BRAINLAB

KNEE

Version 3.1

Software User Guide
Revision 1.1

TABLE OF CONTENTS

1 GENERAL INFORMATION

1.1 Contact Data and Legal Information

1.1.1 Contact Details

Support

If you cannot find information you need in this guide, or if you have questions or problems, contact Brainlab support:

Region	Telephone and Fax	Email
United States, Canada, Central and South America	Tel: +1 (800) 597-5911 Fax: +1 (708) 409-1619	us.support@brainlab.com
Brazil	Tel: (0800) 892-1217	
UK	Tel: +44 1223 755 333	support@brainlab.com
Spain	Tel: +34 (900) 649 115	
France and French-speaking regions	Tel: +33 800 676 030	
Africa, Asia, Australia, Europe	Tel: +49 89 991568-44 Fax: +49 89 991568-811	
Japan	Tel: +81 3 3769 6900 Fax: +81 3 3769 6901	

Expected Service Life

Unless specifically stated otherwise Brainlab provides five years of service for this product. During this period of time, spare parts as well as field support are offered.

Feedback

Despite careful review, this manual may contain errors.

Please contact us at igs.manuals@brainlab.com if you have suggestions as to how we can improve this manual.

Manufacturer

Brainlab AG
Kapellenstr. 12
85622 Feldkirchen
Germany

1.1.2 Legal Information

Copyright

Non-Brainlab Trademarks

Microsoft® and Windows® are registered trademarks of Microsoft Corporation in the United States and other countries.

Integrated 3rd-Party Software

- This software is based in part on the work of the Independent JPEG Group.
- Portions of this software are based in part on the CyberVrml97 package written by Satoshi Konno.
- Other company and product names mentioned herein may be trademarks of these respective companies.

CE Label

CE 0123

- The CE label shows that the Brainlab product complies with the essential requirements of Council Directive 93/42/EEC (the “MDD”).
- According to the principles set out in the MDD, **Knee** software is a Class IIa product.

NOTE: The validity of the CE label can only be confirmed for products manufactured by Brainlab.

Disposal Instructions

When a surgical instrument reaches the end of its functional life, clean the instrument of all biomaterial/biohazards and safely dispose of the instrument in accordance with applicable laws and regulations.

Only dispose of electrical and electronic equipment in accordance with statutory regulations. For information regarding the WEEE (Waste Electrical and Electronic Equipment) directive, visit:

http://www.brainlab.com/en/sustainability/

Sales in the US

U.S. federal law restricts this device to sale by or on the order of a physician.

1.2 Symbols

1.2.1 Symbols Used in This Guide

Warnings

Warnings are indicated by triangular warning symbols. They contain safety-critical information regarding possible injury, death or other serious consequences associated with equipment misuse.

Cautions

Cautions are indicated by circular caution symbols. They contain safety-critical information regarding possible problems with the device. Such problems include device malfunctions, device failure, damage to device or damage to property.

Notes

NOTE: Notes are formatted in italic type and indicate additional useful hints.

1.3 Intended Use

1.3.1 Using the System

Medical Purpose

Knee is an image guided surgery system for knee replacement, based on landmark-based visualization of femur and tibia, functioning with different DePuy implants.

Indications for Use

Knee includes four different workflows:

- Knee3 Motion
- Knee3 Universal
- Knee3 Express
- Knee3 Partial

For Knee3 Motion, Knee3 Universal and Knee3 Express, the following indications apply:

Knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to a virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR-based model of the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by **Knee**.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Replacement
- Ligament Balancing
- Range of Motion Analysis

Indications for Use - Knee3 Partial Only

For the Knee3 Partial workflow only, the following indications for use apply:

Knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to a virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray, MR-based model of the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by **Knee**.

Example orthopedic surgical procedures include but are not limited to:

- Unicondylar Knee Replacement
- Ligament Balancing
- Range of Motion Analysis

Intended User

Knee is to be used by trained orthopedic surgeons. The users should be experienced in performing unsupervised knee replacement surgery and should fully understand knee kinematics and anatomy.

Place and Conditions of Use

Knee is an image guided surgery system that is used in operating rooms. The system consists of parts that can be used multiple times, such as the software, tracking system, and computer platform, and parts that are single-use items, such as reflective marker spheres for instruments. Instruments and navigation disposables must be sterile during use. The computer platform and tracking system may be mobile, according to platform specification.

Patient Population

Fully grown adults requiring a Total Knee Replacement. Contraindications for certain patient populations are as follows:

- Patients that suffer from osteoporosis should not be treated using the implant based total knee navigation procedure with the tibia and femur array. In this case, the fixated reference arrays may become loose during navigation due to reduced bone density rendering navigation inaccurate or not possible. For those patients, the pinless Alignment Verification procedure is an alternative.
- Patients that suffer from dysplasia or other pelvic deformities should not be treated using knee navigation software. In this case, it is not possible to register the center of rotation correctly. Thus, the registration/navigation result could be inaccurate or navigation not possible.

Plausibility Review

Before patient treatment, review the plausibility of all information input to and output from the system.

1.3.2 Camera System

Camera Accuracy

Accuracy Measurement	Value
Tracking	0.3 mm RMS (Root Mean Square)
Navigation Values	+/- 1° (angles), +/- 1 mm (distances)

1.3.3 Potential Side Effects

Additional Incisions

During **Knee** navigation, additional skin incisions or bone holes are needed on the tibia and femur to securely fixate reference arrays using bone screws.

Alternatively, the femur and tibia reference arrays may be fixed directly inside the wound to avoid an additional incision.

1.4 Compatibility with Medical Devices

1.4.1 Brainlab Medical Instruments

Compatible Brainlab Medical Instruments

Knee is compatible with:

- 4 in 1 Cutting Block Template
- Bone Fixator “1-Pin”, X-Press (Sizes S, M or L)
- Bone Fixator “2-Pin”, X-Press
- Knee Plane Tool
- Disposable Clip-On Remote Control
- Disposable Reflective Marker Spheres
- Femoral and Tibial Cutting Block Adapter “Universal”
- Fine-adjustable Cutting Block
- Pointer Angled
- Pointer Straight for Knee
- Reference Array, X-Press (Y-Geometry and T-Geometry)

*NOTE: For more specific information, refer to the **Hip and Knee Instrument User Guide**.*

Other Brainlab Instruments

Additional instrumentation may become available after release of this manual. Contact Brainlab support if you have any questions regarding instrument compatibility with Brainlab software.

Only use instruments and spare parts specified by Brainlab. Using unauthorized instruments/spare parts may adversely affect safety and/or effectiveness of the medical device and endanger safety of patient, user and/or environment.

1.4.2 Brainlab Medical Software

Compatible Brainlab Medical Software

Knee is compatible with:

- Content Manager 2.2
- Patient Browser 4.1
- DICOM Viewer 2.2

Other Brainlab Software

If you are running software versions other than those specified above, contact Brainlab support for clarification regarding compatibility with Brainlab devices.

Only Brainlab medical software specified by Brainlab may be installed and used with the system.

1.4.3 Non-Brainlab Medical Devices

Compatible Non-Brainlab Medical Devices

Medical Device	Manufacturer
Implants *NOTE: **Knee** is compatible with specified implants and toolsets available from the listed manufacturers. For questions regarding compatibility, contact Brainlab support.* *NOTE: For implant compatibility refer to the specifications of the implant manufacturer. The information provided in the software are indicative only.*	DePuy
Footswitch	steute

Other Non-Brainlab Devices

Using medical device combinations which have not been authorized by Brainlab may adversely affect safety and/or effectiveness of the devices and endanger safety of patient, user and/or environment.

1.4.4 Non-Brainlab Software

Compatible Non-Brainlab Software

Knee is compatible with:

- Windows 7
- Windows 8.1

NOTE: For information regarding compatible service packs please contact Brainlab support.

Other Non-Brainlab Software

Only non-Brainlab software applications specified by Brainlab may be installed and used with the system.

1.5 Training and Documentation

1.5.1 Training

Brainlab Training

To ensure safe and appropriate use, before using the system all users must participate in a training program held by a Brainlab representative.

Supervised Support

Before using the system for surgical procedures where computer-aided navigation is considered critical, perform a sufficient number of complete procedures with a Brainlab representative present to provide guidance where necessary.

Responsibility

This system solely provides assistance to the surgeon and does not substitute or replace the surgeon’s experience and/or responsibility during its use.

1.5.2 Documentation

Reading User Guides

The user guides describe complex medical devices and surgical navigation software that must be used with care.

It is important that all users of system, instruments and software:

- Read the user guides carefully before handling the equipment
- Have access to the user guides at all times

Available User Guides

User Guide	Contents
Software User Guides	• Overview of treatment planning and navigation • Description of OR system setup • Detailed software instructions
Instrument User Guides	Detailed instructions on instrument handling
Cleaning, Disinfection and Sterilization Guide	Details on cleaning, disinfecting and sterilizing instruments
System User Guides	Comprehensive information on system setup
Technical User Guide	Detailed technical information on the system, including specifications and compliances

2 SYSTEM SETUP

2.1 Operating Room Setup

Before You Begin

Ensure that:

- The camera and monitor do not restrict the work of the surgeon.
- The camera has a clear view of the reference arrays during all registration and navigation procedures.

OR Setup Example

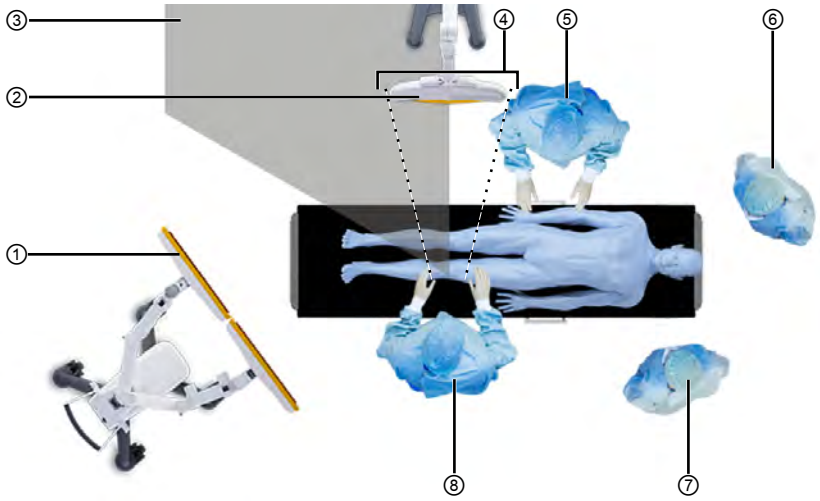


Figure 1

For optimum visibility, position the camera directly opposite the surgeon.

No.	Component
①	Navigation Monitor
②	Camera Placement Angle (45 - 90 degrees)
③	Camera Field of View
④	Camera
⑤	Assistant
⑥	Anesthesiologist
⑦	Nurse
⑧	Surgeon

2.1.1 Camera Setup

How to Set Up the Camera

Steps	
1.	Position the camera in the required OR location. The camera should be positioned: • approximately 1.5 - 2 m (5 - 6.5 feet) from the surgical field for optimum viewing. • opposite the surgeon. • between 45 - 90 degrees from the foot of the patient.
2.	Open **Camera** from the tool bar, see page 23. Verify the distance using the camera distance graph.
3.	Adjust the camera until the lenses have an unobstructed view of all reference arrays in the surgical field. *NOTE: You can verify reference array detection at any point within registration and navigation.*

The camera lenses must have an unobstructed view of the reflective marker spheres on patient reference arrays and active instruments at all times during registration and navigation.

The camera has a 2-10 minute warm up phase after it is connected to the system. A dialog opens and the tracking system is unavailable during this time.

2.1.2 Camera

General Information

For registration and navigation, the camera must have an unobstructed view of the instruments.

The camera gives you real-time feedback about the visibility of instruments to the camera and can be accessed at any time.

Camera Display

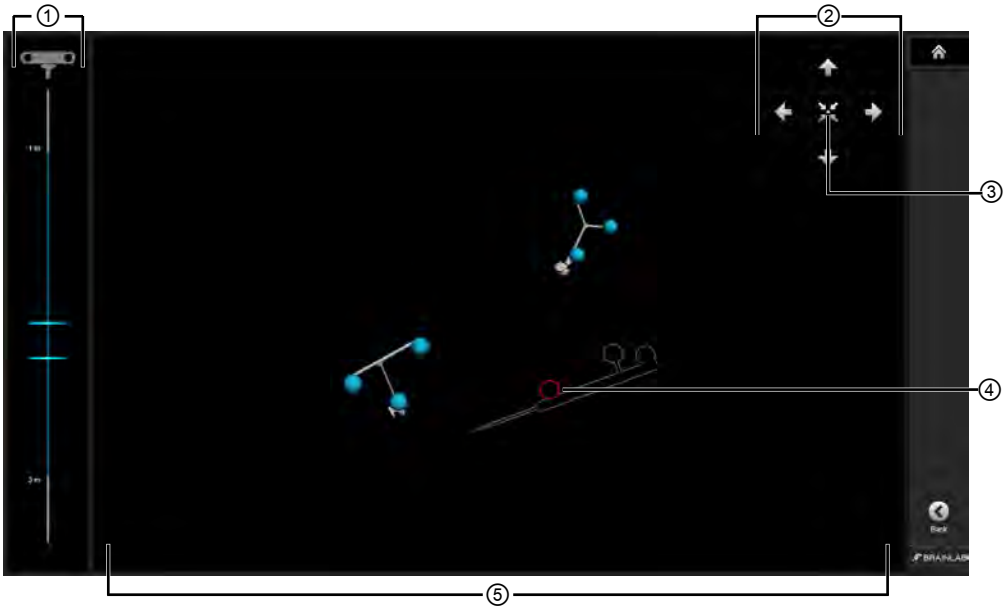


Figure 2

No.	Component	Explanation
①	Tracking corridor	Displays the distance of the instruments and/or reference arrays in relation to the camera. For optimum visibility and accuracy, all tracking spheres shall be inside the blue corridor.
②	Camera controls	Displays the camera motor control positioning buttons. *NOTE: This feature is only available on **Curve 1.1**.*
③	Camera centering button	Used to center the camera. Centering the camera takes up to 5 seconds. A second click de-activates the centering feature. *NOTE: This feature is only available on **Curve 1.1**.*
④	Marker sphere	The marker sphere from an instrument and/or array is marked red when invisible to the camera.
⑤	Camera field of view	Displays the position of the instruments and/or reference arrays in relation to the camera.

How to Access the Camera

Steps
1. Select an icon from the tool bar ③ or the fly-out menu (see page 113).

Steps	
2.	View status.
3.	Press **Back** to return to knee navigation.

Visibility Status

Screen Status	Visibility
Full 3D display of instrument or array with blue marker spheres	Full visibility
Outline of instrument or array	Partial visibility
Red marker spheres	Not visible

2.1.3 Optimal Positioning of Reference Arrays

Reference Array Geometry

To enable registration and navigation, you must attach reference arrays to the femur and tibia of the leg to be operated upon.

The software identifies the bone by the geometry of the attached reference array:

Figure 3

No.	Geometry	Bone Tracked
①	Reference Array Y-Geometry	Femur
②	Reference Array T-Geometry	Tibia

How to Position Reference Arrays

Steps	
1.	Ensure that the femoral and tibial reference arrays are positioned side by side from the camera's perspective, so that neither blocks the camera's view of the other.
2.	Adjust the camera to ensure reference array visibility at all times during the procedure.
3.	Make sure that the reference array geometries do not overlap.

Ensure you attach the Y-geometry reference array to the femur and the T-geometry reference array to the tibia. Consider the leg movement during the procedure when attaching the reference arrays to the bone.

Position the camera so that reference arrays within the surgical field are seen by the camera. Make sure that reference arrays are visible in both flexion and extension. The reference array must be visible to the camera at all times during navigation, otherwise tracking is not possible.

Ensure the center of the Y-reference array is positioned anterior of the femur mechanical axis.

Femoral Fixation

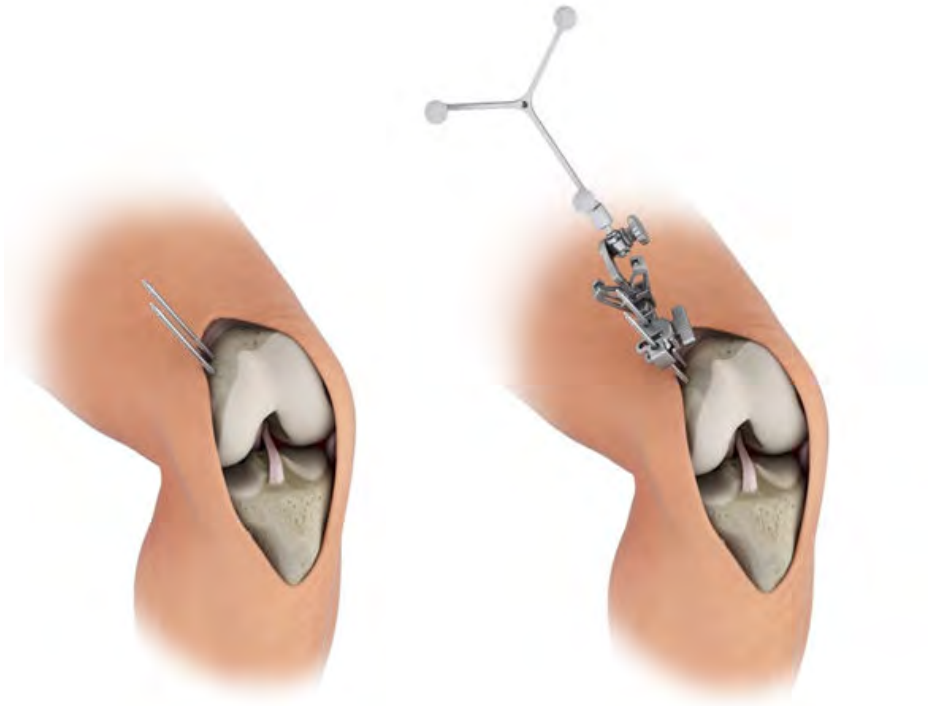


Figure 4

Steps	
1.	Using 3.2 mm or 4 mm Schanz pins, place the first pin 1 cm proximal and 1 cm anterior of the medial epicondyle.
2.	From a horizontal position, angle the pin 45° toward the lateral posterior cortex. *NOTE: If a posterior stabilized implant is used, angle the pin 30° in the proximal direction to ensure box cut clearance.*
3.	Slide the bone fixator over the pins with the array attachment point directed away from the joint, leaving enough room between the skin and the bone fixator. Tighten in place with the thumb screw.

Tibial Fixation

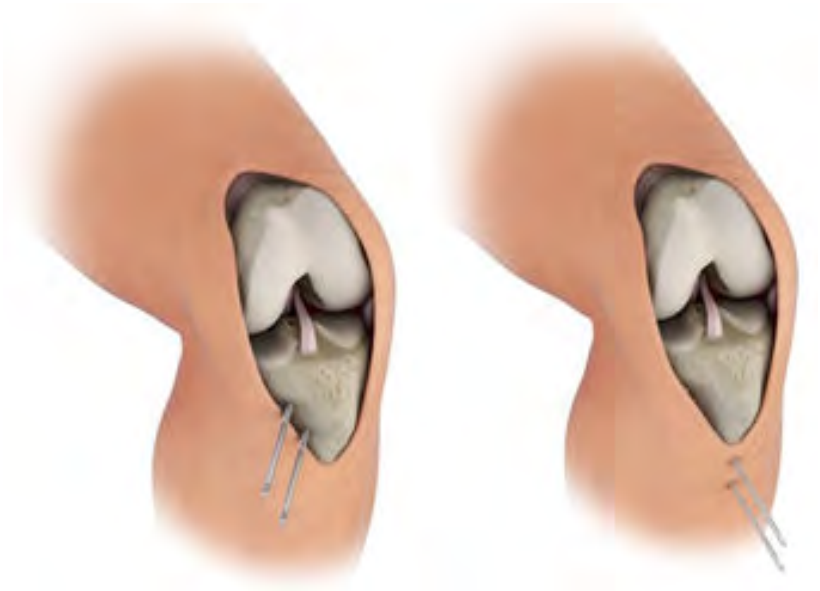


Figure 5

Steps	
1.	Place the first pin distal to the joint line, avoiding any keel or punch used by the specific implant system. Consider using extra-medullary alignment guides/conventional instruments when placing the pins (inside or outside the wound).
2.	Perform a small stab incision and clear the underlying soft tissue.
3.	Place the pins perpendicular to the bone surface, placing the second parallel and distal to the first, using the same alignment technique as on the femur.

Reference Array Placement for Y- and T- Reference Arrays

Figure 6

Steps	
1.	Slide the reference array onto the pins.
2.	Rotate the array to a position that is visible to the camera in both full flexion and full extension, adjusting the reference array angle, if necessary.
3.	Ensure the array is seated correctly and clicked into position.
4.	Fasten the side screw to lock the array firmly to the pins, ensuring all joints are tight.

Ensuring Sufficient Operating Space

Ensure sufficient space to enable incision and implanting without moving the reference arrays.

To avoid contact between reference arrays and surgical instruments, take the size of the implant, the cutting blocks and the surgical instruments into account when placing the reference arrays.

Make sure that the position of the reference arrays do not hinder the surgeon's work before attaching them to the bone.

Ensuring Secure Attachment

Securely tighten the screws of the reference arrays to the bone before patient registration.

Do not adjust any of the reference array screws after patient registration is complete.

Make sure that bone quality is suitable for array fixation.

Reflection Artifacts

Artifacts caused by external infrared reflections can cause inaccuracy. Make sure that light sources or items which are highly reflective do not affect the camera field of view.

Marker Sphere Visibility

Ensure the marker spheres are securely fastened to the instruments and reference arrays.

Use only clean, dry new marker spheres to ensure precision during navigation. Marker spheres are for single use only.

If the camera cannot detect a reference array, verify that the marker spheres are clean and undamaged, and that the reference array is not bent.

Movement of Reference Arrays

Do not move the reference array relative to the patient's anatomy during the procedure. Movement affects the entire measurement coordinate system, leading to incorrect instrument display and injury to the patient.

If a reference array changes position relative to the bone, or the array becomes unstable, check its accuracy, and re-register it if necessary.

If the accuracy decreases or if a reference array must be re-attached, you must re-register the patient before proceeding to navigation.

Remove X-Press reference arrays prior to sawing.

Removal of Reference Arrays

Be aware that the joint stability data is continuously and automatically recorded. Shield the marker spheres when detaching a reference array as joint stability graph values continue recording.

2.1.4 Navigation Accuracy

How to Check Accuracy

Steps	
1.	Place the pointer on the bone where the corresponding landmarks are on the navigation screen.
2.	Check if the area shown on the screen correctly corresponds to the actual area on the bone.

2.1.5 Navigation Instruments in Use

Instrument Overview

The table below outlines the instruments used in conjunction with **Knee** software.

Instrument	Description
	The **4 in 1 Cutting Block Template** is used to navigate the anterior femur cut. *NOTE: For further information regarding implant system availability, contact Brainlab support.*
	The **Brainlab Angled Pointer** or **Straight Pointer** for **Knee** is used for anatomical landmark registration and resection measuring.
	**Disposable Reflective Marker Spheres** are attached to reference arrays and instruments allowing the system to detect the position of the patient and instruments in the surgical field.
	The **Knee Plane Tool - Tracking Array** provides the Infrared reference for either: • Knee Plane Tool - Cutting Block • Bone Verification Plate

Instrument	Description
	The **Knee Plane Tool - Cutting Block Adapter** holds the cutting block that guides the surgeon when cutting the bone.
	The **Knee Plane Tool - Bone Verification Plate with Spikes** is used to verify bone cuts in the Knee3 Express workflow.
	The **Knee Plane Tool - Bone Verification Plate Small** verifies bone cuts with the software.
	The **Femoral and Tibial Cutting Block Adapter "Universal"** allows the system to track the cutting block during navigation of the cutting block to the planned resection plane. It self-adjusts to cutting blocks with a slot thickness of 1.0 mm - 1.8 mm.

3 STARTING KNEE

3.1 Starting the Software and Selecting a Patient

How to Start the Software

Figure 7

On system launch, **Content Manager** starts.

Step
Select your Knee workflow ①: • **Knee3 Motion** • **Knee3 Universal** • **Knee3 Express** • **Knee3 Partial** Patient selection opens.

How to Select a Patient

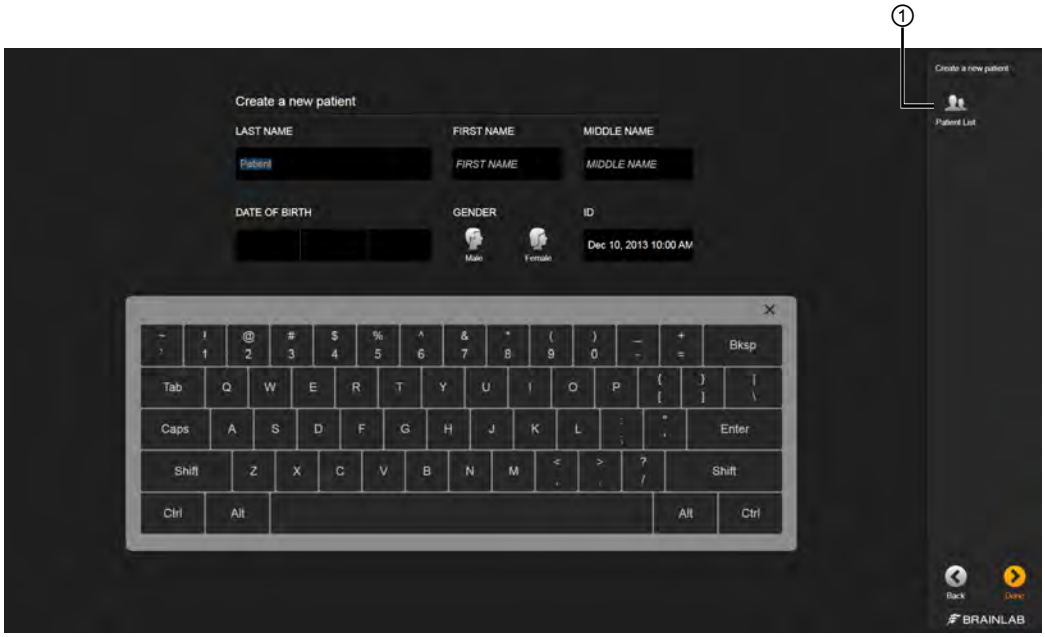


Figure 8

Steps	
1.	Enter new patient details as prompted or select **Patient List** ① to select an existing patient.
2.	Select **Done**.

*NOTE: For further information on patient selection, refer to the **Patient Browser Software User Guide**.*

How to Start Knee

Step


Select e.g., **Knee3 Motion** ① to open the software.

4 KNEE WORKFLOWS

4.1 Introduction

Knee Workflow Types

Depending on your selected workflow type, you are required to perform a registration sequence. Each workflow type requires different steps to provide the surgeon with positioning information.

You can choose between four different navigation workflows as outlined below:

Workflow Type	Use	Provided Information
Knee3 Motion	DePuy implants only.	• Proximal tibia cut • Distal femur cut • Anterior femur cut • Long leg alignment • Joint stability
Knee3 Universal	Every implant but no joint stability information is provided by the software.	• Proximal tibia cut • Distal femur cut • Anterior femur cut • Long leg alignment
Knee3 Express	Can be adapted to surgeons preferences. Example combinations are: • Pinless tibia navigation • Live femur navigation • Providing positioning information of proximal tibia cut and distal femur cut without using pinned references.	• Proximal tibia cut • Distal femur cut
Knee3 Partial	Unicondylar knee replacement interventions.	• Proximal tibia cut • Distal femur cut • Long leg alignment

4.2 General Navigation

General Information

Knee consists of four different workflows and every workflow offers a different solution for the type of surgery you want to perform. Some features are important for all four workflows and these are described in the following chapter. Please read this chapter and the information contained for your chosen workflow to get all the information you need.

Context Sensitivity

Knee is context sensitive, which means that the software recognizes the position of the **Knee Plane Tool** (or the **Universal Cutting Block Adapter**) and automatically displays the right navigation step.

If you place the **Knee Navigation Tool** on the bone cut, keeping it still for 2 seconds, the cut is automatically verified, without screen interaction.

Initial and Final Leg Alignment

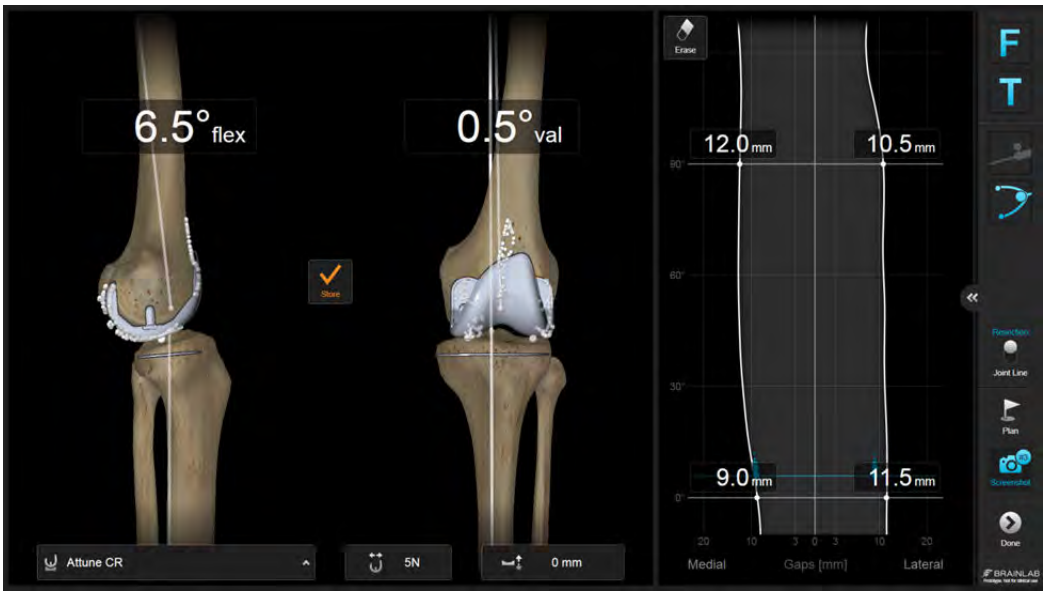


Figure 9

In the leg alignment view, the initial and final leg alignment values are stored. These values are shown in a patient report, see page 111 for more information.

How to Store Initial and Final Leg Alignment

Leg Flexion/ Function	Explanation
Leg flexion is less than 40°	When the leg flexion is less than 40°, the current leg alignment values are stored in the report by using the following: • Pressing **Store** • Using a gesture: Lift the extended leg and hold still for 2 seconds, a progress bar indicates the verification progress
Leg flexion is more than 40°	No storage of the current leg alignment is possible.

Pointer Mode

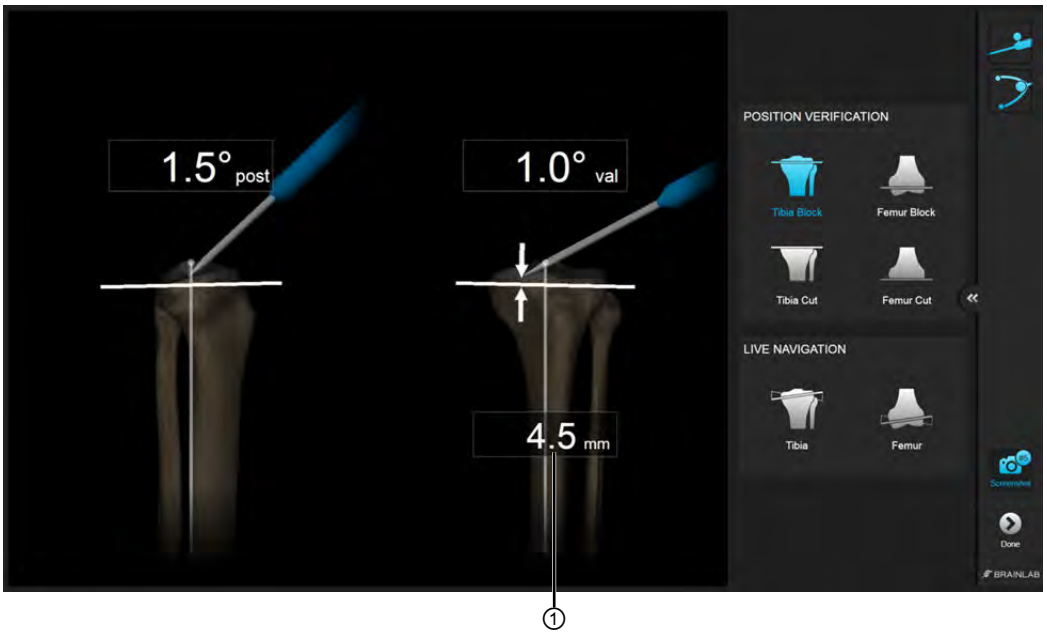


Figure 10

In every workflow you can check the cut resection height and check for notching, using the pointer.

The distance between the pointer tip and planned/live resection levels ① is measured. The resection level is represented by a small line.

When the software is in joint line mode (Knee3 Motion only) the joint line shift between planned/live joint line and pointer tip is measured. The joint line level is represented by a small dashed line.

Cut Verification

Cut verification is very important in order to receive accurate results using navigation. There are three cut verification options using the **Knee Plane Tool** with the **Bone Verification Plate** on the bone cut:

- Keep it still for 2 seconds. The software shows a progress bar and verifies the cut automatically.
- Press **Verify** on screen.
- Press the blue button on the footswitch.

4.3 Knee3 Motion

General Information

Knee3 Motion is for use with DePuy implants only.

Software Workflow

Knee3 Motion follows a sequential approach for implant selection, registration and navigation. The navigation screen is context sensitive and does not follow a preset sequence.

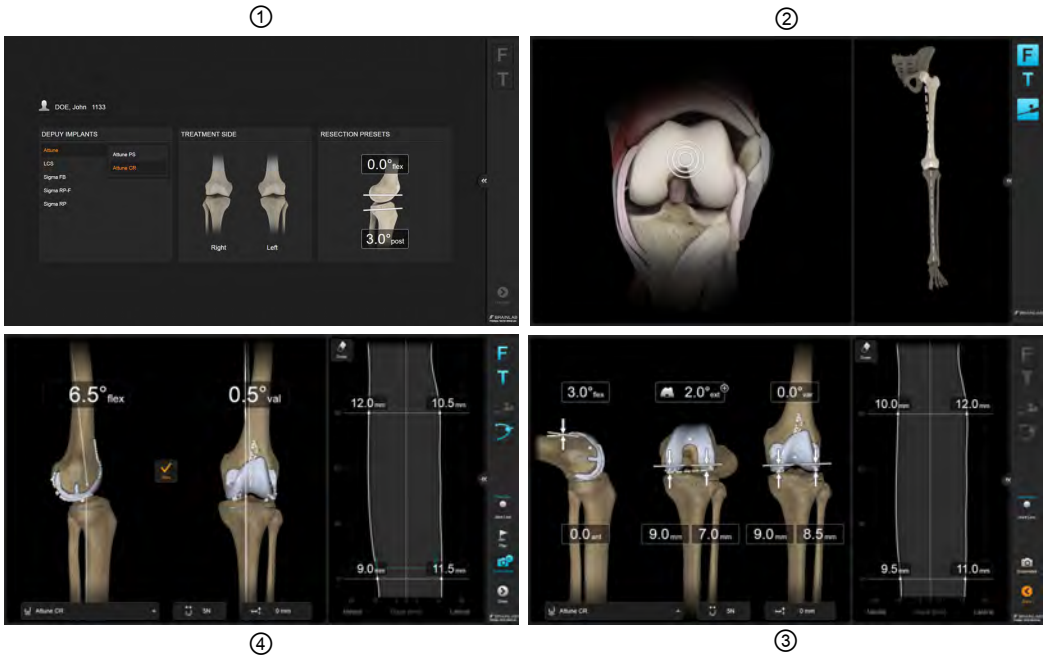


Figure 11

No.	Workflow Step	Explanation
①	Implant and treatment side selection	Select the implant and treatment side, adjusting the resection presets if needed.
②	Registration	Acquire anatomical landmarks on the patient.
③	Navigation	Navigate the femur and tibia resections.
④	Planning (optional)	View and if necessary adjust the proposed resections calculated by the software.

4.3.1 Implants, Treatment Side and Resection Presets

How to Select Implants, Treatment Side and Resection Presets

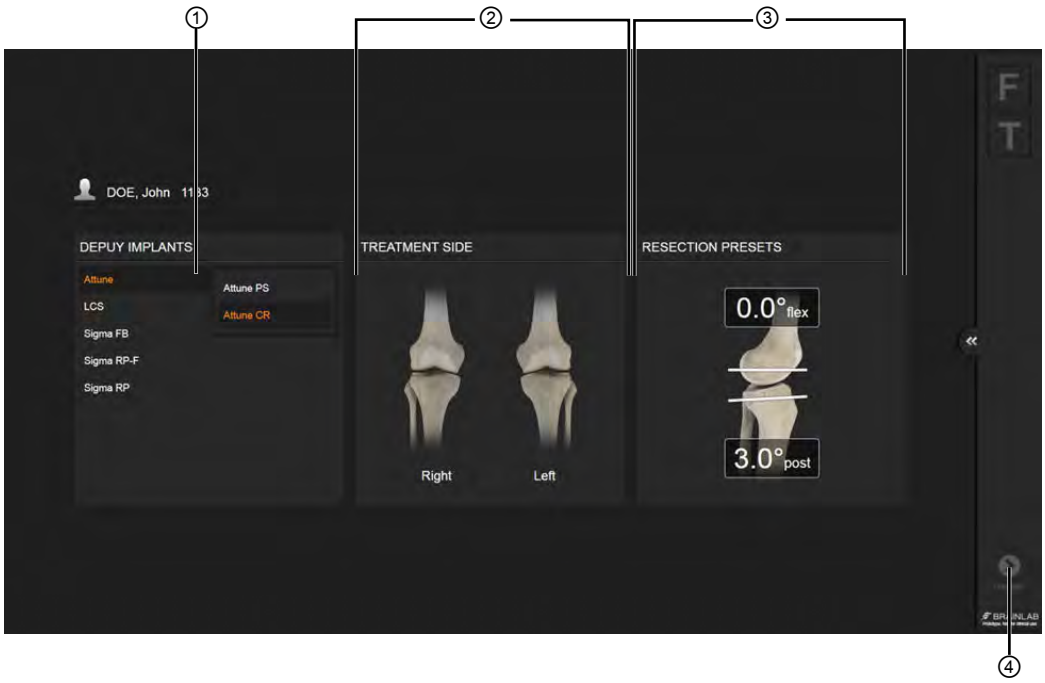


Figure 12

The software prompts you to select the implant manufacturer and implant system.

Steps	
1.	Select an implant ①. A side menu containing implant systems opens.
2.	Select an implant system from the menu ②.
3.	Select **Right** or **Left** ③ from **TREATMENT SIDE** for the knee receiving treatment.
4.	Adjust **RESECTION PRESETS** ③ if needed.
5.	Select **Navigate** ④.

4.3.2 Registration

Registration Steps

You are required to acquire the following landmarks:

Femur Landmarks	Tibia Landmarks
Femur Head Center	Medial and Lateral Malleoli
Distal Femur Axis Point	Proximal Tibial Axis Point
Medial and Lateral Epicondylar Points (Epicondylar Line)	Tibia Anterior-Posterior Direction
Anteroposterior Axis (Whiteside's Line) (optional)	Medial Plateau (optional)
Medial Condyle (optional)	Lateral Plateau (optional)
Lateral Condyle (optional)	
Anterior Cortex	

NOTE: Landmarks marked as optional are not mandatory for the workflow and can be skipped.

For more information regarding registration, see page 83.

NOTE: For Knee3 Motion only: Prior to registration you can reset the user profiles. After starting registration this button disappears.

4.3.3 Navigation

General Information

From the leg alignment view, the software automatically enters the relevant cut navigation step when it detects the **Plane Tool** in its respective cut position.

The following cuts can be navigated:

- Tibia resection
- Distal femur resection
- Anterior femur resection

Navigating to Plan

The colors of the planes indicate the position of the cutting block with reference to the plan.

Figure 13

When the values of the live cut position (blue line) match the planned line (white), the values for the following turn blue:

- Varus angle
- Valgus angle
- Posterior angle
- Anterior slope
- Resection height

Verified cuts turn from blue to yellow.

NOTE: Deviation for resection heights is ±0.5 mm and deviation for angles is ±0.5°.

Line Color	Indication
Blue	Live cut position
White	Planned cut position
Yellow	Verified cut

Navigation Workflow

The software switches between leg alignment and individual resection views depending on the area where the plane tool was recognized by the software.

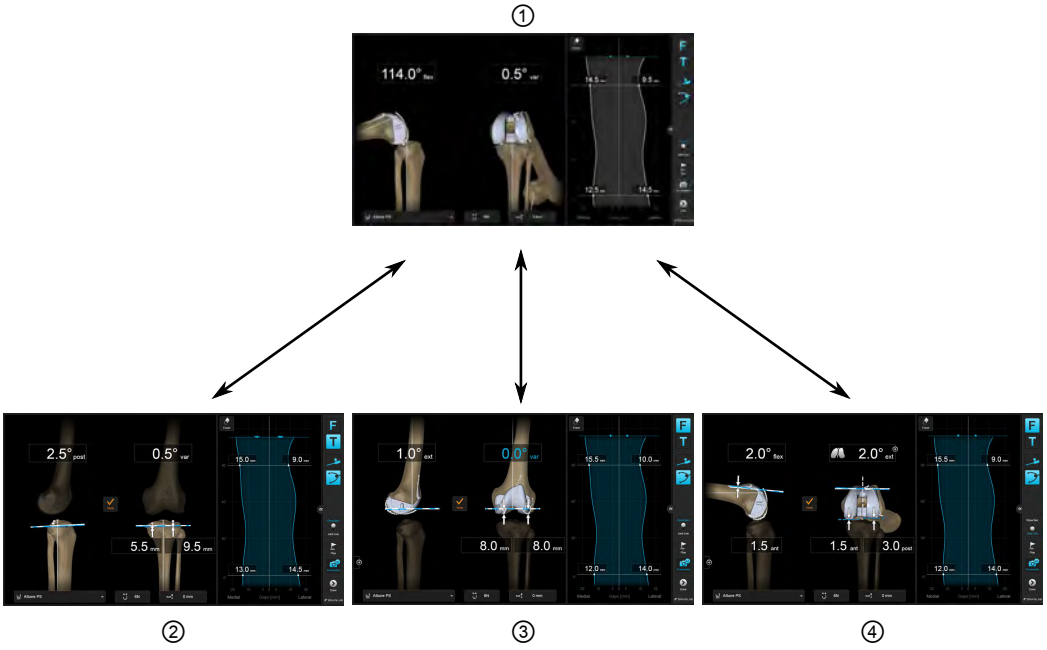


Figure 14

No.	Workflow Steps
①	Leg alignment
②	Tibia resection
③	Distal femur resection
④	Anterior femur resection

Plane Tool Placement

The software detects the relevant cut navigation step based on the position of the **Plane Tool** in relation to the femur and tibia.

The software displays the distal femur, anterior femur or tibia resection screens as soon as the **Plane Tool** is placed into the cutting block for a given resection and when the cutting block is positioned on the respective bone.

There is no predefined order; all cut resections can be entered at any time during the procedure.

When a resection is performed, the actual resection values are verified by placing the **Plane Tool** on the cut surface. The software stores the cut values when the **Plane Tool** is held still for three seconds.

NOTE: When the footswitch is used, the cut values are stored by pressing the blue pedal. Automatic verification is disabled.

Screen Components

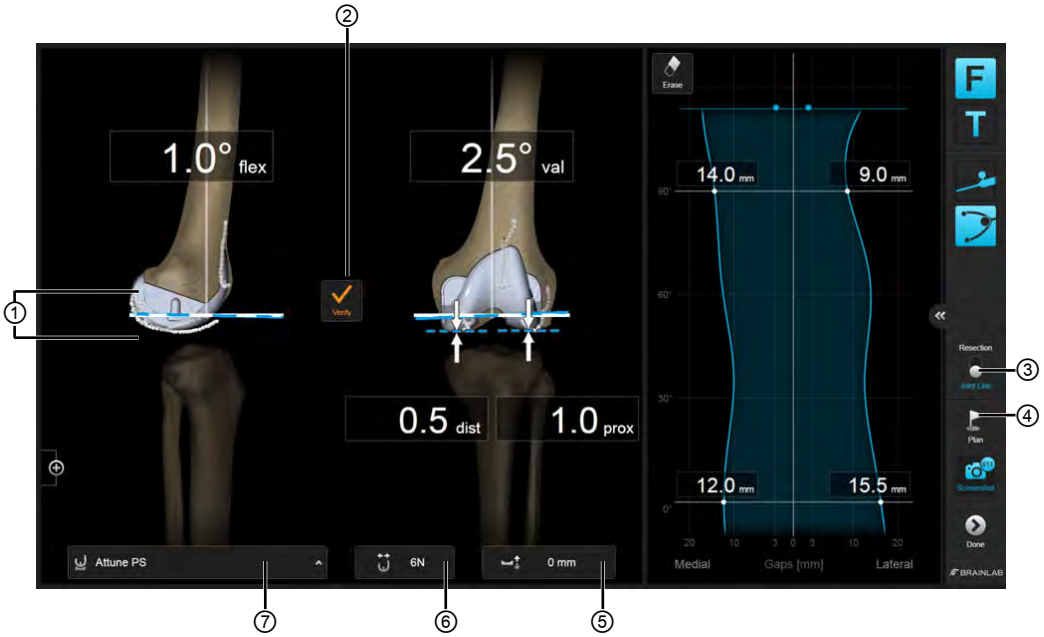


Figure 15

No.	Component	Explanation
①	Cutting block position	• The white line indicates the planned resection plane. • The blue line indicates the live/current cutting block position.
②	Verify	Use **Verify** to confirm new values when parameters are adjusted.
③	Resection/Joint Line Toggle	• **Resection** displays the current resection distance relative to the registered landmarks. • **Joint Line** displays the joint line shift between the registered landmarks and the current implant position.
④	Plan	Toggle between navigation and femur planning.
⑤	Implant selection	Tibia insert thickness
⑥		Femur implant size
⑦		Implant type (e.g., posterior stabilized)

Leg Alignment

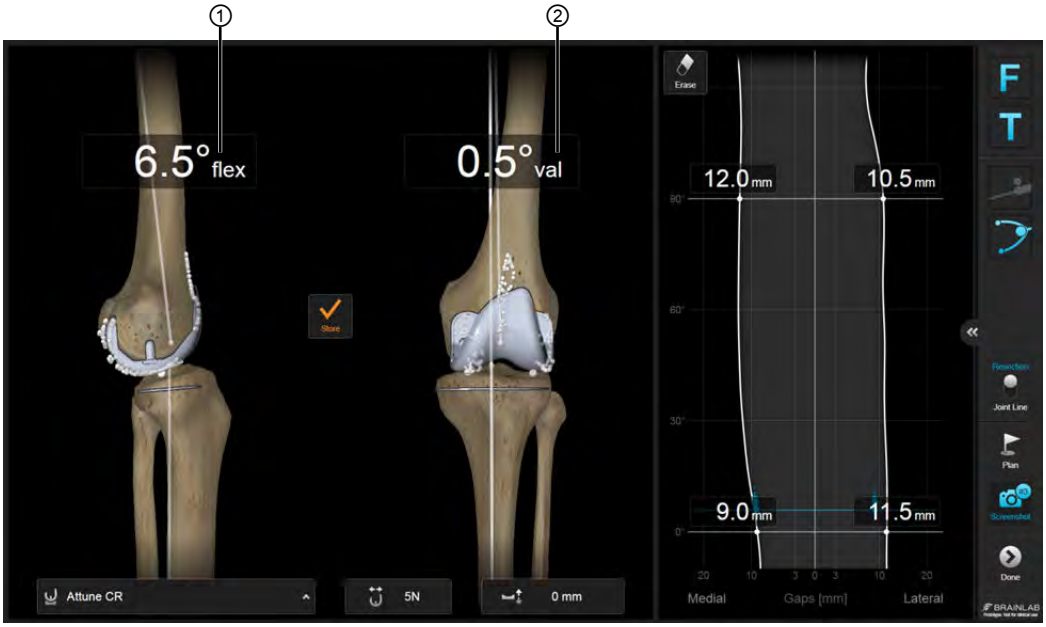


Figure 16

The femur and tibia are visible, leg alignment becomes active.

The flexion and varus/valgus angles are displayed and the joint stability graph can be recorded.

No.	Item
①	Leg flexion angle
②	Varus/valgus angle

Distal Femur Resection

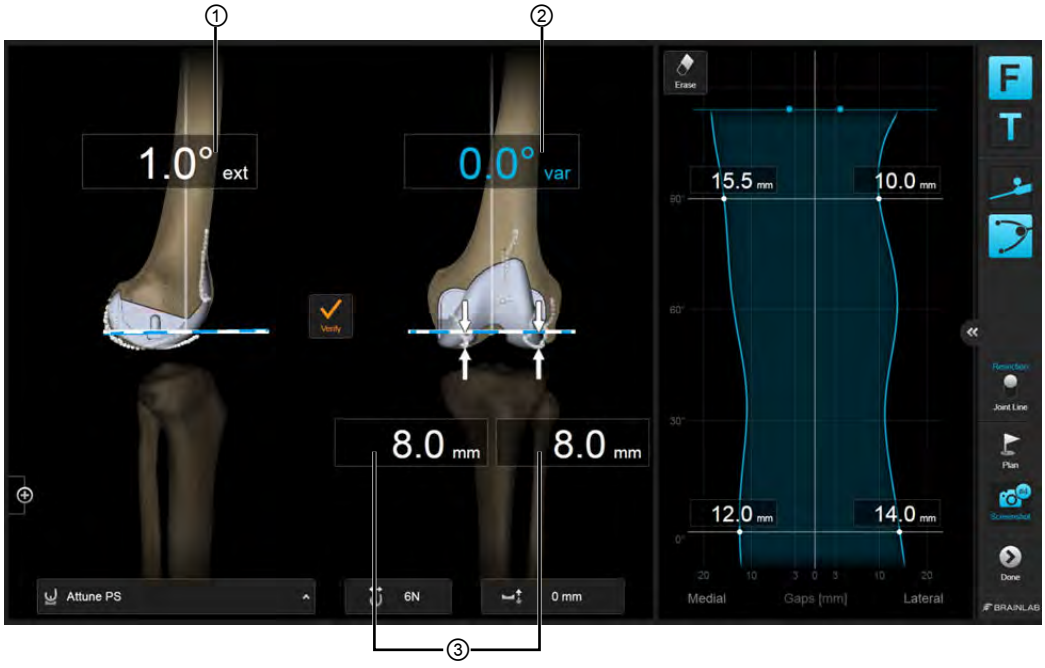


Figure 17

No.	Item
①	Implant flexion angle
②	Implant varus/valgus angle
③	Medial and lateral distal resection height or joint line shift

Anterior Femur Resection

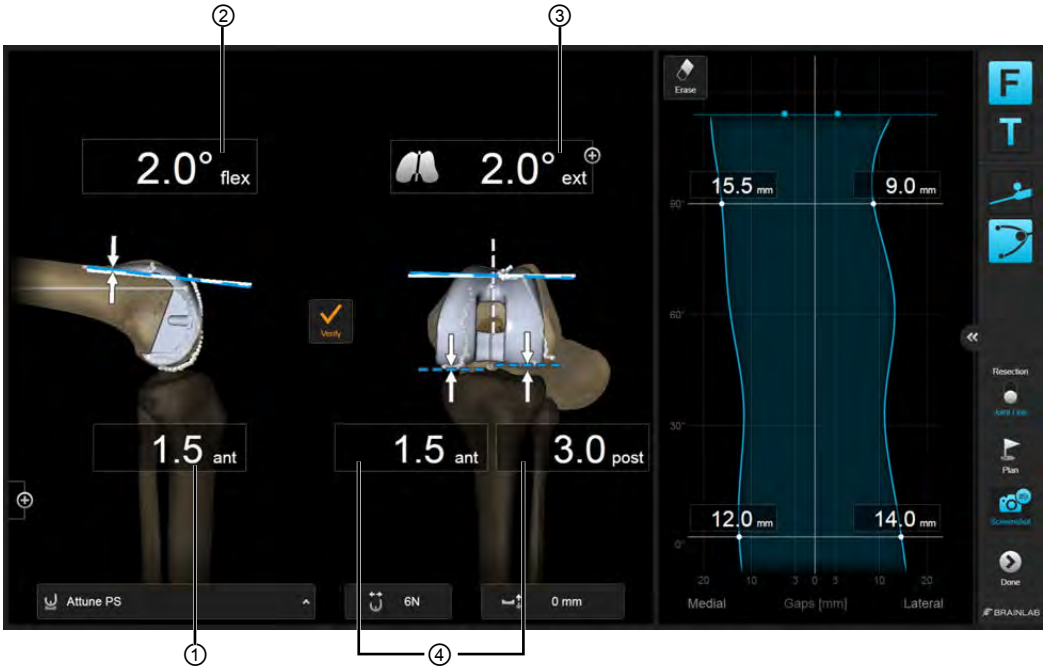


Figure 18

No.	Item
①	Anterior shift of the implant
②	Implant flexion angle
③	Implant rotation angle based on the chosen rotation reference
④	Medial and lateral posterior resection height or joint line shift

Tibia Resection

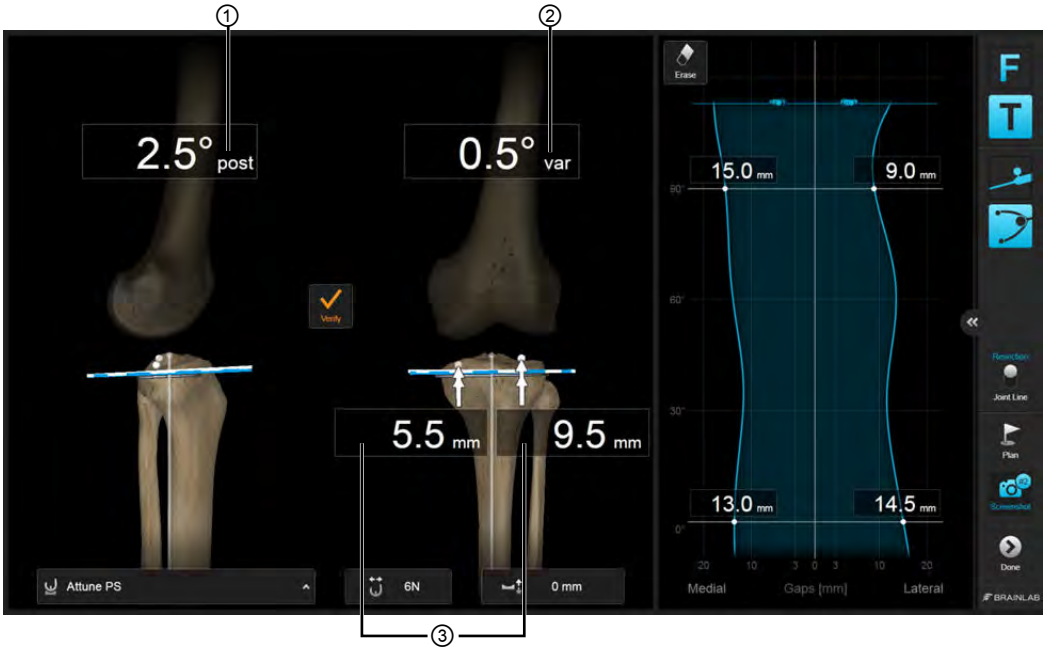


Figure 19

No.	Item
①	Implant slope
②	Implant varus/valgus angle
③	Medial and lateral resection height

How to Verify the Resection

Figure 20

Steps	
1.	Place the **Plane Tool** on the bone cutting surface. The software detects the position and verifies the type of cut from the following: • Distal femur cut • Anterior femur cut • Tibia cut
2.	Hold the **Plane Tool** still for approx. 2 seconds, observing the progress bar. Verification status is indicated by the progress bar. Alternatively, press **Verify** ①, either: • on screen • using the footswitch *NOTE: When the footswitch is used, verification is triggered by the blue pedal.*

After cut verification the white line turns yellow ② (indicating cut verification). Blue values for varus/valgus show that the cut is within the plan ③.

4.3.4 Planning

Planning Screen

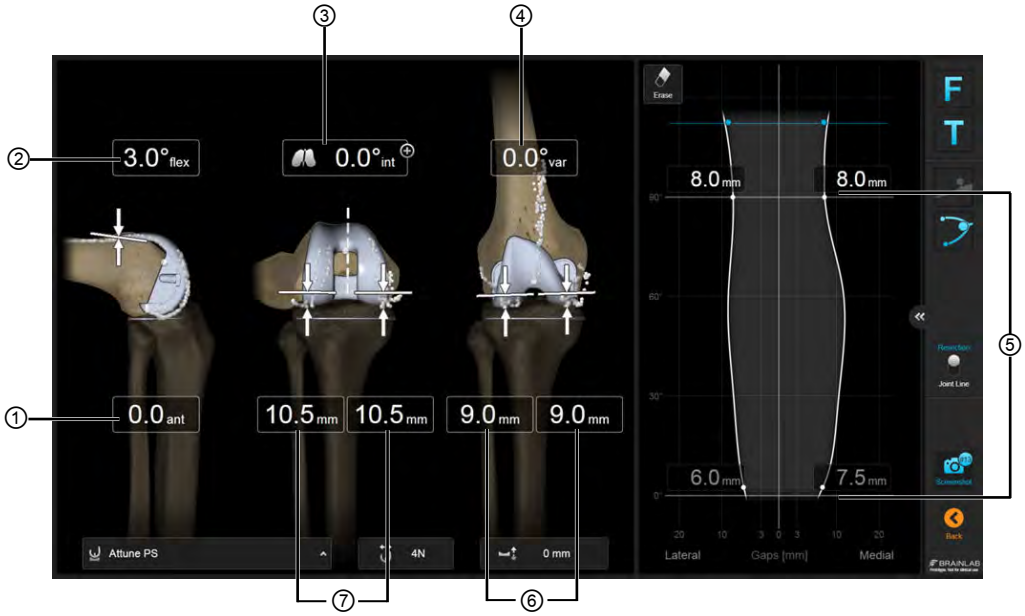


Figure 21

The planning screen enables you to plan femur resections, and if necessary adjust the values proposed by the software.

When resection planes are verified during navigation, the values for the plan and the graph are automatically updated.

No.	Adjustable value
①	Anterior shift
②	Implant flexion angle
③	Implant rotation
④	Implant varus/valgus angle
⑤	Joint stability graph
⑥	Medial and lateral resection/joint line shift
⑦	Medial and lateral posterior resection/joint line shift

How to Adjust Values

Steps		
1.		Select the currently displayed value on the screen. Arrow buttons appear alongside.
2.	Adjust to the desired value.	

NOTE: Value adjustment is optional.

4.3.5 Joint Stability Graph

General Information

The joint stability graph shows two curves for the medial and the lateral gap between the femur and tibia implants over the leg's flexion range.

Planned Cut View Example

Figure 22

The graph only displays valid curves for flexion positions where stress was applied to the medial and lateral soft tissue structure.

Color	Line Description
Blue	Live Navigation
Red	Negative Gaps
White	Planned Values
Yellow	Verified Cuts

Live Navigation View Example

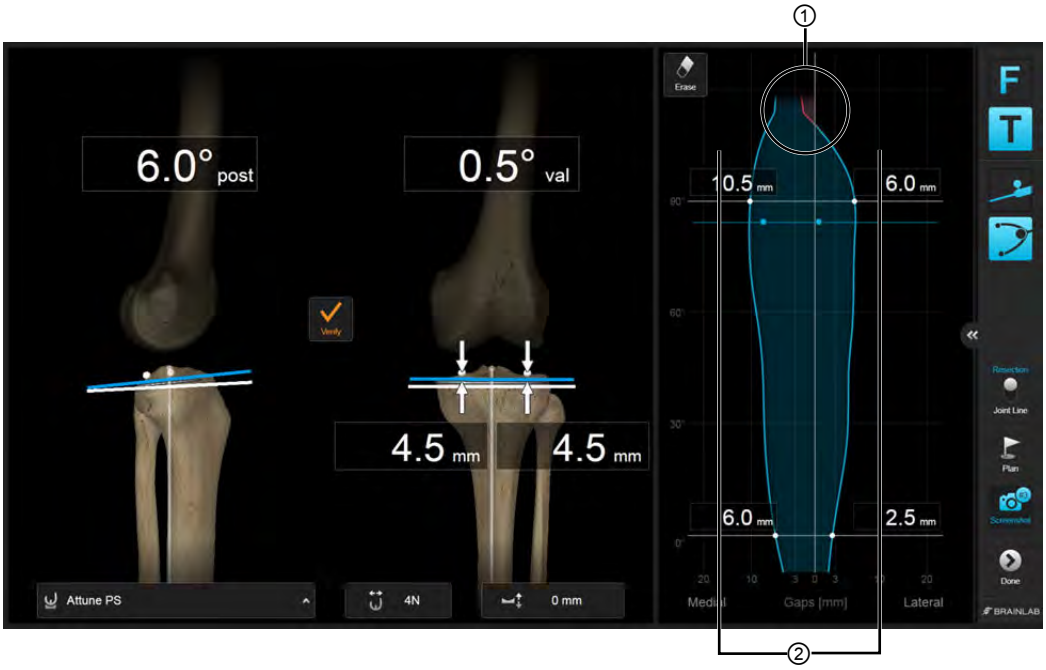


Figure 23

The blue marked area ① displays live real-time values, the red area ② indicates that the gap is too tight.

Verified Cut View Example

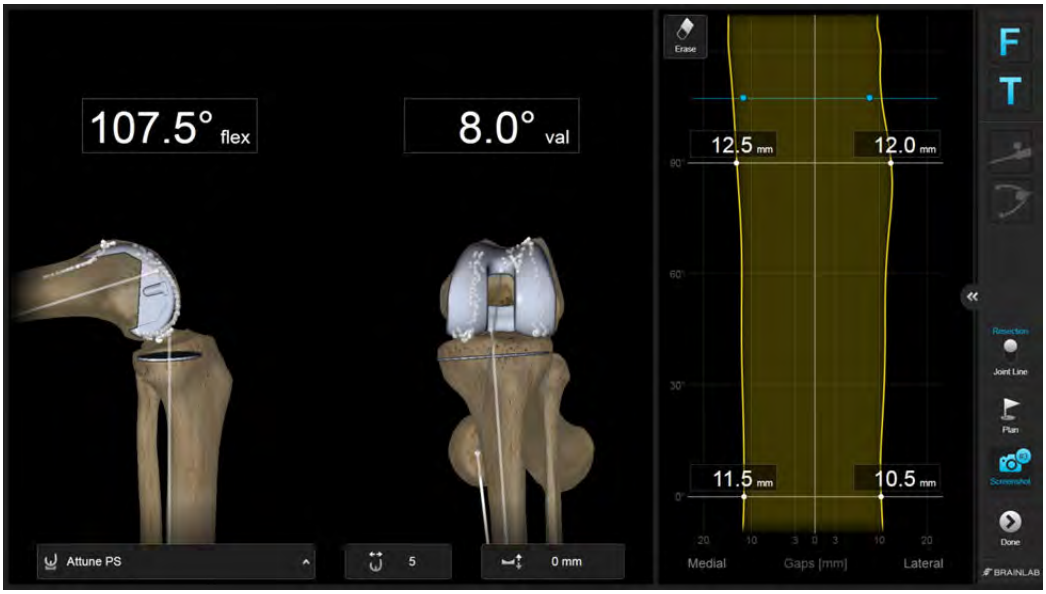


Figure 24

The yellow marked area indicates that all cuts have been verified.

Joint Stability Data Acquisition

The joint stability graph shows the maximum available gap range. It is therefore necessary to extend the medial and lateral tendons. This is done by using an injoint spreader or by applying

medial and lateral stress. When the ligament situation changes, e.g., by performing the tibia cut or ligament releases, the acquisition must be updated for the flexion ranges which are dependent on ligament change.

Be aware that the joint stability data is continuously and automatically recorded.

How to Delete Recorded Data

Step	
	Press **Erase** to delete all recorded joint stability data. *NOTE: **Erase** is not available for every surgical step.* *NOTE: Recording restarts again automatically.*

Implant Position Adjustment and Cut Verification

The implant position influences the joint stability graph. Any adjustment results in an immediate update of the graph. Use the **Plane Tool** to navigate cuts, place implants or use the **Plan** page to adapt the plan.

Verifying the cuts with the Plane Tool synchronizes the performed cuts with the software.

4.3.6 Research and Recording

General Information

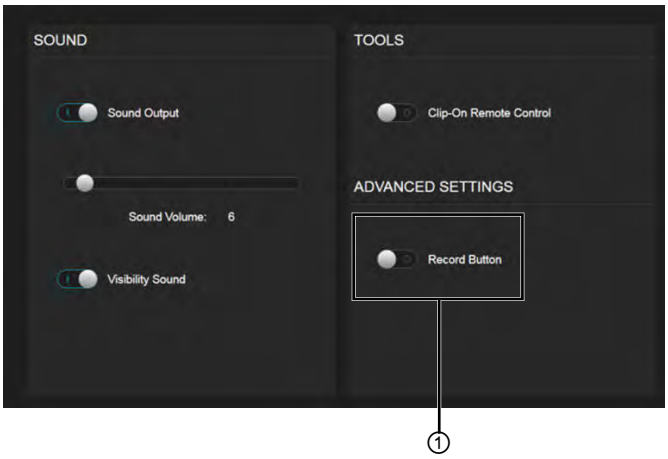


Figure 25

By activating **Record Button** ① from **Settings**, the user can record live leg alignment and gap values for later studies or research purposes. The recorded values are then attached to the case report (e.g., ResearchData_ROMRecording.raw1).

A number traces the number of recordings the user has made.

How to Record

Figure 26

A record button is displayed in the leg alignment view, once activated.

Step	
	Press **Record** to commence recording, press again to stop.

Research Data

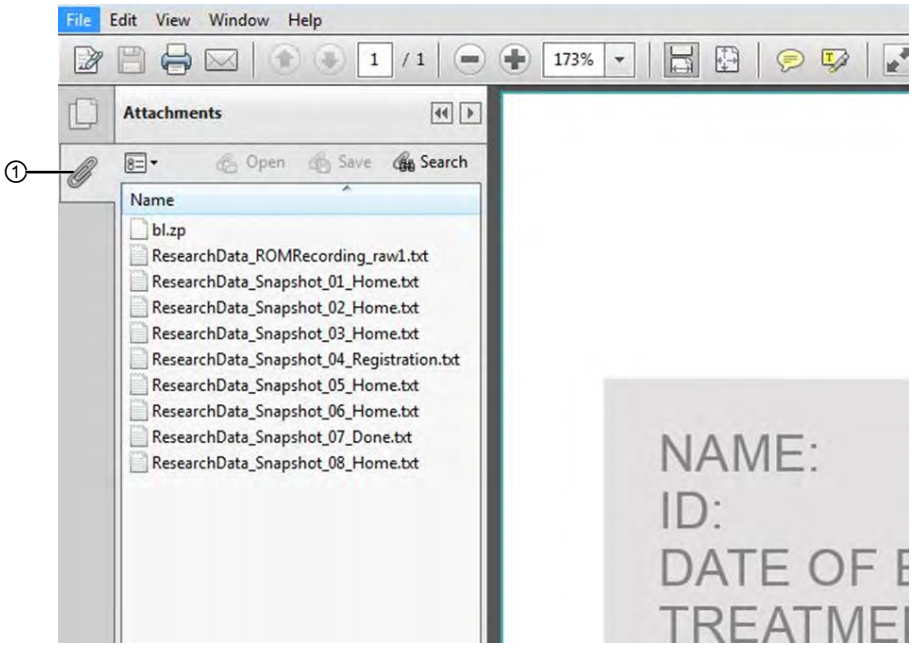


Figure 27

The recorded research data is attached to the case report. Pressing the paper clip ① in the pdf opens all attachments.

4.4 Knee3 Universal

General Information

Knee3 Universal can be used with implants that are not integrated into the database.
You can navigate:

- the distal femur resection
- the rotational alignment of the femoral implant
- the tibial resection

NOTE: As no implant data is used, the software cannot calculate the joint stability graph.

Software Workflow

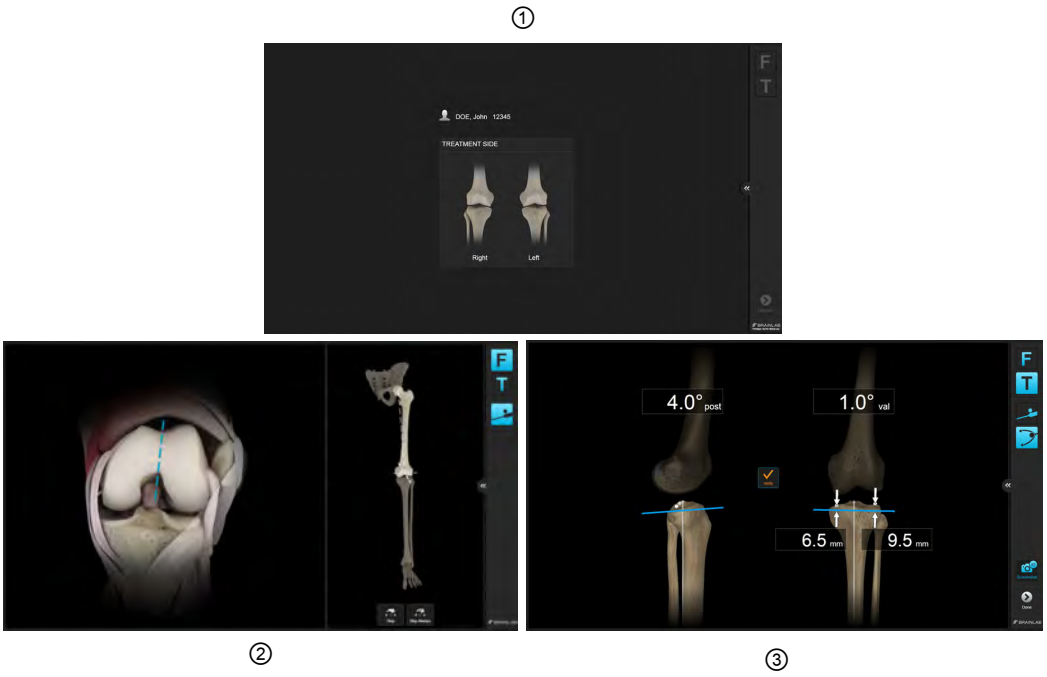


Figure 28

No.	Workflow Step	Explanation
①	Treatment side selection	Select the treatment side.
②	Registration	Acquire anatomical landmarks on the patient.
③	Navigation	Navigate the femur and tibia resections.

4.4.1 Treatment Side Selection

How to Select the Treatment Side

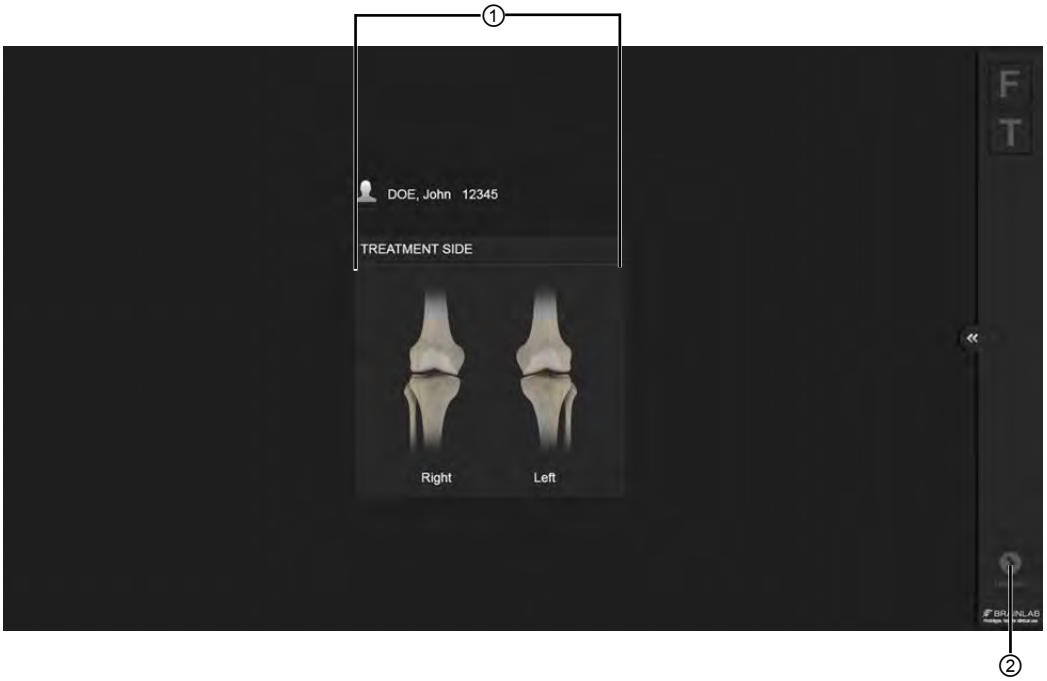


Figure 29

Steps	
1.	Select **Right** or **Left** ① for the knee receiving treatment.
2.	Select **Navigate** ②.

4.4.2 Registration

Landmarks Requiring Registration

You are required to acquire the following landmarks:

Femur Landmarks	Tibia Landmarks
Femur Head Center	Medial and Lateral Malleoli
Distal Femur Axis Point	Proximal Tibial Axis Point
Medial and Lateral Epicondylar Points (Epicondylar Line)	Tibia Anterior-Posterior Direction
Anteroposterior Axis (Whiteside's Line) (optional)	Medial Plateau (optional)
Medial Condyles (optional)	Lateral Plateau (optional)
Lateral Condyles (optional)	

For more information regarding registration, see page 83.

4.4.3 Navigation

General Information

From the leg alignment view, the software automatically enters the relevant cut navigation step when it detects the **Plane Tool** in its respective cut position.

The following cuts can be navigated:

- Tibia resection
- Distal femur resection
- Anterior femur resection

Navigation Workflow

You can switch between leg alignment and individual resection views.

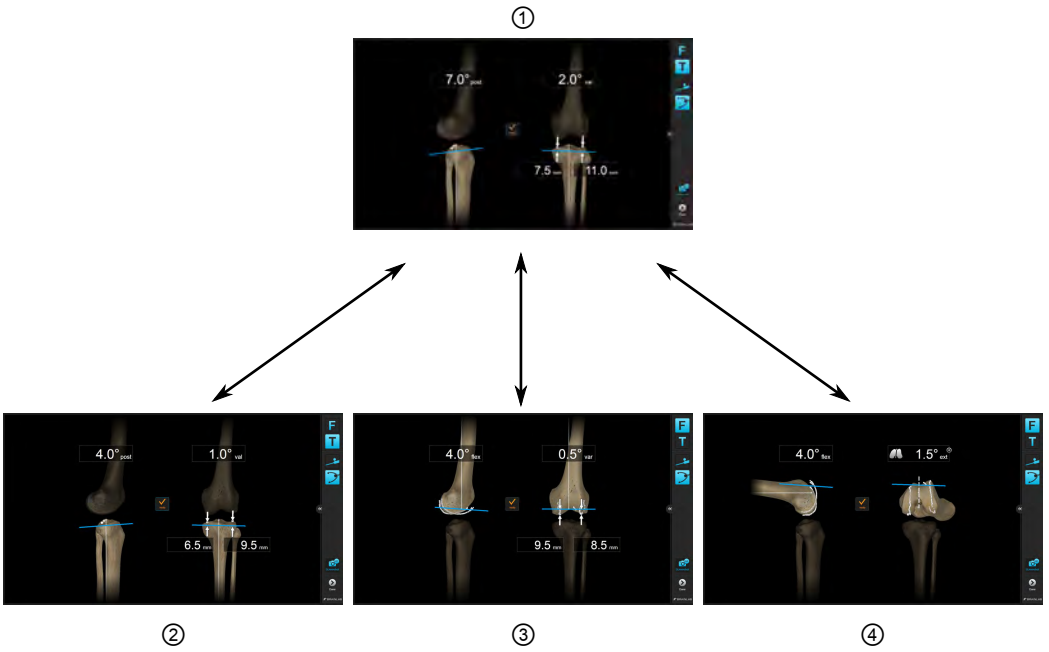


Figure 30

No.	Workflow Steps
①	Leg alignment
②	Tibia resection
③	Distal femur resection
④	Anterior femur resection

Leg Alignment

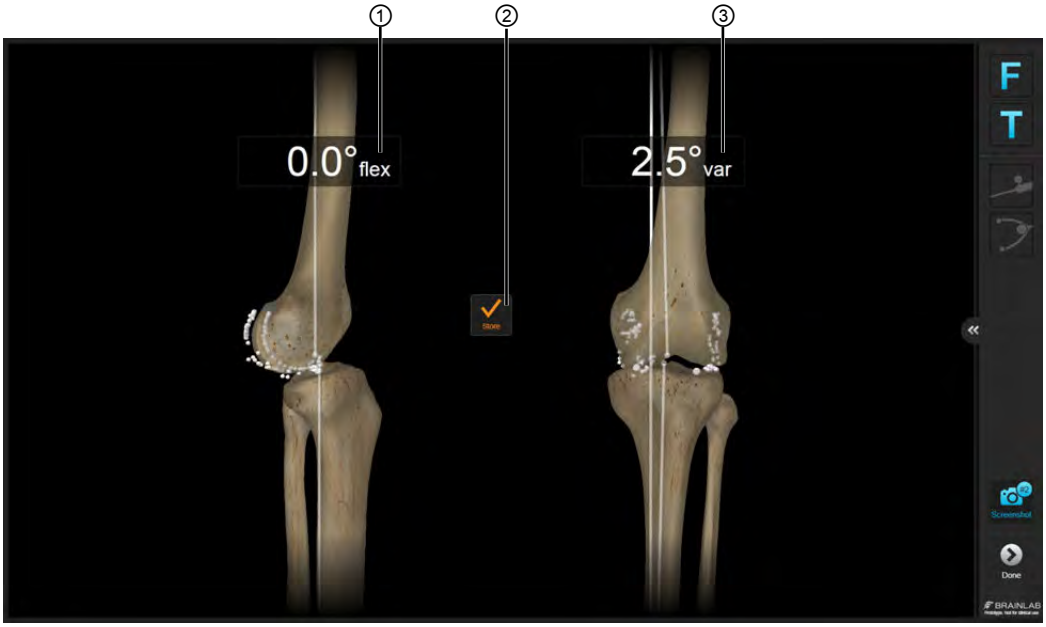


Figure 31

If the Y- and T-reference arrays are visible, the leg alignment view becomes active.
The flexion and varus/valgus angles are displayed.

No.	Item
①	Leg flexion angle
②	Varus/valgus angle
③	Store button for saving initial/final leg alignment

Distal Femur Resection

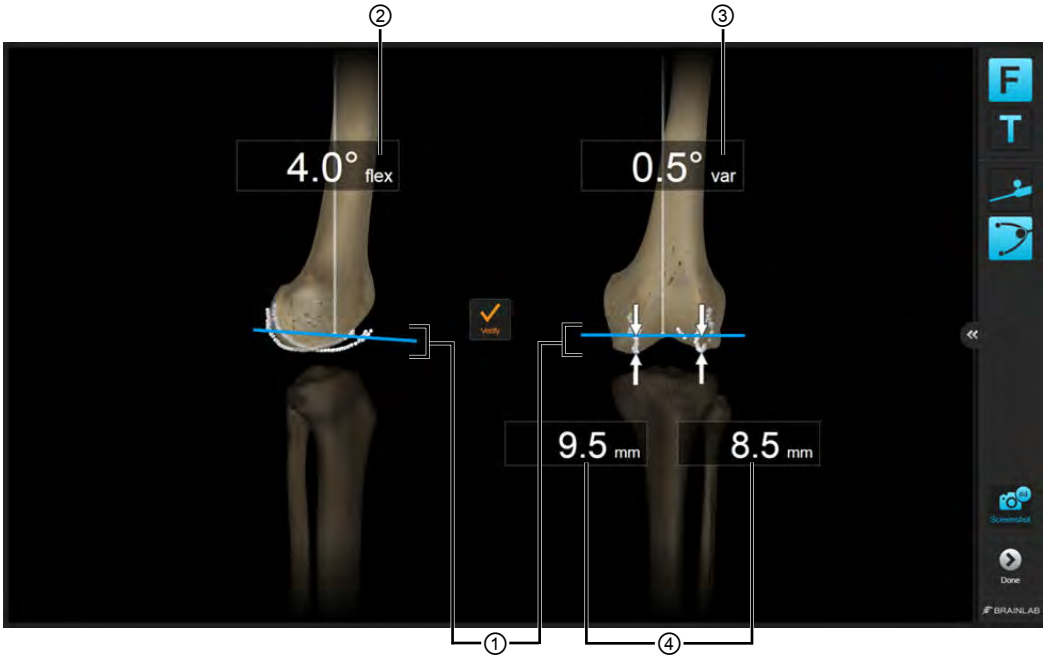


Figure 32

No.	Item
①	Cutting block position
②	Implant flexion angle
③	Implant varus/valgus angle
④	Medial and lateral distal resection height

Anterior Femur Resection

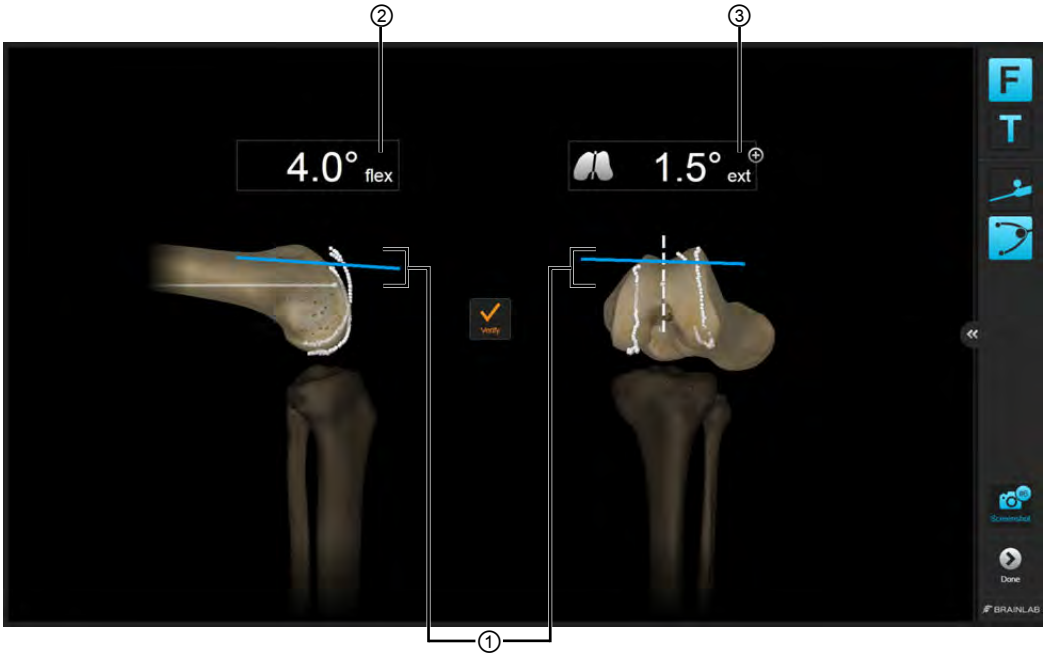


Figure 33

No.	Item
①	Cutting block position
②	Implant flexion angle
③	Implant rotation angle of the chosen rotation reference

Tibia Resection

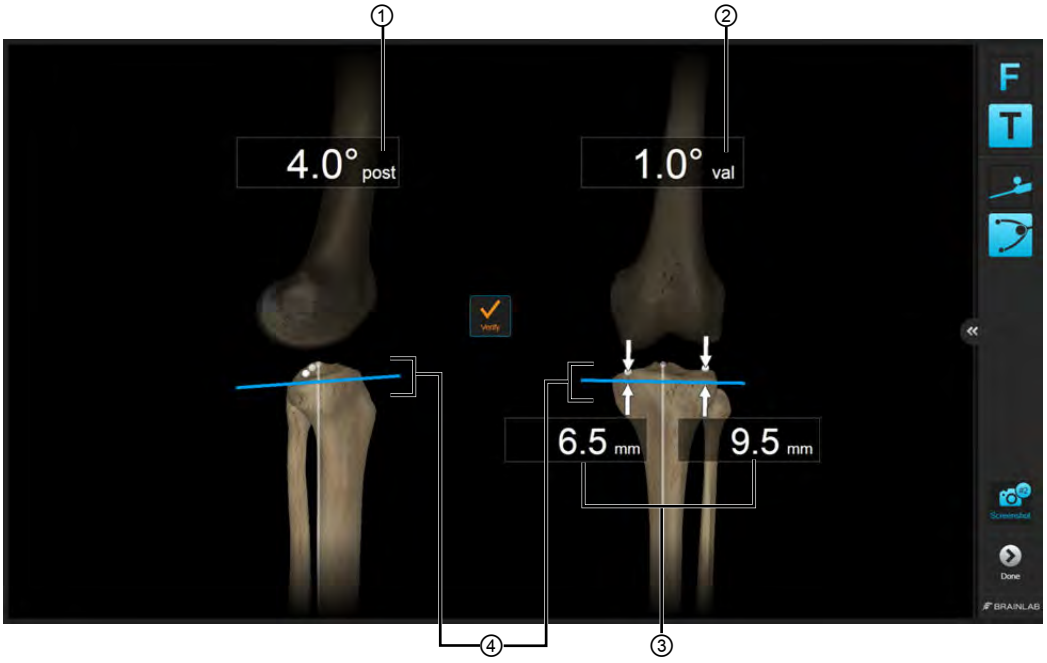


Figure 34

No.	Item
①	Implant slope
②	Implant varus/valgus angle
③	Medial and lateral resection height
④	Cutting Block position

4.5 Knee3 Express

General Information

Knee3 Express allows you to measure the position of the tibia and distal femoral cutting blocks and the resections relative to the tibial and femoral mechanical axis.

Knee3 Express is a pinless workflow, using the **Knee Plane Tool** on its own or combined with a cutting block as a reference. As the software works without fixed references it is intended as a static measurement tool. The measured values are displayed immediately after registration and become invalid if the **Knee Plane Tool** or cutting block position changes in relation to the bone. The measurements provided by the alignment verification depend on accurate landmark registration and minimal movement of the **Knee Plane Tool** relative to the cutting block and bone.

Knee3 Express also allows live navigation of the tibia or femur, so you can adapt the navigation to your preferences, e.g., you can fully navigate the femur but only check your tibia cut or vice versa.

Do not use or rely on the measurement information when the clinical situation has changed or after an extended period of time. To assess accuracy of the measurement re-registration is required. Repeat registration if accuracy is in doubt.

Workflow

Required Instruments for the **Knee3 Express** workflow:

- Knee Plane Tool
- Pointer

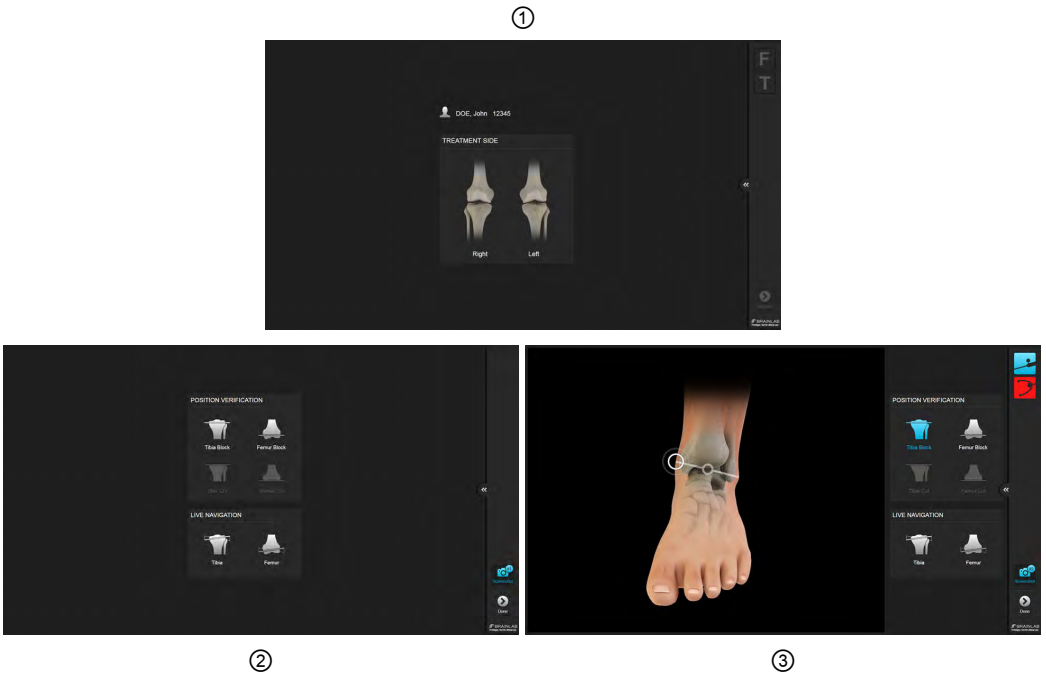


Figure 35

No.	Workflow Step	Explanation
①	Treatment side selection	Select the treatment side.
②	Start Navigation	Choose between: • Measuring the cutting block position • Live Navigation

No.	Workflow Step	Explanation
③	Registration and Measurement/ Navigation	Acquire anatomical landmarks on the patient or navigate the femur and tibia resections.

4.5.1 Treatment Side Selection

How to Select the Treatment Side

Figure 36

The software first prompts you to select the treatment side.

Steps	
1.	Select **Right** or **Left** ① for the knee receiving treatment.
2.	Select **Navigate** ②.

How to Select the Navigation Type

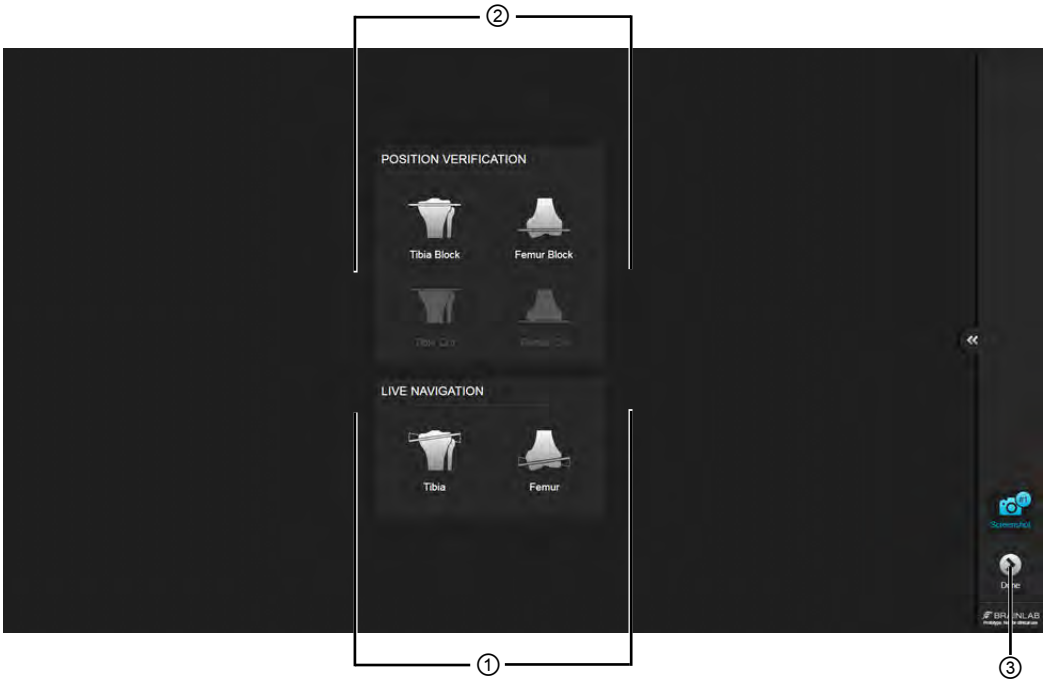


Figure 37

Choose whether to measure the cutting block position or perform live navigation.

Steps	
1.	Select either: • Select **Tibia** or **Femur** in **LIVE NAVIGATION** ① or; • Your cutting block positioning step from **POSITION VERIFICATION** ②.
2.	Select **Done** ③.

4.5.2 Registration

Registration Steps

You are required to acquire the following landmarks:

Femur	Tibia
Femur Block: • Femur Head Center • Distal Femur Axis Point • Anteroposterior Axis (Whiteside Line) or Epicondylar Line (medial and lateral Epicondyle)	Tibia Block: • Medial and lateral Malleoli • Proximal Tibia axis point • Tibial A-P direction
Femur Cut: • Bone Verification Plate • Femoral Head Center	Tibia Cut: • Bone Verification Plate • Medial and lateral Malleoli
Femur Live Navigation: • Femur Head Center • Distal Femur Axis Point • Anteroposterior Axis (Whiteside Line) or Epicondylar Line (medial and lateral Epicondyle) • Medial Distal Condyle • Lateral Distal Condyle	Tibia Live Navigation: • Medial and lateral Malleoli • Proximal Tibia axis point • Tibia A-P direction • Medial Plateau • Lateral Plateau

For more information regarding registration, see page 83.

4.5.3 Navigation

General Information

Use the **Plane Tool** on its own or combined with a cutting block as a reference to measure the position of the tibia and distal femoral cutting blocks and the resections relative to the tibial and femoral mechanical axis.

The software works without fixed references and is intended as a static measurement tool.

You can also perform live navigation of the tibia or femur, so you can adapt the navigation to your preference.

The following cuts can be navigated:

- Tibia resection
- Distal femur resection

Cutting Block Positioning

Choose your cutting block position ①, **Tibia Block** or **Femur Block** from **POSITION VERIFICATION** depending on your procedure.

Figure 38

Plane Tool Placement

Position the **Knee Plane Tool** in the cutting block and start registration (see page 83).

*NOTE: The software displays the tibia or femur resection screens as soon as the **Plane Tool** is placed into the cutting block and when the cutting block is positioned on the respective bone.*

Register Points

Figure 39

Registration restarts as soon the **Knee Plane Tool** has moved.

Step
Place the **Knee Plane Tool** laterally in the cutting block so that you can still register directions and mechanical axis points.

NOTE: After registration the software gives you the measurements for the current cutting block position.

4.5.4 Block Position Verification

Tibia Block Position Verification

Figure 40

No.	Item
①	Implant slope
②	Implant varus/valgus angle

Tibia Block Position Verification using a Pointer

Figure 41

You can check the resection height with a pointer ③.

No.	Item
①	Implant slope
②	Implant varus/valgus angle
③	Resection height check

Femur Block Position Verification

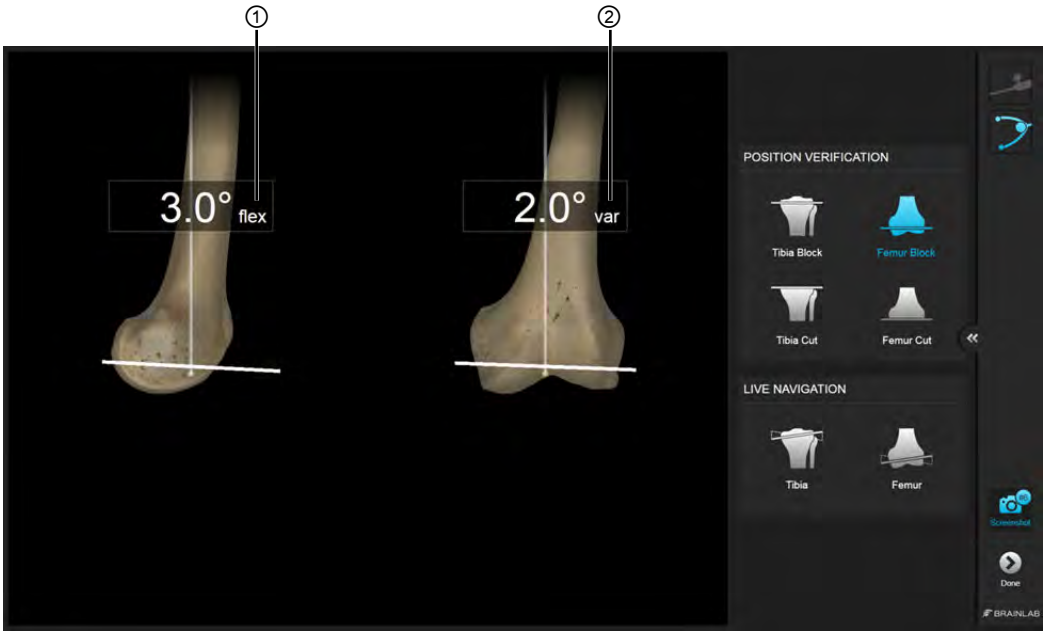


Figure 42

No.	Item
①	Implant flexion angle
②	Implant varus/valgus angle

Femur Block Position Verification Using a Pointer

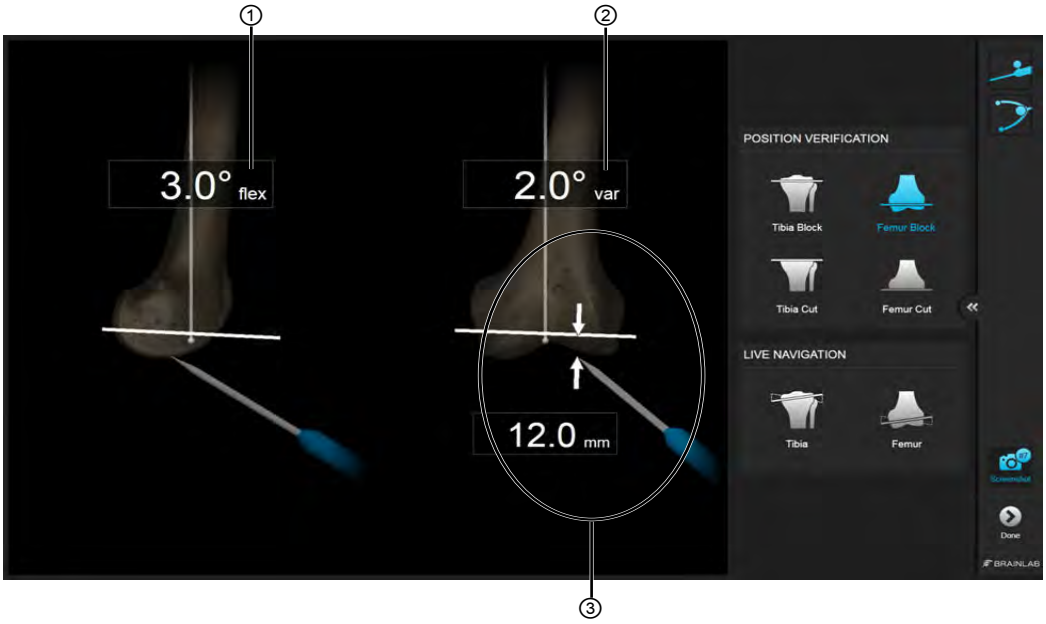


Figure 43

No.	Item
①	Implant flexion angle
②	Implant varus/valgus angle
③	Resection height check

4.5.5 Cut Verification

How to Verify a Tibia Cut

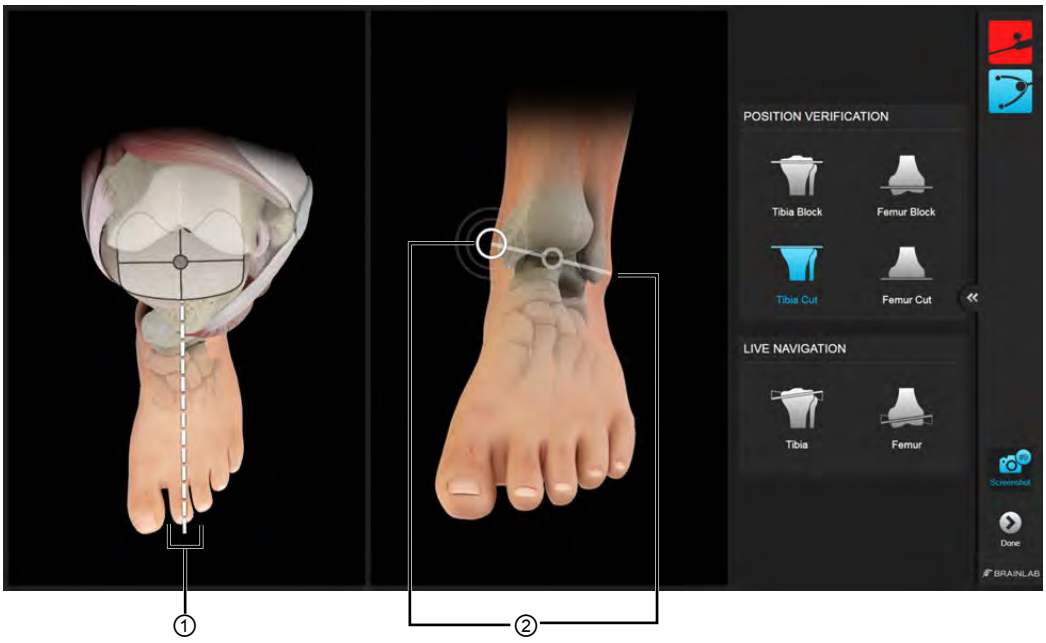


Figure 44

For cut verification you need to change the **Knee Plane Tool Cutting Block Adapter** with the **Knee Plane Tool Verification Plate**.

Verification starts with registration using the **Knee Plane Tool**.

Steps	
1.	 Select the cut you want to verify from **POSITION VERIFICATION**, e.g., **Tibia Cut**.
2.	Place the **Knee Plane Tool Verification Plate** on the cut surface, aligning it with : • The A-P direction ① and; • The hole on the mechanical axis point
3.	Register the malleoli points ② as prompted on screen.

Verification Values

Figure 45

The verification values are displayed following registration.

How to Verify a Femur Cut

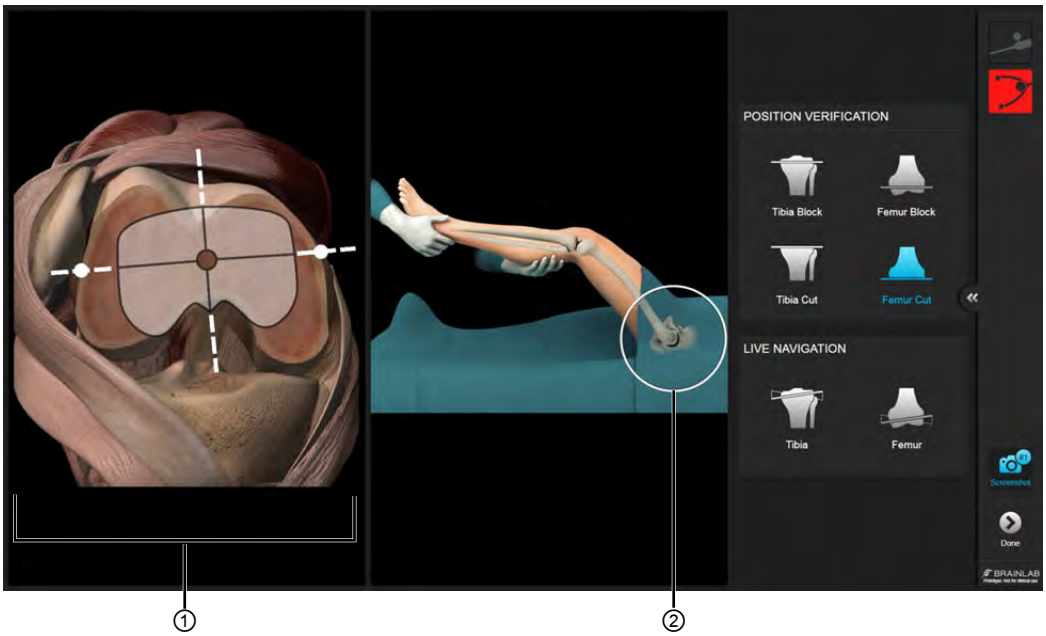


Figure 46

Steps		
1.		Select **Femur Cut** from **POSITION VERIFICATION**.

Steps	
2.	Place the **Knee Plane Tool**as shown ①. The software automatically registers the axis endpoint and defines the A-P direction.
3.	Pivot the hip to register the center of rotation ②, without moving the plane tool.

Verification Values

Figure 47

The verification values are displayed following registration.

Live Navigation

Knee3 Express gives you also the opportunity to switch to live navigation for navigating the tibia or femur block. If you want to use live navigation you need a fixed reference array on the part of the knee you want to navigate.

How to Use Live Navigation

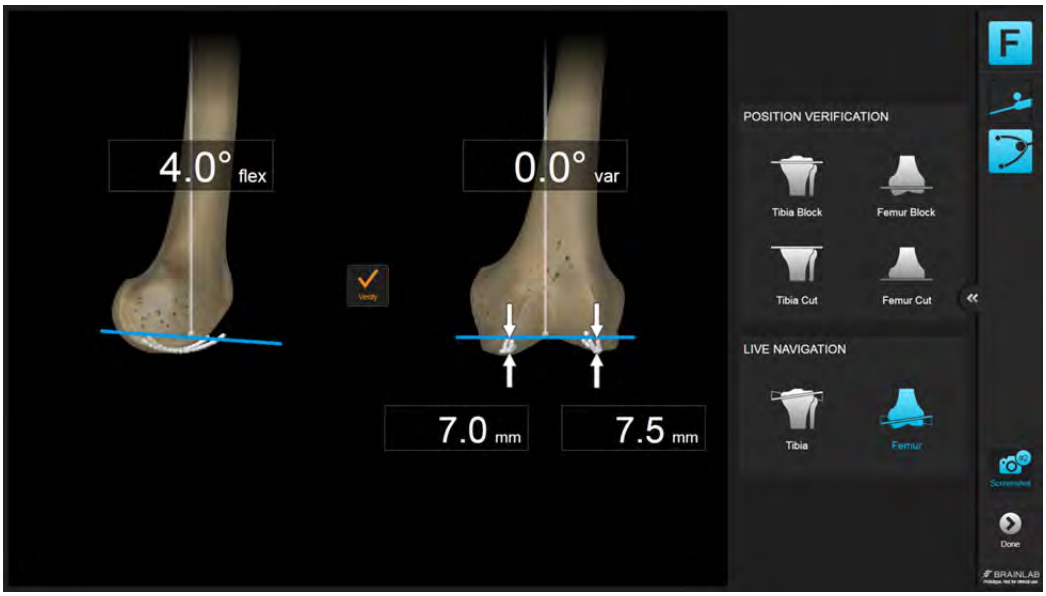


Figure 48

Steps	
1.	Choose **Tibia** or **Femur** from **LIVE NAVIGATION**.
2.	Start full registration, see page 83.
3.	Navigate the cutting block.
4.	Verify the cut.

4.6 Knee3 Partial

General Information

Knee3 Partial provides the surgeon with positioning information for the following during unicondylar knee replacements:

- Proximal tibia cut
- Distal femur cut
- Limb axis alignment

Workflow

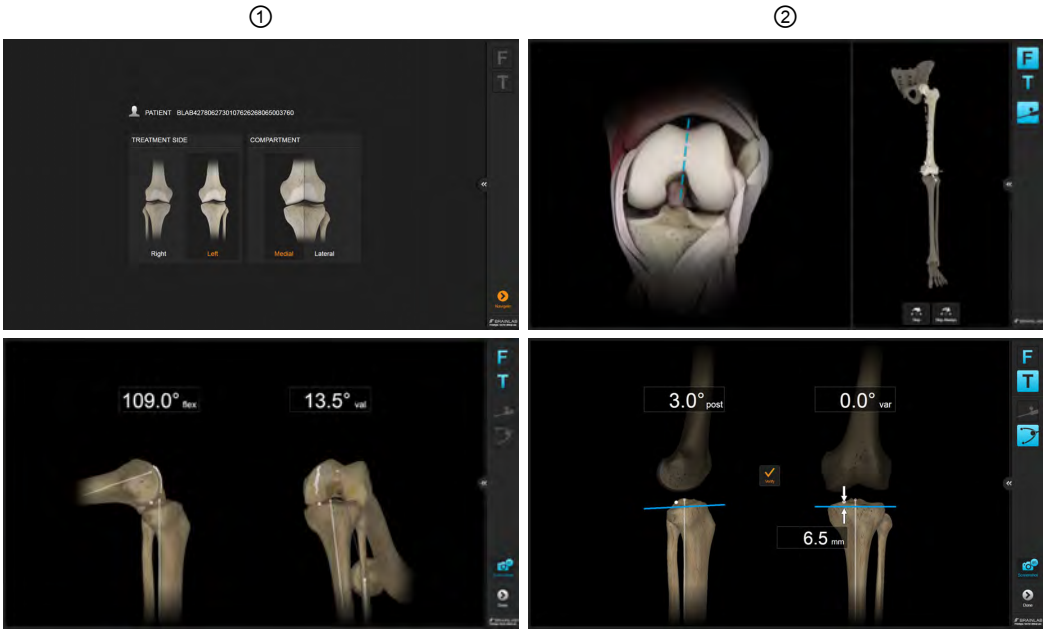


Figure 49

No.	Workflow Step	Explanation
①	Treatment side selection and Compartment	Select the treatment side and the treated compartment.
②	Start Registration	Acquire anatomical landmarks on the patient.
③	Leg Alignment/ Start Navigation	Navigate the femur and tibia resections.
④	Navigation	

4.6.1 Treatment Side Selection

How to Select the Treatment Side and Compartment

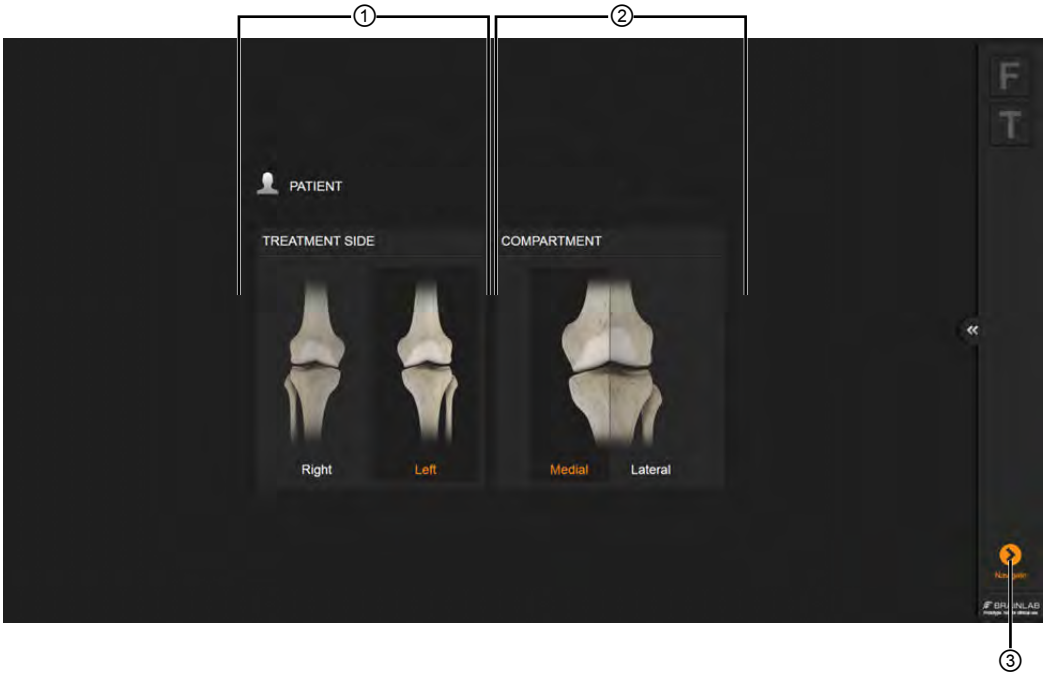


Figure 50

The software first prompts you to select the treatment side.

Steps	
1.	Select **Right** or **Left** ① for the knee receiving treatment.
2.	Select **Medial** or **Lateral** for **COMPARTMENT** ②.
3.	Select **Navigate** ③.

4.6.2 Registration

Registration Steps

You are required to acquire the following landmarks.

Femur	Tibia
• Femur Head Center • Distal Femur Axis Point • Anteroposterior Axis (Whiteside Line) or Epicondylar Line (medial and lateral Epicondyle) • Selected Distal Condyle (optional)	• Medial and Lateral Malleoli • Proximal Tibia Axis Point • Tibial A-P direction • Selected Tibia Plateau Point (optional)

For more information regarding registration, see page 83.

4.6.3 Navigation

General Information

From the leg alignment view, the software automatically enters the relevant cut navigation step when it detects the **Plane Tool** in its respective cut position.

The following cuts can be navigated:

- Tibia resection
- Distal femur resection

Position Verification

You can switch between the leg alignment and individual resection views.

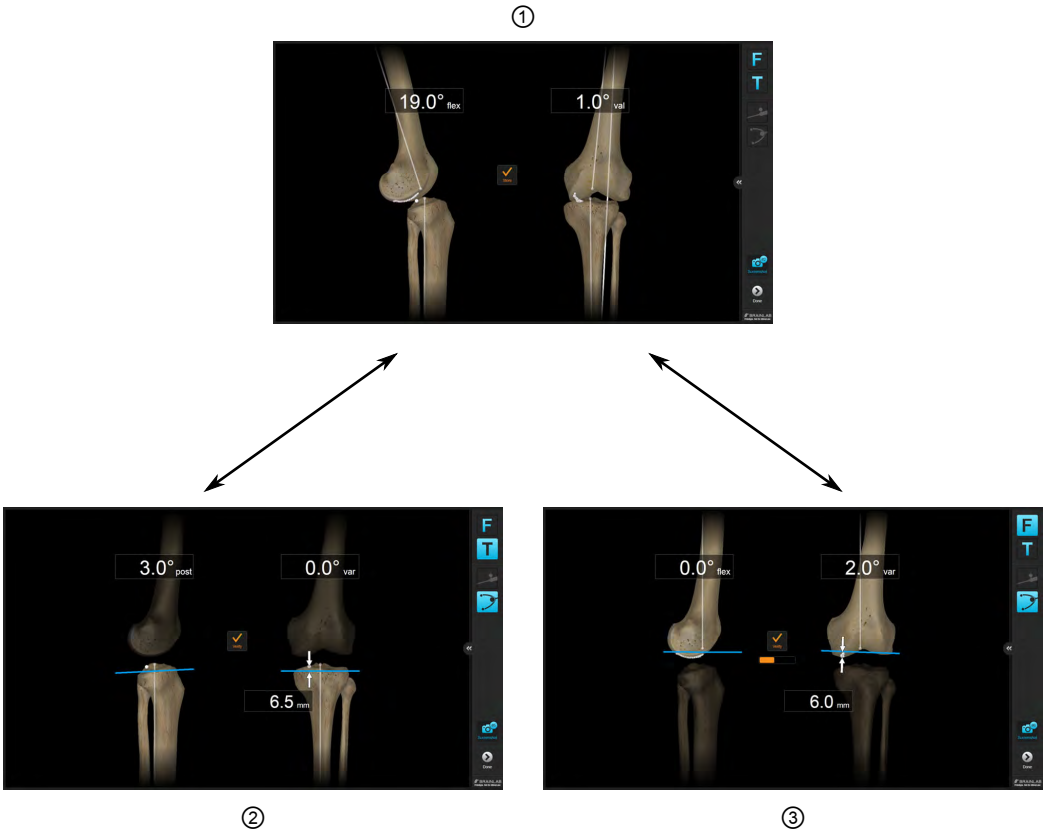


Figure 51

No.	Workflow Steps
①	Leg alignment
②	Tibia resection
③	Distal femur resection

Leg Alignment

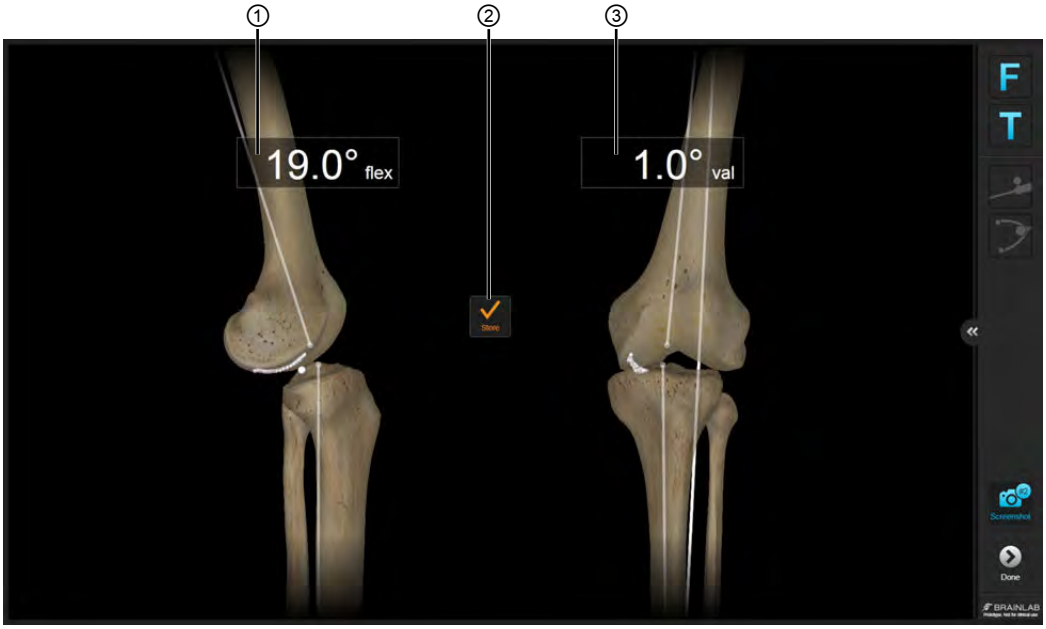


Figure 52

The femur and tibia are visible, leg alignment becomes active.

No.	Item
①	Leg flexion angle
②	**Verify**, used for saving initial/final leg alignment
③	Varus/valgus angle

Tibia Cut

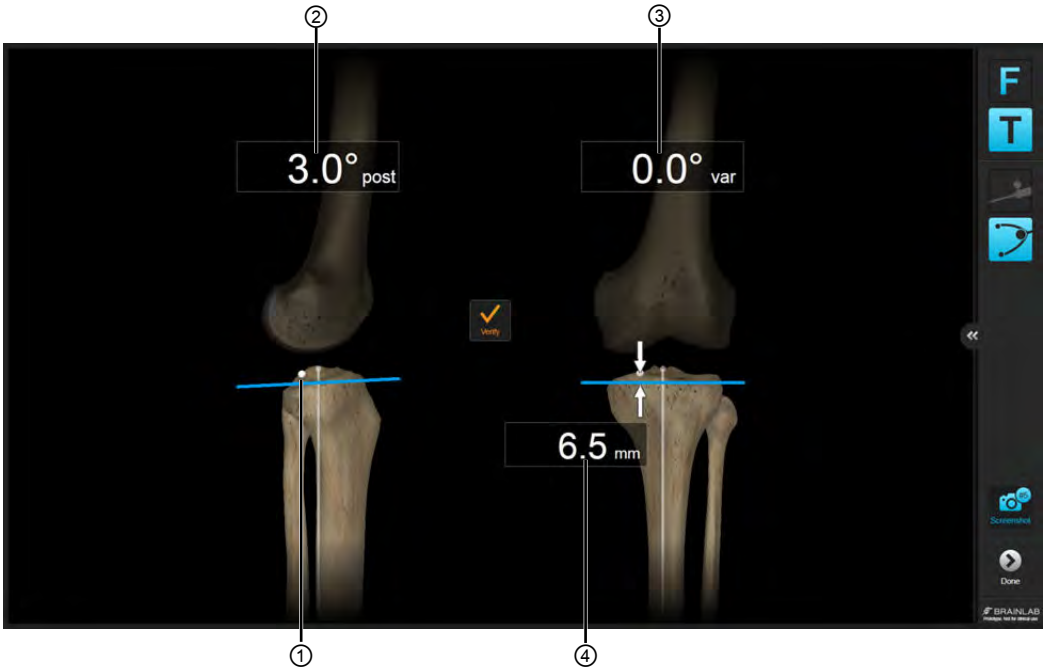


Figure 53

No.	Item
①	Cutting block position
②	Implant slope
③	Implant varus/valgus angle
④	Resection height for the selected compartment

Distal Femur Cut

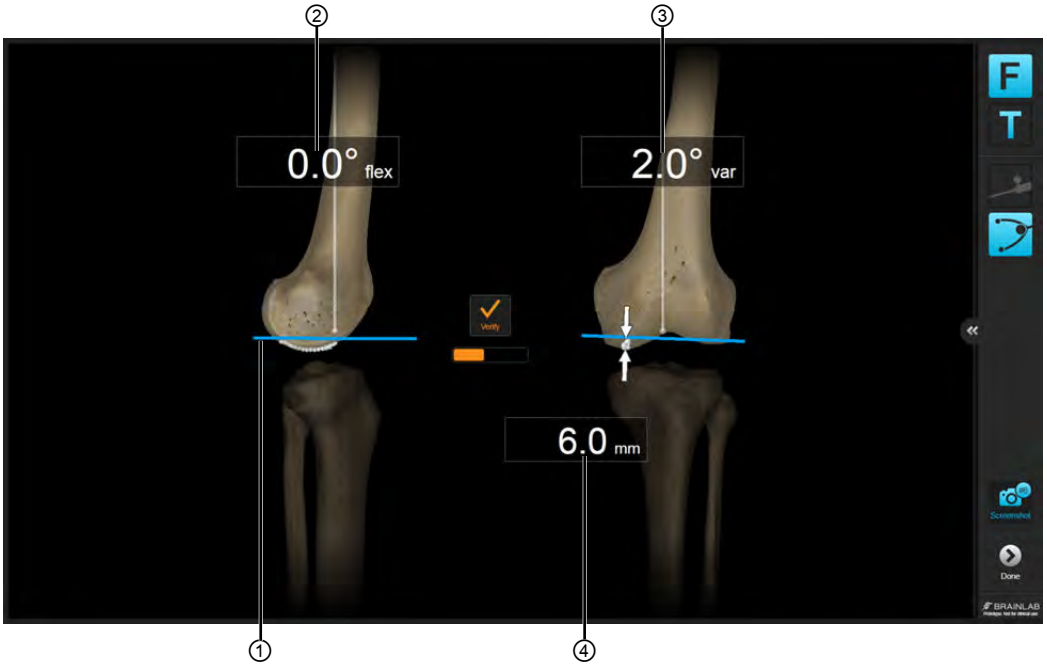


Figure 54

No.	Item
①	Cutting block position
②	Implant flexion angle
③	Implant varus/valgus angle
④	Distal resection height for the selected compartment

5 REGISTRATION

5.1 Registration Overview

About Registration

Registration is the process of acquiring specific landmarks to calculate the length and angles required for resection. This enables the software to provide measurement information during surgery.

During registration, you use the pointer to acquire (register) landmarks and bone surfaces on the patient's femur and tibia.

The software uses the registered points to automatically plan and calculate the following:

- Implant size
- Implant position
- Resection levels

Total Landmarks Requiring Registration

Femur Landmarks	Tibia Landmarks
Femur Head Center	Proximal Tibial Axis Point
Distal Femur Axis Point	Tibia Anterior-Posterior Direction
Medial and Lateral Epicondylar Points	Medial and Lateral Plateau Points
Anteroposterior Axis (Whiteside's Line)	Medial and Lateral Malleoli
Medial and Lateral Condyles	
Medial and Lateral Distal Condyles	
Anterior Cortex	

5.1.1 Registration Workflows

Overview

Knee has 4 workflow types available for performing registration:

- Knee3 Motion
- Knee3 Universal
- Knee3 Express
- Knee3 Partial

The following sections outline which landmarks are required for registration within each workflow:

Knee3 Motion

No.	Workflow Section	Registration Steps
①	Registration	Femur: • Femoral Head Center • Distal femur axis point • Medial and Lateral Epicondyles (Epicondylar Line) • Anteroposterior Axis (Whiteside's Line) • Medial Condyle • Lateral Condyle • Anterior Cortex Tibia: • Medial and lateral Malleoli • Proximal Tibia axis point • Tibia anterior-posterior direction • Medial plateau • Lateral plateau
②	Implants and Treatment Side Selection	
③	Planning	
④	Navigation	
⑤	Joint Stability	

Knee3 Universal

No.	Workflow Section	Registration Steps
①	Registration	Femur: • Femoral Head Center • Distal femur axis point • Medial and Lateral Epicondyles (Epicondylar Line) • Anteroposterior Axis (Whiteside's Line) • Medial Condyle • Lateral Condyle Tibia: • Medial and lateral Malleoli • Proximal Tibia axis point • Tibia anterior-posterior direction • Medial plateau • Lateral plateau
②	Treatment Side Selection	
③	Planning	
④	Navigation	

Knee3 Express

No.	Workflow Section	Registration Steps
①	Registration	Femur Block: • Femoral Head Center • Distal femur axis point • Anteroposterior Axis (Whiteside's Line) Femur Cut: • Bone Verification Plate • Femoral Head Center Tibia Block: • Medial and lateral Malleoli • Proximal Tibia axis point • Tibial A-P direction Tibia Cut: • Bone Verification Plate • Medial and lateral Malleoli Femur Live Navigation: • Femoral Head Center • Distal femur axis point • Anteroposterior Axis (Whiteside's Line) Tibia Live Navigation: • Medial and lateral Malleoli • Proximal Tibia axis point • Tibia anterior-posterior direction • Medial plateau • Lateral plateau
②	Treatment Side Selection	

No.	Workflow Section	Registration Steps
③	Navigation	

Knee3 Partial

No.	Workflow Section	Registration Steps
①	Registration	Femur: • Femoral head center • Distal femur axis point • Anteroposterior axis (Whiteside's Line) • Selected distal condyle Tibia: • Proximal tibia axis point • Tibia anterior-posterior direction • Selected tibia plateau

5.1.2 Point Acquisition

Overview

You can register landmarks using the following options:

- Pointer
- Clip-On Remote
- Footswitch

How to Use a Brainlab Pointer

Figure 55

In standard pointer registration, you pivot a calibrated pointer to acquire (register) specific landmarks on the patient's bone.

Step
Hold the pointer tip on the landmark indicated and pivot the pointer slightly around its tip. • If the tip moves during pivoting, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step.

How to Use a Clip-On Remote Control

Registration using **Brainlab Angled Pointer** can also be performed with the aid of a disposable clip-on remote control.

Step
Hold the pointer tip on the indicated landmark and press the control button on the remote control ①. • If the tip moves when you press the button, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step. *NOTE: The **Clip-On Remote Control** reacts upon pressing the control button, not upon releasing.*

How to Activate the Clip-On Remote Control

Steps	
1.	 Choose **Settings** from the fly-out menu.
2.	Select **Clip-on Remote Control** from **TOOLS**. *NOTE: When the **Clip-On Remote Control** is activated pivoting is disabled.*

How to Use a Footswitch

Figure 56

Registration can also be performed by using a footswitch to reduce touchscreen interaction.

Step
Hold the pointer tip on the indicated landmark and press the blue button on the footswitch. • If the tip moves when you press the button, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step. *NOTE: The **Clip-On Remote Control** reacts upon pressing the control button, not upon releasing.*

NOTE: The footswitch activates automatically when plugged-in.

*NOTE: The **Clip-On Remote Control** and footswitch can be used concurrently.*

Footswitch Pedal Functions

Pedal	Function
Blue	Registers landmarks or select element marked in blue.
Yellow	Selects element marked in yellow.

Pedal	Function
Black	Cycles through controllable elements in navigation and planning.

5.1.3 Landmark Registration

Overview

You can register landmarks using the following options:

- Pointer
- Clip-On Remote
- Footswitch

Landmark Registration Example

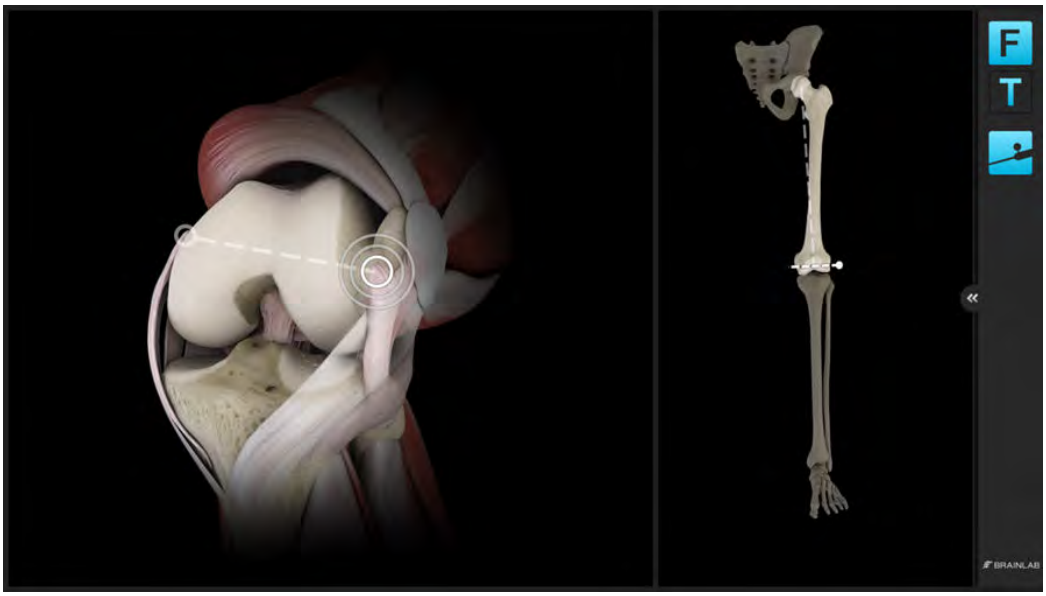


Figure 57

How to Register Landmarks Using a Brainlab Pointer

Step
Hold the pointer tip on the landmark indicated and pivot the pointer slightly around its tip. • If the tip moves during pivoting, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step.

How to Register Landmarks Using the Clip-On Remote Control

Step
Hold the pointer tip on the indicated landmark and press the control button on the remote control. • If the tip moves when you press the button, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step. *NOTE: The **Clip-On Remote Control** reacts upon pressing the control button, not upon releasing.*

How to Register Landmarks Using the Footswitch

Step
Hold the pointer tip on the indicated landmark and press the blue button on the footswitch. • If the tip moves when you press the button, the point is not acquired. • When a point is acquired, the software indicates the next point to acquire, or opens the next step. *NOTE: The **Clip-On Remote Control** reacts upon pressing the control button, not upon releasing.*

NOTE: The footswitch activates automatically when plugged-in.

*NOTE: The **Clip-On Remote Control** and footswitch can be used concurrently.*

5.1.4 Axis Direction Registration

Axis Registration Example

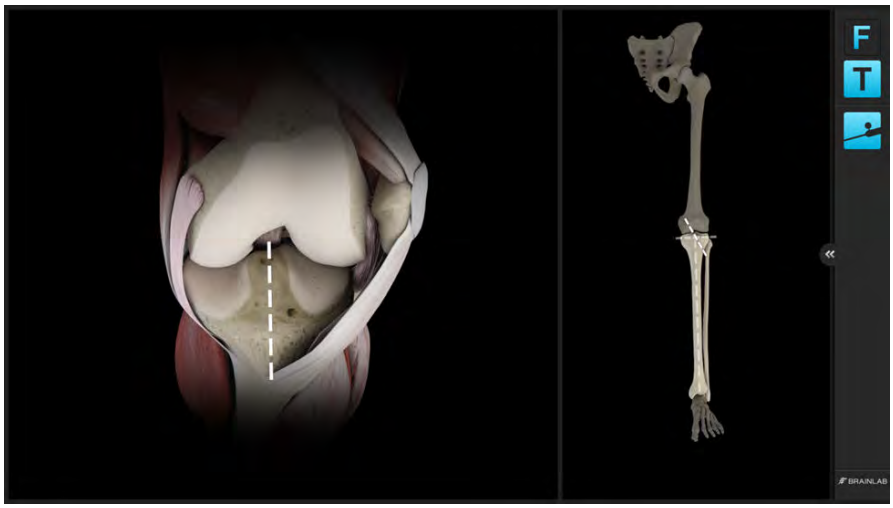


Figure 58

How to Register an Axis Direction Using a Brainlab Pointer

In standard pointer registration, you pivot a calibrated pointer to acquire (register) specific landmarks on the patient's bone.

Step
Hold the pointer tip still, angling it along the required axis as indicated on screen. The axis is registered after approx. 2 seconds. A progress bar indicates the registration status.

How to Register an Axis Direction Using the Clip-On Remote Control

Steps	
1.	Hold the pointer tip still, angling it along the required axis as indicated on screen.
2.	Press the control button to register the axis direction. *NOTE: The **Clip-On Remote Control** reacts upon pressing the control button, not upon releasing.*

How to Register an Axis Direction Using the Footswitch

Steps	
1.	Hold the pointer tip still, angling it along the required axis as indicated on screen.
2.	Press the blue pedal on the footswitch to register the axis direction. *NOTE: The **Clip-On Remote Control** reacts upon pressing the control button, not upon releasing.*

NOTE: The footswitch activates automatically when plugged-in.

*NOTE: The **Clip-On Remote Control** and footswitch can be used concurrently.*

5.1.5 Surface Registration

Surface Registration Example

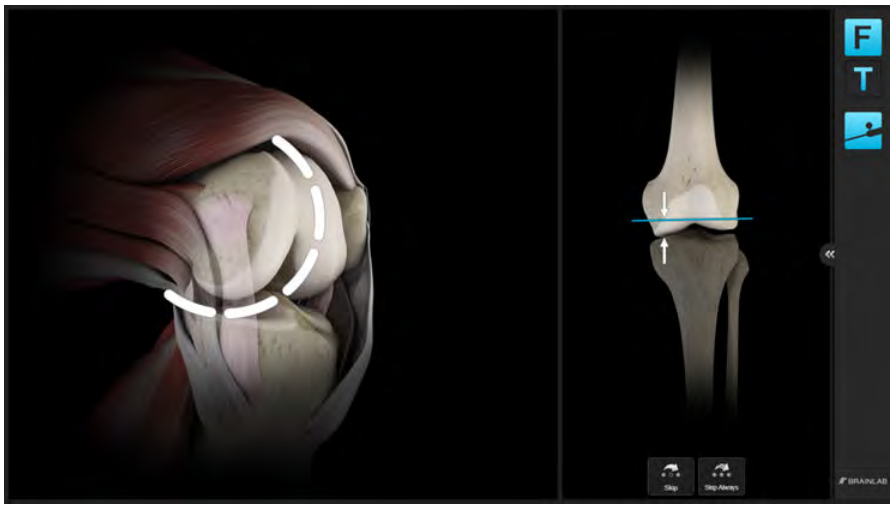


Figure 59

How to Register Surfaces Using Brainlab Angled Pointer

Steps	
1.	Hold the pointer tip on the condyle.
2.	Pivot the pointer to initiate registration.
3.	Glide the pointer tip over the condyle, making sure to include the entire area indicated. *NOTE: Registration can be paused by pivoting the pointer.*

How to Register Surfaces Using the Clip-On Remote Control

Steps	
1.	Hold the pointer tip on the condyle.
2.	Press the control button to start condyle surface registration.
3.	Glide the pointer tip over the condyle, making sure to include the entire area indicated. *NOTE: Registration can be paused by pivoting the pointer.*

How to Register Surfaces Using the Footswitch

Steps	
1.	Hold the pointer tip on the condyle.
2.	Press the blue pedal to start condyle surface registration.
3.	Glide the pointer tip over the condyle, making sure to include the entire area indicated. *NOTE: Registration can be paused by pivoting the pointer.*

*NOTE: The **Clip-On Remote Control** and footswitch can be used concurrently.*

5.2 Femur Registration

5.2.1 Femor Head Center

Overview

The registration sequence performed during surgery depends on the selected workflow. See below for available workflow options:

- Knee3 Motion
- Knee3 Universal
- Knee3 Express
- Knee3 Partial

How to Register the Femoral Head Center

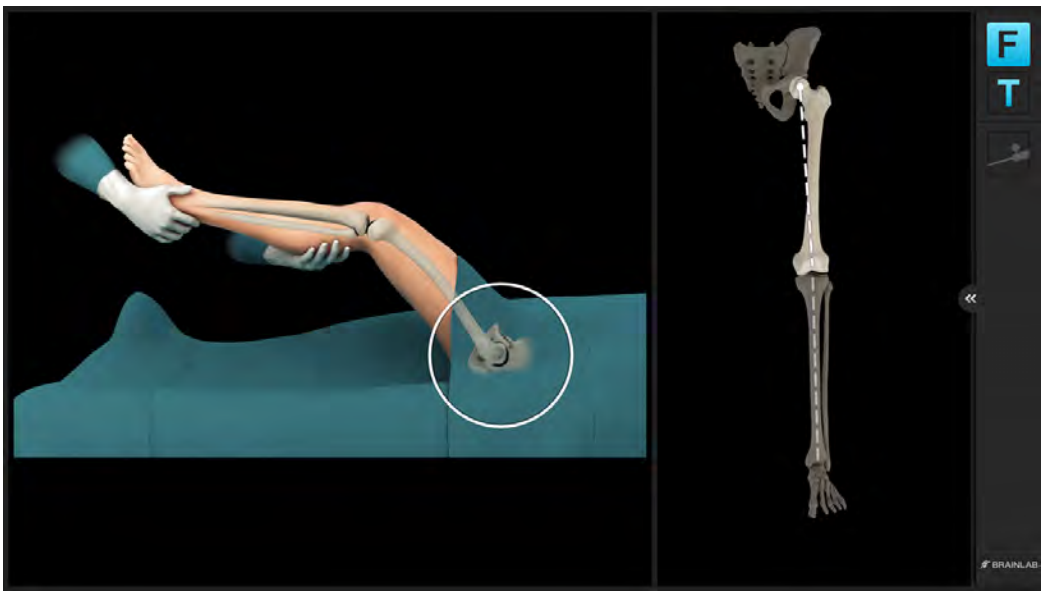


Figure 60

This step defines the:

- Proximal point of the femoral mechanical axis
- Start point of the weight bearing axis (Mikulicz line)

Step
Rotate the leg in the hip joint in a circular manner. Begin with larger circles and gradually decrease to smaller circles. *NOTE: The screen indicates the status of the registration.*

During the Calculation

Make sure that the femoral reference array is visible to the camera as the leg is being rotated.

To ensure accurate measurement, avoid too much movement of the hip during pivoting and do not change the camera position.

5.2.2 Distal Femur Axis Point

Overview

Defining the femoral mechanical axis point is very important to get a good planning result. The femoral mechanical axis determines the varus/valgus and flexion/extension alignment of the femoral component, as well as overall leg alignment. The acquisition of this point, along with the femoral head center, completes the femoral mechanical axis.

NOTE: Remove any osteophytes before proceeding registration.

How to Register the Distal Femur Axis Point Using the Pointer

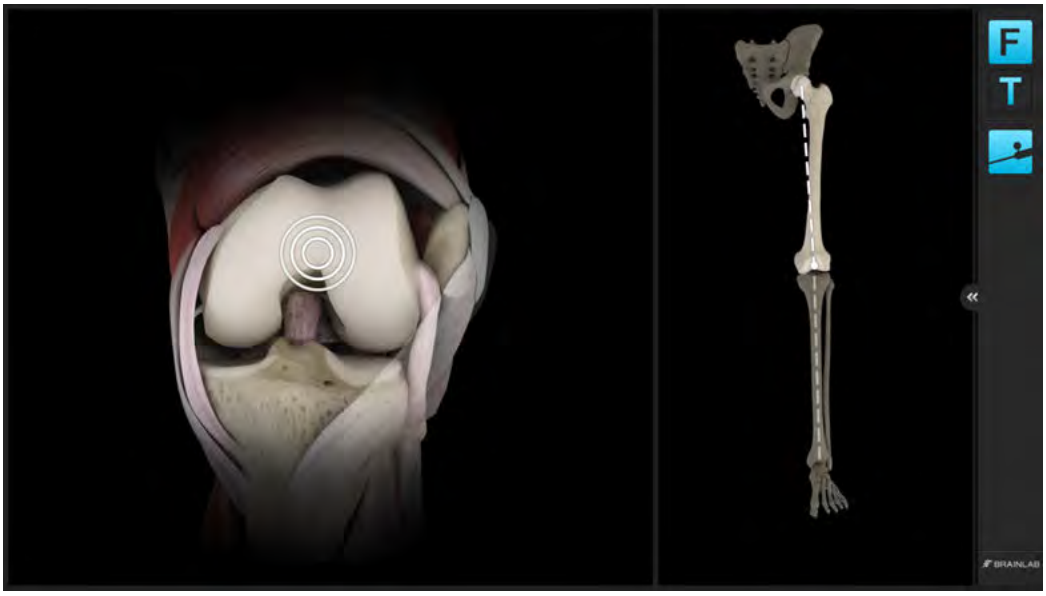


Figure 61

The pointer should be placed slightly medial at the posterior aspect of the femoral notch point (as indicated on screen).

The software uses the femoral mechanical axis point to determine the varus/valgus and the flexion/extension alignment of the femoral resection planes. This affects the overall leg alignment.

Step
Hold the pointer tip on the indicated bone landmark and pivot the pointer slightly around its tip.

5.2.3 Medial and Lateral Epicondylar Points

Overview

The points defined on the medial and lateral epicondyles define the epicondylar axis, the first of three possible references for the rotational alignment of the femoral implant.

The software also uses these points for a secondary sizing check of the femoral component in order to prevent medial-lateral overhang of the component.

How to Register the Medial and Lateral Epicondylar Points Using the Pointer

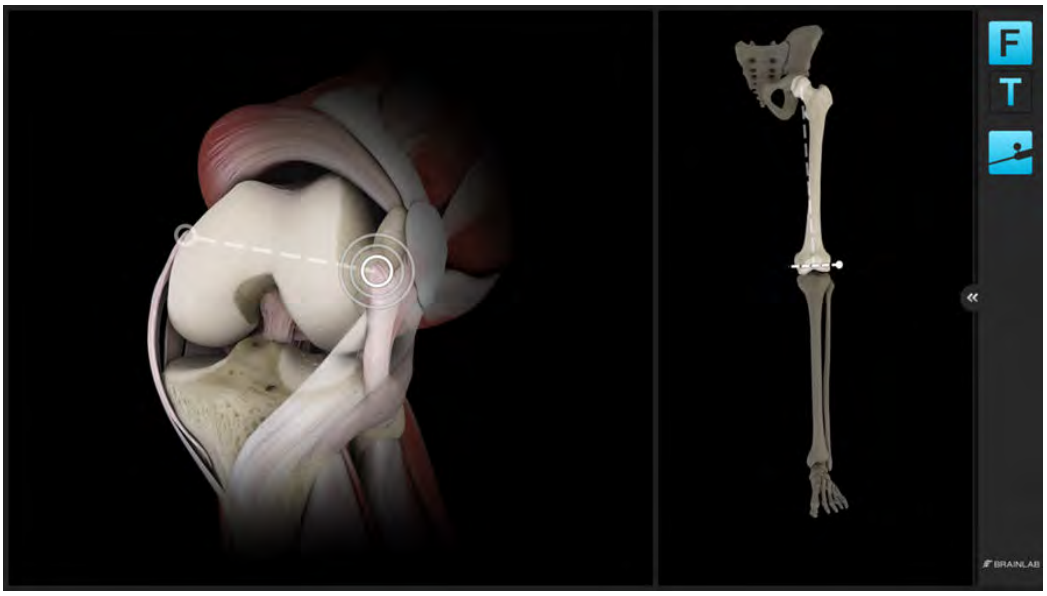


Figure 62

Step
Register a single point at the medial and then lateral epicondyle using the pointer tip as indicated on screen.

5.2.4 Anteroposterior Axis (Whiteside’s Line)

Overview

The Anteroposterior axis is one of three possible references for calculating the rotational alignment of the femoral implant.

How to Register Axis Direction Using the Pointer

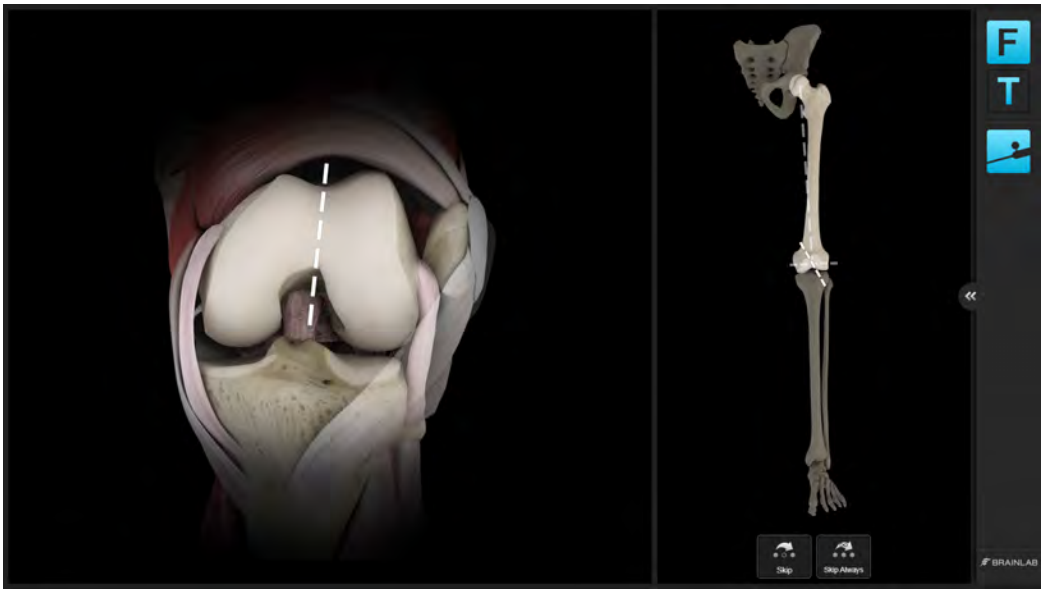


Figure 63

This axis is a line drawn from the deepest part of the trochlear groove anteriorly to the center of the intercondylar notch posteriorly.

Step
Hold the pointer still and angle it along the required axis in the direction indicated on screen. The axis is registered after approx. 2 seconds. A progress bar indicates the status of the acquisition.

Ensure you acquire the tibia A-P direction, with the pointer pointing from anterior to posterior.

Ensure the Whiteside’s line is acquired accurately, even small deviations can cause the axis to rotate.

5.2.5 Medial and Lateral Condyles

Overview

The condyle surfaces are registered by acquiring a point cloud or cluster.

The software uses the acquired points on the medial and lateral condyles to calculate the most distal and posterior points on the condyles.

It is important to reach the posterior parts of the condyles, as the posterior line is used as a reference for the axial rotation of the femoral implant. Additionally, the epicondylar points are used for implant sizing to avoid overlapping. These points are used as references for resection levels and joint lines.

Condyle Segmentation

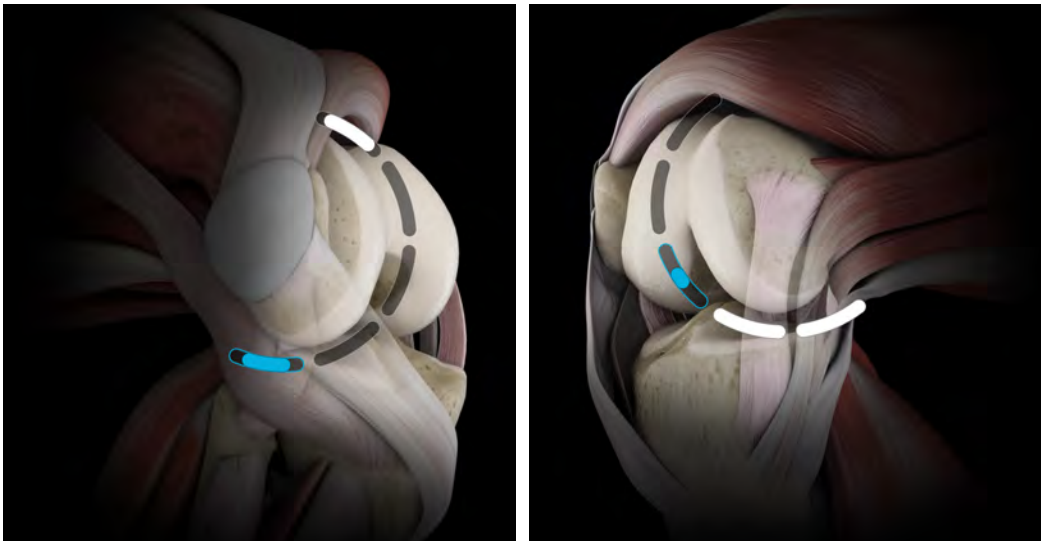


Figure 64

Items to note when acquiring points:

- The condyle is divided into segments.
- A minimum number of points must be acquired for each segment.
- Once a sufficient number of points are acquired, the segments are no longer visible.
- Point acquisition continues until all segments are no longer visible.

Color	Status
White	Current segment
Blue	Segment(s) still requiring acquisition

How to Register the Condyles

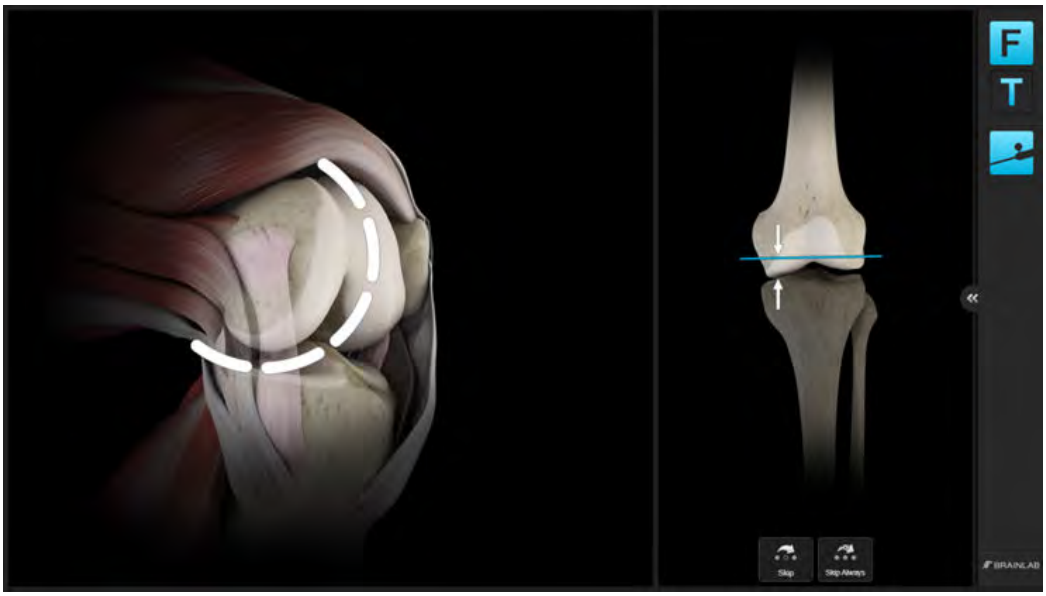


Figure 65

Steps	
1.	Hold the pointer tip on the condyle.
2.	Pivot the pointer to initiate registration.
3.	Glide the pointer tip over the condyle, making sure to include the entire area indicated. *NOTE: Registration can be paused by pivoting the pointer.*

5.2.6 Medial and Lateral Distal Condyles

Overview

The condyle surfaces are registered by acquiring a point cloud or cluster.

The software uses the acquired points on the medial and lateral condyles to calculate the most distal points on the condyles.

These points are used as references for resection levels.

Condyle Segmentation

Points to note when acquiring points:

- The condyle is divided into segments.
- A minimum number of points must be acquired for each segment.
- Once a sufficient number points have been acquired, the segments are no longer visible.
- Point acquisition continues until all segments are no longer visible.

Color	Status
White	Current segment
Blue	Segment(s) still requiring acquisition

How to Register the Distal Condyles

Figure 66

Steps	
1.	Hold the pointer tip on the condyle.
2.	Pivot the pointer to initiate registration.
3.	Glide the pointer tip over the condyle, making sure to include the entire area indicated. *NOTE: Registration can be paused by pivoting the pointer.*

5.2.7 Anterior Cortex

General Information

The collected points on the anterior cortex are used as a reference for the exit of the anterior cut plane and they determine the femoral components A-P position.

How to Register the Anterior Contex

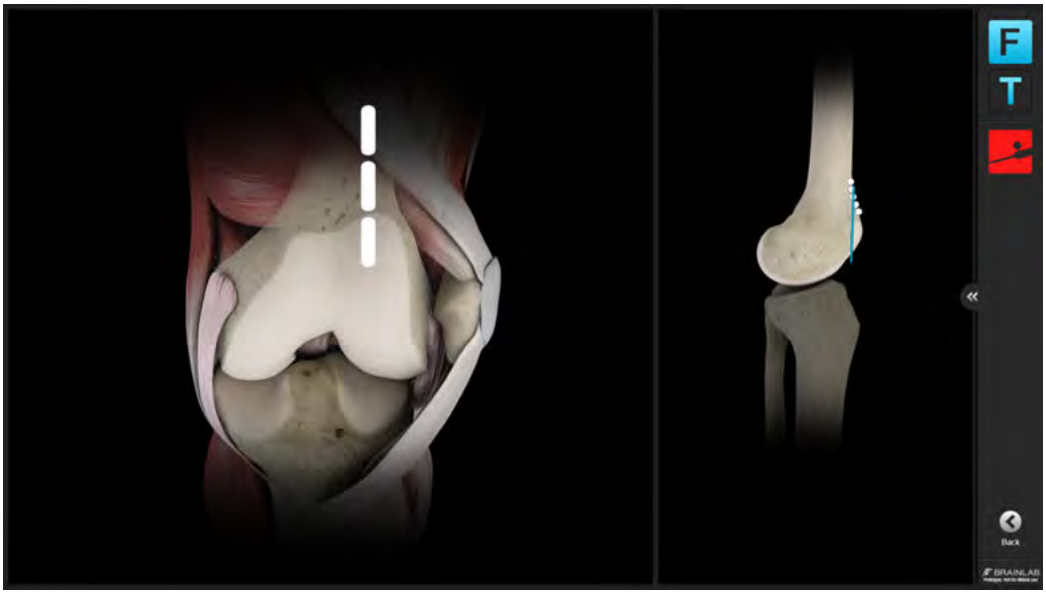


Figure 67

Steps	
1.	Hold the pointer tip on the condyle.
2.	Pivot the pointer to initiate registration.
3.	Glide the pointer tip over the condyle, making sure to include the entire area indicated. *NOTE: Registration can be paused by pivoting the pointer.*

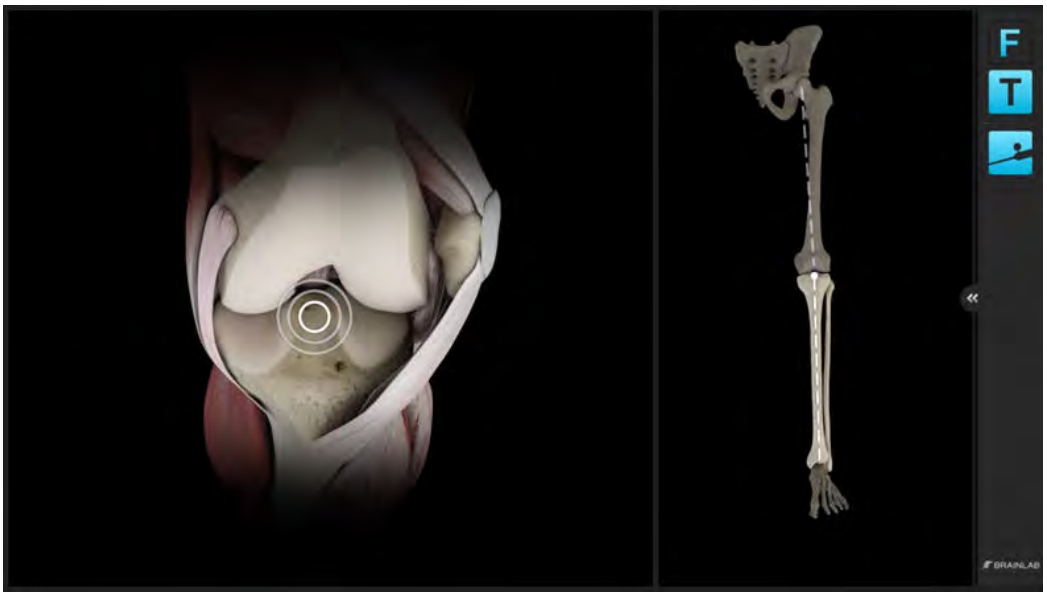
5.3 Tibia Registration

5.3.1 Proximal Tibia Axis Point

Overview

The proximal point on the tibial mechanical axis is defined by acquiring the posterior aspect of the ACL tibial insertion point. You can also use the intersection of the mid-coronal and mid-sagittal planes to register this point.

How to Register the Proximal Tibia Axis Point



Step
Hold the pointer tip on the indicated bone landmark and pivot the pointer slightly around its tip.

5.3.2 Tibia Anterior-Posterior (A-P) Direction

Overview

The Tibia Anterior-Posterior (A-P) direction is the reference for the neutral rotational alignment. The pointer direction defines the initial rotation of the tibial implant. The system determines the direction the tibia is facing and the direction of any intended slope which may need to be cut, avoiding a compound tibial slope (oblique tibial slope).

Accurate acquisition of the A-P direction avoids an oblique tibial slope in the anteromedial to posterolateral or anterolateral to posteromedial directions.

Do not register the tibia A-P direction in reverse (pointing from posterior to anterior).

How to Register the Tibia A-P Direction

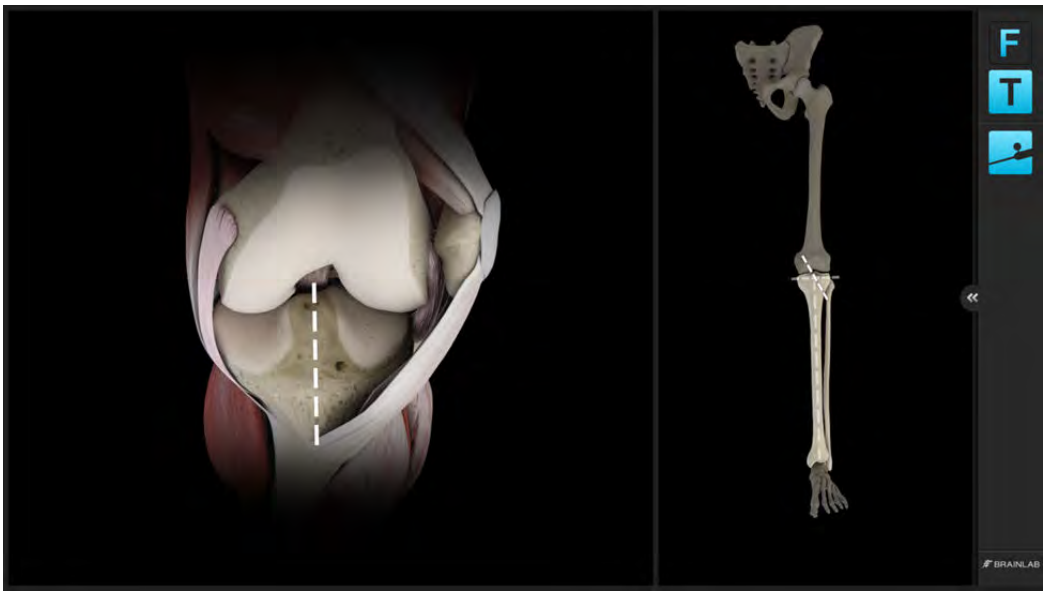


Figure 68

To define the slope direction exactly, use the medial 1/3 of the tibial tubercle, the tibial mechanical axis point and the posterior cruciate ligament for orientation.

Step
Hold the pointer still and angle it along the required axis in the direction indicated on screen. The axis is registered after approx. 2 seconds.

5.3.3 Medial and Lateral Plateau Points

Overview

The software shows the resection height from this reference point.

How to Register the Medial and Lateral Plateau Points

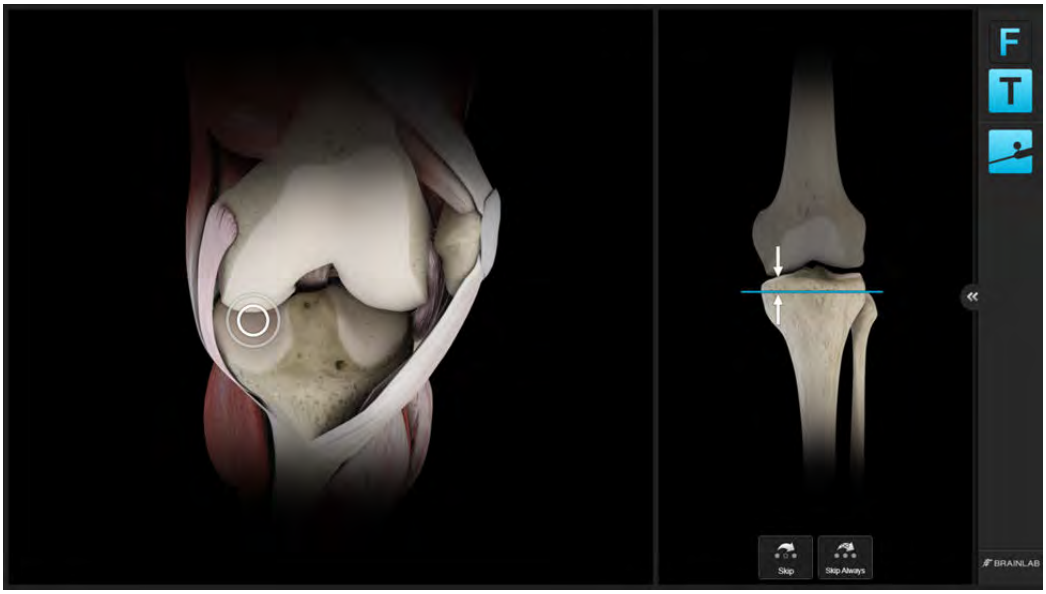


Figure 69

A single point on each plateau is used to calculate the tibial resection level. The acquisition of the tibia points has to be at the deepest point of the plateaus.

NOTE: Careful consideration should be given if there is a bone defect present.

Step
Hold the pointer tip on the indicated bone landmark and pivot the pointer slightly around its tip.

5.3.4 Medial and Lateral Malleoli

Overview

Acquiring the malleoli defines the distal point of the axis.

How to Register the Medial and Lateral Malleoli

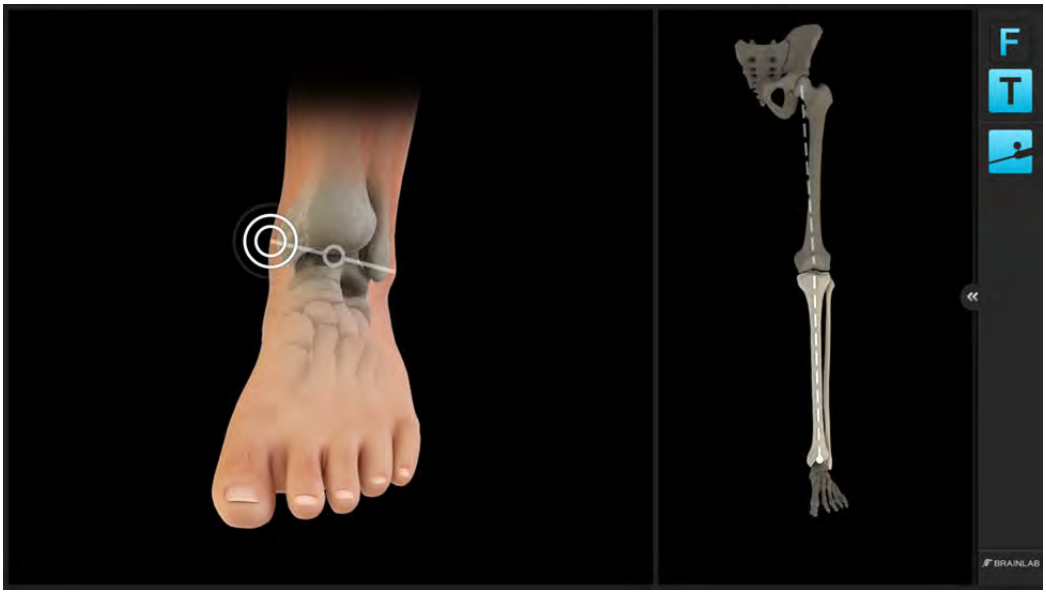


Figure 70

Step
Hold the pointer tip on the indicated bone landmark and pivot the pointer slightly around its tip.

5.4 Verification in Knee3 Express

5.4.1 Femoral Mechanical Axis and A-P Direction

Overview

Register the axis endpoint to define the A-P direction of the femur using the **Bone Verification Plate**.

How to Register the Femoral Mechanical Axis and A-P direction

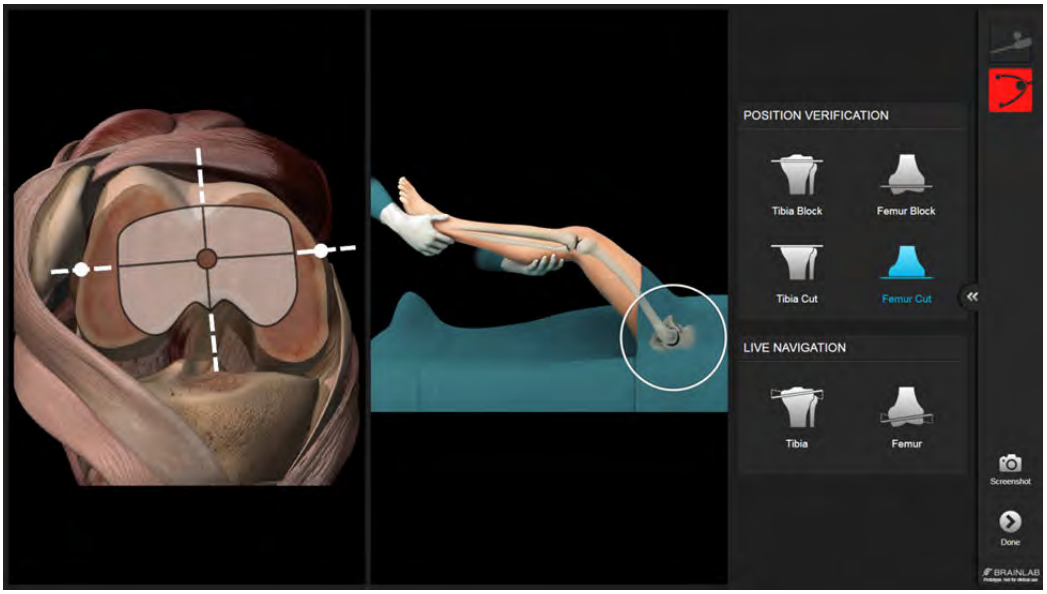


Figure 71

Step	
1.	 Select **Femur Cut** to begin registration with the **Bone Verification Plate**.
2.	Place the **Bone Verification Plate** onto the resected femur as shown on screen.
3.	Ensure the arrow on the instrument is facing in the A-P direction and the opening of the **Bone Verification Plate** is positioned on the axis endpoint.
4.	Hold the **Bone Verification Plate** in place and press **Register** to acquire the Femoral A-P direction and axis endpoint. *NOTE: You can fix the verification plate onto the distal femoral cut using screws.*
5.	Register the hip center as shown on screen.

5.4.2 Tibial Mechanical Axis and A-P Direction

Overview

Register the axis endpoint to define the A-P direction of the tibia using the **Bone Verification Plate**.

How to Register the Tibial Mechanical Axis and A-P Direction

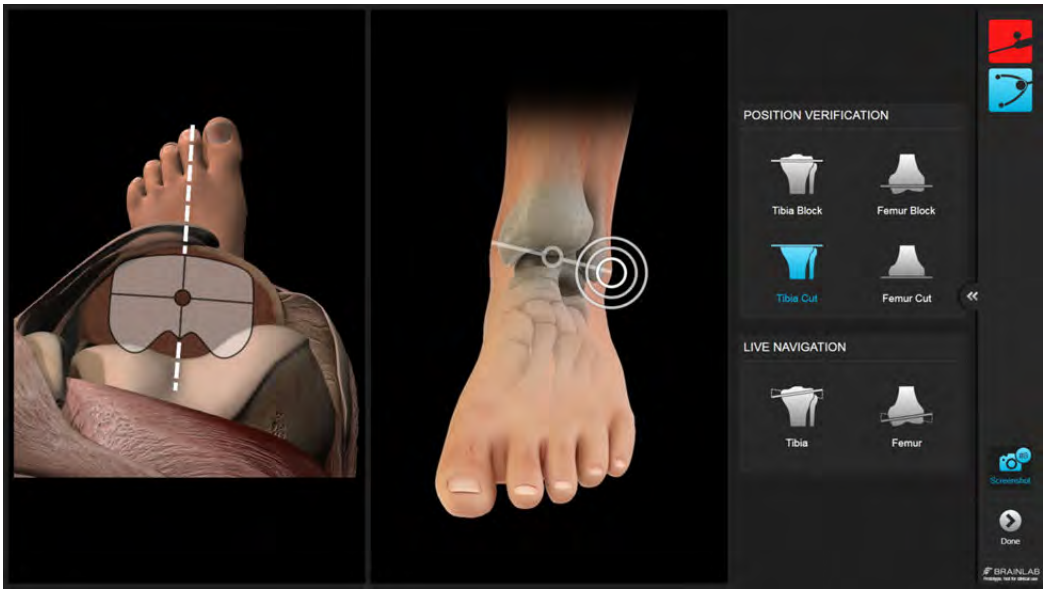


Figure 72

Step	
1.	 Select **Tibia Cut** to begin registration with the **Bone Verification Plate**.
2.	Place the **Bone Verification Plate** onto the resected tibia as shown on screen.
3.	Ensure the arrow on the instrument is facing in the A-P direction and the opening of the **Bone Verification Plate** is positioned on the axis endpoint.
4.	Hold the **Bone Verification Plate** in place and press **Register** to acquire the tibial A-P direction and axis endpoint.
5.	Register the tibial malleoli.

5.5 Additional Registration Functions

5.5.1 Skipping Landmarks

Overview

To reduce the registration effort, certain landmarks can be skipped. However, this results in less information during navigation.

The table below explains the effects of skipping specific landmarks:

Skipped Landmark	Effect
Tibia Plateaus	No tibia resection heights are shown
Condyles	• No tibia resection heights are shown • The initial femoral implant size is determined from the anterior cortex point
Whiteside's Line	Only the epicondylar axis is available as a rotation reference

Skip Options

Button	Explanation
	Skips the landmark for the current workflow.
	Skips the landmark for the current and future workflows.

NOTE: A skipped landmark can be registered later by selecting it from the fly-out menu.

How to Skip Landmarks

Step
Press **Skip** or **Skip Always** on the registration screen. Registration proceeds to the next step.

NOTE: If landmarks are skipped, less navigation information is displayed during cut navigation.

5.5.2 Re-Registration

Overview

Specific landmarks or even a whole femur or tibia can be re-registered (e.g., due to an array becoming loose) at any point in the workflow by selecting that registration step in the menu.

Once re-registration is complete, the software returns to its previous step.

NOTE: Re-registration of landmarks is not possible with the Pinless Workflow. If you want to re-register landmarks in that workflow, you have to start a new registration.

How to Perform Re-Registration

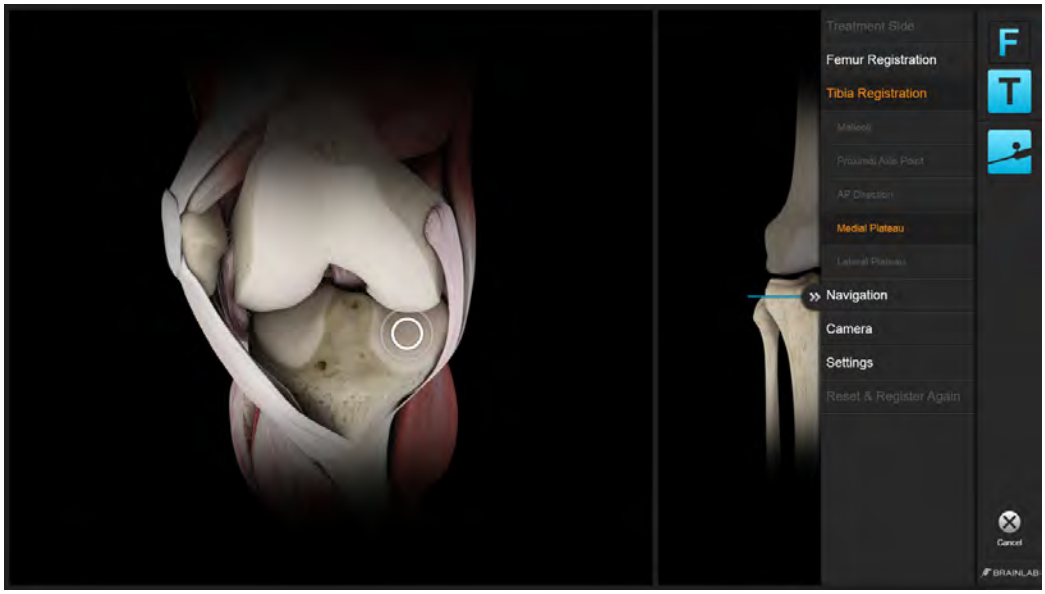


Figure 73

Steps	
1.	 Select the fly-out menu.
2.	Select the landmark for re-registration from either **Femur Registration** or **Tibia Registration**.
3.	Register the point(s) as prompted. On completion, the software takes you back to the previous step.

Reset & Register Again

After full registration of the femur and tibia, **Reset & Register Again** becomes active. This allows you to re-register the whole femur or tibia.

6 PATIENT REPORT

6.1 Creating a Patient Report

General Information

Following surgery, you can create a patient report containing the most important data.

How to Create a Patient Report

Figure 74

Steps		
1.		Select **Done** after surgery is finished. The report app opens.
2.		Select **Back** to return to navigation or **Done** to save the report to the patient folder. The software switches back to **Content Manager**.

7 FLY-OUT MENU AND TOOL BAR

7.1 Fly-out Menu

How to Access the Fly-out Menu

Step	
	Select the arrow icon from the tool bar.

Menu Options

The fly-out menu provides links to the following:

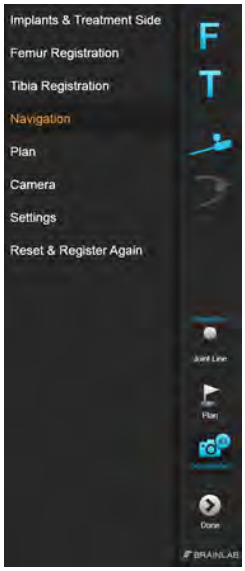


Figure 75

Options	See
Implants & Treatment Side	Page 39
Femur Registration	Page 94
Tibia Registration	Page 102
Navigation	Page 41
Plan	Page 48
Camera	Page 23

Options	See
Settings	Page 117
Reset & Register Again (not available for Knee3 Express)	Page 109

7.2 Tool Bar

Tool Bar Overview

The tool bar contains color-coded camera status indicators for the reference arrays and instruments.

Also available on the navigation and plan screens are the following functions:

- **Plan**
- **Done**
- **Screenshot**
- **Resection** or **Joint Line** toggle switch

Tool Bar Color-Coding

Status	Explanation
	Reference array or instrument is visible, in active use and interacting with the software (reference array or instrument is on a blue background).
	Reference array or instrument is visible (highlighted in blue).
	Reference array or instrument is NOT visible (grayed out).
	Reference array or instrument is NOT visible but is required for the procedure step (reference array or instrument is on a red background).

Tool Bar Components

Icon	Explanation
	Represents the femur reference array.
	Represents the tibia reference array.

Icon	Explanation
	Represents the pointer.
	Represents the plane tool.
	Represents the cutting block template.
	Indicates tracking errors.

NOTE: If the camera becomes disconnected during the workflow, the software displays the tracking error icon. If you press an icon, the camera application opens and provides you detailed information about the problem and possible solutions.

8 SETTINGS

8.1 Sound and Tools

General Information

Additional settings are accessed from the fly-out menu.

How to Access Sound and Tools Settings

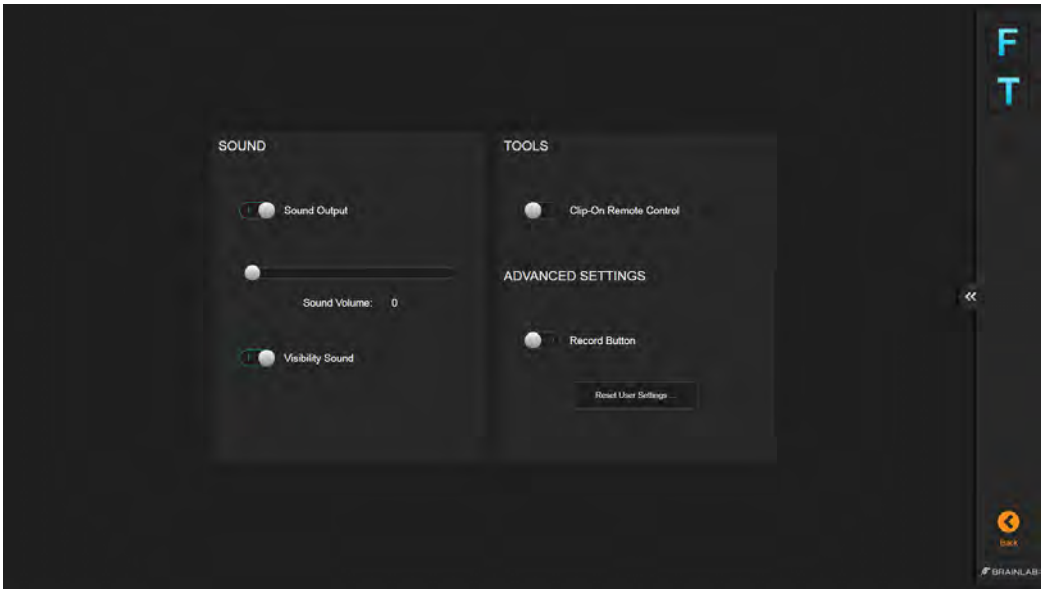


Figure 76

Step
Press **Settings** in the fly-out menu to adjust: • **SOUND** - Sound Output (On/Off) - Sound Volume - Visibility Sound (On/Off) • **TOOLS** - Clip-On Remote Control activation • **ADVANCED SETTINGS** - Record Button - Reset User Settings...

8.2 Screenshots

How to Take a Screenshot

You can take screenshots at any point throughout navigation or planning.

Step	
	Press **Screenshot** on any navigation or planning page. The images are stored in the patient folder.

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