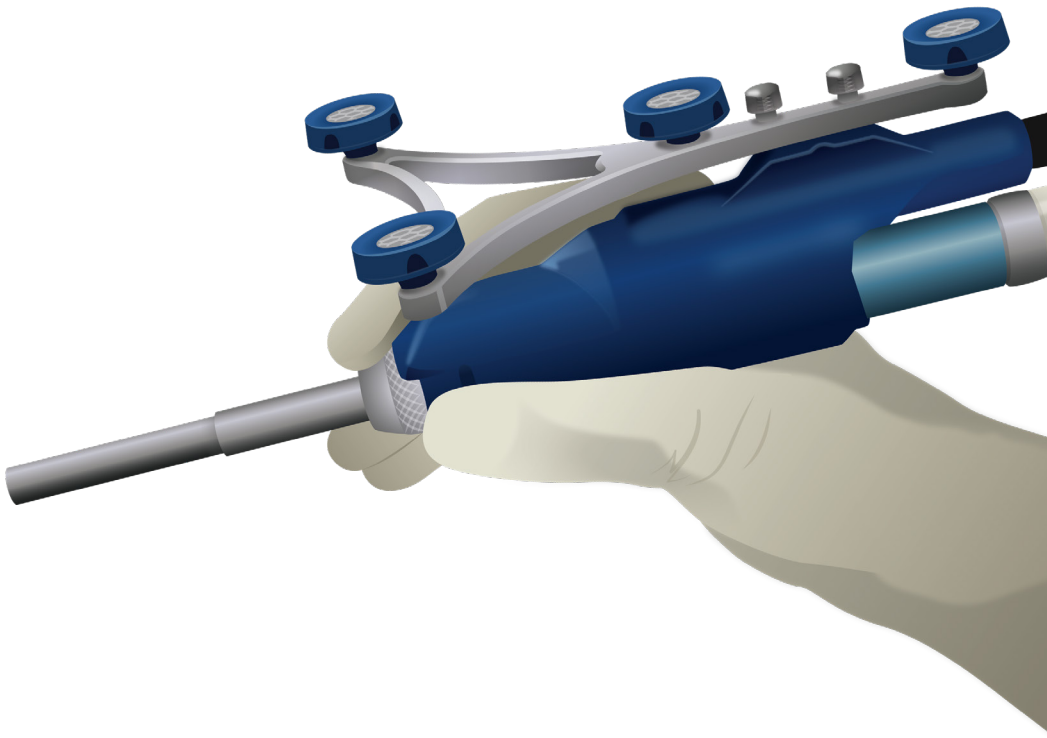
smith&nephew

NAVIO®

Surgical System

NAVIO Surgical System Surgical Technique for Total Knee Arthroplasty



Contents

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.

Introduction

This guide provides an overview of the recommended surgical technique for using the NAVIO® Surgical System with the Smith & Nephew Total Knee Systems including the:

- JOURNEY® II BCS (Bi-Cruciate Stabilized)
- JOURNEY II CR (Cruciate Retaining)
- JOURNEY II XR (Bi-Cruciate Retaining)
- LEGION® CR
- LEGION PS (Posterior Stabilized)
- GENESIS® II CR
- GENESIS II PS

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

This guide should be used in conjunction with, not replacing, the information contained within the *User's Manual* that accompanied the purchase of the NAVIO Surgical System, and the *Surgical Technique* document that accompanied the purchase of the applicable implant.

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

WARNING The NAVIO® Surgical System is a surgical tool designed to provide assistance to 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.

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.

Figure 1. JOURNEY II Total Knee Implant System.

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 patents, or any other patients contraindicated for unicondylar knee replacement, patellofemoral arthroplasty, or total knee arthroplasty.

Consult the applicable Total Knee System labeling for its full intended use, indications and contraindications.

WARNING: Please reference the implant manufacturer's *instructions for use* and recommendations for the compatibility of implant system combinations.

Overview

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 2).

The NAVIO Surgical System's TKA application uses data gathered during the beginning of the surgical procedure (planning phase) to generate a computer model of the knee surface to guide the surgeon in placing the cut guides. Once the cut guides are placed, manual instrumentation is used to perform the saw cuts to prepare the bone surface for the selected knee implant. Additional fine cuts can be made, as needed, using the surgical bur.

Figure 2. Computer cart nested with camera cart (left); Handpiece (right).

The NAVIO® Surgical System's TKA application can be broken up into the following stages:

1. Patient and System Setup
2. Surgical Preferences
3. Bone Tracking Hardware
4. Registration
5. Implant Planning
6. Bone Cutting
7. Trial Reduction
8. Cement and Close

This *surgical technique* guide is separated into the same stages for clarity.

NAVIO Instrument Kit

The NAVIO instrument kit (Figure 3) consists of a two-level tray that contains the required instrumentation for surgery using the NAVIO Surgical System.

NAVIO Total Knee Instrument Kit

The NAVIO total knee instrument kit (Figure 4) is a single-level tray that contains the required instrumentation for TKA using the NAVIO Surgical System.

NOTE: If the equipment breaks or fails during surgery, sterile backup kits are on-site and can be unwrapped to replace a broken or dropped instrument.

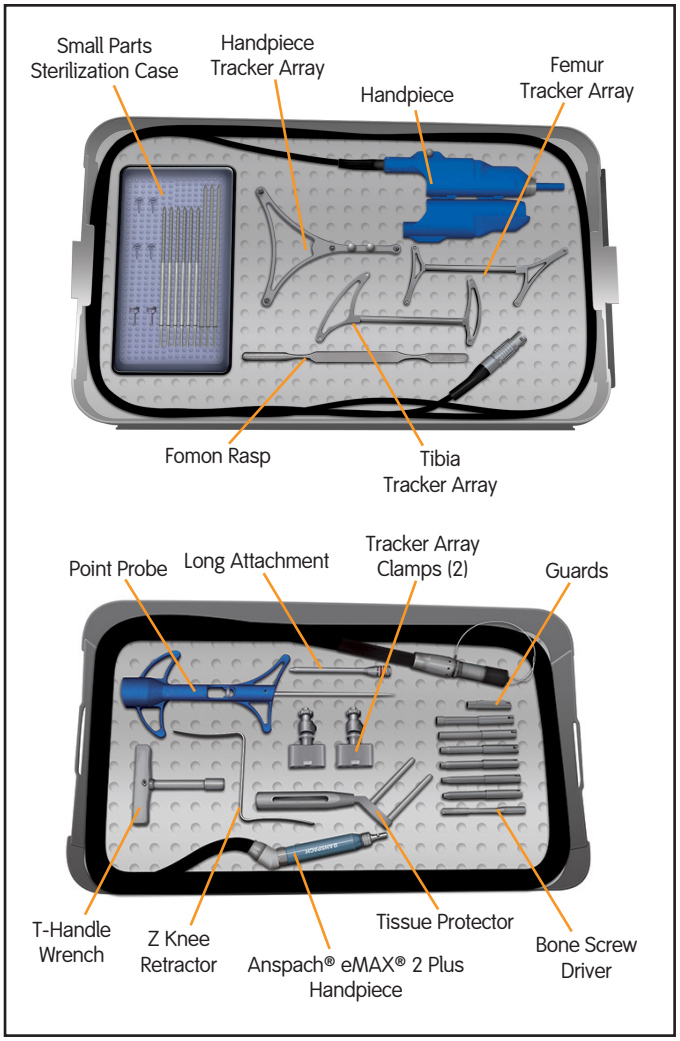


Figure 3. Instrument kit.

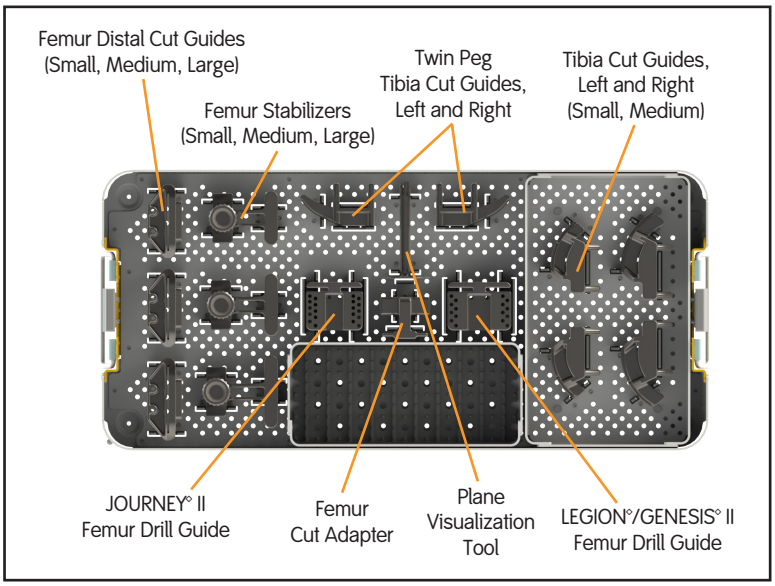


Figure 4. Total knee instrument kit.

Patient and System Setup

Patient Setup

- Avoid wrapping the ankle with bulky drapes or coverings. Using bulky material in this area may make it difficult to locate the malleoli points during patient registration.
- Use a leg positioner, like the IMP® De Mayo Knee Positioner®, to elevate the femur to approximately 45° and flex the knee to approximately 90° (Figure 5).
- If possible, remove the pad on the operative leg side to allow the positioner to sit below hip-level. This will help to provide natural kinematics during positioning and flexion.

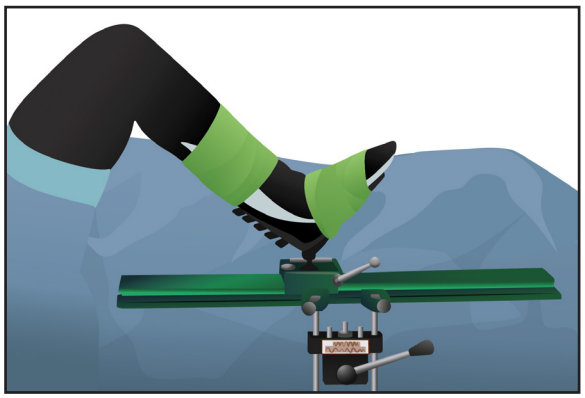


Figure 5. Initial leg setup.

System Draping and Positioning (Figure 6, 7)

- Apply the sterile drape to the monitor by following the included *Monitor Drape Instructions for Use*. An additional drape may be used to cover the computer cart below the monitor drape.
- Position the computer cart so that the surgeon can clearly see and easily operate the graphical user interface at all times. The computer cart should be positioned on the opposite side of the leg to be operated. Rotate the monitor to cantilever over the patient, aimed diagonally at the surgeon's line of sight.
- The camera cart should also be placed on the opposite side of the leg to be operated, with the camera approximately 1.5 m from the surgical site and 1.6 to 1.9 m high.
- Use the laser pointer integrated into the faceplate of the camera head to direct the laser beam at the knee joint to be operated.
- Except during determination of the hip center, the camera cart positioning may be adjusted at any point during the operation to meet the needs of the surgeon.
- Guidance for optimal camera positioning is provided in the ***Camera Orientation Adjustment*** stage of the NAVIO® Surgical System's TKA application.

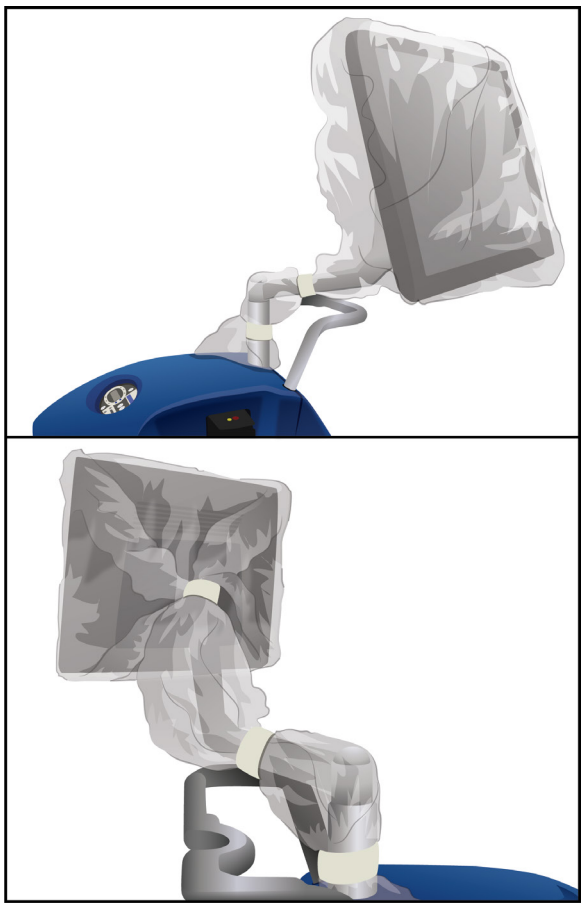


Figure 6. Monitor drape application.

System and Tool Preparation

Assemble the NAVIO® handpiece according to the operating surgeon's preference. Refer to the *NAVIO Surgical System User's Manual* for additional information. The configuration found to be most conducive to bone removal in this procedure consists of the following:

- 5 mm Spherical Bur
- 5 mm Cylindrical Bur
- Speed Control Guard
- 5 mm Exposure Control Guard

The integrated irrigation system will administer continuous irrigation throughout bone removal.

Exposure

- The NAVIO® Surgical System is compatible with the typical exposure recommendations for total knee arthroplasty.
- For exposure recommendations specified by the implant system manufacturer, please consult their *instructions for use* and product documentation.
- Upon making the incision, carefully debride and inspect the joint. If any prominent spurs or osteophytes are present, especially in the area of the superior posterior femoral condyle, remove them with an osteotome or rongeur, as they could inhibit the leg motion.
- With medial compartment disease, osteophytes are typically found on the lateral aspect of the medial tibial eminence and anterior to the origin of the anterior cruciate ligament (ACL).
- Remove intracondylar osteophytes to avoid impingement with the tibial spine or cruciate ligament, as well as peripheral osteophytes that interfere with the collateral ligaments and capsule. In order to reliably assess joint stability, it is crucial that all osteophytes are removed from the entire medial edge of both the femur and tibia.
- Resect the deep meniscotibial layer of the medial capsule to provide access to any tibial osteophytes. Exposure can also be improved with excision of patellar osteophytes.
- With the patient in the supine position, ensure the knee is able to achieve 120° of flexion. A larger incision may be necessary to create sufficient exposure.
- For a cruciate retaining (CR) or a posterior stabilized (PS) knee surgery, resect the ACL before proceeding with patient registration using the NAVIO Surgical System.
- Final debridement will be performed before component implantation.

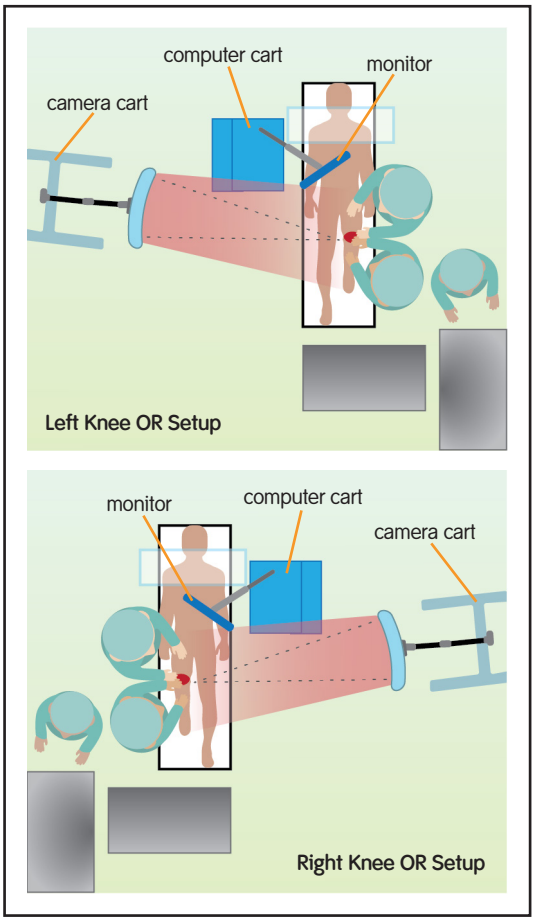


Figure 7. Typical operating room (OR) setups.

Surgical Preferences

Rotational References (Figure 8)

For the femur, the following options are available to define the reference for computing the rotation of the component on the femur (Figure 9):

- Transepicondylar Axis
- Femoral AP (anterior-posterior) Axis
- Posterior Condylar Axis

If **Posterior Condylar Axis** is selected, the ***Adjust Posterior Condylar Axis*** screen will open (Figure 10), enabling you to specify a rotation angle between 0° and +10° for the condylar axis in 0.5° increments.

For the tibia, the following options are available to define the reference for computing the rotation of the component on the tibia (Figure 11):

- Tibia AP Axis
- Transfer Femoral Mechanical Axis
- Medial Third of the Tibia Tubercle

Based on the chosen preference for rotational reference, the collection stage is presented during registration of the patient anatomy. Further details on the above choices are highlighted in the ***Registration*** stage, after femur and tibia landmark collections, respectively.

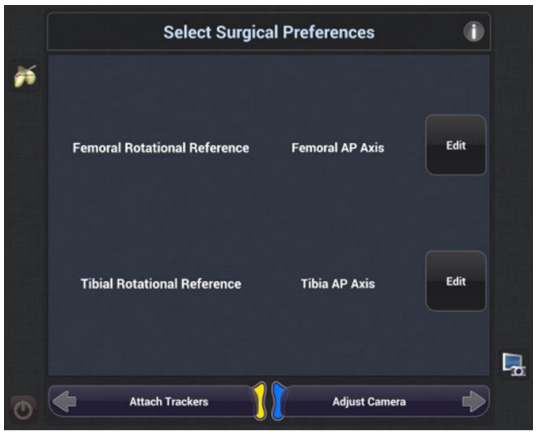


Figure 8. Surgical Preferences.

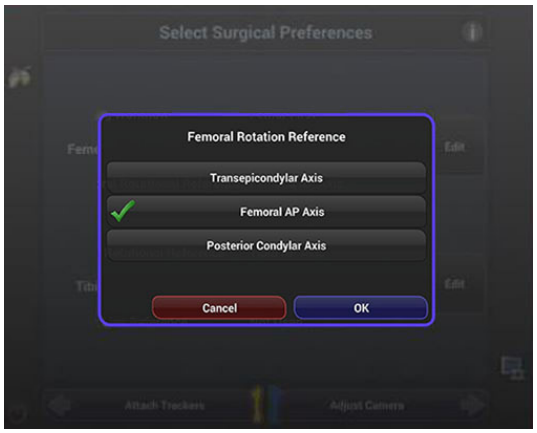


Figure 9. Femoral Rotation Reference.

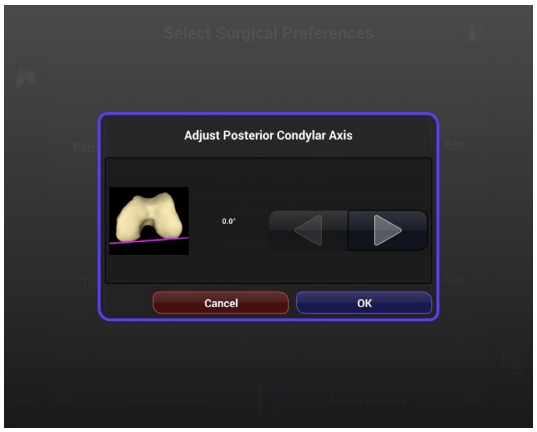


Figure 10. Adjust Posterior Condylar Axis.

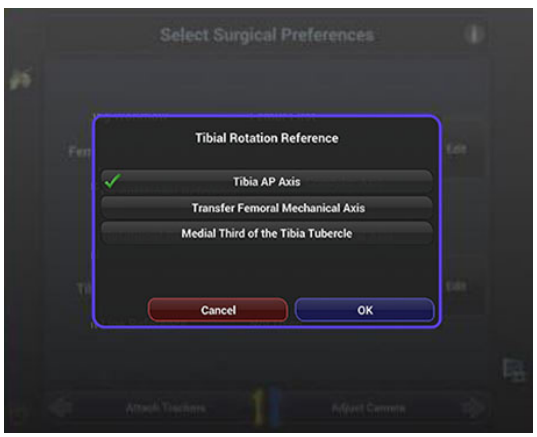


Figure 11. Tibial Rotation Reference.

Bone Tracking Hardware

Placing Tracking Hardware

The NAVIO® Surgical System utilizes a two-pin bicortical fixation system, comprised of the tools pictured in Figure 12. These tools allow for the tracking arrays (Figure 13) to be fixed to the bone and for the tracking markers to be oriented towards the optical tracking camera. With the operative leg in 90° of flexion, utilize the following procedure.

Tibia Tracker Array Placement

1. Percutaneously place the first bone pin one hand's breadth (four fingers) inferior to the tibial tubercle on the medial side of the tibial crest (Figure 14).

   WARNING: Be sure to place the proximal bone pin as directed. If placed too close to the tibial plateau, it may interfere with placement of the tibial implant component, causing damage to the bone pin and possible patient harm.

2. Slowly drill the bone pin into the tibia, perpendicular to the bony surface, taking care to engage the opposing cortex and stop.
3. Utilize the tissue protector to mark the position of the second bone pin inferior to the initial placement. Engage the second pin with the bone through the tissue protector to ensure the pins are placed parallel to each other.
4. 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. Take care not to place the clamp touching the skin.
5. Clamp the tracker array into the tracker array clamp along the length of the bar on the array. Place the smaller side of the tracker array closest to the operative site. Orient the markers towards the camera and slide the array away from the incision site.
6. Use the T-handle wrench to tighten the screw on the top of the tracker array clamp to secure the assembly. Be sure to confirm the array visibility on the ***Camera Orientation Adjustment*** screen before tightening the assembly.

Figure 12. Hardware (from left: bone pins, tissue protector, tracker array clamp).

Figure 13. Bone tracking arrays: Femur (top) and tibia (bottom). Keep the smaller end of the array toward the operative site.

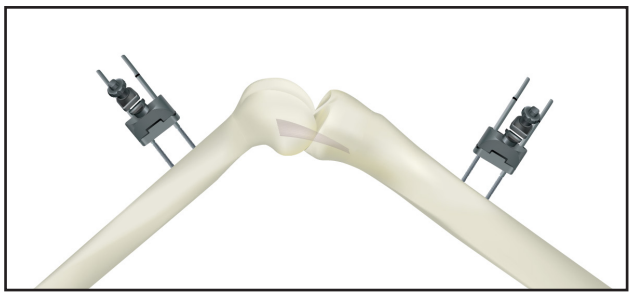


Figure 14. Femur and tibia tracking array positions.

Femur Tracker Array Placement

1. Percutaneously place the first bone pin one hand's breadth (four fingers) superior to the patella in the center of the femur (Figure 14), leaving room for the handpiece tracker to be fully visible to the camera during preparation of the femur.
2. Slowly drill the bone pin into the femur, perpendicular to the bony surface, taking care to engage the opposing cortex and stop.
3. Refer to steps 3 through 6 of the *Tibia Tracker Array Placement* section in this guide.

Confirm Array Visibility

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

- Advance to the ***Camera Orientation Adjustment*** screen (Figure 15) in the surgical system's onscreen workflow and confirm visibility of the Femur ***(F)*** and Tibia ***(T)*** tracker arrays in the following three positions:

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

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.

Figure 15. Tracker array visibility.

Checkpoint Verification Pins

- Checkpoint verification pins should be placed in both the femur and the tibia (Figure 16), 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.

WARNING: Ensure that the checkpoint verification pins are placed away from the bone to be removed to avoid cutting through or dislocating the checkpoint verification pins.

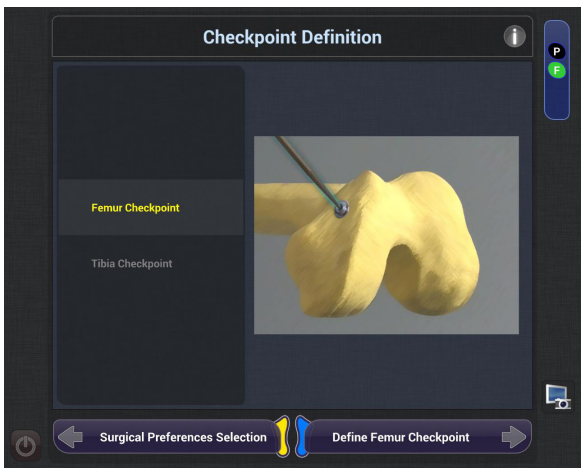


Figure 16. Checkpoint definition.

Registration

CT-free Registration

The NAVIO® Surgical System's CT-free registration process utilizes standard image-free principles to construct a virtual representation of a patient's anatomy and kinematics. Move through the software's workflow via the included footpedal or touchscreen controls. Any collected point may be re-collected in sequence, by moving backwards through the workflow stages.

Ankle Center

- Using the point probe, input the locations of the medial and lateral malleoli points (Figure 17). Ensure that the point probe is visible throughout the point collection. If the probe is not visible, check that the tracking markers on the point probe array are not overlapping (in front, or behind) the tracking markers on the tibia tracker array.

Figure 17. Collect the medial and lateral malleoli points to calculate the ankle center.

Hip Center

The ***Hip Center Calculation*** stage will follow the femoral tracker array, and is collected through circular movements at the hip. These circular movements should be unrestricted and unhindered by holding or fixing equipment. Avoid pelvic movement, which can be a source of error.

- Prior to beginning collection, the femur should start at approximately 20° of hip flexion, in order to provide enough room to rotate the hip.
- Slowly rotate the leg at the hip until all sectors of the graphic have changed to green (Figure 18).

  NOTE: Stay as close as possible to the center when collecting these sectors.
- There should be no transmission of force from the femur onto the pelvis. Avoid a hip flexion angle greater than 45°.

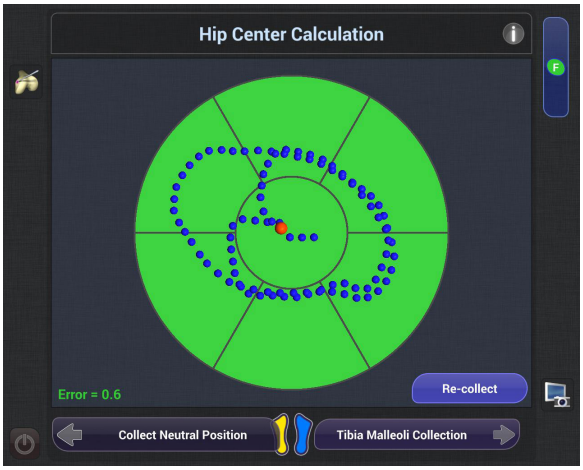


Figure 18. Rotate the leg at the hip to collect hip center.

Femur Neutral Position

- Place the leg in full extension, applying slight axial pressure to both compartments. Support the leg below the knee with one hand to avoid hyper-extension. This position will be utilized when calculating the patient's preoperative varus/valgus deformity. Press and hold the right footpedal to collect the position (Figure 19). When the bar on the bottom reads as fully green (100%), release the footpedal to allow the software to automatically proceed to the next workflow step.

Figure 19. Collect the leg in full extension.

Non-Stressed ROM Collection

- The ***Preoperative Knee Motion Collection*** screen (Figure 20) will record normal flexion motion. Press and hold the right footpedal. 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 all sectors between 20° and 50° of flexion.

Stressed ROM Collection

- Apply constant varus and valgus stress to the collateral ligaments and collect the data throughout flexion (Figure 21). As you collect the data, the sectors will turn orange for the medial compartment, and purple for the lateral compartment. Collect as many 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°).

  This data is collected for use during the ***Implant Planning*** and ***Gap Planning*** stages. You want to identify how much room the ligaments have. This will inform how much gap (laxity) will be built into the joint balance.

Femoral Condyle

There are four femoral landmark points to collect (Figure 22). These points are to be used as visual references during ***Implant Planning***. Be sure to flex the leg as much as possible when collecting these points.

Using the point probe, collect the following:

- **Knee Center**

  Collect the center of the knee, which will be referenced as part of the HKA (hip-knee-ankle) weight-bearing axis. This point collection, along with the hip center collection, defines the femur mechanical axis.

- **Most Posterior Medial Point**

  Collect the point at 90° of flexion on the apex on the condyle.

- **Most Posterior Lateral Point**

  This point is used in conjunction with the anterior notch point and the most posterior medial point for initial sizing of the implant component.

- **Anterior Notch Point**

  This point is used as a reference during implant planning to prevent notching of the anterior cortex.

Figure 20. Collect non-stressed range of motion.

Figure 21. Collect stressed range of motion.

Figure 22. Femur landmark point collection.

Femoral Condyle Rotational References

As defined during the ***Surgical Preference*** stage, there are three options to define the femur rotational reference. These rotational references are used during ***Implant Planning*** for component placement onto the patient anatomy.

- **Transepicondylar Axis Collection**

  Collect the medial and lateral epicondyle points on the femur (Figure 23). This will be used to create the ML (medial-lateral) axis for the femur. The AP axis is then derived from both the femur mechanical axis and the ML axis defined in this stage.

- **Femoral AP Axis Collection**

  While the other collections listed are singular points referencing the tip of the point probe, this collection will reference the axis of the point probe. Collect the AP axis for the femur, normal to the transepicondylar axis, by using the length of the point probe (Figure 24). This collection, along with the femur mechanical axis, will define the ML axis of the femur.

- **Posterior Condylar Axis Collection**

  The posterior condylar axis selection for defining the femur rotational reference uses the most medial and lateral posterior condyle points (Figure 25), and allows you to collect the ML axis angle with respect to the two collected points.

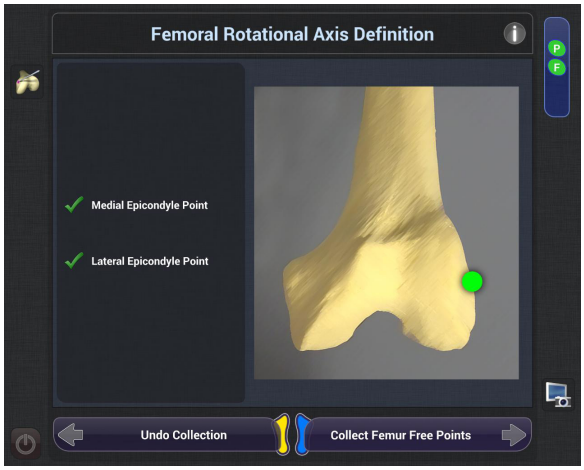


Figure 23. Transepicondylar axis collection.

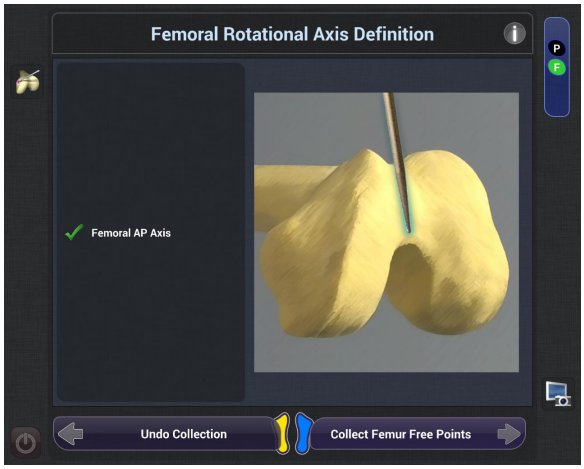


Figure 24. Femoral AP axis collection.

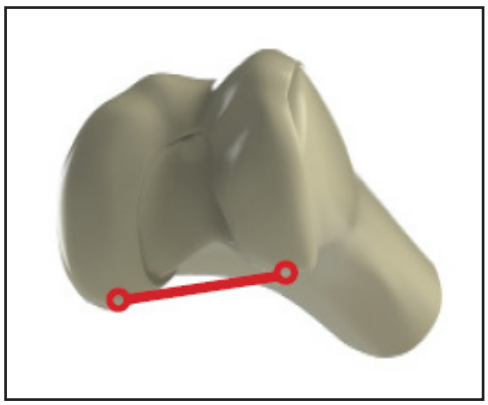


Figure 25. Posterior condylar axis collection.

Femoral Condyle Surface Mapping

The ***Femur Free Collection*** stage (Figure 26) offers a visualization of the previously collected femoral mechanical axis and rotational axis (blue lines), as well as the four discreet femur landmark points (yellow dots).

- Digitize the femoral condyle by moving the point probe over the entire surface, while holding down the footpedal. Use both hands to ensure constant contact of the point probe with the bone surface. Start by outlining the surface you want to digitize, then fill in the entire surface.
- Ensure there is enough coverage beyond the anterior notch point, specifically the proximal portion of the anterior femur implant position, and beyond the edges of the condyle in order to best fit the component. You must input enough information into the system to appropriately localize the implant during planning.
- While digitizing the surface beyond the anterior notch point, ensure that soft tissue does not alter the depiction of the bone.
- Ensure to map the epicondyles to assess the previously defined ML axis.
- Flex the leg to map the posterior portion. Manipulate the touchscreen to view the collected virtual bone surface in 3D (three dimensions).

NOTE: Do not hyperflex the knee when using the JOURNEY® II XR implant; use caution to prevent overstraining of ACL during collection.

Figure 26. The software presents a virtual representation of the bone surface of the operative condyle, generated from the collected free points. Manipulate the visualization to view in 3D.

Femur Axis Redefinition

- If, when entering the ***Femur Free Collection*** stage, you do not feel that the rotational axis is properly aligned, you may redefine the rotational axis for the femur.
- On the ***Femur Free Collection*** screen, press the **Femur Axis Redefinition** icon in the upper right corner. The ***Femur Axis Redefinition*** screen will be displayed (Figure 27). Use the point probe to rotate the grid to align the AP axis to the desired location.
- The adjustment angle displayed onscreen shows the angular difference between the originally calculated rotational axis and the redefined rotational axis.

NOTE: Axis redefinition will change the selected rotational reference for this case to the Femoral AP Axis.

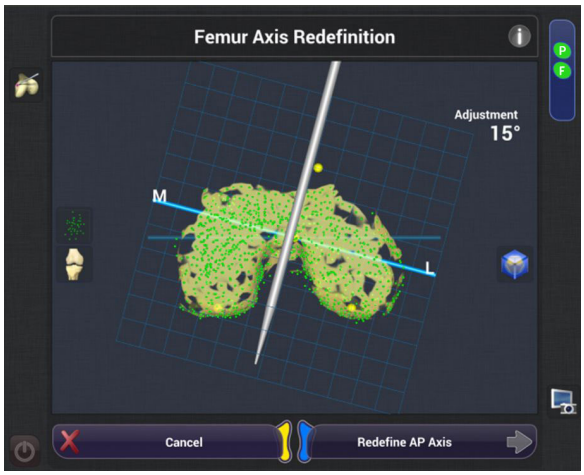


Figure 27. Redefine the Femoral AP Axis.

Tibial Condyle

There are three tibial landmark points to collect (Figure 28). These points will be used as visual references during ***Implant Planning***.

Using the point probe, collect the following:

- **Knee Center**

  Collect the tibial knee center at the origin of the ACL. The knee center along with the ankle center define the tibia mechanical axis.

- **Medial Plateau Point**

  Collect the singular low-point of cartilage wear on the medial side of the tibial plateau.

- **Lateral Plateau Point**

  Access the lateral side of the tibial condyle by flexing the leg and internally rotating the tibia and manually distracting the joint. Ensure that the point is collected on the bone surface by removing any meniscal layer that may interfere. This collection along with the medial plateau point collection are used as references for component placement and resection depth during the ***Implant Planning*** stage.

Tibia Condyle Rotational References

As defined during the ***Surgical Preference*** stage, there are three options to define the tibia rotational reference. These rotational references are used during ***Implant Planning*** for component placement onto the patient anatomy.

- **Tibia AP Axis Collection**

  While the other collections listed are singular points referencing the tip of the point probe, this collection will reference the axis of the point probe. Collect the AP axis for the tibia, normal to the transepicondylar axis, by using the length of the point probe (Figure 29). This collection, along with the tibia mechanical axis, will define the ML axis of the patient's tibia.

- **Transfer Femoral Mechanical Axis Collection**

  This tibial rotational reference is derived from the femur mechanical axis definition. Flex the knee to 90°, keeping the tibia at 0° of internal/external rotation. A live reading of the flexion angle is displayed. Collect the tibial AP axis (Figure 30). From this, the system will calculate the ML axis.

- **Medial Third of the Tibia Tubercle Collection**

  Collect the medial third of the tibia tubercle. This point collection, along with the tibia knee center, defines the tibia AP axis (Figure 31). From this, the system will calculate the ML axis.

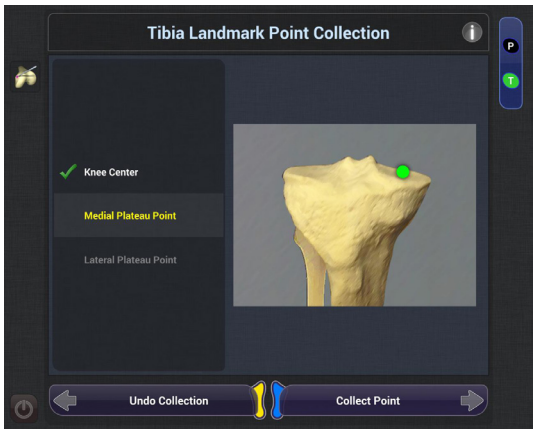


Figure 28. Tibia landmark point collection.

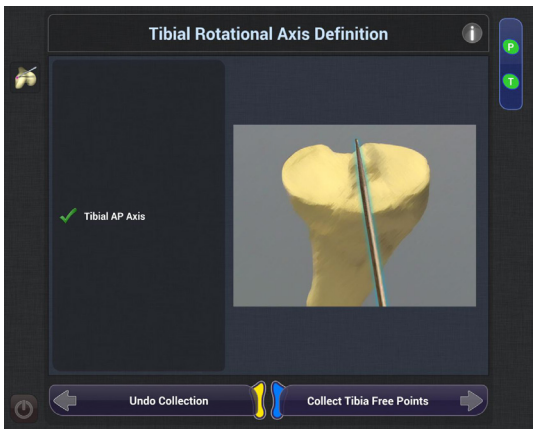


Figure 29. Tibia AP axis collection.

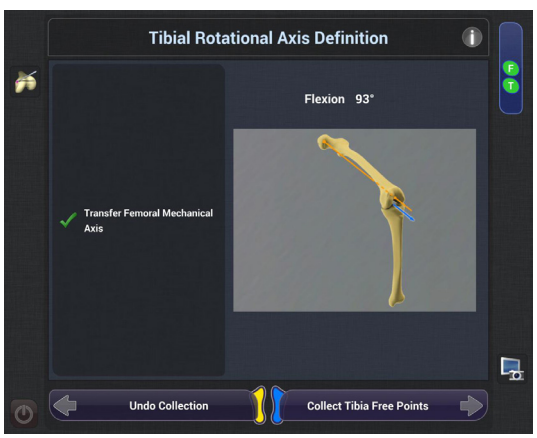


Figure 30. Transfer femoral mechanical axis collection.

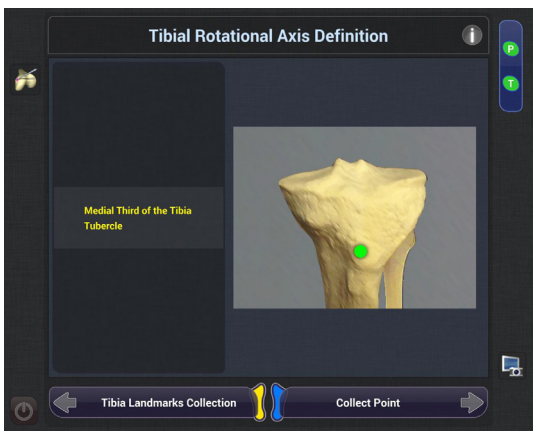


Figure 31. Medial third of the tibia tubercle collection.

Tibial Condyle Surface Mapping

The ***Tibia Free Collection*** stage (Figure 32) offers a visualization of the tibial mechanical axis and rotational axis (blue lines) as well as the three discrete tibial landmark points (yellow dots).

- Digitize the tibial condyle similarly to the ***Femur Free Collection*** stage.
- Define anterior and medial edges of the condyle as far posterior as is accessible. Ensure that you map the tibial tubercle. 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 condylar anatomy. Collect points approximately 15 to 20 mm down the anterior and medial side of the condyle, so that overhang can be identified during the ***Implant Planning*** stage, and the tibia cut guide can be visualized on the patient's anatomy, for placement without interference.

  NOTE: Do not hyperflex the knee when using the JOURNEY® II XR implant; use caution to prevent overstraining of ACL during collection.
- Compare ML axis to rotational landmarks visible on the virtual bone surface.
- 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 condyle up to the eminence ridge, marking the boundary for the implant placement.

  •Map the lateral condyle up to the eminence ridge, marking the boundary for the implant placement.

  NOTE: Do not violate the ACL footprint. Map only to the eminence ridge.

  •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.

Tibia Axis Redefinition

- 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 Redefinition*** screen (Figure 33) by selecting the **Tibia Axis Redefinition** icon in the upper right corner.

  NOTE: Axis redefinition will change the selected rotational reference for this case to the Tibia AP Axis.

Figure 32. Digitize the tibial condyle for utilization during the ***Implant Planning*** stage; you can always return to this stage to define more points if needed.

Figure 33. Redefine the Tibia AP Axis.

- If desired, to see rotation of the implant component with respect to the medial eminence ridge (instead of the Tibia AP Axis), use this stage to align the probe to the medial eminence ridge and redefine the axis.

Implant Planning

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

There are two view modes for implant planning: Solid Surface view (Figure 34), and Cross Section view (Figure 35).

The Solid Surface view allows manipulation of these views in 3D space. You can visualize virtual bone cuts based on the implant plan and toggle the virtual trial implant component on the virtually prepared bone by using the indicated button (Figure 36). In each viewscreen, the bright yellow mesh represents the virtual bone surface collected during the ***Free Collection*** stage. A transparent brown bone model is also shown to provide you with an estimated anatomical frame of reference.

The Cross Section view allows you to drag a finger vertically over the active window to view cross sectional slices of the bone in either the sagittal, coronal or transverse planes, and visualize the position of the implant in that particular slice within the plane.

There are three steps in the ***Implant Planning*** stage:

- Implant Sizing and Placement
- Gap Planning
- Cut Guide Placement

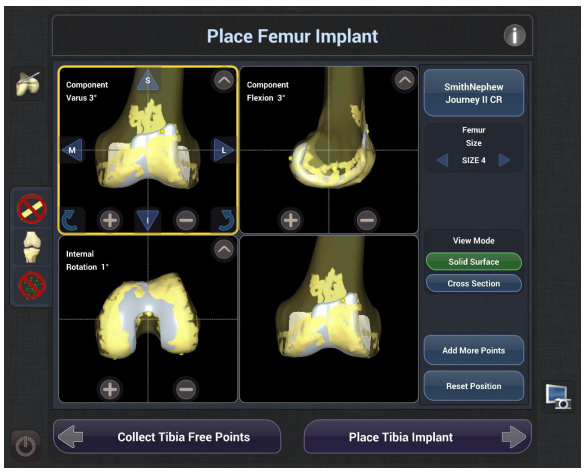


Figure 34. Femoral implant placement in Solid Surface view.

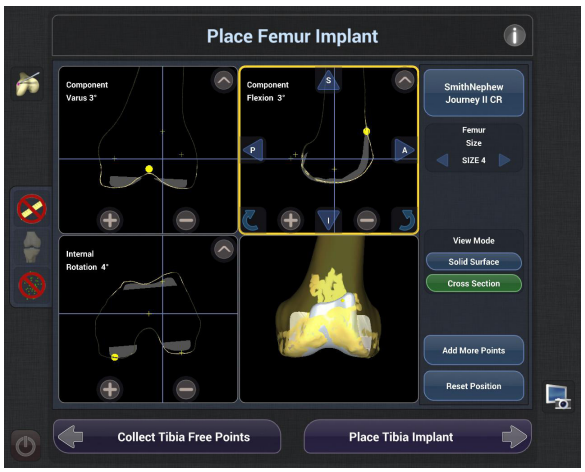


Figure 35. Femoral implant placement in Cross Section view.

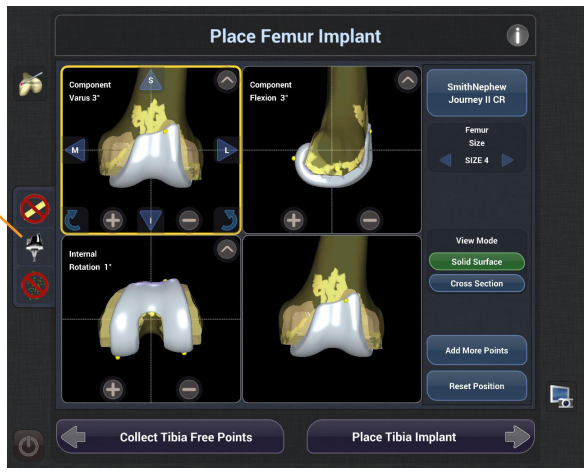


Figure 36. Femoral implant placement with the virtual bone cuts and implant components displayed.

Screen Overview: Place Implant (Femur and Tibia)

The screen displays four primary viewscreens used to manipulate the implant component. Counter-clockwise from upper right are standard sagittal, coronal and transverse planes of view. The lower right view is a 3D "sticky" view that will hold its orientation when manipulated.

The following buttons on these screens (Figures 37 and 38) are particularly critical to understand.

1 – **Checkpoint Verification** button is used to manually force a verification of the defined checkpoint positions on the femur and tibia. This button should be utilized if there is any concern that either of the tracker arrays has moved during registration or planning.

2 – **Resection Depth** button is used to show or hide the resection depth values.

3 – **Virtual Bone/Implant** button is used to toggle between the following three views:

- Bone view (virtual bone and implant)
- Implant view (cut bone and implant)
- Cut bone view (cut bone only)

This feature is only enabled in the Solid Surface view.

4 – **Green Dots** button is used to show or hide the cloud of discrete green points collected during ***Free Collection*** stages. It is generally helpful to hide the green points in order to view the virtual bone surface unobstructed.

5 – **Femur/Tibia Size** arrows will size up (right) or size down (left) the selected component size and display the size currently selected. This sizing option will correspond with the manufacturer's available sizes.

6 – **Tibia Thickness** arrows will increase (right) or decrease (left) the bearing component thickness and display the bearing thickness currently selected.

7 – **Solid Surface** and **Cross Section** buttons allow you to choose between a 2D and 3D view of the virtual implant placement with respect to the virtual bone surface.

8 – **Add More Points** button may be selected to navigate directly back to the ***Femur/Tibia Free Collection*** stage, where additional surface points may be collected.

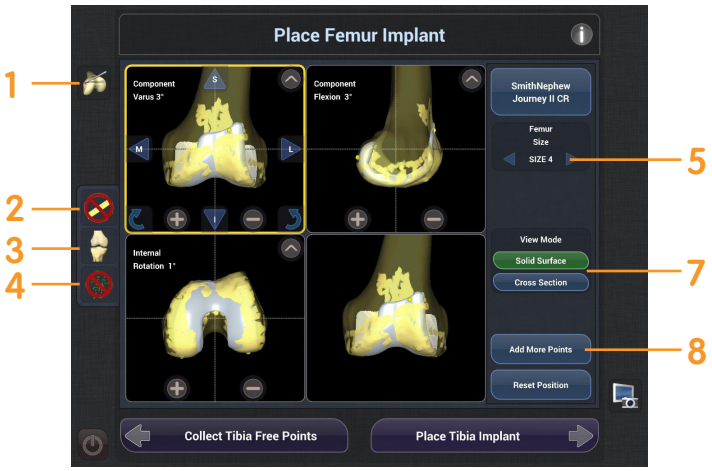


Figure 37. Place Femur Implant screen.

Figure 38. Place Tibia Implant screen.

Step 1. Implant Sizing and Placement

Femoral Component

The NAVIO® Surgical System software will provide a starting size and initial placement of the femoral component, utilizing the landmark points and the femur free collection points that were 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 femoral component on the digitized surface, the following are key metrics to review:

- Using the Cross Section view, in the transverse and coronal planes of view, confirm that the component size provides adequate coverage on the digitized femur bone surface (Figure 39). Slide a finger vertically on this viewscreen to visualize the superior-most part of the component on the bone. Assess the transition of the component's superior tip with the bone surface to avoid notching.
- In the sagittal plane of view, verify the transition of the component to prevent notching. Adjust the component AP position and flexion (use the **A** and **P** buttons and/or **Rotation** arrows in the viewscreen) to achieve the desired anterior transition within the bone-morphed condylar surface (Figure 40). Component flexion angle is defined as the angle between the femoral mechanical axis and the axis perpendicular to the distal cut plane of the femoral component. Assess the posterior coverage of the component in the sagittal and transverse planes of view by sliding a finger vertically on the viewscreen.
- Using the Solid Surface view, in the coronal plane of view, check to see if the surface map is behind the implant (on the cement side, as opposed to the articulating side) distally. This is indicative of a shallow distal bone resection, or little-to-no bone/cartilage resection. You should consider burying the component deeper into the condyle.

NOTE: Refer to the applicable Total Knee System *Surgical Technique* for more information on recommended bone resection and alignment of component on the bone surface.

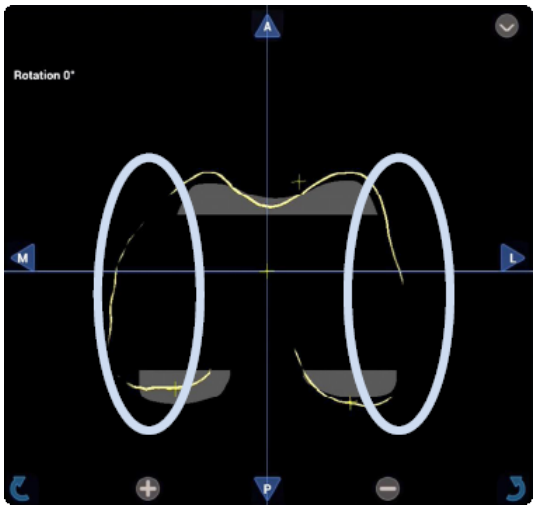


Figure 39. Confirm implant sizing and coverage (lower left, transverse plane of view).

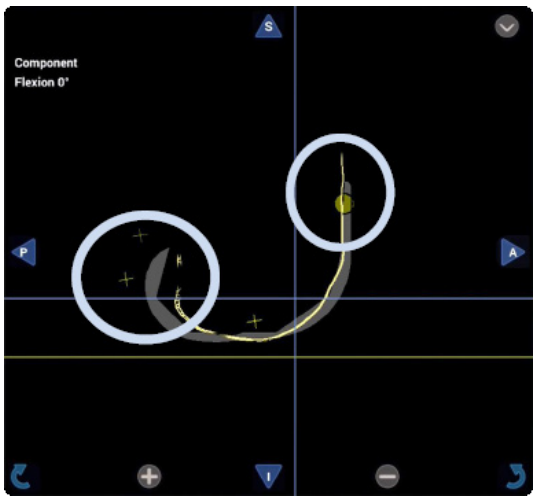


Figure 40. Confirm that the component is either flush with the center of the anterior notch point or proud, but never below (upper right, sagittal plane of view).

- The femoral components for ***Implant Planning*** are anterior referenced. Therefore, in order to have greater resection on the posterior bone and to increase posterior gap, the component may be downsized without any change to the anterior transition of the component on the bone.
- Toggle on the implant view of the bone model to visualize the implant component on the cut bone surface, in order to assess size coverage, implant anterior transition, and the bone resection plan.
- You should confirm that the component is not overhanging medially or laterally, which will be evident if the dark gray of the virtual implant is breaking through the virtual bone surface (Figure 39).
- If required, you can apply internal/external rotation to the component using the **Rotation** arrows in the active viewscreen. The software will indicate how much rotation you are applying with respect to the user defined mediolateral axis.

  NOTE: Refer to the applicable Total Knee System *Surgical Technique* for recommended implant component rotational constraints.
- Ensure that there is sufficient coverage of the proximal portion of the anterior femur implant position on the bone (bright yellow mesh).

  NOTE: If at any point during ***Implant Planning*** you feel as if the current virtualization (bright yellow mesh) of the femoral condyle is not sufficient, press the **Add More Points** button in the lower right portion of the screen. Collect additional points in ***Femur Free Collection*** in the deficient areas. Continuing forward from this screen will bring you back to the ***Implant Planning*** stage.

Tibial Component

The NAVIO® Surgical System software will provide a starting size and initial placement of the tibial component (Figure 41) utilizing the tibia free collection points that were 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 tibial component on the digitized surface, the following are key metrics to review:

- Confirm the size of the implant component using the transverse plane of view (lower left quadrant), along with the **Tibia Size** arrows on the right side of the screen.
- Confirm the posterior slope using the sagittal plane of view (upper right quadrant). The software will display the posterior slope within this viewscreen (Figure 42), which reflects the slope of the tibial implant component with respect to the mechanical axis defined during the ***Registration*** stage. The software will initially place the tibia with a 3° posterior slope.
- The initial rotation of the tibial component is 0° with respect to the tibial axis defined. This rotation can be adjusted using the arrows in the transverse plane of view. For total knee 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 a JOURNEY® II XR implant, the NAVIO Surgical System will prepare the bone with respect to the rotation set during Implant Planning in order to preserve the eminence as executed with manual instruments.
- For the JOURNEY II XR implant, it is recommended to use the Solid Surface, implant view (Figure 43) to visually confirm implant placement and size based on the virtual bone surface (bright yellow mesh) in order to not violate the ACL footprint. Ensure that the unmapped ACL footprint falls within the intercondylar space of the tibia implant.
- The tibial component will default to the thinnest bearing thickness option. The thickness can be adjusted using the **Tibia Thickness** arrows on the right side of the screen. Using the position control arrows active in the coronal plane of view, you may move the component superior, decreasing resection depth. The resection depth displayed on the viewscreen is based on the two plateau points collected on the tibia during the ***Tibia Landmark Point Collection*** stage.

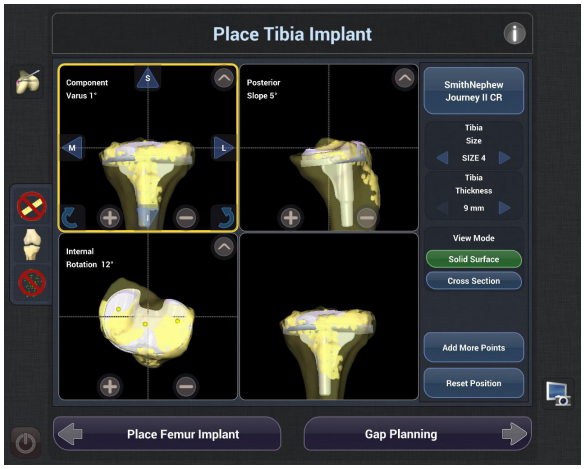


Figure 41. Tibial prosthesis placement in Solid Surface view.

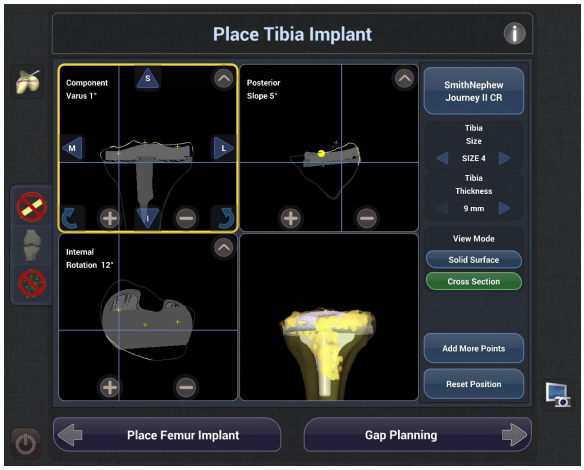


Figure 42. Confirm posterior slope is appropriate for patient. Component will be placed initially at 3° of posterior slope (upper right, sagittal plane of view). Confirm resection depth of the tibial component (upper left, coronal plane of view). Confirm ML sizing and AP placement of the tibia component (lower left, transverse plane of view).

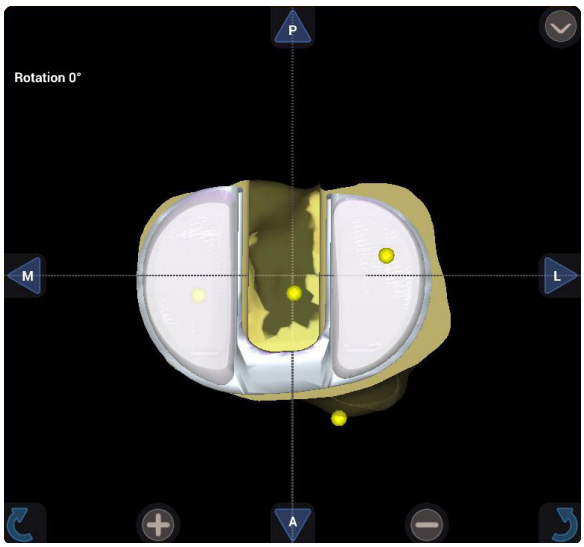


Figure 43. Confirm JOURNEY II XR implant size and placement.

NOTE: Refer to the applicable Total Knee System *Surgical Technique* for recommendations on depth and slope of tibial resection.

NOTE: If at any point during ***Implant Planning*** you feel as if the current virtualization of the tibial condyle is not sufficient, press the **Add More Points** button in the lower right portion of the screen. Collect additional points in ***Tibia Free Collection*** in the deficient areas. Continuing forward from this screen will bring you back to the ***Implant Planning*** stage.

Step 2. Gap Planning

This stage helps you adjust the plan based on gap information between the femur and tibia implants. The ***Gap Planning*** screen has four interactive views for translating and rotating the components with respect to the patient's virtualized joint. The left two viewscreens show the femur on top and the tibia on bottom in the coronal plane of view. The right two viewscreens show the femur on top and the tibia on bottom in the transverse plane of view. You can toggle the right two viewscreens to the sagittal plane of view by pressing the **Rotate View** arrow button in the upper right hand corner of the femur viewscreen. Beneath these four viewscreens are gap graphs.

On entry into this stage, the implants are set to the angles from the ***Implant Placement*** stage. The gap graphs are obtained from the ***Stressed ROM Collection*** stage. These 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 balance 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 (Figure 44) or the full range of motion (ROM) view (Figure 45).

Extension/Flexion View

Two viewscreens are presented: extension (left) and flexion (right). Each 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. White and red coloring indicates gap or overlap, respectively. For extension, the discrete points represent the values collected in each compartment during ***Stressed ROM Collection*** that were closest to 0°. For flexion, the discrete points represent the values collected in each compartment during ***Stressed ROM Collection*** that were closest to 90°. Magnitude of gap or overlap is represented by the height of the left and right edges of the graph.

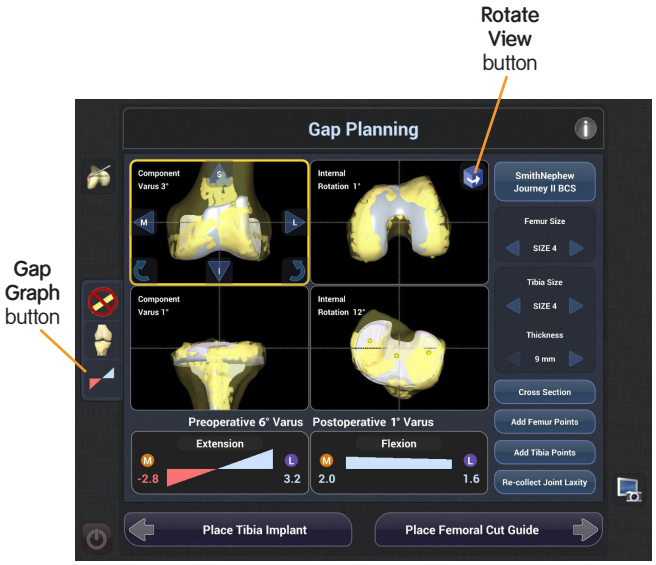


Figure 44. Gap Planning screen showing the Extension/Flexion gap graph.

Figure 45 Gap Planning screen showing the Full ROM gap graph.

Full ROM View

A line graph is presented with two lines plotted. The medial compartment (orange line) and lateral compartment (purple line) gaps are plotted throughout flexion. 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 relatively flat plot lines with equal gap between both compartments throughout range of motion (1 to 2 mm for medial and slightly looser for lateral).

- The goal of this stage is to have balanced extension and flexion gaps, with no overlap in either condyle (medial or lateral). 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 can now be performed, and laxity information can be re-collected by clicking on the **Re-collect Joint Laxity** button (Figure 46), to depict what the joint space will actually 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.

- Manipulate the position and orientation of the implant components such that the resulting extension view gap graph is approximately 2 to 3 mm above the zero line (2 to 3 mm laxity under stress, in the looser compartment). The resulting flexion view gap graph should be slightly greater and balanced in the medial and lateral compartment (Figure 47). Balancing the flexion gap in the medial and lateral compartments can be performed by rotating the femur component internally or externally.
- To balance gaps in only extension, manipulate the superior-inferior positioning of the femur component. To balance gaps in both flexion and extension, manipulate the tibia resection level or adjust bearing thickness.
- To balance flexion gaps, manipulate the femur sizing and position, keeping in mind that AP adjustments and component rotation will require re-evaluation of notching criteria on the femur bone surface. Use the **Rotate View** button to toggle between sagittal and transverse views.

Figure 46 Press the **Re-collect Joint Laxity** button to access the ***Joint Laxity – Extension*** screen.

Figure 47. Balanced Extension/Flexion gap graph.

- 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 carefully considered 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.

Joint Laxity Collection in Extension

The ***Joint Laxity*** stage consists of collecting ligament stress or laxity (gap) information in full extension (Figure 48). You can assess imbalance between the medial and lateral compartments and use this stage as a guidance to perform ligament releases or adjust implant placement.

- Based on the extension joint laxity collection, the extension view gap graph on the ***Gap Planning*** screen will show medial-lateral difference in gaps. To balance medial-lateral gaps, you may perform ligament release in the tighter compartment, and re-collect stress information, or plan with the looser compartment space.
- After performing ligament release, the stress information is re-collected in extension and the respective change is observed in the ***Gap Planning*** screen.
- To access the ***Joint Laxity – Extension*** screen press the **Re-collect Joint Laxity** button in the lower right portion on the ***Gap Planning*** screen (Figure 46).
- Keeping the operative leg in full extension, apply constant and maximal stress to the collateral ligaments and collect varus and valgus data, maintaining knee flexion between -10° and +30°. Input can either be continuous, which requires constant application of stress while the leg is in extension, or in discrete poses in order to record the maximum stress that can be applied to the collateral ligaments.
- The blue bar on the top of the screen depicts the maximum stresses being applied to the leg in extension, in the terms of varus and valgus angles of the operative knee. The green line represents the current varus/valgus angle along that range. The white line represents the pre-op varus/valgus collection in neutral position.

Figure 48. With the leg in full extension, apply stress to the MCL and LCL to collect varus/valgus information for use in gap balancing.

- The graph below the varus/valgus reading depicts the gap or tightness in millimeters of the medial or lateral compartment of the knee, based on the stress collections.
- This graphic illustration can be used to determine the amount of ligament release that may be required to restore equal gaps in the medial and lateral compartments.
- After collecting joint laxity in extension, the workflow will take you back to the ***Collect Stressed ROM*** screen (Figure 49, refer to the ***Registration*** stage in this guide). After re-collecting the stressed range of motion, you will return to ***Gap Planning***.

Figure 49. Collect stressed range of motion.

Ligament Balancing Manipulations

Scenario	Manipulation
flexion.	
Balance is loose in extension and flexion.	Move tibial component superior and/or increase thickness.
Balance is tight in extension and loose in flexion.	Move femoral component superior. Increase the femoral component size.
	–or– Reduce femoral component flexion.
Balance is tight in flexion and loose in extension.	Downsize the femoral component, or move it anterior. **NOTE:** The femur implants are anterior referenced. Upsizing or downsizing the components does not change the anterior cut from the plan, unless the component is moved by the user. **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. Move the femur component inferior to tighten the extension gap.
	–or– Increase posterior slope of tibial component.
Balance is loose in the medial compartment in flexion.	Internally rotate the femur implant to balance gap in the medial and lateral compartments
Balance is tight in the medial compartment in flexion.	Externally rotate the femur implant to balance gap in medial and lateral compartments
Balance is loose in the lateral compartment in extension.	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. Move the femur component inferior in extension, to tighten the gap presented.
Balance is tight in the lateral compartment in extension.	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.
The medial and lateral compartments are not balanced in extension.	The component default rotation in varus/valgus is 0° to ensure a perpendicular distal cut with respect to the femur mechanical axis. To balance the medial and lateral space in extension, re-collect ligament stress in extension, after performing medial-collateral ligament release.

Step 3. Cut Guide Placement

Prior to the ***Bone Cutting*** stage, you are presented with a cut guide placement screen. Select the appropriate cut guide for the operation.

Femur Cut Guide Placement

- 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 (Figure 50). The cross section view on the left side of the screen depicts a transverse cross section and functions similarly to the ***Place Implant*** screens.
- Choose an appropriate cut guide option by selecting from Small, Medium, or Large on the top of the screen. 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 are also embedded into the bone surface.

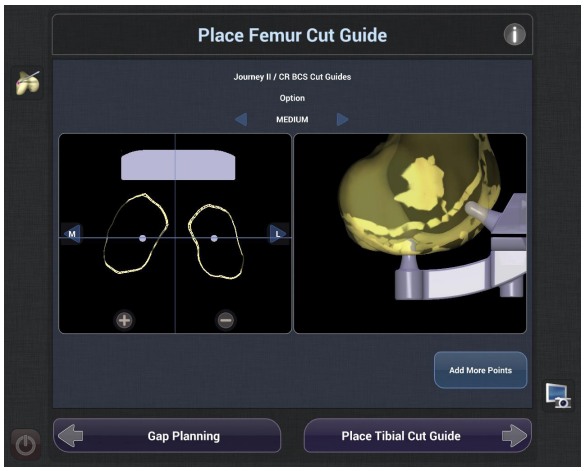


Figure 50. Visualize the femur cut guide placement on the cross section and solid surface models. Ensure engagement of the locking features on to the bone surface.

Tibia Cut Guide Placement

NOTE: For JOURNEY® II XR implants, the NAVIO® Surgical System does not support tibia cut guides. Skip this stage.

- Ensure that all of the locking features on the tibia cut guide assembly have purchase into the bone surface (Figure 1).
- Choose an appropriate cut guide option by selecting from Twin Peg, Small, or Medium on the top of the screen. Use the cross section view to ensure that the locking features of the cut guide have sufficient purchase into the bone surface, and do not interfere with soft tissue. 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.

  NOTE: 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.
- This screen allows you to move the cut guide anterior and posterior, as well as rotate it in the cut plane. 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.

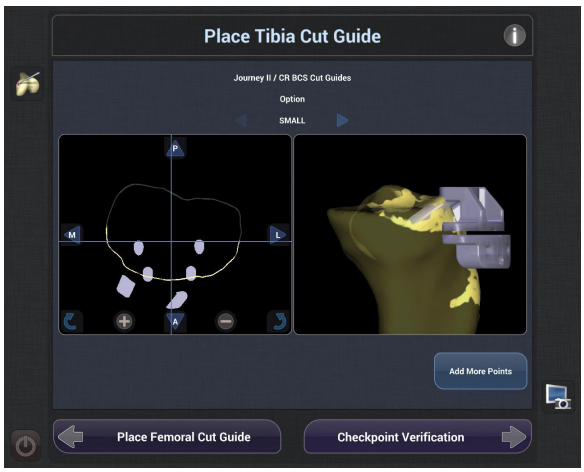


Figure 51. Visualize the tibia cut guide placement on the cross section and solid surface models. Ensure engagement of the locking features onto the bone surface, especially on the concave medial condyle. Ensure that the cutting geometry does not interfere with the anterior portion of the tibia bone.

Bone Cutting

Bone Preparation

For total knee replacement, the NAVIO® Surgical System utilizes a hybrid approach for complete bone preparation, with the combined use of burs and saws.

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 bulk bone preparation using recommended saws.

For the Smith & Nephew JOURNEY® II, LEGION®, and GENESIS® II total knee implant systems, the recommended saw blade thickness is 1.35 mm.

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

Setup

- 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 running below the trackers and 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.
- The irrigation needs to prime for approximately 20 seconds prior to active irrigation (Figure 52). 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.
- Remove any remaining osteophytes that may be visible. Remove the anterior horn of the meniscus.
- A self-retaining retractor, like the Gelpie retractor, has proven useful at keeping the incision open and bone exposed during cutting. This allows your assistant to focus on other retractions or tasks.

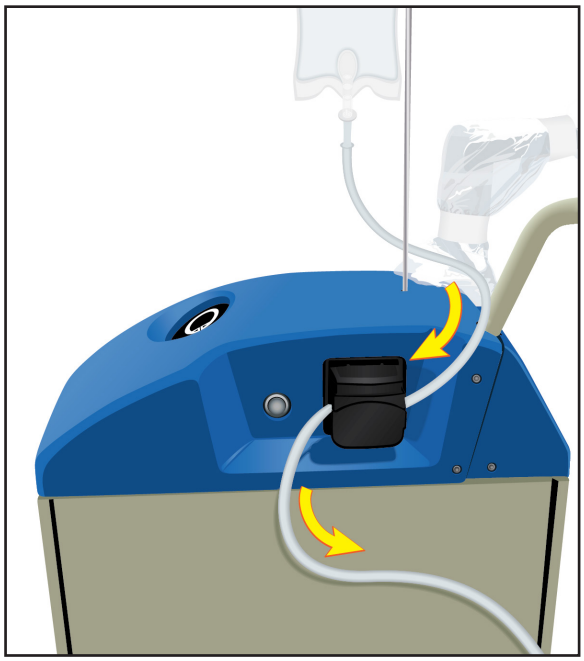


Figure 52. Irrigation is set up on the side of the NAVIO system cart to flow when the drill footpedal is depressed.

- Ensure that the NAVIO® handpiece has been assembled properly. Tug on the Anspach drill cylinder inserted into the back of the handpiece. If it comes loose, reattach the two properly for use. Figure 53 demonstrates the suggested way to hold the handpiece while orienting the tracking markers towards the camera. To provide support for the cutting implement, your dominant hand should be placed on the body of the tool, with the opposing hand placed near the tip.
- 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.

WARNING: 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.

WARNING: The cutting control modes do not establish “no-cut” zones beyond the protected-bone surfaces. Therefore, posterior to the cut plan and medial (lateral) to the cut plan, burring should be done with care.

WARNING: Using the cut blocks in the incorrect order or not using the stabilizer while making the distal femur cut may result in improper implant placement or ligament stress.

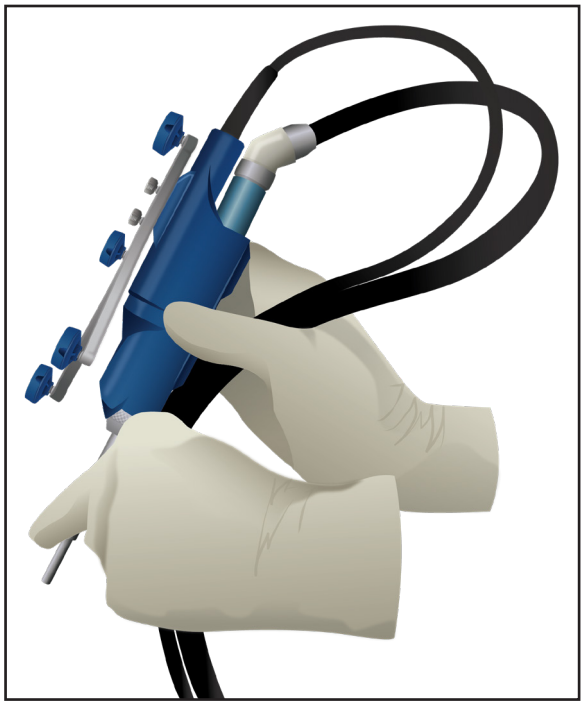


Figure 53. Right-hand-dominant technique for holding the handpiece during bone preparation. Do not hold the drill barrel sticking out the back of the handpiece, as this may prevent the tool from functioning properly.

Screen Overview

Figure 54 shows a typical ***Bone Removal*** screen with the following icons/buttons identified:

1 – **Checkpoint Verification** button is used to manually force a verification of the defined checkpoints on the femur and tibia.

2 – **Change Bur** button is used to update the system about a change you made to the selected bur size.

3 – **Back to Planning** button returns you to the ***Gap Planning*** screens to make adjustments to the implant placement plan.

4 – **Tool's Eye View** displays "what the tool sees," similar to a scope view, and it is continuously active.

5 – **Isometric Cut Model** can be manipulated based on your view preference.

6 – **Control Mode Indicator** displays which control mode (exposure or speed) you are currently using. Pressing the button will allow you to change the selected control mode.

7 – **Tracker Array Status** will show if a tracker array is visible 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. You may also press this icon to present a ***Field of View*** screen to confirm tracker array visibility within the camera's field of view.

8 – **Femur Distal Cut Plane** button is used to show or hide the virtual distal cut plane in ***Femur Bone Removal*** screens only.

9 – **Tool's Eye View** button is used to toggle between bird's-eye view (default view) and tool's eye view.

10 – **Crosshair View** button is used to show or hide the crosshair view.

11 – **Virtual Cut Guide** button is used to activate a virtual cut guide that will be shown on the main viewscreen.

12 – **Virtual Trial Implant** button may be used to activate a virtual implant that will be shown on the main viewscreen. This is useful to confirm progress to the cut plan, and to check for overhang of implant on bone.

13 – **Screenshot** button can be used at any time to capture a screenshot of whatever is currently on the monitor. The screenshot will be saved for access when archiving the patient.

14 – **Cutting Mode** (Bur Cut Guide, Visualize Cut, Refine, and Bur All) highlights the current mode that you are using, and can be used to navigate to other modes.

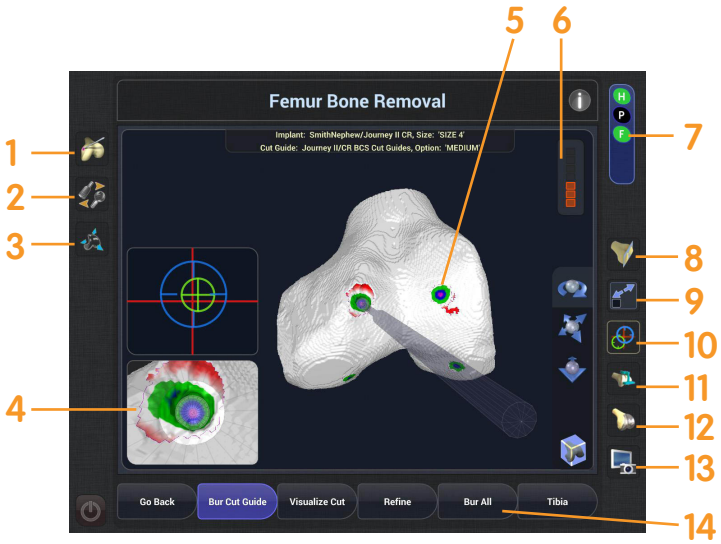


Figure 54. Typical ***Bone Removal*** screen.

Bur Cut Guide – Femur

The handpiece is used to prepare four cylindrical fixation features in the bone in order to lock the femur cut guide onto the bone surface (Figure 55).

1. The Crosshair view can be utilized to set the appropriate trajectory of the handpiece, where the green (small) crosshair represents the tip of the tool (bur) and the blue (big) crosshair represents the back of the tool. When both crosshairs are centered over the red crosshair, the tool is in the correct trajectory. Speed Control mode will prevent you from cutting beyond the bottom of the hole, and beyond the cylindrical sides down the depth of the hole.
2. With the drill footpedal engaged, slowly plunge into the bone surface, taking care to remove all the colors until the white target surface is reached.
3. Avoid "feathering" the tool over the surface. Slow methodic plunge motion will remove bone with the greatest efficiency.

   NOTE: It is recommended to bur the cut guide fixation features for the tibia immediately after the femur, and then return to step 4. (This is not applicable for the JOURNEY II XR implant.)
4. Once the locking features are prepared, clear the surface of any residual debris using irrigation, suction, and/or hand tools.

   NOTE: Refer to Figure 56 for the remaining steps.
5. 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.

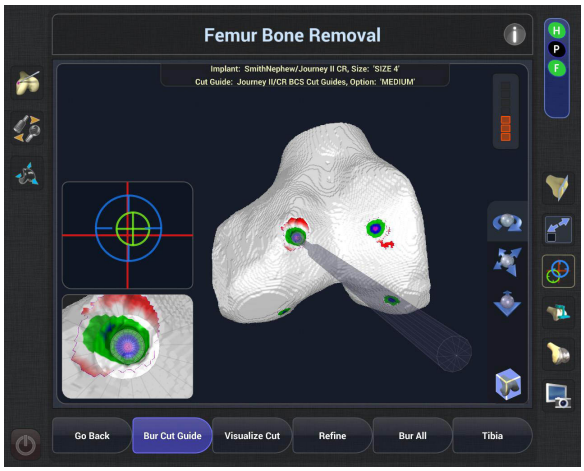


Figure 55. Remove bone, working cleanly all the way down to the white target surface.

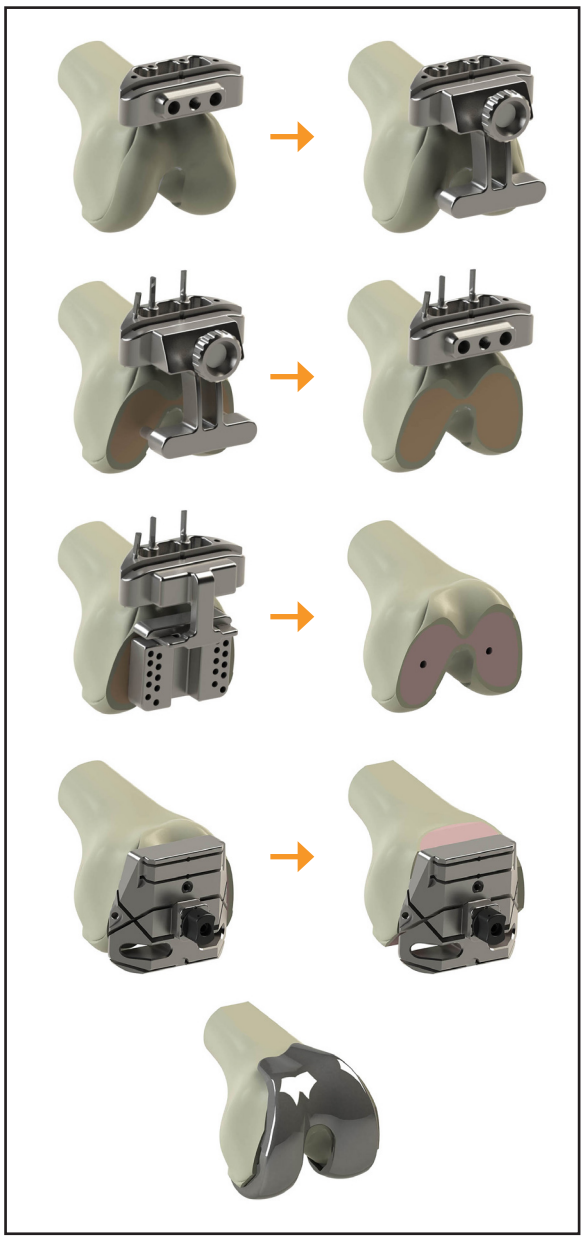


Figure 56 Workflow for femur bone preparation using cut guides.

6. 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. 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.
7. Using the recommended saw with a blade thickness of 1.35 mm, prepare the distal cut on the patient bone. The femur stabilizer can be left on at this stage for additional rigidity of the cutting block on the bone surface.
8. 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. Attach this assembly to the distal cut guide, and drill through the appropriate holes in the guide, based on the femur implant sizing plan.
9. Remove the femur cut adapter and the distal cut guide. 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 Total Knee System *Surgical Technique*.
10. 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.
11. Using the recommended saw, prepare the planar AP femur cuts, as recommended in the applicable Total Knee System *Surgical Technique*.

Visualize Cut – Femur

This screen (Figure 57) 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 will enable you to visualize how the actual cut with the current location of the cut guide will compare to the planned cut.

The plane visualization tool attaches to the handpiece, similar to the speed control guard, and can be used 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 58). 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 can also be used after bone removal to visualize the actual cut prepared (Figure 59).

Counterclockwise from the upper right, these views are the sagittal, coronal and transverse. The lower right view is a 3D “sticky” 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 or the anterior cut plane. The angle between these lines is calculated as an angle error (shown 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.

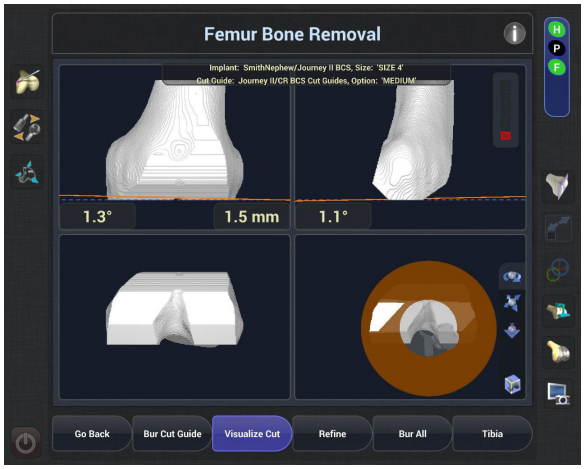


Figure 57. Visualize cut for the femur.

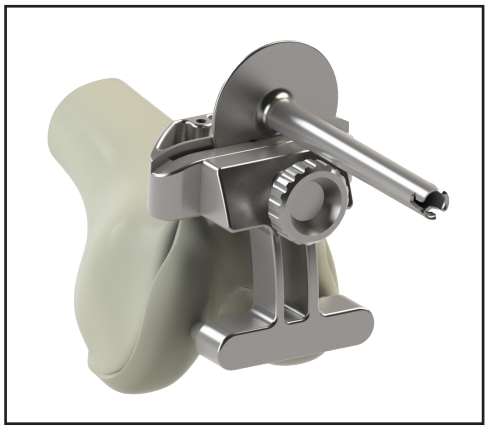


Figure 58. Visualize cut before bone removal.

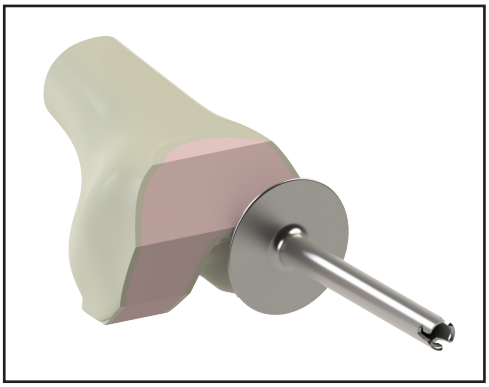


Figure 59. Visualize cut after bone removal.

Refine – Femur

Prior to ***Bur All*** mode, you are encouraged to enter the ***Refine*** mode. The ***Refine*** mode will update the visual model to match the patient's bone after the saw cuts were made using the cut guides.

- Make sure the system is in Exposure Control mode. Run the barrel of the exposure control guard over the patient's bone with the femur tracker array visible to the camera. The visualization on the cutting screen will show over-modeled bone being "erased" by the guard (Figure 60).

NOTE: Only the visual model is being updated in ***Refine*** mode. This step has no bearing on the final outcome of a procedure, the accuracy of the cutting, or the behavior of the handpiece. 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.

Figure 60. Refine femur.

Bur All – Femur

Prior to ***Bur All*** mode, you are encouraged to enter the ***Refine*** mode. The ***Bur All*** mode allows you to bur away any remaining bone to be removed in order for the femur surface to accept the selected implant.

You should work anterior to posterior, cutting away bone to remove color indicated on the model, until the target (white) surface is reached (Figure 61).

- Make sure the system is in Exposure Control mode. Allow the tool to plunge the bur into the bone. 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.
- Widen the cut, moving at a deliberate pace. Trace around the outer edge of the implant cut plan. Make left-right or up-down passes to remove the remaining middle bone.
- Avoid “feathering” the tool over the surface. Methodical motion will remove bone with the greatest efficiency.
- 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.
- In the posterior part of the femur, it is generally difficult to bring the handpiece cutting perpendicular to the bone surface; therefore, a “dragging” technique is suggested for efficient bone removal. In the “dragging” technique, you push the tool into the joint space, and lever it against the bone, while pulling the handpiece out (Figure 62). For varus knees (medial osteoarthritis), posterior femoral access may be optimized by applying deep flexion and valgus stress. For valgus knees (lateral osteoarthritis) deep flexion and varus stress can help gain posterior femoral access.
- When working on the femur, the tibia tracker array can be covered to protect it from wet splatter from the irrigation or incision. This will help extend the life of the tracking markers and limit exposure to view-obstructing matter.

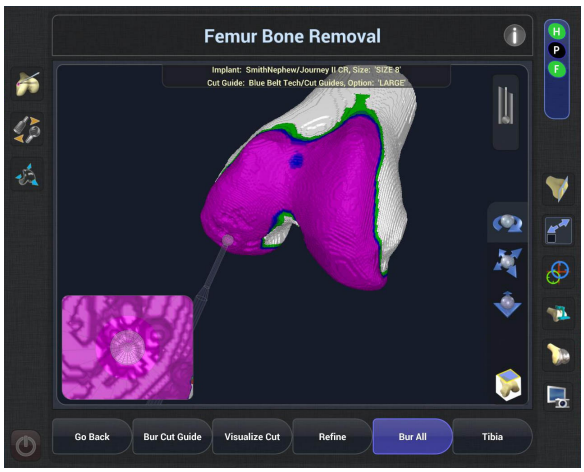


Figure 61. Bur All for the femur.

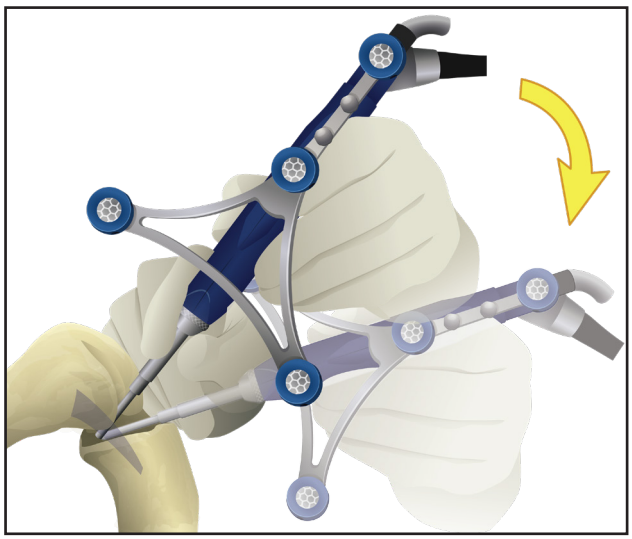


Figure 62. Illustration of the “dragging” technique that can be utilized to efficiently remove posterior femur bone with the handpiece.

Additional Notes

If the sterile reflective markers become soiled and the marker visibility is compromised (markers are not visible in the ***Camera Orientation Adjustment*** screen or there is flickering of the **marker visibility indicator**), replace the markers on the affected tracker. Use clean, sterile gloves to handle the markers. Support the tracker frame behind the marker attachment point. Avoid transferring force to the entire tracker frame.

If markers are replaced during a procedure, the handpiece must be recalibrated. Be sure to remove irrigation clips during attachment of the point probe.

After calibration/homing is completed, separate the handpiece from the point probe. Hold the point probe close to the back for easier separation (Figure 63).

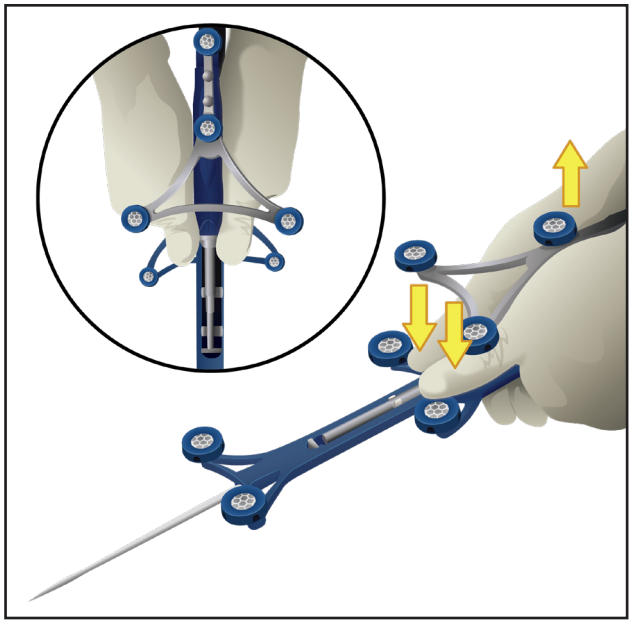


Figure 63. Suggested hand position to separate the handpiece from the point probe.

Bur Cut Guide – Tibia

NOTE: For JOURNEY® II XR implants, skip this stage. It is not applicable.

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 64). A Z knee retractor is included in the NAVIO® instrument kit and provides a low-profile option, minimizing obstruction of tracker arrays.

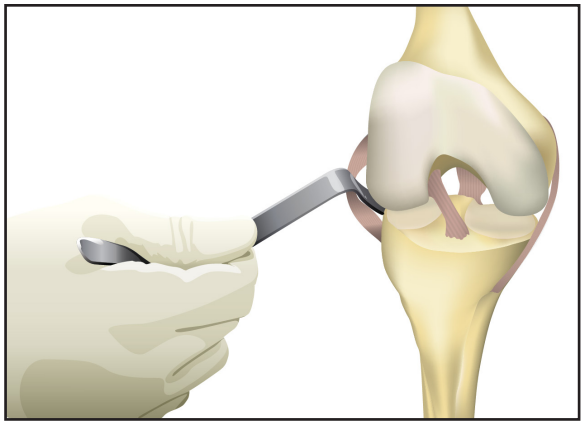


Figure 64. Use a soft tissue protector (a Z knee retractor is included in the instrument set) to spare the MCL/LCL from damage by the bur.

Using the handpiece, prepare the fixation features in the patient's bone in order to lock the tibia cut guide onto the bone surface (Figure 65). There are four features for the Small and Medium cut guides and two features for the Twin Peg design. Make sure to uncover the tibia tracker array if it was covered for protection while preparing the femur.

NOTE: It is recommended to bur the cut guide fixation features for the tibia at the same time as the femur.

1. Ensure the physician's assistant has various ligament protecting retractors readily available for use.
2. The Crosshair view can be utilized to set the appropriate trajectory of the handpiece, where the green (small) crosshair represents the tip of the tool (bur) and the blue (big) crosshair represents the back of the tool. When both crosshairs are centered over the red crosshair, the tool is in the correct trajectory. Speed Control mode will prevent you from cutting beyond the bottom of the hole, and beyond the cylindrical sides down the depth of the hole.

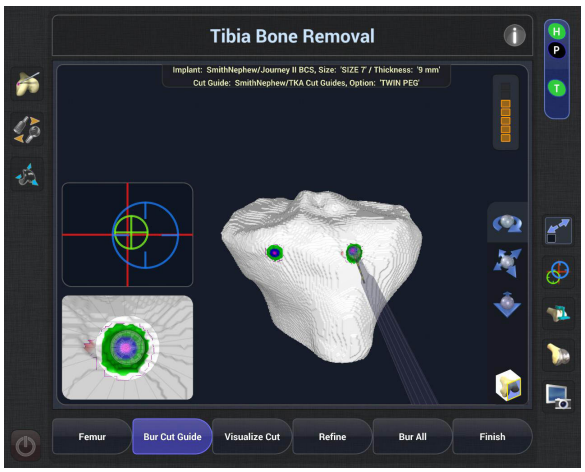


Figure 65. Remove bone in the guided regions using Speed Control mode until the white target surface is reached.

3. The Tool's Eye view (lower left) is the most useful viewscreen for tunneling down the post holes.
4. With the drill footpedal engaged, slowly plunge into the bone surface, taking care to remove all the colors until the white target surface is reached. For the anterior features, it is recommended to approach the bone horizontally with the cutting tool.
5. Avoid "feathering" the tool over the surface. A slow methodic plunge motion will remove bone with the greatest efficiency.
6. Once the burred fixation features are prepared, clear the surface of any residual debris using irrigation, suction, and/or hand tools.

   NOTE: The cut guide attaches to the bone using a press fit.
7. Place the tibia cut guide on the prepared bone features (Figure 66). Using ***Visualize Cut*** mode, ensure that the cut guide is placed according to the plan. Secure the cut guide on the bone surface using ⅛" diameter non-rimmed speed pins provided in the Smith & Nephew implant system trays.
8. Using the recommended saw blade (1.35 mm), perform the tibia cut through the cut guide.

Visualize Cut – Tibia

The ***Visualize Cut*** mode for the tibia (Figure 67) functions similarly to the ***Visualize Cut*** mode for the femur. Refer to the *Visualize Cut – Femur* section in this guide.

Counterclockwise from the upper right, these views are the sagittal, coronal and transverse. The lower right view is a 3D "sticky" view that can be manipulated to change its orientation.

Both the sagittal and coronal views are active when evaluating the proximal cut. The angle error and the distance error are displayed. The transverse view is not active.

Figure 66. Workflow for tibia bone preparation. (Left images show the tibia cut guide; Right images show the twin peg tibia cut guide).

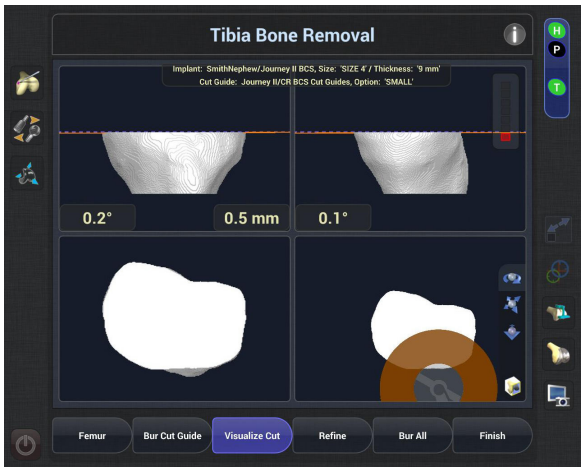


Figure 67. Visualize cut for the tibia.

Refine – Tibia

Prior to ***Bur All*** mode, you are encouraged to enter the ***Refine*** mode. The ***Refine*** mode for the tibia (Figure 68) functions similarly to the ***Refine*** mode for the femur. Refer to the *Refine – Femur* section in this guide.

Bur All – Tibia

Prior to ***Bur All*** mode, you are encouraged to enter the ***Refine*** mode. The ***Bur All*** mode allows you to bur away any remaining bone to be removed in order for the tibia surface to accept the selected implant.

- Ensure that your assistant has various ligament protecting retractors readily available for use.
- Make sure the system is in Exposure Control mode. You should prepare the bone in the same anterior-to-posterior approach as is used on the femur. This approach creates space for the guard as the cutting moves into the posterior portion of the joint. It is strongly recommended that you remove the color down to the white target surface as cutting moves posterior (Figure 69).
- 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. A Z knee retractor is included in the NAVIO® instrument kit and provides a low-profile option, which minimizes obstruction of tracker arrays.
- Start at the anterior and bur with the handpiece held vertically to maximize exposure of the bur.
- Externally rotate the knee to aid in accessing a tight posterior tibial resection. Utilize a similar “dragging” technique, as is suggested for the posterior femur. To clean up remaining pieces of color on the floor of the tibia, start posterior and drag anterior.
- If the access becomes limited, switch to Speed Control mode. Use the icon in the upper-right corner of the touchscreen to switch control mode and finish the tibial cut.
- For the JOURNEY® II XR implant, it is recommended to use speed control mode for burring the tibia. Use a tunneling technique, starting from the anterior and working to the posterior. "Undermine" cartilage close to the eminence ridge to avoid having the bur skip on the bone and inadvertently hitting the ACL.

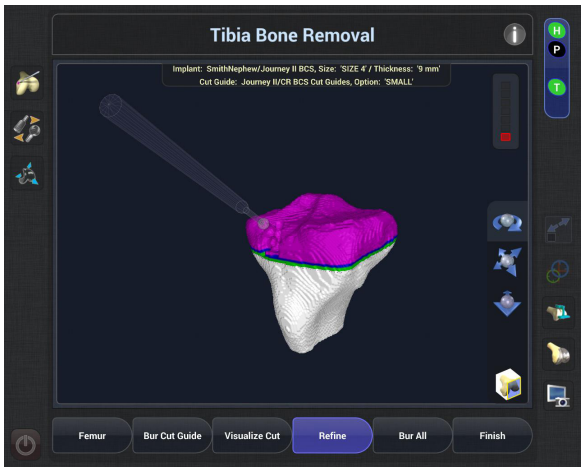


Figure 68. Refine tibia.

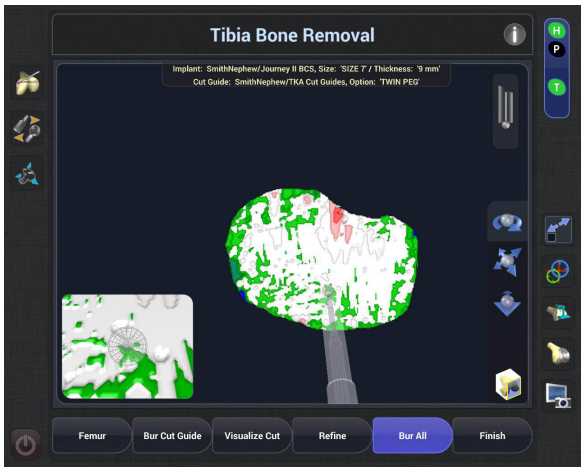


Figure 69. Bur All for the tibia.

- For the JOURNEY II XR implant, prepare the medial condyle first, and then you can check ligament balance using manual instruments before proceeding. Next, prepare the lateral condyle and then you can once again check ligament balance using manual instruments. Finally, prepare the anterior cut last, and then check ligament balance using manual instruments. At any point during the preparation of these three areas, you can use the Back to Planning button to return to the Gap Planning screens in order to make adjustments to the implant placement plan.

  NOTE: For the JOURNEY II XR implant, do not prepare the tibia fixation features with the bur on the NAVIO handpiece, they must be prepared with manual instrumentation.

Trial Reduction

Confirm Sizing

- After completing all of the bone cuts and adjustments to the final surfaces, the incision should be cleaned and dried thoroughly.
- Once bone surface preparation is complete, perform a trial reduction (Figure 70) 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, size the bearing component down to a thinner component or resect more tibial bone.

  NOTE: For the JOURNEY® II XR implant, if the ACL is compromised, switch to a CR implant.

Dynamic Test

- The ***Collect Postop Baseline*** screen (Figure 71) will record normal flexion motion. Press and hold the right footpedal. 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°).

Figure 70. Insert femoral and tibia trial components using the appropriate impactor set and select the appropriate bearing component.

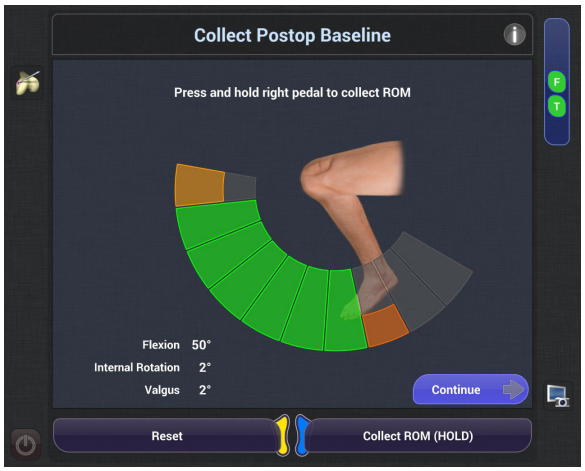


Figure 71. Collect non-stressed range of motion.

- The ***Postop Stressed Gap Assessment*** screen (Figure 72) lets you assess the post-op gap throughout flexion in both the medial and lateral components. 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 Planning*** stage. Apply constant varus and/or valgus stress to the collateral ligaments and collect the data throughout flexion. As you collect the data, the new line plots will be filled solid and display along with the previous line plots. You can collect these points either continuously or discretely.
- Be sure the trial femoral and tibial components are in contact throughout ROM collection. The femoral component should be stable on the tibial tray component. The tibial component should not lift off in flexion.

Figure 72. Collect stressed range of motion.

Cement and Close

Remove Checkpoint Verification Pins

WARNING: Prior to closing the patient's incision, be sure to remove both the femoral and tibial bone checkpoint verification pins.

Final Components

- Finish the implantation of the final components, as recommended in the applicable implant *Surgical Technique*, using appropriate instruments and tools.

Recovery Procedure Guidelines

The following guidelines provide a framework for recovering to a fully manual procedure in the case of a NAVIO® Surgical System failure at any point during the surgical case. 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 Total Knee System *Surgical Technique* document that accompanied the purchase of the implant.

Point of Failure	Recovery Action
Planning	
1. Bone landmark, surface and kinematic data collection	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 Total Knee System *Surgical Technique*.
2. Planning	Remove the tracker arrays, the bone pins and the checkpoint pins and proceed with conventional instrumentation. Use conventional procedure as described in the applicable Total Knee System *Surgical Technique*.
3. Refining	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 Total Knee System *Surgical Technique*.
Bone Removal	
4. Femur cut	Remove the trackers and the bone pins from bones and proceed with conventional instrumentation, as described in the applicable Total Knee Surgical Technique. Begin the manual technique by assembling and placing the tibial guide on the operative femur as described in the applicable Total Knee System *Surgical Technique*.
5. Tibia cut	Use the technique described in the applicable Total Knee System *Surgical Technique*.
6. Posts and keels	Use the technique described in the applicable Total Knee System *Surgical Technique*.
Trial Implant ROM Evaluation	
7. ROM Evaluation	Follow the instruction in the *Trial Reduction* section of the applicable Total Knee System *Surgical Technique*.
8. Refinement	Follow the instruction in the *Trial Reduction* section of the applicable Total Knee System *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.

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