manually the prosthesis in the event of system failure.

<table>
<thead>
<tr>
<th>Point of Failure</th>
<th>Recovery Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Planning</strong></td>
<td></td>
</tr>
<tr>
<td>Bone landmark, surface and kinematic data collection</td>
<td>The knee is unaffected by the procedure. Remove the tracker arrays, the bone pins and the checkpoint pins and proceed with conventional instrumentation. Use conventional procedure as described in the applicable implant surgical technique.</td>
</tr>
<tr>
<td>Planning</td>
<td>Remove the tracker arrays, the bone pins and the checkpoint pins and proceed with conventional instrumentation. Use conventional procedure as described in the applicable implant Surgical Technique.</td>
</tr>
<tr>
<td>Refining</td>
<td>The knee is unaffected by the procedure. Remove the tracker arrays, the bone pins and the checkpoint pins and proceed with conventional instrumentation. Use conventional procedure as described in the applicable implant surgical technique.</td>
</tr>
<tr>
<td><strong>Bone Removal</strong></td>
<td></td>
</tr>
<tr>
<td>Femur cut</td>
<td>Remove the trackers and the bone pins from bones and proceed with conventional instrumentation, as described in the applicable implant surgical technique.</td>
</tr>
<tr>
<td>Tibia cut</td>
<td></td>
</tr>
<tr>
<td>Posts and keels</td>
<td></td>
</tr>
<tr>
<td><strong>Trial Implant ROM Evaluation</strong></td>
<td></td>
</tr>
<tr>
<td>ROM Evaluation</td>
<td>Follow the instruction in the Trial Reduction section of the applicable implant surgical technique</td>
</tr>
<tr>
<td>Refinement</td>
<td>Follow the instruction in the Trial Reduction section of the applicable implant surgical technique. If adjustments are necessary, use the tibial cutting guide to recut the tibia and increase joint space, or increase the thickness of the tibial component to reduce joint space.</td>
</tr>
</tbody>
</table>

Table 11. Recovery actions