



# AESCULAP® OrthoPilot®

Pheno4U® TKA Level 1

Navigated Surgical Technique



# OrthoPilot® Pheno4U® TKA Level 1

## TKA – Total Knee Arthroplasty



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- (2) Jenny JY, Miehle RK, Giurea A. Learning curve in navigated total knee replacement. A multi-centre study comparing experienced and beginner centres. *Knee*. 2008 Mar;15(2):80-4.
- (3) Bätis H, Shafizadeh S, Paffrath T, Simanski C, Grifka J, Lüning C. Are computer assisted total knee replacements more accurately placed? A metaanalysis of comparative studies. *Orthopäde*. 2006 Oct;35(10):1056-65.
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# AESCULAP® OrthoPilot®

## Trust in your ambition

OrthoPilot® helps with precise implantation of knee and hip endoprotheses (1). Significant criteria when developing the OrthoPilot® included integration into surgical procedure and operation times (2). Another central consideration for us was gentle, patient-friendly navigation: from the very beginning, our goal was to develop a method that did not require expensive and stressful CT/MRI scans, and that kept operation times as short as possible.

- CT-free
- Ergonomic instruments adapted to the procedure
- User-friendly navigation system integrates easily into operation
- Intraoperative documentation with OrthoPilot®
- Numerous international studies confirm precise implant alignment (3-6)
- Routinely used in more than 600 hospitals
- Over 300 OrthoPilot® publications around the world (7-9)



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# 1 | Overview of Universal Instruments

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Drill, drill sleeve,  
screw length measuring device



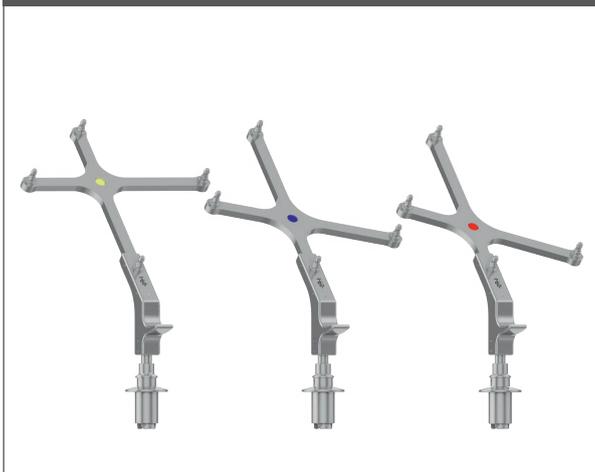
Drill, D= 3.2 mm	NP615R
Drill sleeve	NP616R
Screw length measuring device	NP281R

Tissue protection sleeve, bicortical screws,  
Rigid Body (RB)



MIOS® tissue protection sleeve	NQ941R
Bicortical screws	NP620R - NP625R
Rigid Body	NP619R

Passive transmitter



Yellow	FS633
Blue	FS634
Red	FS635

2-pin transmitter fixation



2-pin transmitter fixation element	NP1016R*
Pin for 2-pin transmitter fixation, D= 3.2, short	NP1012R*
Pin for 2-pin transmitter fixation, D= 3.2, long	NP1013R*

### Tibia check plate



Tibia check plate

NP617R

Tibia check plate, modified

NP617RM

### Spreader and spreading pliers



Spreader

NE750R

Spreading pliers

NP609R

Alternative:

NP605R

Power-controlled spreading pliers

### Tibial rotation navigation adapter



Tibial rotation navigation adapter

NP1017R\*

### Pointer, straight



Pointer, straight

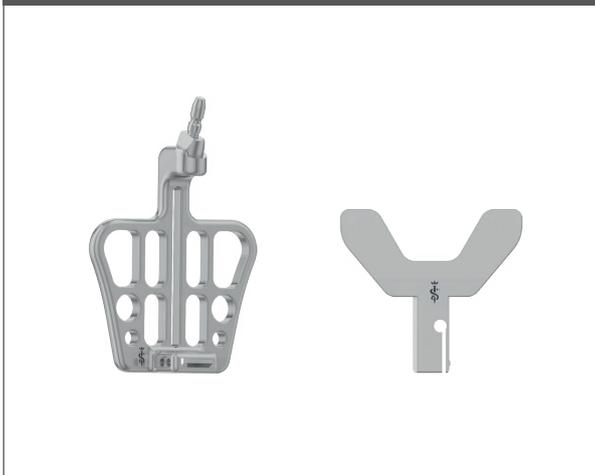
FS604

\* Only available in NP1000/NP1002

# 1 | Overview of IQ Instruments

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## Femoral alignment block with foot plates



Femoral alignment block	NS320R
Y foot plate	NQ958R

## Tibial/distal femoral cutting block and RB adapter, modular



Tibial/distal femoral sawing guide	NS334R
Tibial sawing guide, asymm. left-medial	NS406R
Tibial sawing guide, asymm. right-medial	NS407R
RB adapter, modular	FS626R

## 4-in-1 femoral cutting block and RB adapter, modular



e.motion® F2 - F8	NS582R - NS588R
VEGA System® F1 - F8	NS321R - NS328R
Columbus® F1 - F8	NQ1041R - NQ1048R
RB adapter, modular	FS626R

## IQ Alignment instrument for femur/tibia cutting block



IQ Alignment instrument for femur/tibia cutting block	NP1018R*
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# 1 | Overview of Instruments



Multitool

FS640\*



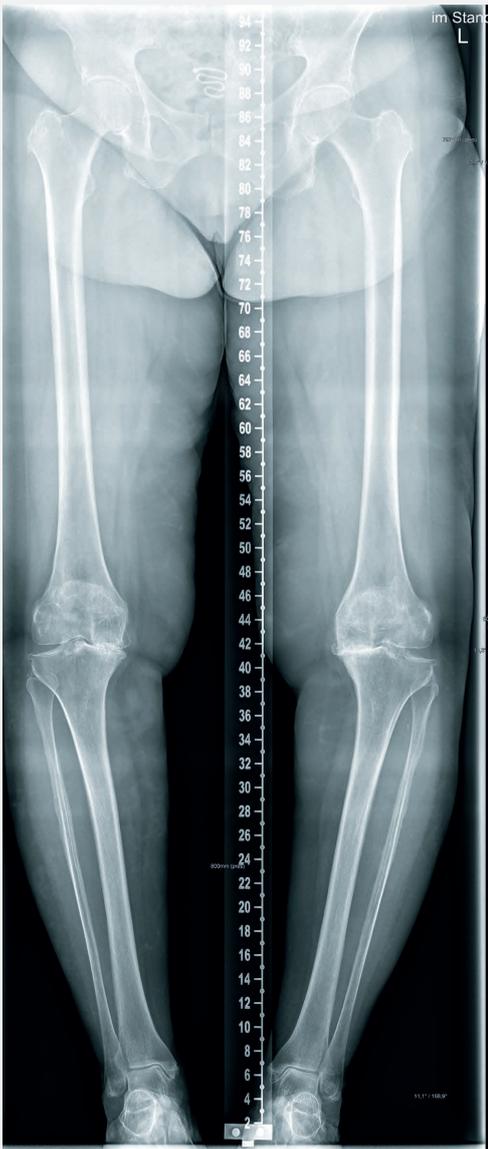
Passive click transmitter, yellow

FS636\*

\* Only available in NP1000/NP1002

## 2 | Preoperative Planning Using X-ray

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The OrthoPilot® system and the TKA software can be used in any cases for which knee endoprostheses are indicated as primary therapy, provided that the patient has sufficient bone quality and hip joint mobility.

**Note** | Be sure to follow the instructions in the corresponding surgical technique manuals, instructions for use, and package inserts, especially the instructions for use for the OrthoPilot® application software Pheno4U® TKA Level 1 TA016478.

During surgery, users should check all data for plausibility using the known possibilities as for example plausibility checks to the X-ray images and check of the instruments used. In addition instruments are available, e.g. like the angel-wing or rods for axis verification of the cut.



**AESCULAP® considers it necessary to conduct sufficient pre-operative planning on the basis of the following radiographic images:**

- Full-leg standing radiograph

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- Knee joint in A/P projection

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- Knee joint, lateral projection

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- Patella – tangential image

**Selected information that may be obtainable from radiographic images:**

- Axis malalignment, lateral distal femur angle (LDFA), medial proximal tibia angle (MPTA)

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- Implant alignment, joint gap, implant size ML

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- Slope, implant size A/P

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- Patella shape, joint gap

## 2 | Preoperative Planning Using X-ray

AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



Analyzing whether a total knee endoprosthesis is necessary is an essential part of pre-operative planning. In addition to standard radiographic examinations, the surgeon should consider the following factors before performing a total knee endoprosthesis:

- Soft tissue situation
- Extensor mechanism functionality
- Bone conservation
- Restoration of proper axis alignment
- Functional stability
- Restoration of the joint line



The AESCULAP® Columbus®, e.motion®, e.motion® Pro System and VEGA System® radiographic templates can provide the following information when analyzing radiographic images:

- Angle between anatomical and mechanical femoral axis
- Resection levels
- Implant sizes

## 3 | Set-up & Transmitter Position

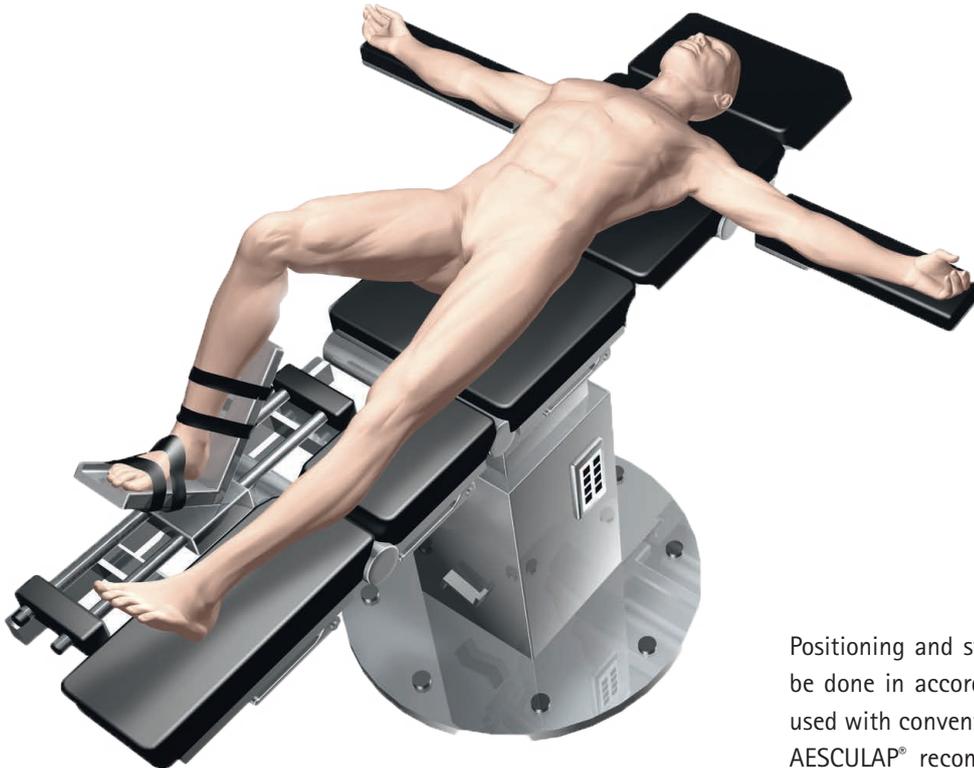


Fig. 1

Positioning and sterile covering of the patient are to be done in accordance with the standard procedures used with conventional surgical techniques.

AESCULAP® recommends using a leg holder to help adjust the patient's leg during different phases of the operation. The leg will need to be repositioned several times while recording the registration points and performing bone cuts. The leg holder allows users complete flexibility in knee positioning, from full flexion to full extension.

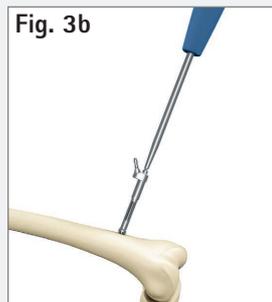
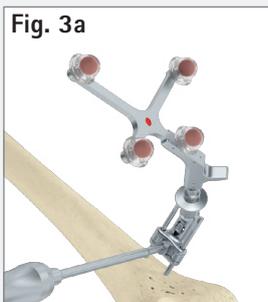
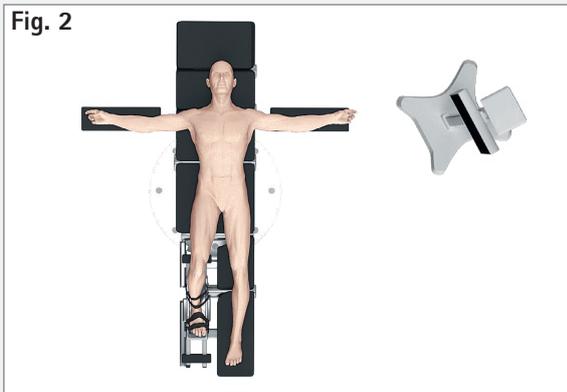
**Note** | To facilitate quadriceps mobilization, place the knee in 100° flexion before activating the tourniquet if used. If using a cushion, make sure it does not hinder the hip movement required in order to register the center of the femoral head.

### 3.1 OrthoPilot® positioning

When positioning the OrthoPilot®, make sure that the surgeon will have a clear view of the screen at all times. The device and/or the camera can be positioned either on the opposite side of the operated leg (contralateral) or on the same side (ipsilateral). The mean distance to the transmitters should be around 2.5 m (for the OrthoPilot® *Elite*). Enter the chosen position (ipsi- or contralateral) in the settings within the step System, Implant & Instruments screen. Positioning the camera at shoulder level on the patient's opposite side, tilted around 45° to the operating area, has often proven highly effective.

# 3 | Set-up & Transmitter Position

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



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### Note

When anchoring the device into place, make sure it will not come into conflict with any instruments being used later on.

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### Note

Please turn the screw until it is in contact with the pins, then verify a tight fit and if necessary tighten a little more with moderate force until the assembly is stable. Do not overtighten or force the screw!

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### Note

When removing the 2-pin fixation element at the end of the operation, it is essential to release the anchoring screw before screwing the pins out.

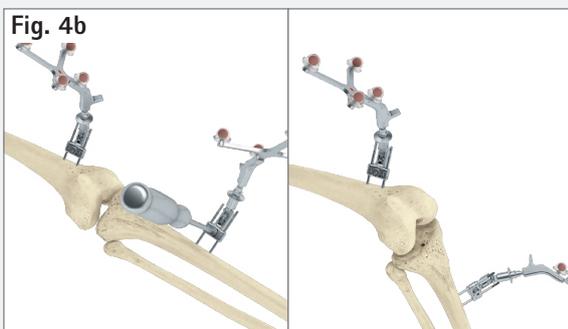
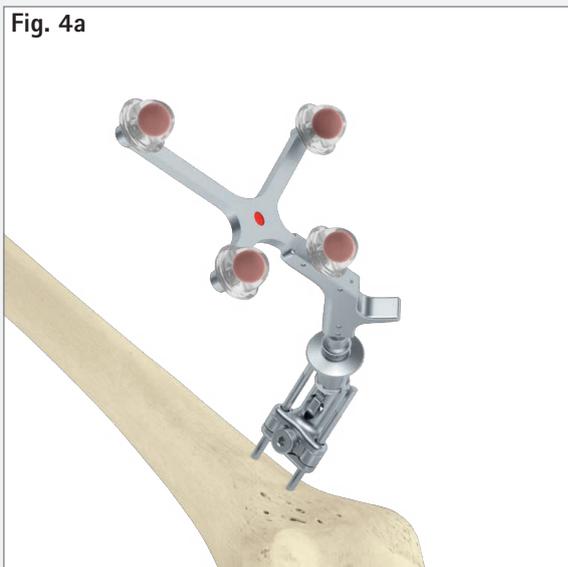
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If desired, 4.5 mm bicortical screws and RB sleeve NP619R can be used to keep the femoral transmitter anchored to the femur bicortically, approximately 10 cm proximal to the joint line. Pre-drilling for the bicortical screw is done using a 3.2 mm drill NP615R through drill sleeve NP616R. Use the scale on the drill to determine what length of bicortical screw will be necessary. Rigid Body NP619R is advanced and brought into contact with the bone, and then one of the bicortical screws (NP620R - NP625R) is inserted. Initial insertion is mechanical, but then the last few turns should be completed using a manual screwdriver. The transmitter adapter should be pointing toward the femoral head and angled in the direction of the camera; check that it is firmly seated.

---

### 3.2 Femoral transmitter

General instructions: Position the transmitter such that it will be visible to the camera throughout the entire operation. The transmitter can be positioned monocortically using a 2-pin fixation system. With the clamping screw on the anchoring element open, use two pins to attach it to the femur, up to around 10 cm in the proximal direction from the joint line. AESCULAP® recommends using the fixation pins NP1012R or NP1013R with a diameter of 3.2 mm. In principle, the transmitter fixation element is compatible with bone fixation pins of 2.5 mm to 4.0 mm in diameter. The femoral transmitter can be placed in any of four positions; a locking mechanism allows the transmitter adapter to be adjusted into an optimal position for the camera. Once the transmitter is in a good position, use the clamping screw and screwdriver NS423R to lock the adjustment mechanism. This screw also serves to connect the anchoring element to the pins. Check the transmitter to make sure it is firmly anchored into place.



### 3.3 Tibial transmitter

The transmitter can be positioned monocortically using a 2-pin fixation system. With the clamping screw on the anchoring element open, use two pins to attach it to the tibia, up to around 10 cm in the distal direction from the joint line (typically from medial). AESCULAP® recommends using the fixation pins NP1012R or NP1013R with a diameter of 3.2 mm. In principle, the transmitter fixation element is compatible with fixation pins of 2.5 mm to 4.0 mm in diameter. The tibial transmitter can be placed in any of four positions; a locking mechanism allows the transmitter adapter to be adjusted into an optimal position for the camera. Once the transmitter is in a good position, use the clamping screw and screwdriver (NS423R) to lock the adjustment mechanism. This screw also serves to connect the anchoring element to the pins. Check the transmitter to make sure it is firmly anchored into place.

#### Option

After pre-drilling with the 3.2 mm drill (NP615R) and measuring bicortical screw length as described in Chapter 3.2, a RB (NP619R) is fixed to the tibia via a separate incision, approximately 1 cm long, around 10 cm distal from the joint line. The last turns of the screw should be completed using a manual screwdriver.

#### Note

When fixing the device make sure it will not come into conflict with any instruments being used later on.

#### Note

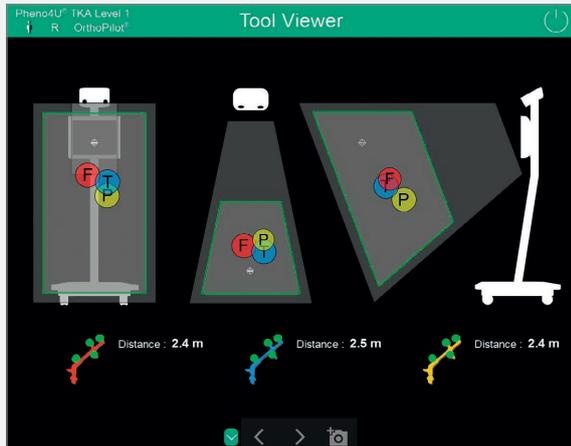
Please turn the screw until it is in contact with the pins, then verify a tight fit and if necessary tighten a little more with moderate force until the assembly is stable. Do not overtighten or force the screw!

#### Note

When removing the 2-pin fixation element at the end of the operation, it is essential to release the anchoring screw before screwing the pins out.

# 3 | Set-up & Transmitter Position

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

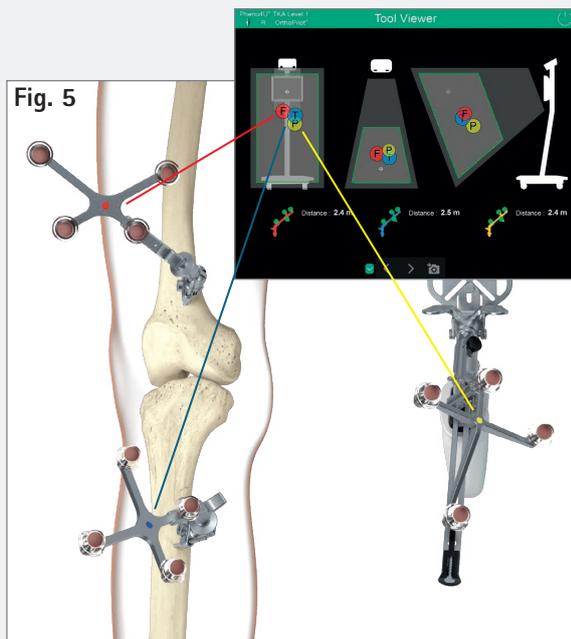


### 3.4 Camera alignment

The camera alignment screen displays the view field of the camera as a three-dimensional volume; users can call it up at any time via the toolbox menu (see instructions for use OrthoPilot® Software Pheno4U® TKA Level 1 TA016478). Transmitters are displayed within this camera view field as colored (color-coded) dots labeled using corresponding letters:

- Femoral transmitter:  
Red dot labeled "F"
- Transmitter on instrument:  
Yellow dot labeled "P"
- Tibial transmitter:  
Blue dot labeled "T"

If all three transmitters are placed at an optimum distance to the camera (2.5 – 3.0 m for OrthoPilot® *Elite*), the camera view field will be displayed outlined in green. The mean distance from the camera to the transmitters is displayed in meters.



#### Note

Whenever a transmitter is removed from the bone fixation, e.g. the 2 pin fixation or one of the instruments, the user must ensure in case of reattaching, that exactly the same position is chosen for the fixation of the transmitter as before. Otherwise the values displayed differ significantly from the values displayed before.

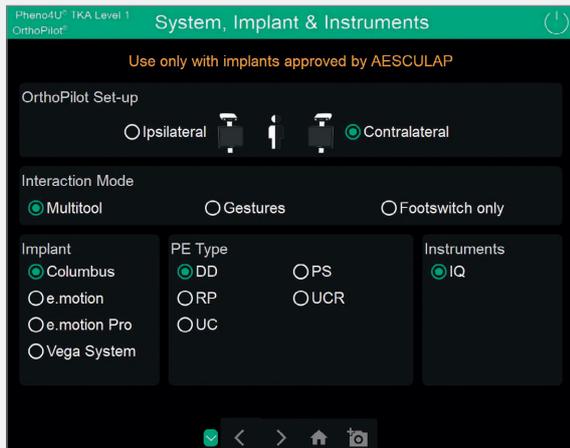
#### Tip

When adjusting camera alignment, make sure that all transmitters remain sufficiently visible as the leg is flexed, extended, adducted or abducted. Sufficient visibility means that the camera can recognize the transmitter in all of these positions. Once users have checked the camera at the beginning of the operation and verified transmitter visibility, it should not be necessary to adjust the camera for the rest of the operation. However, it remains possible to adjust the camera at any time during the operation – except while measuring the center of the hip joint – in order to improve visibility.

The passive transmitter marked in red (FS635) is attached to the femoral Rigid Body adapter; the passive transmitter marked in blue (FS634) is attached to the tibial Rigid Body adapter. The yellow passive transmitter (FS633 or FS636) is attached to whichever instruments are necessary.

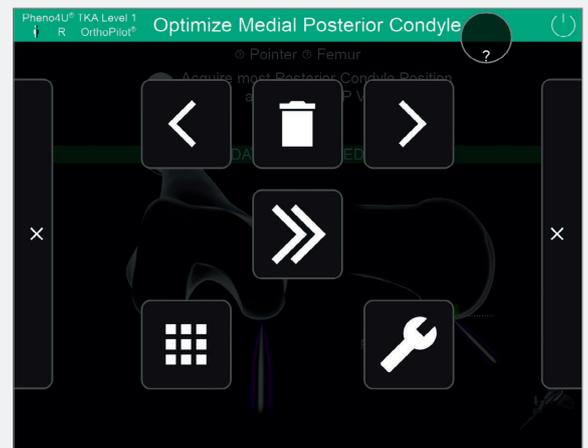
# 4 | Controls and Interaction

The OrthoPilot® system offers three different means of control/interaction.



- Using + and - buttons to adjust femur size (only during the Distal femur cut/4-in-1 Cutting Block Positioning step)
  - Skipping extension/flexion gap measurement and femoral planning (only during Extension and Flexion gap step)
- During software steps in which the Multitool or transmitter FS636 with other instruments (e.g., distal cutting block NS334R or one of the 4-in-1 cutting blocks) are not used, the user can perform the above-named actions with a quick/long press of the manual trigger (black) directly on the transmitter.

Menu functions are independent of the selected interaction.



**4.1 Multitool (FS640 with mounted FS636 transmitter)**  
Multifunctional instrument used for data acquisition and software control. Click the control button in the handle briefly to record data or confirm interactions. Press and hold the control button in order to open **the menu** in the application. From there, users can perform the following actions:

- Toggling forward or backward within the workflow
- Deleting recorded data in current step
- Deleting previously recorded data and returning to the corresponding software step

### Note

This function, the only one marked on the menu with a red symbol, is available if no data recording has taken place during the current software step. It cannot be accessed otherwise.

- Accessing the workflow navigator for navigating quickly and easily to selected workflow steps
- Accessing the toolbox for adjusting the camera, acquiring kinematic data, and opening measurement modules for recording points on the femur/tibia
- Accessing an alternative method of determining the center of the hip joint (only during the Determining Hip Joint Center step)

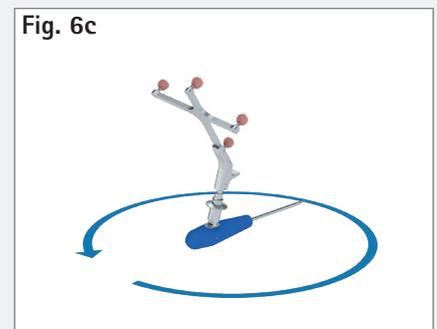
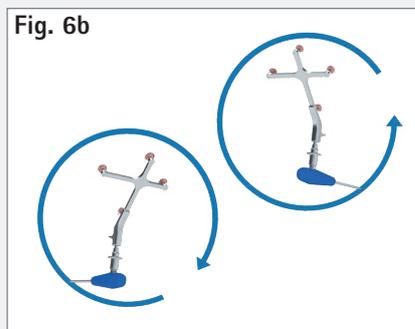
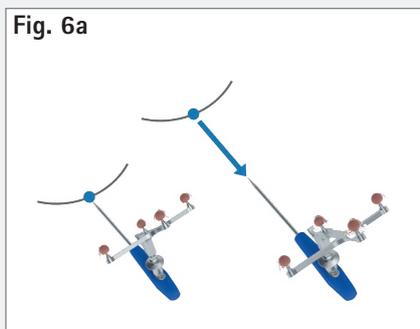
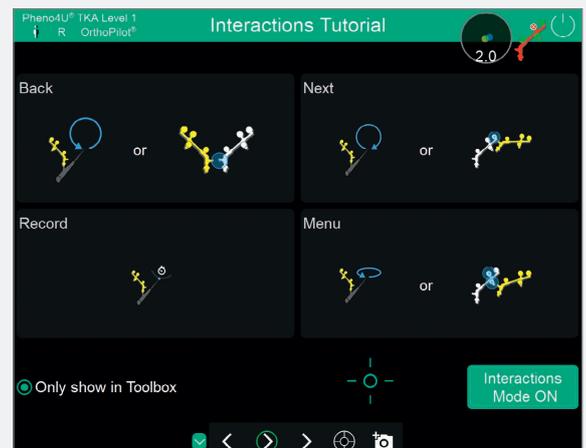
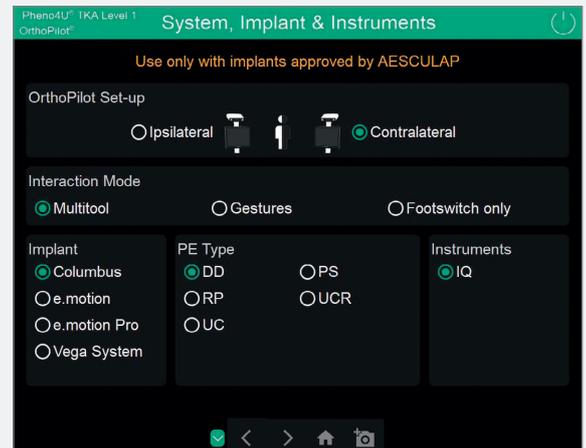
# 4 | Controls and Interaction

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

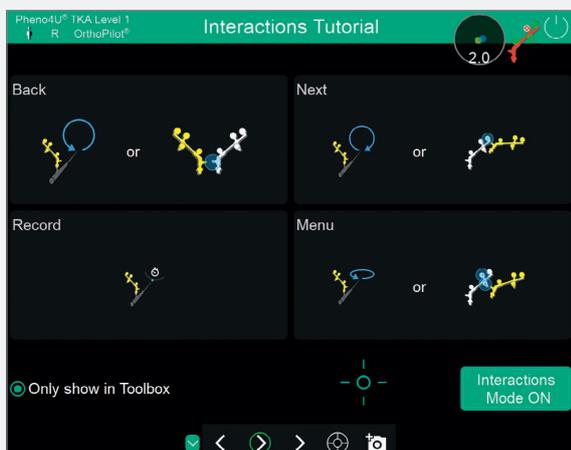
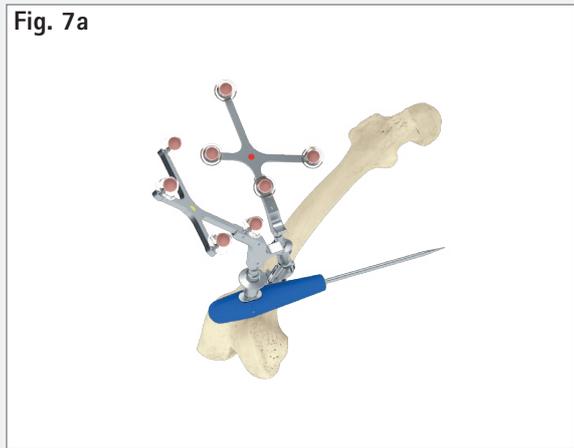
### 4.2 Gesture control (with pointer FS604 and mounted FS633 transmitter)

Users can palpate bone reference points and control the software using specific, defined gestures. To record a point, after placing the pointer precisely and stably on the reference point being recorded in that step, withdraw the pointer axially (Fig. 6a). Be sure to use a controlled motion. Gesturing with the pointer in a vertical clockwise circle will call up the next step in the workflow; a vertical counter-clockwise circle will call up the previous step (Fig. 6b). Gesturing with the pointer in a horizontal counter-clockwise circle will open the menu described in Chapter 4.1 (Fig. 6c).

The pointer also has a timer function for use in data acquisition. Hold the tip of the pointer still until the "record" symbol appears on the OrthoPilot® screen, and a blue highlighted frame begins to complete itself continuously. Once the record symbol is completely outlined in blue, the data has been successfully recorded, and the software will proceed to the next step. The controls used to switch forward through individual software steps are the same as the ones described in Chapter 4.1.



Another software control option is to toggle forward / backward or open the menu by positioning the yellow transmitter near the tibial / femoral transmitter. Bring the base of the yellow transmitter for opening the menu near the color-coding on the tibial or femoral transmitter (Fig. 7c). To toggle forward, the base of the yellow transmitter must be near the marker sphere furthest away from the base of the tibial / femoral transmitter (Fig. 7b). To toggle back, bring it close to the tibial / femoral transmitter base itself (Fig. 7a). The software toolbox includes a tutorial for all gestures, which describes gestures individually and allows users to practice them.



# 4 | Controls and Interaction

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

### 4.3 Foot pedal (wireless, for use with OrthoPilot® system)

The wireless foot pedal is the third control option available to users.



#### 1) Central foot button

**Short click:** Toggle forward/record data

**Long click:** Only triggers an action during four software steps:

1. Starts the optional data acquisition process during measurement of the hip joint center.
2. Skips the measurement process in the "determining extension gap" step.
3. Within the "distal femoral resection" step, it is used to increase the size of the previously selected femoral component in stepwise.
4. Likewise, within the "positioning the 4-in-1 cutting block" step, it is used to increase the size of the previously selected femoral component stepwise.

#### 2) Left foot button

**Short click:** Toggle back within a workflow

**Long click:** Delete data within the current step

A long click on the left button only triggers a different action within two steps:

1. Within the "distal femoral resection" step, it is used to reduce the size of the previously selected femoral component stepwise.
2. Likewise, within the "positioning the 4-in-1 cutting block" step, it is used to reduce the size of the previously selected femoral component stepwise.

#### 3) Right foot button

**Short click:** Open the menu

**Long click:** Screen shot

### 4.4 Special software control features

When using Multitool or gesture controls (not the foot pedal) to toggle forward, the flexion angle range (70 +/- 5°) will be marked in purple colour on the "knee joint center", "mechanical axis" and "kinematic measurement" steps. If the leg is held still within that range for a certain period of time, the software will toggle forward one step. Alternatively, users can always toggle forward or trigger data recording by performing the action specifically defined for their chosen interaction method.

---

#### Note

Should one of the above-named interaction methods experience a technical failure, the OrthoPilot® system touchscreen can also be used as an interaction platform. This will require someone who is not active directly within the operating field to press the symbols on the screen to trigger the corresponding actions during surgery.

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# 5 | Option Settings

## 5.1 Settings

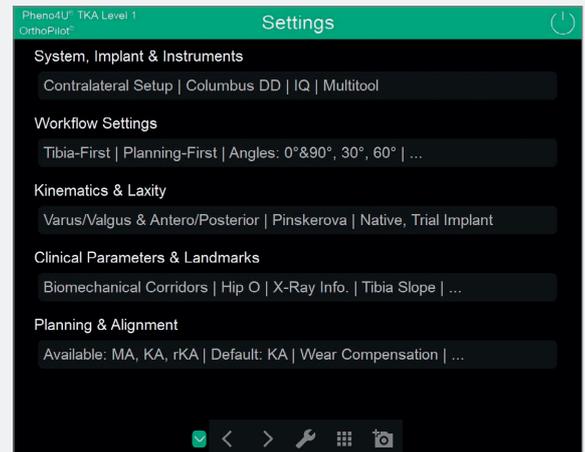
The settings screen provides an overview and a short summary of the options selected in the following categories:

- System, Implant & Instruments,
- Workflow Settings,
- Kinematics & Laxity,
- Clinical Parameters & Landmarks,
- Planning & Alignment

The individual categories can be accessed using the touchscreen.

### Note

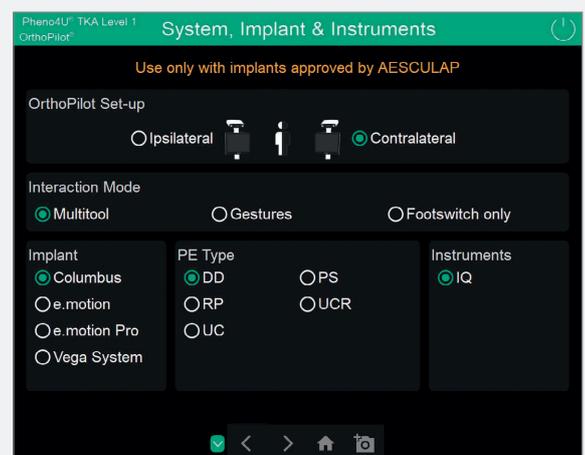
As general rule, a circle stands for an either/or selection to be made, whereas a square offers multiple selections. Sliders are used for a simple on/off tuning. Parameters in grey, symbolize they must be selected based and previously performed selection and cannot be changed or they cannot be tuned because of a previous choice. Pressing the home button in sub-screens will bring users back to the upper-level settings overview.



## 5.2 System, implant and instruments

In this category the choice of **camera position**, either ipsi- or contralateral is made. In addition, one of three **interaction modes**, Multitool, Gestures or footswitch needs to be selected.

The used AESCULAP® **implant** system Columbus®, e.motion® or VEGA System® and respective planned **Polyethylene type** need to be chosen. Pheno4U® TKA Level 1 is compatible with IQ **instruments** only. Implants and instruments not added during installation will not be displayed for selection. The software prevents any impossible combinations of interaction methods and instruments.



# 5 | Option Settings

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

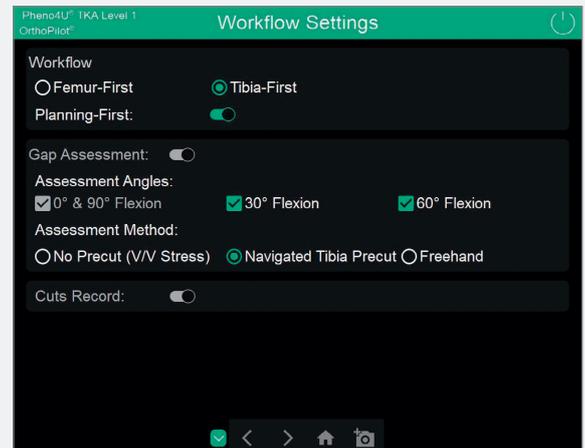
### 5.3 Workflow settings

Here the planned **workflow** femur- or tibia-first needs to be selected.

The **activation of planning-first** leads later in the workflow to a planning screen where both, final femur and final tibia resection can be planned before being executed. The activation of Planning-first, requires automatically **gap assessment** in minimum 0° and 90° flexion, displayed in grey (=not to be changed)

A pure femur- or tibia-first selection without activating planning-first, leads to a simple cut navigation workflow without gap assessment according to the selected order, unless gap assessment is activated in the next section.

If **gap assessment** is activated, minimum selection of 0° and 90° is selected automatically. With 30° and 60° additional angles for the gap assessment can be selected as well as the **assessment method**.



### 5.4 Kinematics and laxity

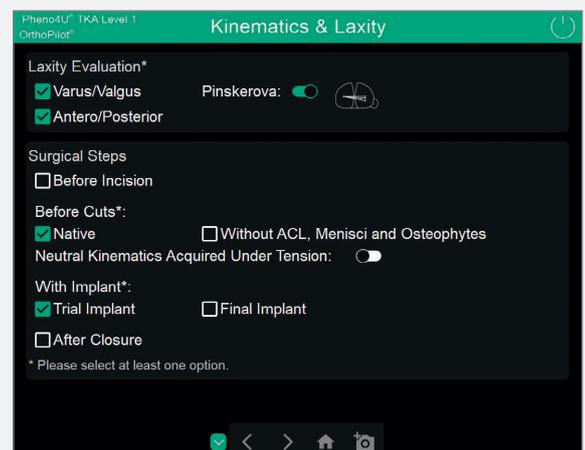
In this section minimum one parameter needs to be selected for the **laxity evaluation** of the leg, either Varus/Valgus or Antero/Posterior, as well as the points of time in which **surgical step** and how to perform the evaluation/s.

The selection of recording the laxity **before incision**, as option, requires a fixation of both tibia and femur transmitter before the approach to the knee joint.

#### Note

Special care must be taken during the fixation of the femoral transmitter.

Sliders offer the possibility to activate or deactivate the Pinskerova-view as well as if neutral kinematics is preferably acquired under tension or not.



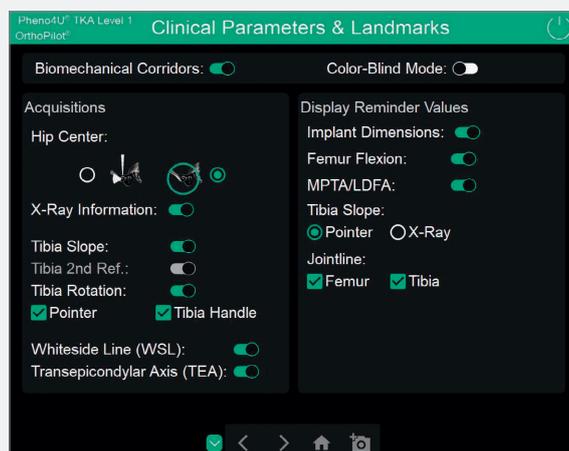
## 5.5 Clinical parameters and landmarks

**Biomechanical corridors** activated will show an additional safety display in terms of implant loads and moments for the placement of the implant components during the planning and resection screens. Activation of **color-blind mode** will help affected people to distinguish different values, symbols or colors.

The section **acquisitions** allows to choose from a variety of optional recordings and information input such as:

- The choice of movement for hip acquisition,
- Input of X-ray information,
- Tibia slope,
- 2<sup>nd</sup> tibia Reference,
- Tibia Rotation and the way of recording it,
- Whitesideline and /or
- transepicondylar axis

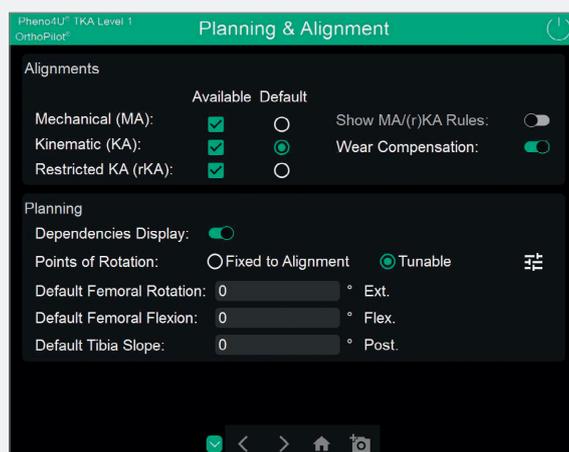
The sub-section **display reminder values**, enables the activation of values to be displayed as reminder in later workflow steps, e.g. the planning screen.



## 5.6 Planning and alignment

The section **alignments** offers to select which of the installed alignment philosophies shall be available during further workflow steps (especially the planning screen) and which of them should appear first by default. If no gap assessment, thus no planning is used and cut record is switched on, the activation of show MA/(r)KA rules will display reminders in the resection screens according to the chosen alignment. With KA and rKA alignment, additionally wear compensation can be activated that brings additional screens to put in the amount of cartilage wear to be compensated on femur and/or tibia.

The **planning** section offers to activate additional arrows in the planning screen that shows the dependencies in which other values will change when tuning one value. Two main choices are available for the points of rotation: Fixed to alignment or tunable. The more options symbol offers the possibility to check the points of rotation or to configure according to individual preferences. Default values that will be preset in the planning screen can be put in for femoral rotation and flexion and tibial slope.



# 6 | Entering Patient-Specific Data

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

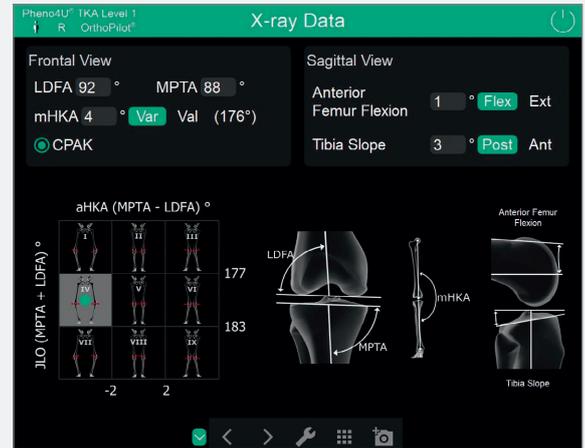
### 6.1 X-ray data

From a **frontal view** radiograph, input of the measured values of lateral distal femur angle (LDFA), medial proximal tibia angle (MPTA) and mechanical hip-knee-ankle angle (HKA) is possible. After choice of CPAK the corresponding Coronal Plane Alignment Of The Knee (CPAK) classification is shown as additional information.

It is based on pre-operative X-rays, oriented towards MacDessi et al. Coronal Plane Alignment Of The Knee (CPAK) (11).

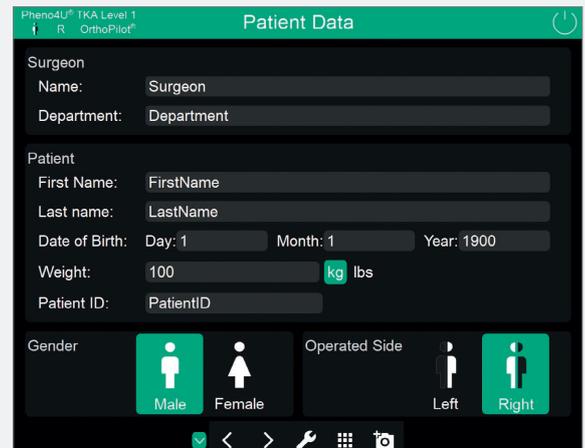
The mechanical hip-knee-ankle angle (mHKA) can be entered as an independent value by selecting "Var" or "Val". The CPAK category will be determined solely by the MPTA and LDFA.

Input values for anterior femur flexion and tibia slope from **sagittal view** X-ray is an additional option. If chosen in the settings, these values will show up later, e.g. in the planning as reminder values.



### 6.2 Patient data

Entering Patient-specific data	
Name of surgeon	
Hospital/department name	
First name	
Last name	
Date of birth	Day: 1 Month: 1 Year: 1900
Weight (optional, but mandatory for biomechanical safety corridor information from 50-140 kg)	100 kg lbs
Patient ID (optional)	PatientID
Gender	Male Female
Operated side	Left Right



### 6.3 Multitool set-up

When the Multitool is selected, a Multitool correctly assembled for the side undergoing surgery and the camera position will be displayed on the right side of the Surgery Data screen as well as on a separate screen.



# 7 | General Data Recording

## 7.1 Kinematics before incision – optional

In case this option has been selected, an **instruction message** on the screen reminds to fix transmitters first and not to proceed to knee incision.

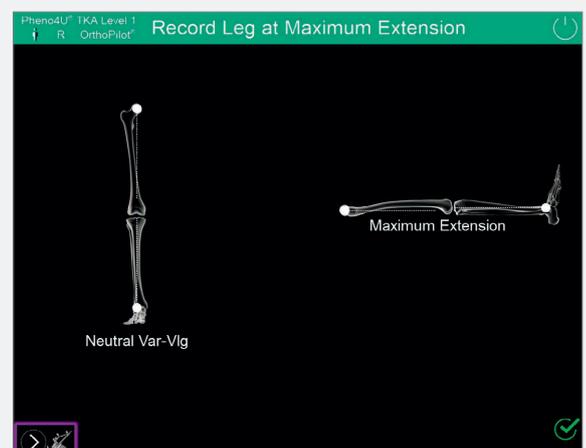
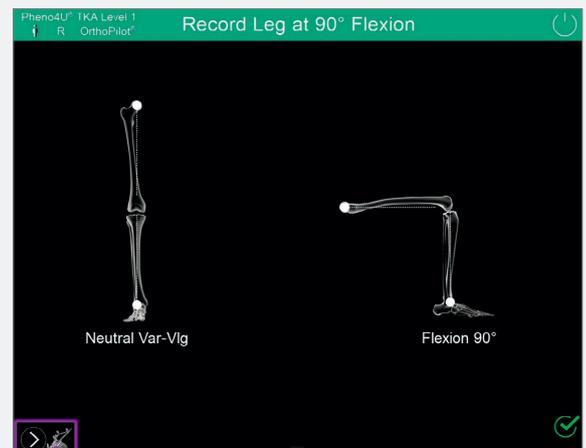
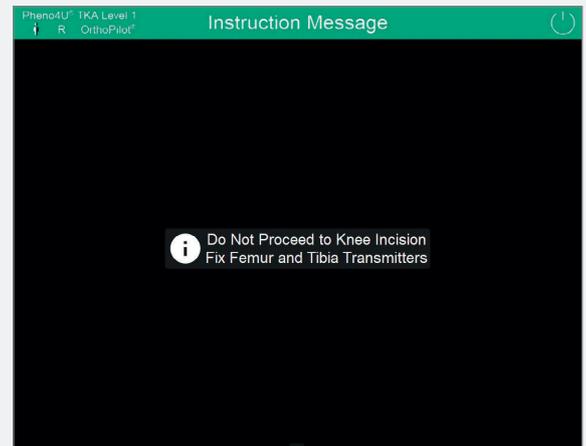
The kinematics is recorded before the incision to the joint, thus having no information yet on angles or axes. Therefore, to start the procedure **one record in 90° flexion** and **maximum extension** needs to be performed.

### Note

An adapted and suitable fixation of the femoral transmitter is important.

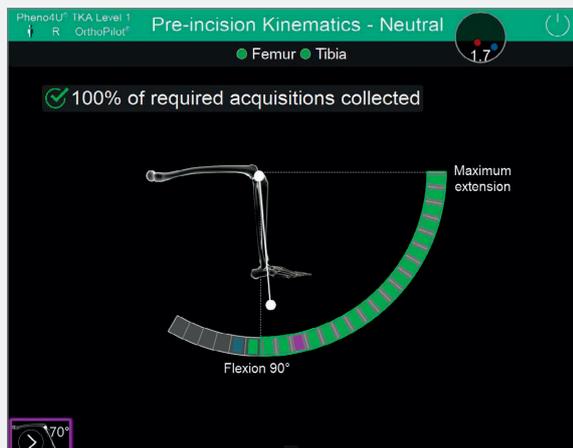
### Tip

In all steps in the lower left corner on the screen, it is indicated in a purple frame how to proceed to the next step.



# 7 | General Data Recording

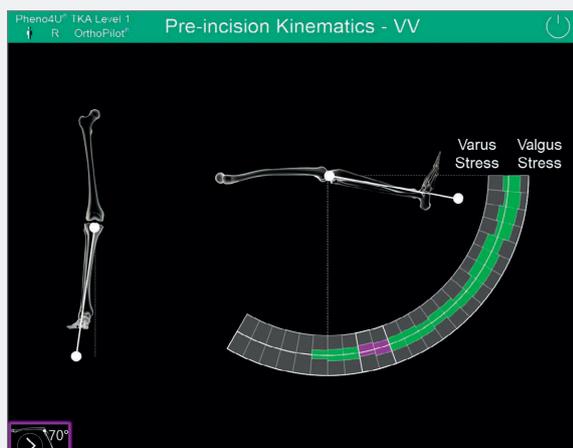
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After the angles have been defined, the measurement can be started by performing the **pre-incision kinematics – neutral** by avoiding varus and valgus stress. Second, the **pre-incision kinematics – VV** is recorded performing varus and valgus stress, which is possible over the whole range of motion.

**Pre-incision kinematics – AP** is an additional possibility to determine the anterior posterior laxity of the knee joint in defined angles of 0, 30, 60 and 90°.

In all steps in the lower left corner on the screen, it is indicated in a purple frame how to proceed to the next step.

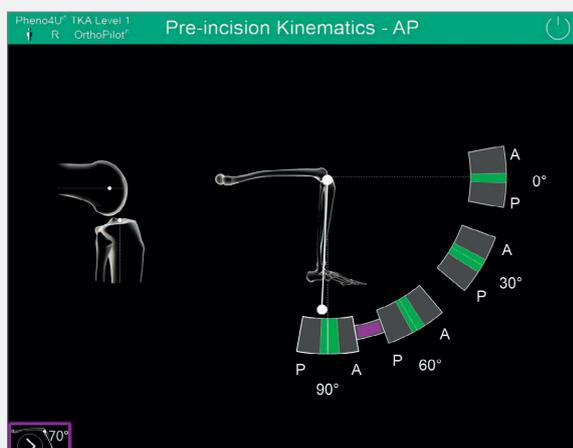


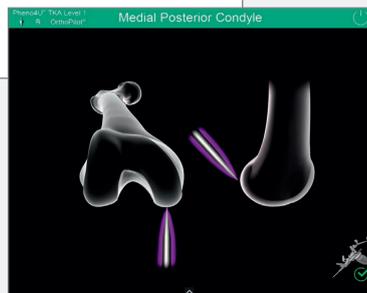
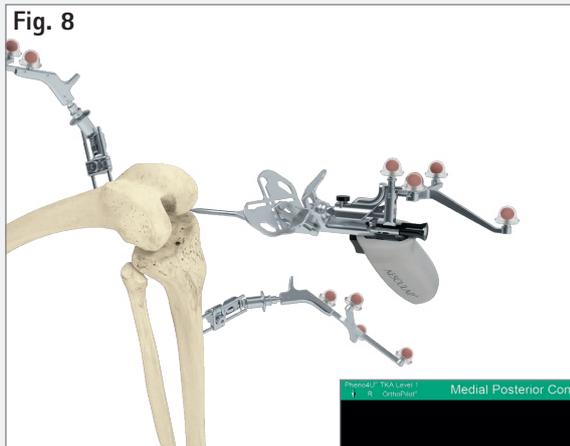
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### Tip

In all steps in the lower left corner on the screen, it is indicated in a purple frame how to proceed to the next step.

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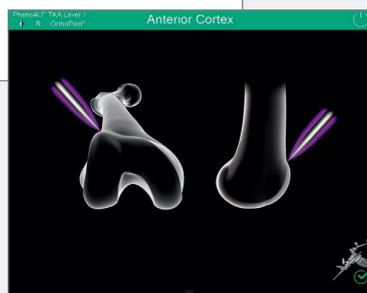
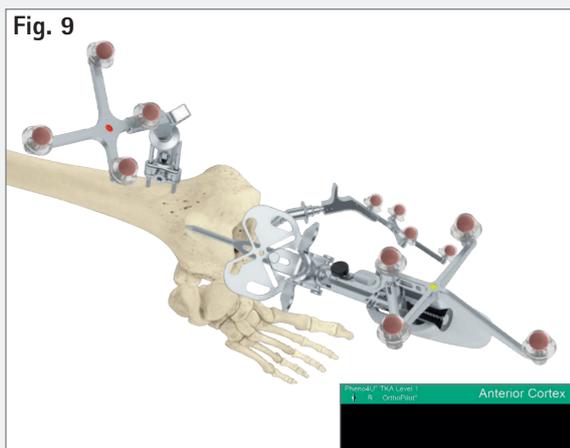




### 7.2

#### Recording the medial and lateral posterior condyles

Place the pointer tip of the Multitool (FS640) or the pointer (FS604) at the center of the posterior medial condyle. Choose the point furthest in the posterior direction – in other words, the one furthest from the anterior femoral cortex point. Do the same for the lateral side.



### 7.3

#### Recording the anterior cortex

This reference point is located at the place where the anterior shield ends proximally. In the medio-lateral direction, palpate the point located furthest in the anterior direction.

The distance between this point and the posterior condyles is used as the basis for suggesting femoral component sizes and for calculating the theoretical center of the knee joint. Later on, it is also used to determine whether there is a risk of anterior notching.

# 7 | General Data Recording

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

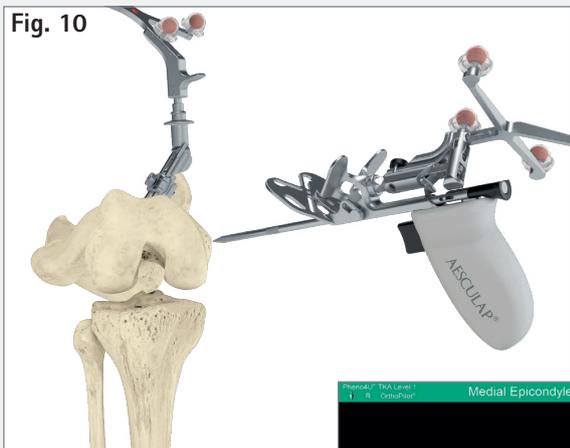
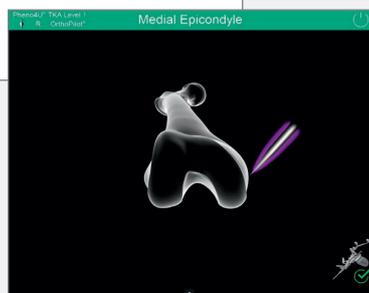


Fig. 10



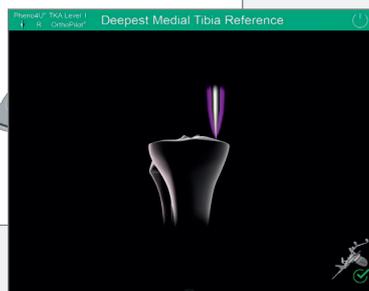
### 7.4 Recording the medial and lateral epicondyles – optional

The trans-epicondylar line can be determined by palpating the medial and lateral epicondyles if the corresponding option has been activated. In a later program step, in addition to the posterior condylar line, the user will also be shown femur rotation in reference to the trans-epicondylar line.

Start by placing the tip of the pointer on the medial epicondyle and record this point. After that, record the lateral point in the same manner.



Fig. 11

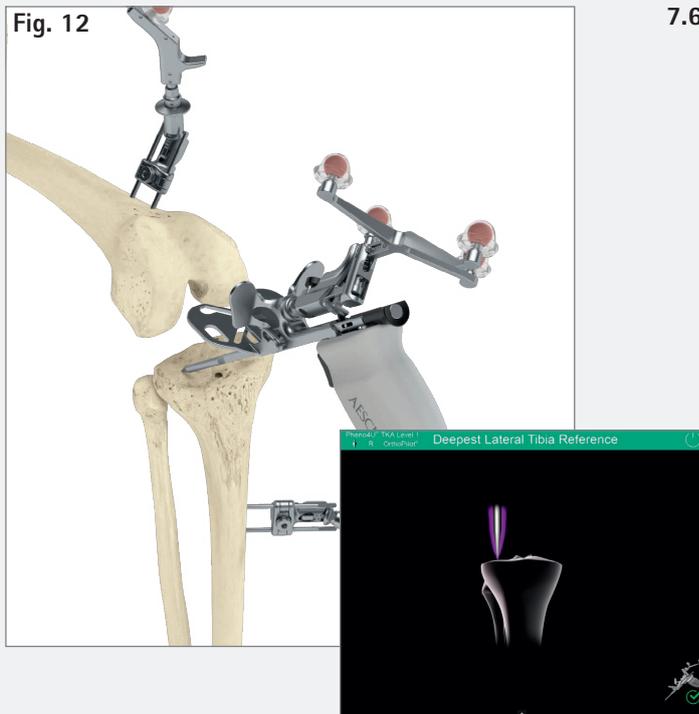


### 7.5 Reference for medial cutting-height display

In this step the bony reference for the medial cutting height display is recorded.

It is advisable to use significant landmarks during palpation, e.g., the deepest point of the defect or the joint surface.

If the option wear compensation has been chosen in the settings, the screen title will show deepest medial tibia reference.



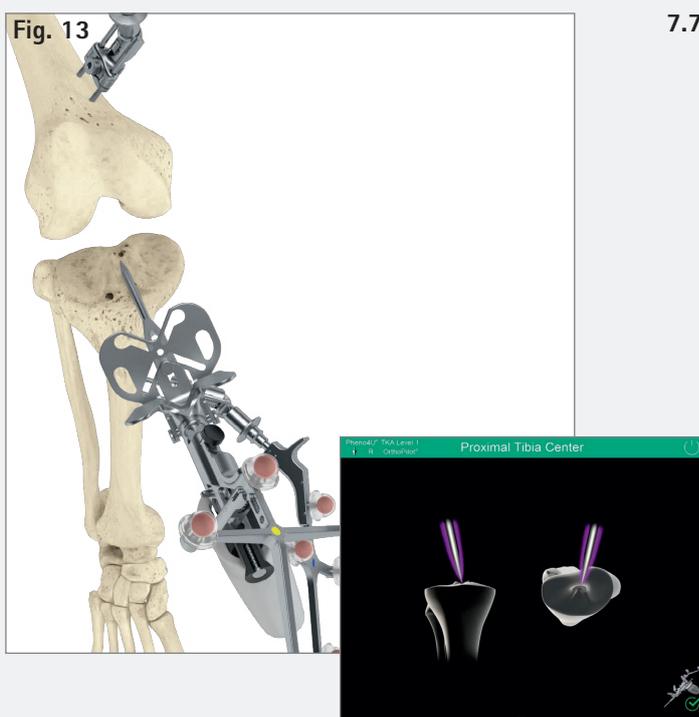
### 7.6 Reference for lateral cutting-height display

This step entails recording the reference point for the lateral cutting-height display. It is advisable to use significant landmarks during palpation, e.g., the deepest point of the defect or the joint surface.

If the option wear compensation has been chosen in the settings, the screen title will show deepest lateral tibia reference.

#### Option

The default settings include palpation of both reference points. Users have the option of changing the settings so that only one reference point is required (not applicable if one of the following options is selected: rKA, KA, Pinskerova, planning first). Changing this setting will mean that only one reference point is recorded, and that single reference point will be used to display the cutting height during the "tibial resection" step.



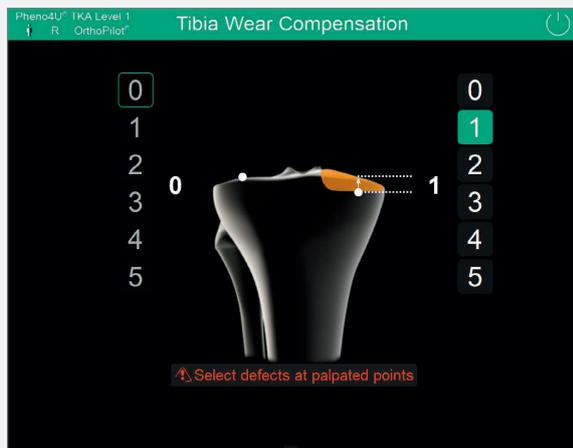
### 7.7 Identifying the tibial center

This step is used to register the center of the anterior insertion of the ACL. If the patient has no ACL, or degenerative changes have occurred, the point can be found:

- in the center of the medial-lateral diametric line of the tibial head,
- at the transition between the first and second thirds of the anterior-posterior diametric line of the tibial head, measured from the anterior edge.

# 7 | General Data Recording

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### 7.8 Tibia wear compensation – optional

If wear compensation is switched on, a separate step to select the amount of wear in mm on medial and lateral side of the tibia appears. The estimated amount of wear in mm **in relation to the previously palpated reference points for the cut-height** medial and lateral can be selected via virtual mouse on the screen. In order to proceed bring the cursor out of the numbers table and click with Multitool or hit the central pedal of the footswitch.

These values show up as grey reminder values and orange area later in the workflow, e.g. the planning screen and tibia resection.



### 7.9 Registering tibial rotation – optional

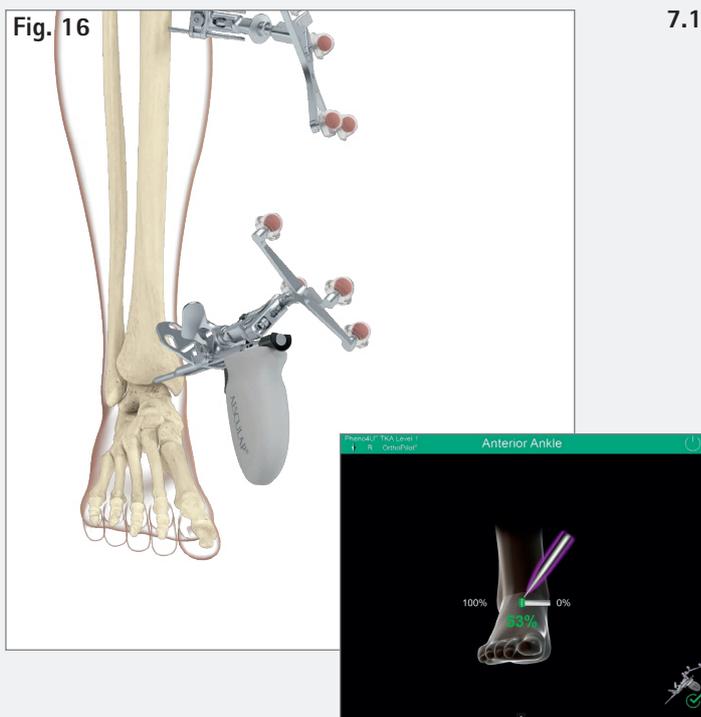
The user has the option of registering approximate tibial rotation in order to perform a dedicated investigation of tibial component rotational alignment later on during the operation. Place the pointer shaft axis on the desired rotation position. For example, the pointer stem can be placed on the tibial plateau along an imaginary line oriented to the medial edge of the tuberositas tibiae, with the tip facing toward the posterior edge of the tibial plateau (target reference: pointer tip at the PCL insertion) (10).

#### Tip

Note the different degrees of variability among different reference points registered intraoperatively; some of these may involve a very high degree of variability (10). Avoid internal rotation of the tibial component, as it would result in lateralization of the tuberositas tibiae, which could cause problems with patella tracking. Internal rotation of both the femoral and the tibial component, in particular, can result in aggravated patella dislocation, increased patella tilt, and subluxation positioning of the patella. Improper rotation of the tibial component also causes excessive stress on the inlay, resulting in accelerated wear.



- 7.10 Recording the medial and lateral malleolus**  
Place the pointer tip at the center of the medial malleolus and record the point. Do the same for the lateral side.



- 7.11 Anterior ankle joint point**  
Register the point by placing the pointer tip at the front edge of the distal tibia, as close as possible to the ankle-joint gap.  
The display on screen will assist the surgeon in verifying the anterior palpation point by showing a percentage display starting from the medial malleolus palpation point, with a green safety zone around 50% +/- 5%.

**Tip**

The second metatarsus/second ray or the M. extensor hallucis longus tendon can be used as a landmark. The percentage display serves as a plausibility check. If the point is outside of the green safety zone, it is advisable to re-palpate the malleoli.

# 7 | General Data Recording

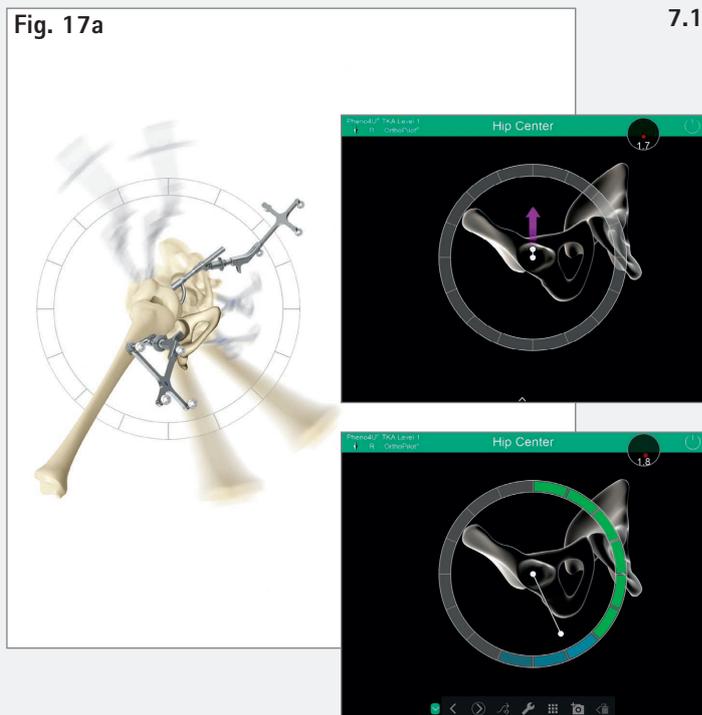
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## 7.12 Tibia slope – optional

If option tibia slope is switched on, the tibial slope can be measured by placing the pointer on top of the tibia in AP direction on the medial or on the lateral side. This value will show up (if selected) as a reminder value later in the workflow in the planning screen.

Fig. 17a

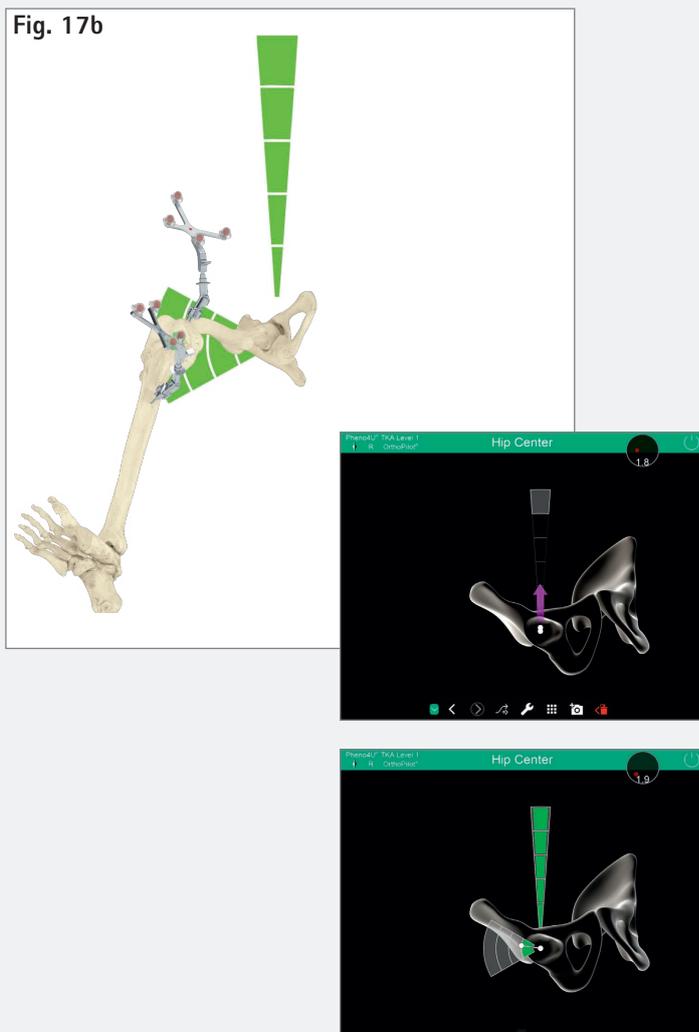


## 7.13 Registration of the hip center

Once the leg is kept still, an arrow pointing upwards will appear, and the user can start to move the leg towards 12 o'clock.

The **default way of hip center registration** is the circle (0) (Fig. 17a). The regular circle registration can be started after having reached the topmost grey segment of the circle at 12 o'clock position. The motion can be performed in a clockwise or counterclockwise direction depending on the physician's preference. Thereby the femur is moved in such a way, so that the white point is moving over the fields arranged in a circle.

Fig. 17b



An alternative hip center acquisition movement (L) pattern can be installed (Fig. 17b). If installed it is the surgeon's choice and decision in the surgery options screen, which movement pattern to be used for this registration. The alternative L-registration can be started after having reached the topmost grey segment at 12 o'clock position. The motion is performed vertically from top to bottom (12 in direction downwards to 6 o'clock). The vertical motion should be followed by a horizontal one in the lateral direction (abduction of the leg). For both acquisition movements, be cautious during the movement to stay within the indicated grey fields until they turn green one by one. Once sufficient data has been obtained, the program will automatically jump to the next step. If the motion described above was uneven or not sufficiently precise, a message reading "Bad acquisition" or "Movement too wide" will appear, and the process will need to be repeated beginning from the first position.

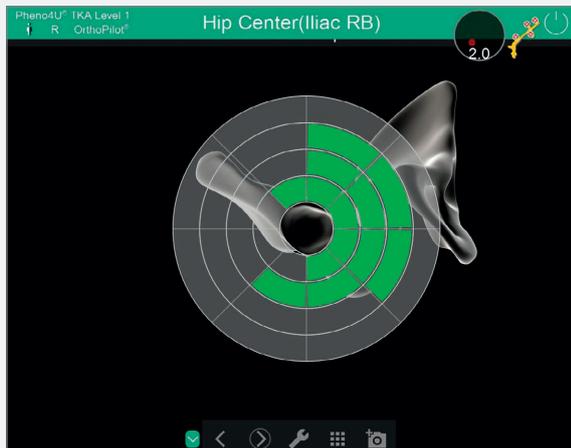
#### Note

Be particularly mindful of:

- not moving the camera during this step,
- whether the femoral transmitter will remain visible through the entire motion,
- whether unrestricted motion is possible (no limitations due to side support, etc.),
- not exerting force on the pelvis through the femur,
- avoiding any type of pelvis movement (responsibility of the surgeon) If this cannot be avoided, please see next Chapter,
- avoidance of a hip flexion angle  $> 45^\circ$  (for O acquisition),
- start with the position of the femur low enough, in order to allow the full upward movement until 12 o'clock position (for L acquisition),
- starting a little in adduction allows for enough movement into abduction (for L acquisition)
- moving the femur back to the initial position before performing the abduction (for L acquisition)

# 7 | General Data Recording

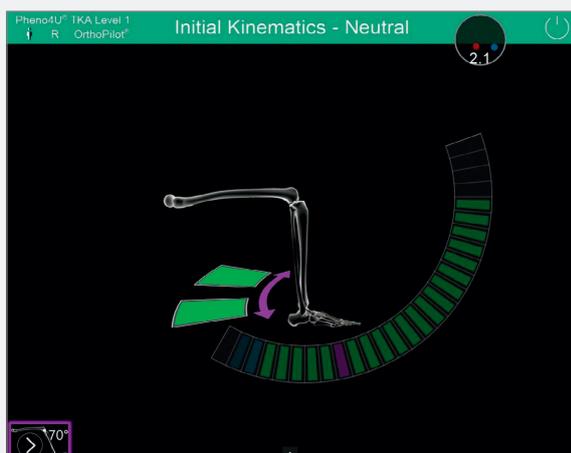
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## 7.14 Optional determination of the hip joint center with pelvic reference

Registering the center of the femoral head will require a reference transmitter firmly anchored to the crista iliaca. This step can be reached via the ring menu in the step "Hip Center" choosing the arrow symbol. The mode itself is displayed in a special window with the note "Femoral head center (pelvic ref)".

Perform large motions with the hip joint until the screen indicates that sufficient data has been obtained. As soon as enough data has been recorded, the program will automatically move to the next step.

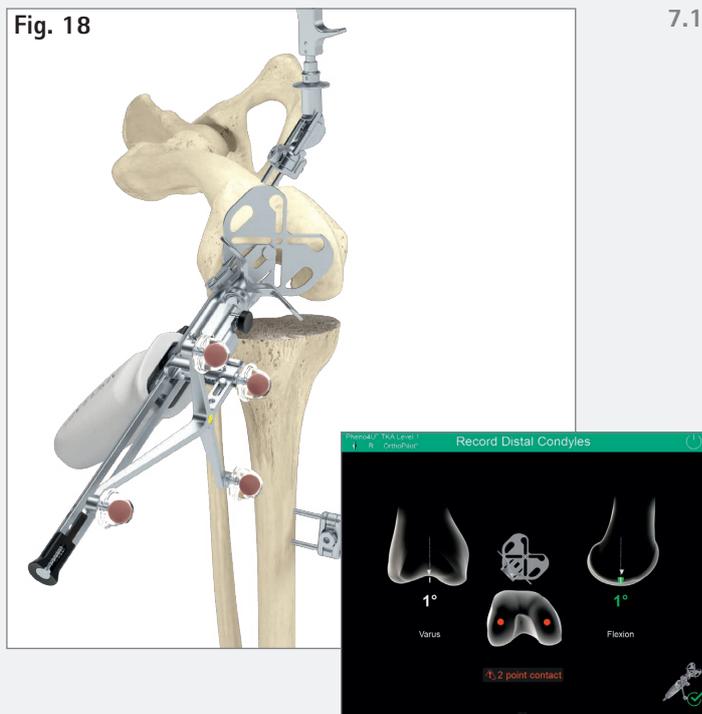


## 7.15 Initial kinematics – neutral

In this step, the program tracks the motion of the femoral transmitter in relation to the tibial transmitter and uses it to determine the center of the knee joint. At the same time this movement determines the neutral curve displayed in white color in the step "native kinematics – varus/valgus" and is basis for the Pinskerova view (projection of the femoral condyles on the tibial plateau) if this option is selected.

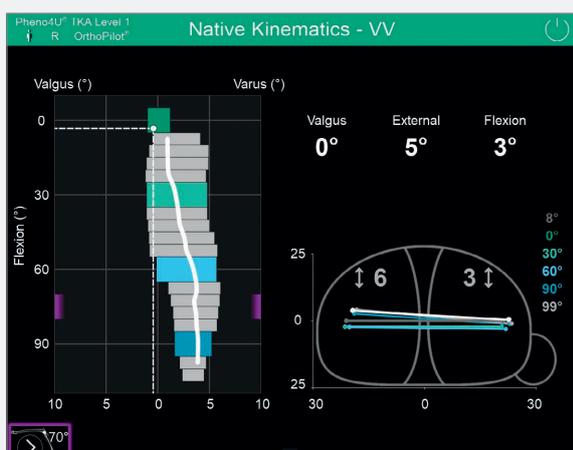
Extend and flex the leg. Hold the leg with one hand in the hollow of the knee. Support with the other hand heel or ankle. Performing a tibial rotation is not absolutely essential, but it can help provide additional precision when performing a 90° bend once two arrows are being displayed on the screen. Fields filled in green indicate that the data has been recorded. Once enough measurement data has been recorded, the software will automatically move on to the next step of the program. After having covered the maximum range of motion (even without inward or outward rotation), the user can also manually trigger the next step, e.g. in case of a flexion contracture that does not allow for full extension.

Fig. 18



### 7.16 Record distal condyles – optional (only if Pinskerova is switched on)

The distal condyles are recorded using the tibia checkplate of the Multitool, or with orientation block NS320R without foot plates in 0° extension / flexion. The distal plane is needed together with the palpated anterior cortex point and posterior condyles to define a virtual position of the best fitting in size femur. This virtual implant fit is needed in order to display the contact points on the Pinskerova chart. Rotation of femur in relation to tibia as well as A/P movement will be projected to the tibia. If Whiteside's Line and Pinskerova is selected as option, this will be recorded instead of the pure distal condyles.

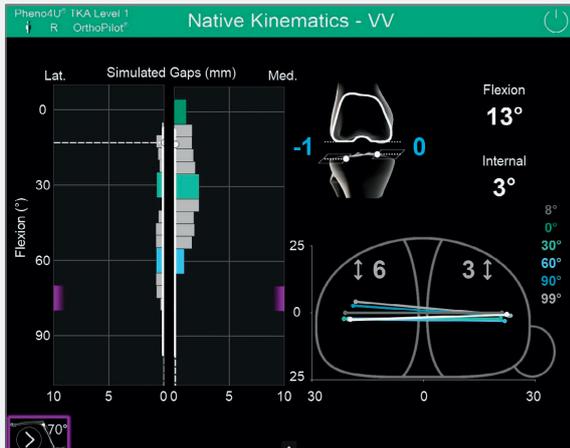


### 7.17 Native kinematics – varus/valgus

The following step graphically displays the current state and position of the leg in coronal and sagittal view. The white curve is the neutral alignment recorded in the previous step Initial kinematics – neutral. Adding varus or valgus stress allows the user to record the maximum values for each flexion angle. This indicates the medio-lateral stability of the knee joint, which can offer initial information on the need for a release to be carried out later on.

# 7 | General Data Recording

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Coloured areas represent values at 0, 30, 60 and 90° of flexion. For these angles, also the A/P translation and rotation of the femur condyles contact points projected onto the tibia is shown in the Pinskerova display on the right (if activated in the settings). In grey numbers the total amount of A/P movement is given on each side (medial and lateral). A legend of color-code is displayed at the right border of the screen.

As per users choice from the menu, the varus/valgus laxity alternatively can be transformed and displayed in medial and lateral gap in mm display. The amount of mm is computed as orthogonal projection of a virtual fitted femur implant surface to the palpated medial and lateral references on the tibia.

### Tip

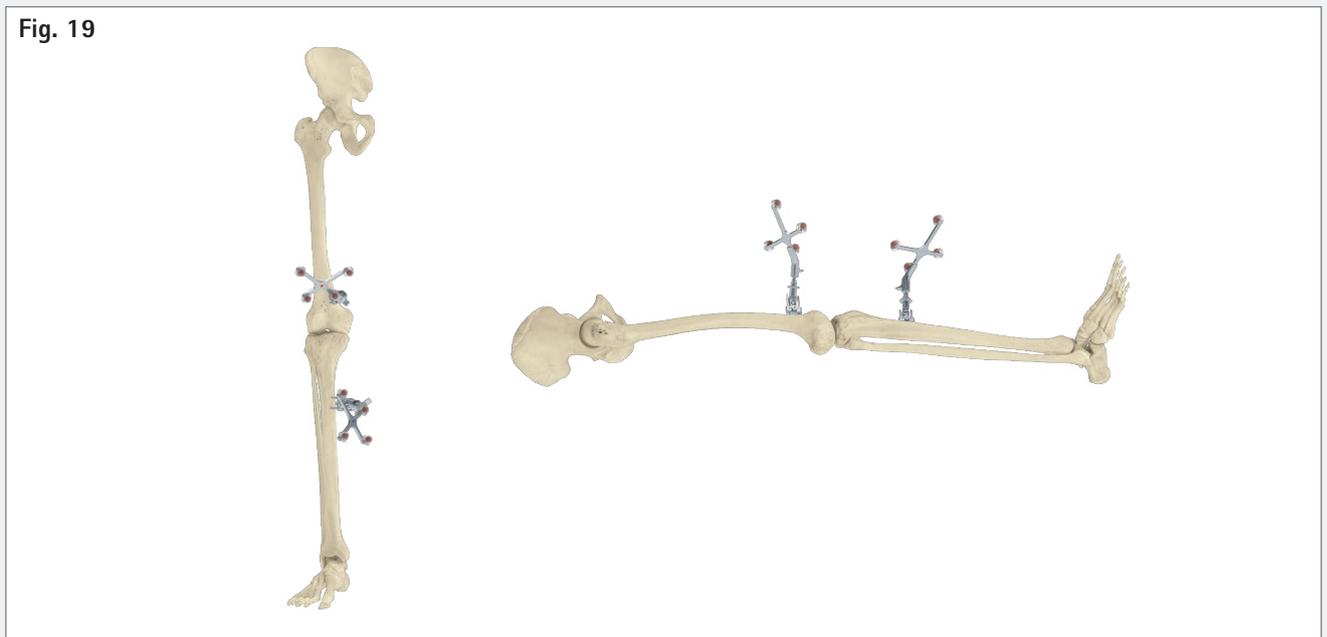
This step serves to check the plausibility of an axis malalignment in comparison to a full-leg X-ray taken pre-operatively. In case plausibility is not given, it is the surgeon's responsibility to redo registrations and check again.

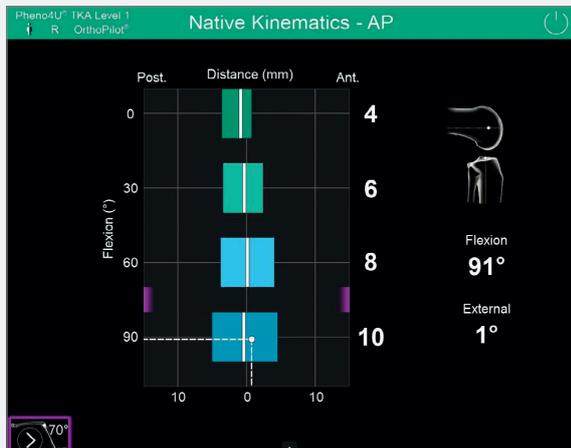
If the settings kinematics record before incision has been selected, an additional display from the menu can be selected directly comparing before incision laxity (grey area) with the current one.

### Note

For information on the Femur first technique, see Chapter 9: Femur first technique

Fig. 19





**7.18 Initial kinematics – anterior/posterior – optional**  
 This step offers to record the A/P shift and laxity of tibia in relation to femur in 0, 30, 60 and 90° of flexion. In addition the rotation of tibia in relation to femur is displayed as well.

# 8 | Tibia First Technique

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

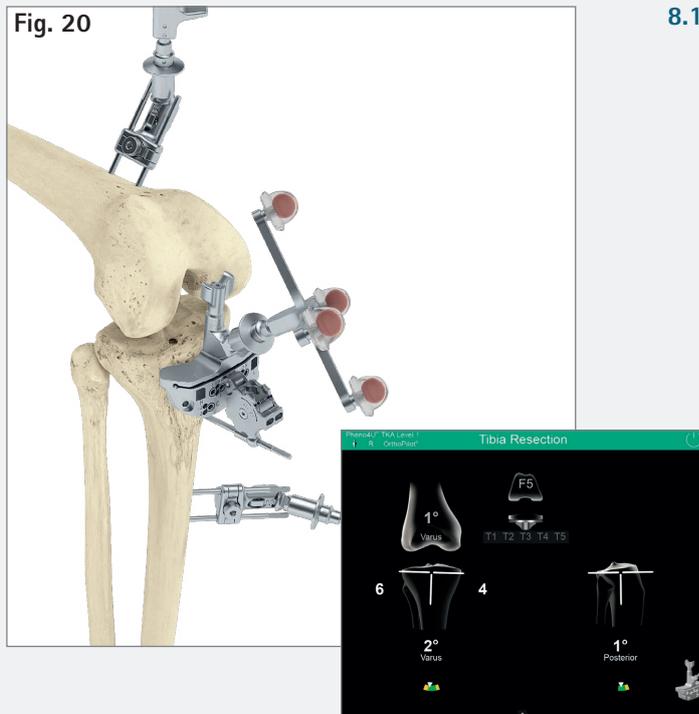


Fig. 20

### 8.1 Resection of the tibial plateau

Connect the modular transmitter adapter (FS626R) and the cutting block (NS334R, IQ instruments) to the corresponding transmitter (FS633 or FS636). Move the cutting block proximally or distally (from the joint line) to determine the exact resection height in relation to the bony reference points palpated medially and laterally on the tibia (program steps "medial tibial reference" and "lateral tibial reference"). The tibial cutting block can be navigated freely to the desired varus/valgus and slope values in relation to the mechanical axis. AESCULAP® recommends a 0° posterior slope for its prosthesis systems.

Start by fixing the tibial cutting block using two headless screw pins from the anterior direction. After that, if necessary, use the available pin holes to maneuver the cutting block and adjust the cutting height in 2 mm steps.

Once the desired resection height, slope, and varus/valgus alignment have been achieved, use an additional screw pin with head (convergent, from the medial/lateral direction) to finish the fixation of the cutting block and then proceed with the resection.

Based on previous palpations in the anterior-posterior dimension, preliminary femoral size calculations and possible combinations with tibial sizes in the selected prosthesis system will be displayed at the top of the screen in the center.

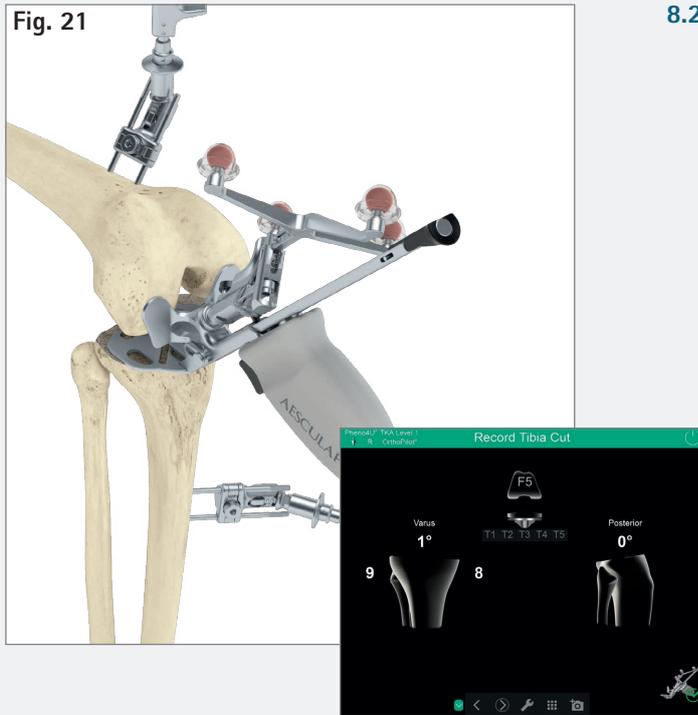
#### Tip

Users also have the option of using an alignment instrument (NP1018R) to assist with IQ cutting block alignment. Start by connecting the alignment instrument to the cutting block (with attached FS626R and corresponding transmitter (FS633 or FS636)) using the correct interface, and then fixing it at a resection height of around 10 mm (distal to the tibial joint line) using a headless screw pin. Rotate around the screw pin to adjust varus/valgus settings. Adjust to the desired resection height (+/- 4 mm) and tibial slope (+/- 8°) manually using the two adjustment knobs or screwdriver NP618R.

#### Tip

To prevent contamination of the marker spheres on the transmitters, it is advisable to either remove the transmitters or cover them until the resection is finished.

Fig. 21

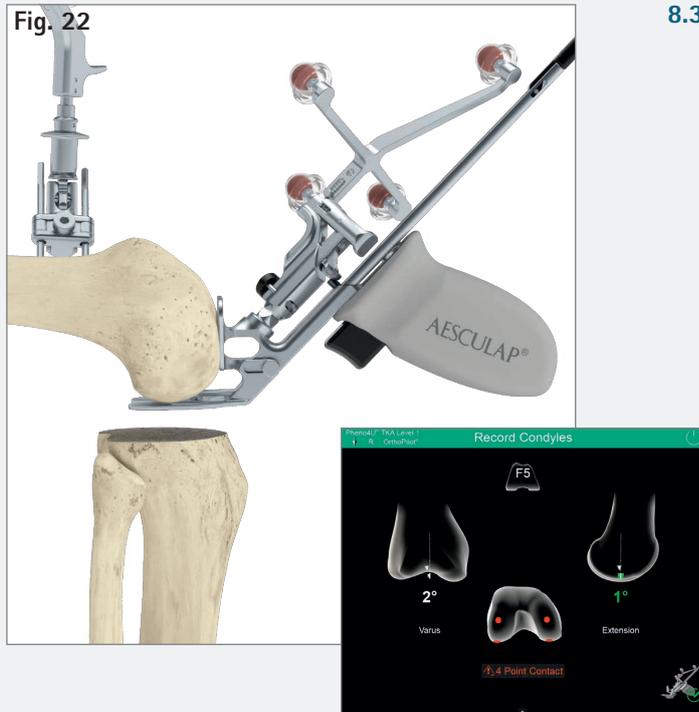


## 8.2 Checking tibial resection

The tibia check plate of the Multitool (or tibia check plate NP617R/NP617RM) is used to check and record the tibial resection. The actual position and orientation of the resection plane in relation to the mechanical axis (with respect to varus/valgus angle and tibial slope) will be shown on the screen. As soon as the check plate is stable, values can be recorded. The data recorded when checking the tibial resection will be used in later calculations, which is why it is essential that the value has to be re-recorded if any tibial resections are performed later on.

# 8 | Tibia First Technique

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



### 8.3 Record condyles

The distal and posterior condyles are registered with the Multitool (see illustration at left). If using gesture or footswitch, it is also possible to register the distal and posterior condyles using the corresponding alignment instrument (NS320R) with foot plates (NQ958R). Sagittal alignment is shown on the right-hand side of the screen. Record the data when the block is vertical to the mechanical femoral axis on the sagittal plane (i.e., the screen shows a slope of around 0°).

If the epicondyles have been palpated (optional), the angle between the trans-epicondylar line and the posterior condylar line (determined using the procedure described above) will be shown in the middle of the screen. If this value is not plausible, it is advisable to re-palpate the epicondyles.

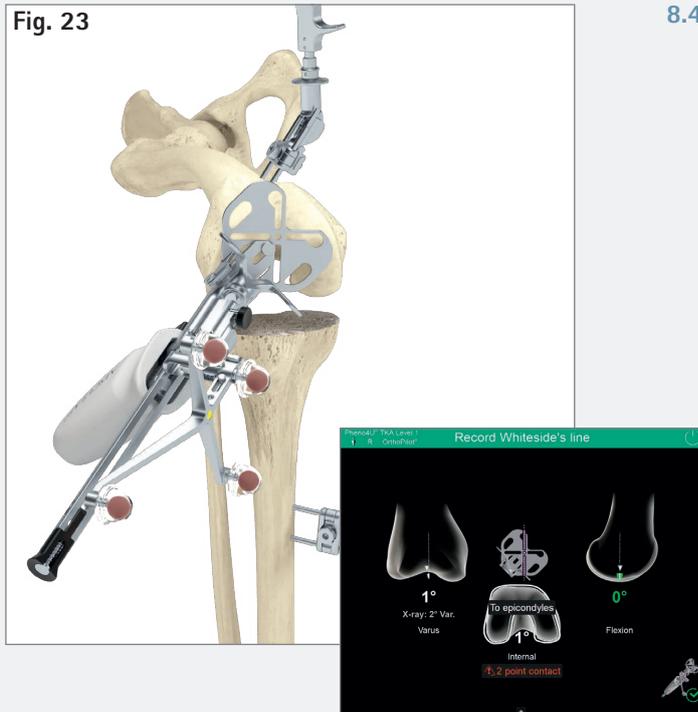
#### Note

Four-point contact is essential!

It is used as the basis for

- recommending femoral component sizes,
- displaying extension and flexion gap measurements,
- displaying cutting height for distal and posterior femoral resections, and
- displaying femoral component rotation.

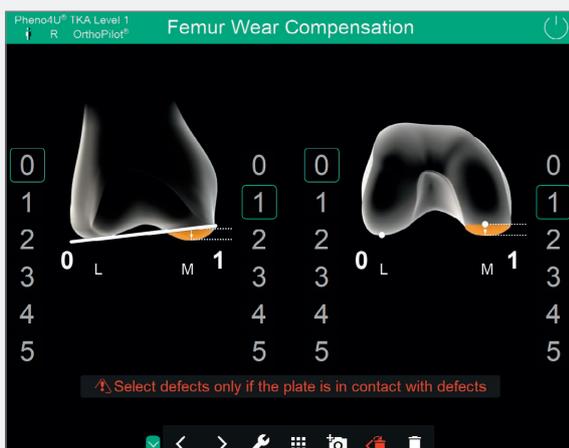
Fig. 23



#### 8.4 Recording Whiteside line (optional)

The Whiteside line is recorded using the tibia check-plate of the Multitool, or with orientation block NS320R without foot plates.

At 0° extension / flexion, maneuver the recess to be used (marked in color on the screen) visually to overlap with the Whiteside line.



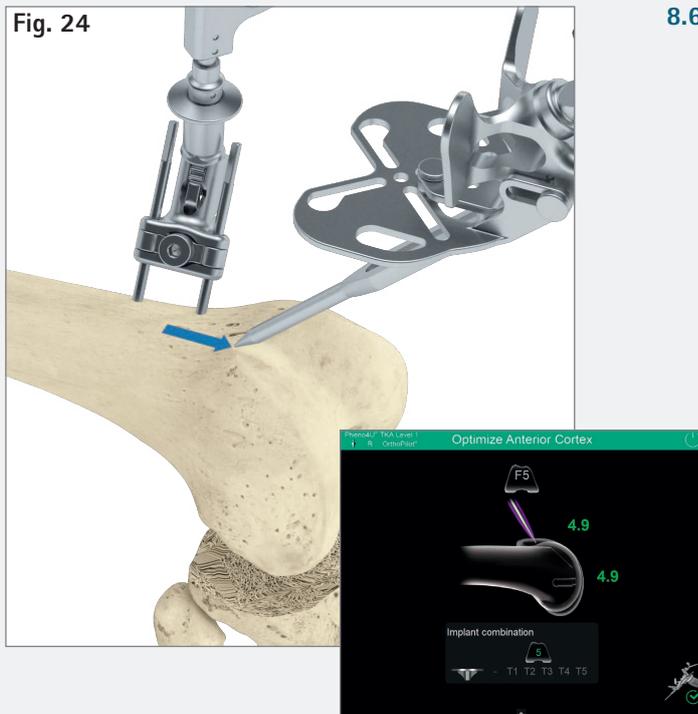
#### 8.5 Femur wear compensation (optional) – limited to KA and rKA

If wear compensation is switched on, a separate step to select the amount of wear in mm on medial and lateral side of the tibia appears. The estimated amount of wear in mm **in relation to the previously recorded distal and posterior condyles** medial and lateral can be selected via virtual mouse on the screen. In order to proceed bring the cursor into out of the numbers table and click with Multitool or hit the central pedal of the footswitch.

These values show up as grey reminder values and orange area later in the workflow, e.g. the planning screen and femur resections.

# 8 | Tibia First Technique

AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

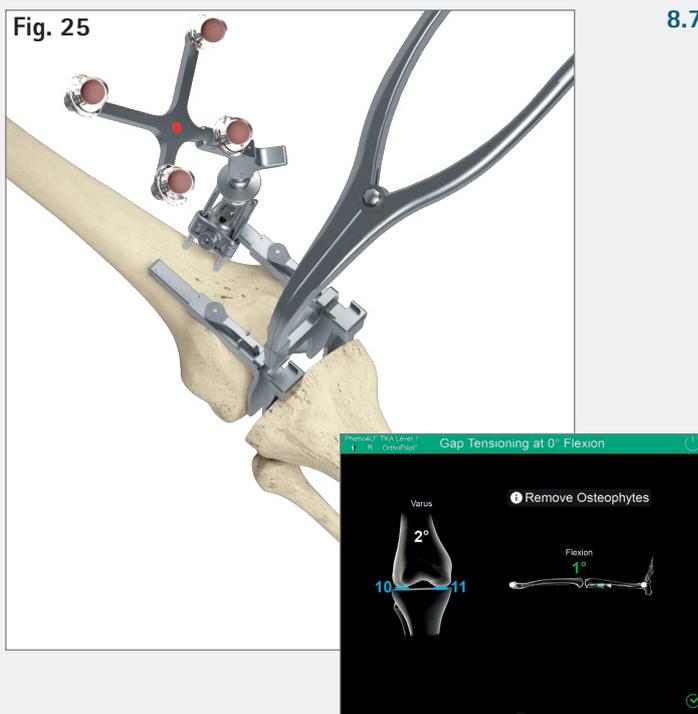


## 8.6 Optimization of the anterior cortex

After the distal and posterior condyles have been recorded, the next step is to optimize the anterior point on the femur using the pointer tip. The initially recorded anterior cortex point. OrthoPilot® will guide you with blue arrows to the spot at which the A/P size of the femoral implant matches the proximo-distal dimension. The value field positioned distally to the femoral component shows the size of the femoral implant in the A/P direction.

The value field above the femoral component shows the size of the femoral implant in the proximo-distal direction.

Underneath, in the center of the screen, there is a "running display" showing the corresponding femoral size when the pointer is moved proximally or distally, and indicating possible combinations with tibial sizes. These combination options are based on the implant system selected at the beginning.



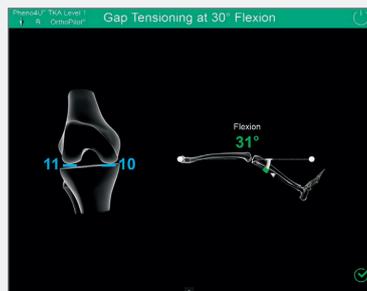
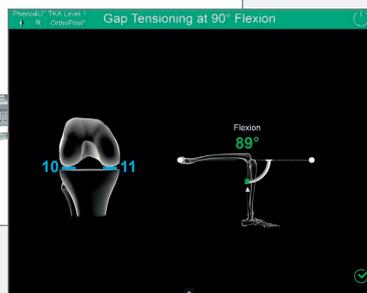
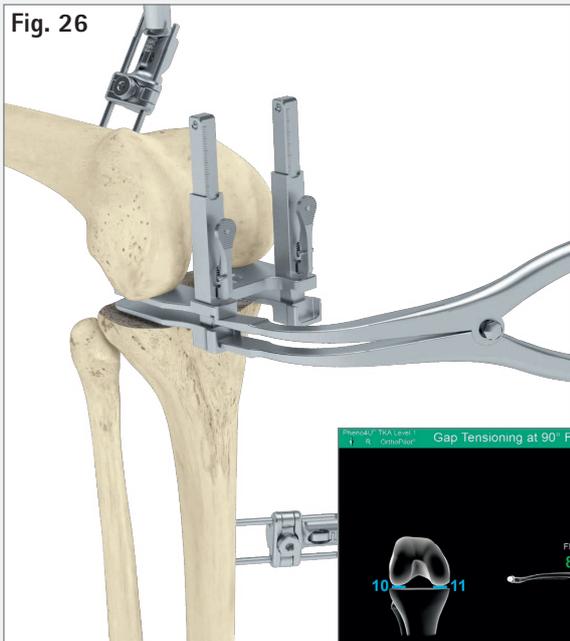
## 8.7 Measuring the joint gap in flexion and extension

Before measuring flexion/extension gaps, remove any osteophytes that could affect ligament and capsular tension. With the leg extended as far as possible ( $0^\circ \pm 5^\circ$ ) place the distractor (NE750R) between the tibial resection and the distal femoral condyles, and then spread using the spreading pliers (NP609R or NP605R), applying equal medial and lateral force. To ensure precise measurement, the plates of the distractor must be flush with the tibial resection plane.

The OrthoPilot® screen will show the medial and lateral gap measurements in millimeters and the mechanical leg axis in degrees (which provides initial information about potential ligament release), as well as the degree of flexion.

Once this data has been recorded, release the distractor and bend the leg at a  $90^\circ$  angle.

Measurements can be taken as long as the leg is in the flexion position marked in green. Make sure to keep



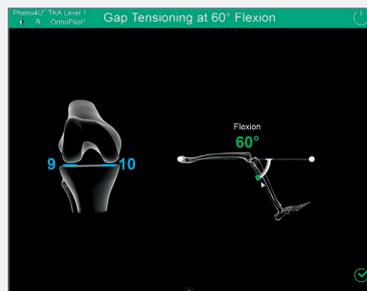
the leg as stable as possible during the measurement process. Real-time gap values will be shown on the tibia in blue. By recording the values, the software takes you into the next step.

In this step, it is possible to skip completely the distraction and the femoral planning steps by choosing the double forward arrow in the toolbar or the ring menu, or by doing a long footswitch press (see Chapter 4).

Data is recorded in this step using the same process as described for extension. As described in Chapter 4, it is always possible to redo these gap measurements (e.g., following a ligament release) using the software's back and delete functions.

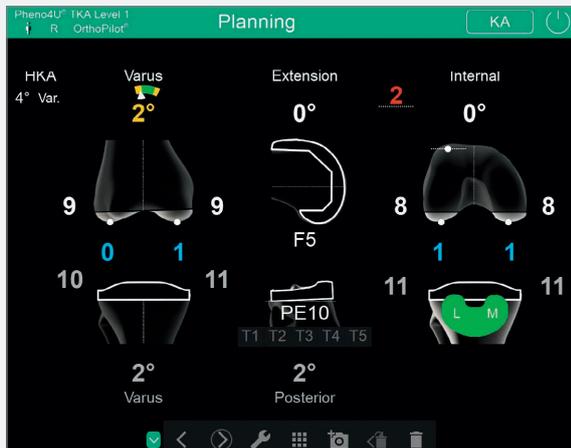
**Tip**

Gaps can additionally be recorded in 30° and 60° if selected in the settings (optional).



# 8 | Tibia First Technique

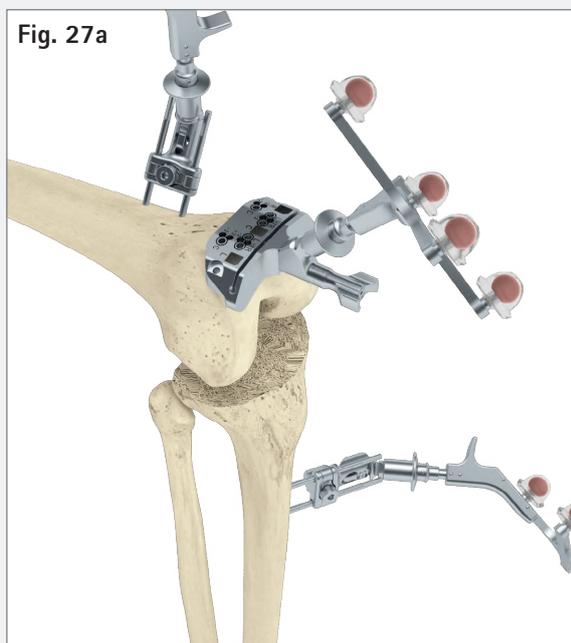
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## 8.8 Femoral planning

In the femoral planning step of the tibia first technique, various possibilities are given to plan the position of the cuts for the femoral component.

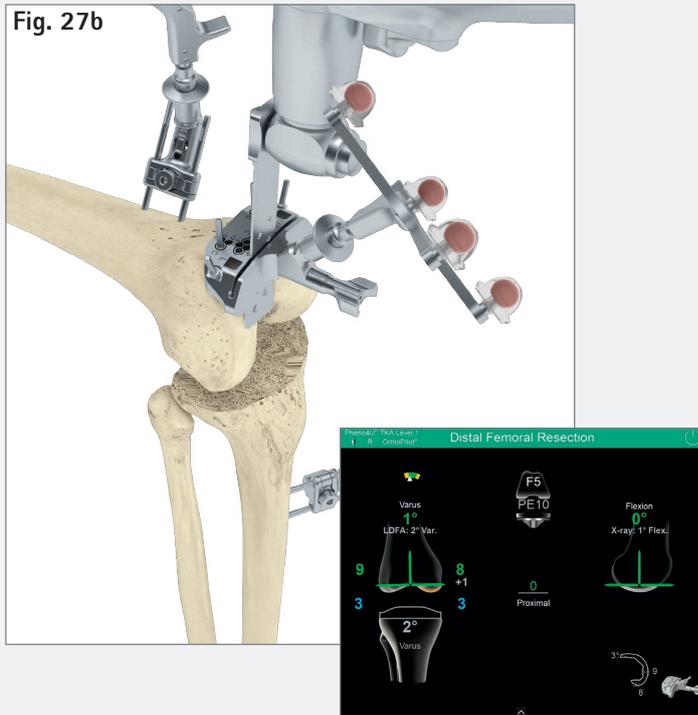
A detailed description of the planning screen in general will be given in the Chapter 11 Planning screen.



## 8.9 Distal femoral resection

Attach the distal femoral cutting block to the corresponding yellow transmitter. The precise resection plane in relation to the medial and lateral distal condyles recorded on the femur is determined by moving the cutting block in the proximal or distal direction. Target values are the values selected during femoral planning. For better orientation they are highlighted graphically as a green T-shaped outline. Once these values are attained in terms of varus/valgus angle, resection plane, and slope, the values will turn green. Another orientation aid for determining approximate resection height is the distal thickness of the femoral implant, which is displayed at the top of the screen in the middle. Users obtain additional information about the joint line shift in relation to the "condyle references" step (in the example shown: 0 mm).

Fig. 27b



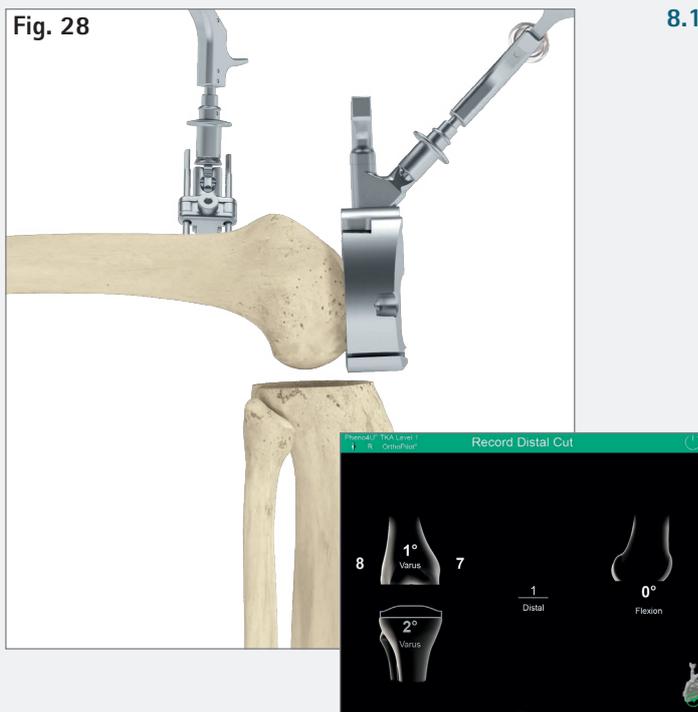
**Tip**

Users also have the option of using an alignment instrument (NP1018R) to assist with IQ cutting block alignment. Start by connecting the alignment instrument to the cutting block (with attached FS626R and corresponding transmitter (FS633 or FS636)) using the correct interface, and then anchoring it at a resection height of around 10 mm (proximal to the femoral joint line) using a headless screw pin. Rotate around the screw pin to adjust varus/valgus settings. Adjust to the desired resection height (+/- 4 mm) and tibial slope (+/- 8°) manually using the two adjustment knobs or screwdriver NP618R.

**Tip**

To prevent contamination of the marker spheres on the transmitters, it is advisable to either remove the transmitters or cover them until the resection is finished.

Fig. 28

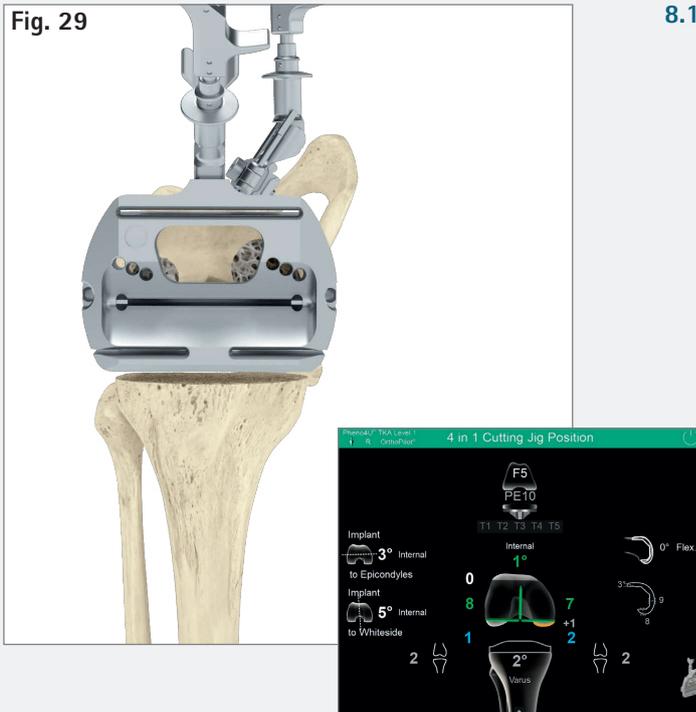


**8.10 Checking distal resection**

After completing the distal femoral resection, check the resection plane using the corresponding 4-in-1 cutting block with adapter FS626R and transmitter (FS633 or FS636).

# 8 | Tibia First Technique

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

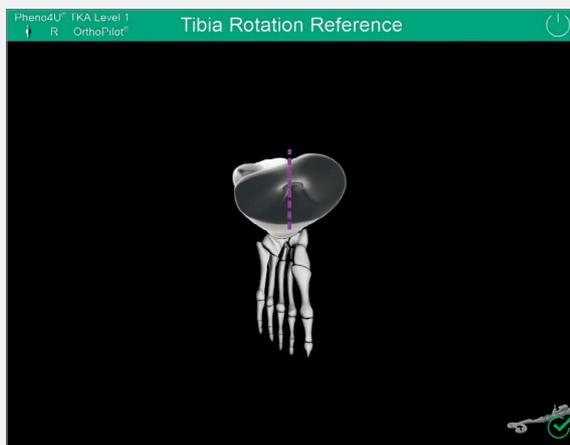


### 8.11 Setting rotation and A/P positioning

Rotation and A/P position is set using the 4-in-1 cutting blocks. The rotation value is displayed in relation to the recorded posterior condyles. The A/P position in relation to the anterior cortex as well as the posterior cutting height and the resultant remaining gaps in flexion are displayed. Once the desired rotation position has been attained, the corresponding cutting block for the femoral size plus transmitter FS633 or FS636 can be fixed by two distal pins and two pins from the medial and lateral side through the convergent pin holes. After that, proceed with resections: first anterior, then posterior, then chamfer. Prior to the chamfer cuts the distal pins need to be removed. After completing the resections, proceed with implantation – starting with trial implants, and then moving to final implants.

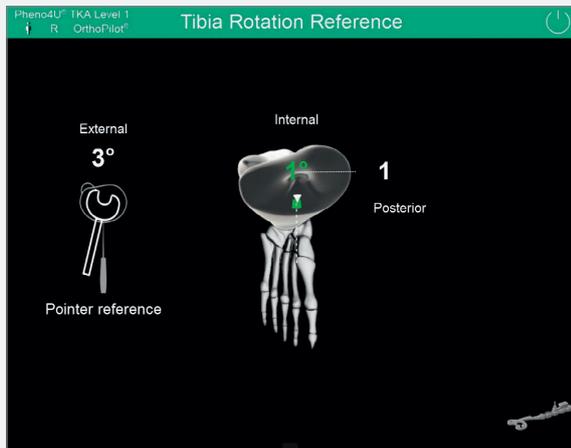
#### Tip

The rotation value is displayed in relation to the recorded posterior condyles. Regarding rotation, users have the option of running a comparison to the palpated epicondyles (optional, see Chapter 7.4) and/or the Whiteside line (optional, see Chapter 8.4). The corresponding information will be displayed at the left edge of the screen. In addition to the planned femoral size, the screen will display possible tibial implant combinations based on the prosthesis system selected. The slope and/or extension/flexion angle of the distal resection will also be shown on the right-hand side of the screen. The femoral size can be adjusted at this stage if desired.



### 8.12 Tibia rotation reference (optional)

The trial tibial plateau and the tibial handle (NQ378R) can be used along with the navigation adapter (NP1017R) to record a reference position. Selected examples include anatomical coverage of the tibial plateau, or positioning the trial tibial plateau after moving the leg into a deep flexion or full extension. With the latter, in particular, make sure to position the femoral transmitter such that it will not conflict with other instruments.

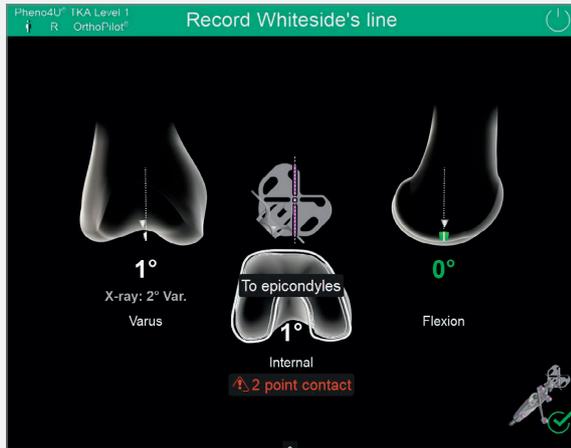


### 8.13 Setting tibial rotation

Use the tibial handle with mounted navigation adapter (NP1017R) and the corresponding transmitter (FS633/FS636) to navigate the position of the tibial plateau in relation to one or both of the previously recorded references (see Chapter 7.9/Chapter 8.12). If both references are selected (optional), a separate window on the left will show the deviation to the pointer reference. The indicator in the middle of the screen will then show the deviation to the plateau reference just recorded, including A/P shift.

# 9 | Femur First Technique

AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



## Note

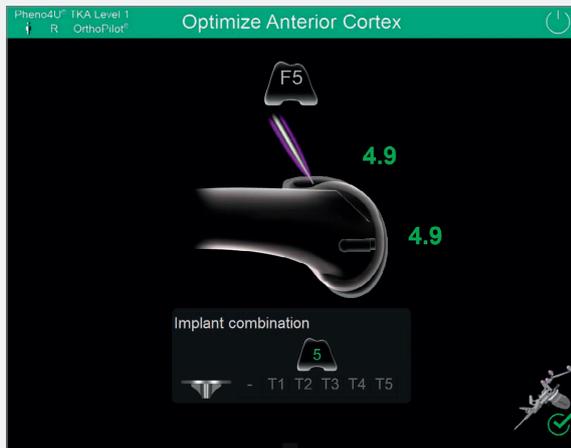
Please follow all steps through the end of Chapter 7 and then proceed from the beginning of Chapter 9.

### 9.1 Condyle reference/Recording the Whiteside line

See Chapter 8.4

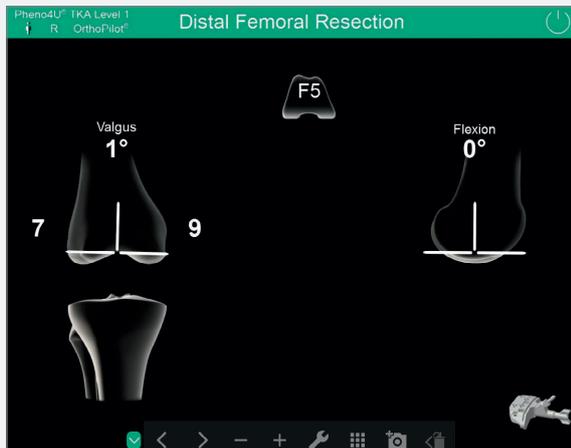
Differences with Femur first:

Simultaneous recording of Whiteside line and distal condyles.



### 9.2 Optimizing the anterior cortex point

See Chapter 8.6



### 9.3 Distal femoral resection

See Chapter 8.9

Differences with Femur first: No target values shown, as femoral planning has not been carried out. No gap information displayed as gaps have not been measured.

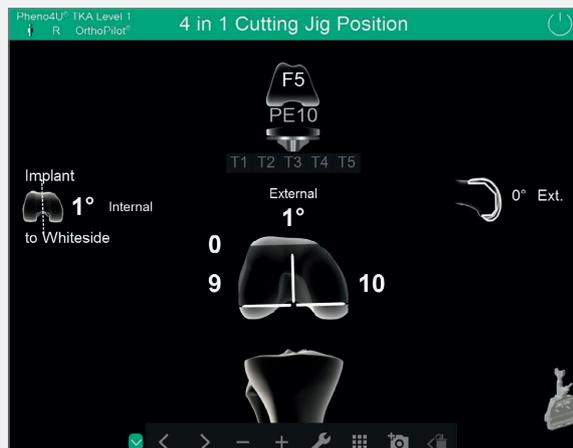


### 9.4 Checking distal resection

See Chapter 8.10

# 9 | Femur First Technique

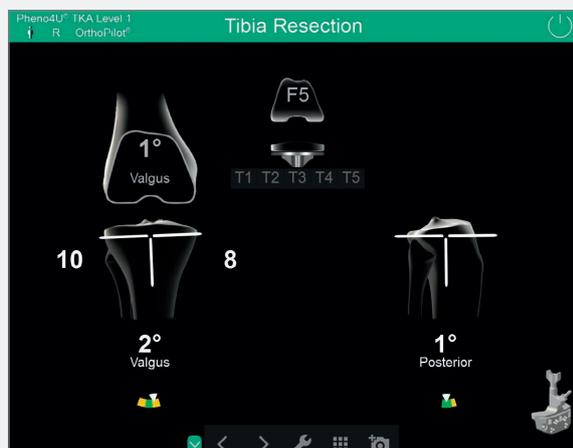
AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



## 9.5 Positioning the 4-in-1 cutting block

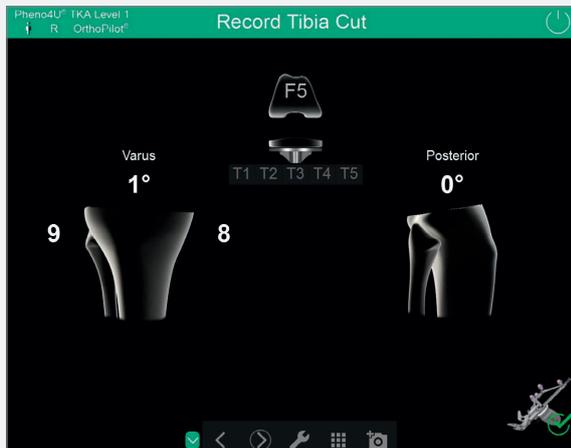
See Chapter 8.4

Differences with Femur first: No gap information displayed as gaps have not been measured. No femoral planning takes place, so no target values from the planning stage are shown. The rotation value in relation to the posterior condyles turns green as soon as it corresponds to the previously recorded position according to Whiteside, i. e. the Whiteside display in the upper left corner shows 0°.



## 9.6 Positioning the tibia cutting block

See Chapter 8.1



## 9.7 Recording the tibial resection

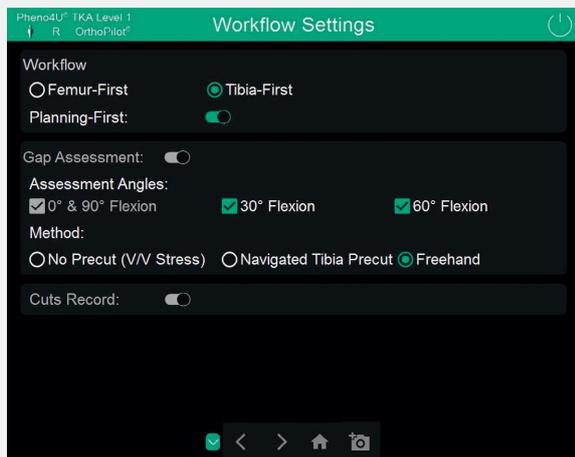
See Chapter 8.2

### Note

After this step, please follow Chapters 13 Implant kinematics and 14 Summary.

# 10 | Planning First

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



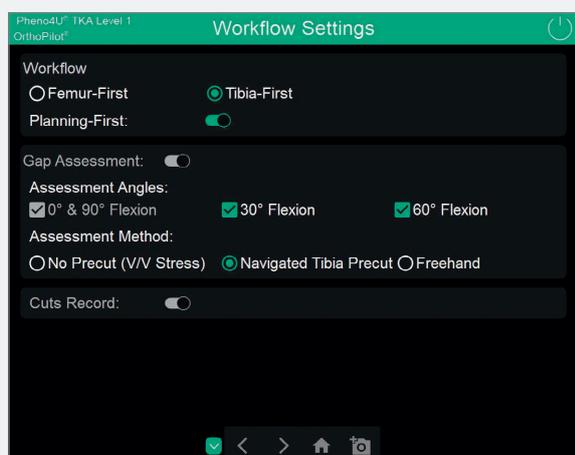
### 10.1 Introduction planning first workflow

The planning first option offers the possibility to plan all final cuts for both femoral as well as tibial components, before execution. One of the following two different ways of recording the gaps must be selected:

1. With laminar spreader and forceps. This **requires a tibia precut** to be able to bring the spreader in. (whereas the precut can be navigated or freehand). In any case the precut needs to be recorded. OR:
2. With varus/valgus stress performed manually or with the help of additional instruments (e.g. spacers, etc.). This **requires additional optimization palpation of both posterior condyles**.

#### Note

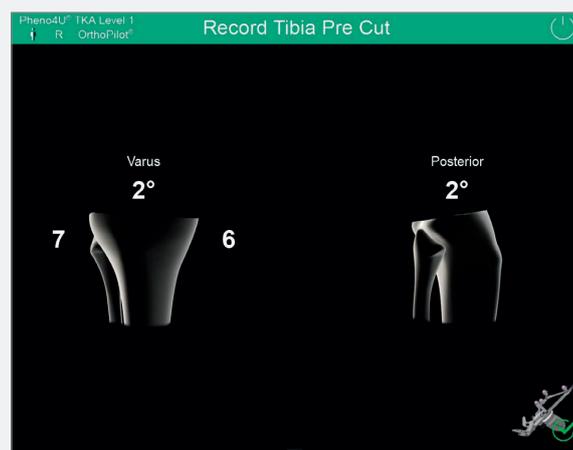
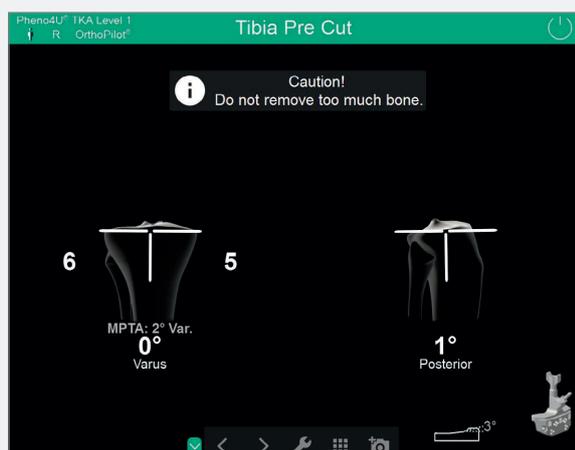
Please follow steps until End of Chapter 7, then proceed with Chapter 10.

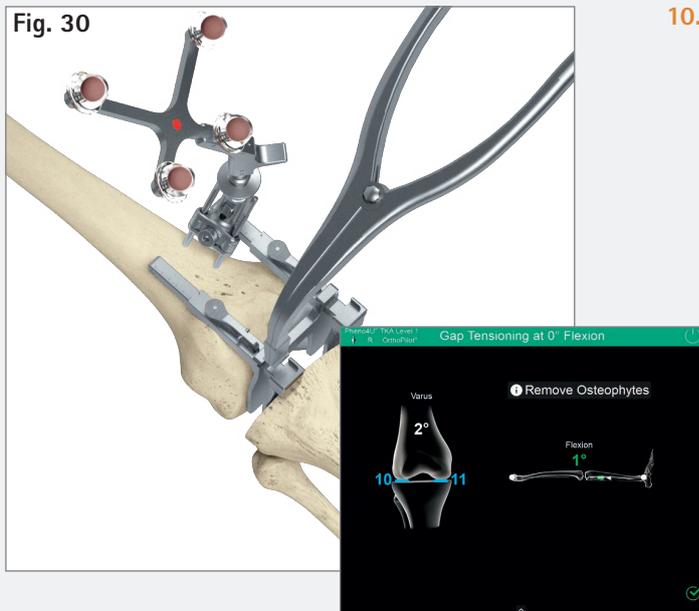


### 10.2 Tibia precut – optional

The corresponding resection guide can be used to perform the **tibia precut** according to the desired values for the precut.

Alternatively, the precut can be performed freehand. The precut together with laxity of the knee joint needs to give enough space for the AESCULAP® spreaders, that have a defined thickness of 6 mm to be inserted. It should be smaller than a regular final cut, otherwise tibia first approach can be chosen. If the precut is performed, independent if freehand or navigated, it must be recorded in the step **record tibia precut**.





### 10.3 Measuring the joint gap in flexion and extension

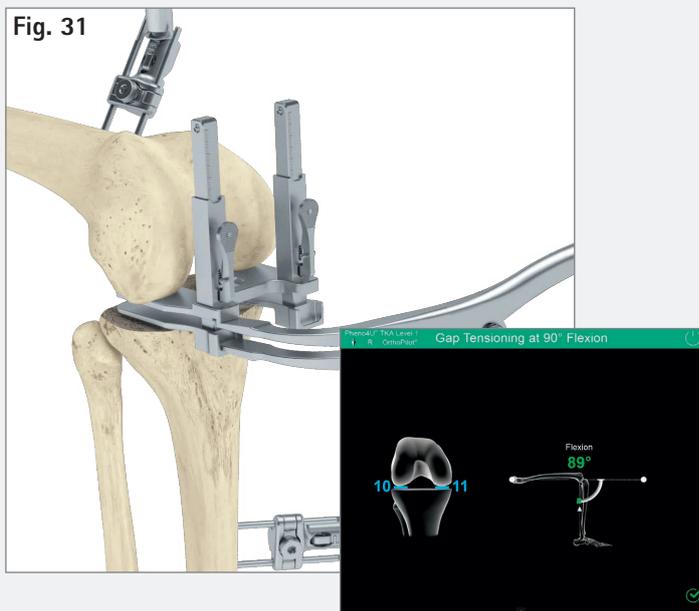
Before measuring flexion/extension gaps, remove any osteophytes that could affect ligament and capsular tension. With the leg extended as far as possible ( $0^\circ \pm 5^\circ$ ) place the distractor (NE750R) between the tibial resection and the distal femoral condyles, and then spread using the spreading pliers (NP609R or NP605R), applying equal medial and lateral force. To ensure precise measurement, the plates of the distractor must be flush with the tibial resection plane.

The OrthoPilot® screen will show the medial and lateral gap measurements in millimeters and the mechanical leg axis in degrees (which provides initial information about potential ligament release), as well as the degree of flexion.

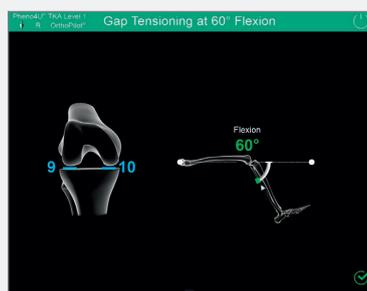
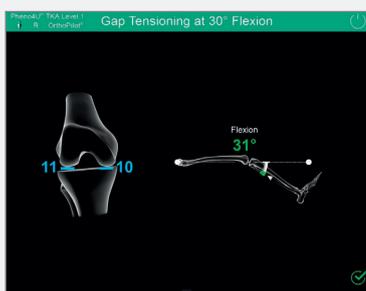
Once this data has been recorded, release the distractor and bend the leg at a  $90^\circ$  angle.

Measurements can be taken as long as the leg is in the flexion position marked in green. Make sure to keep the leg as stable as possible during the measurement process. Real-time gap values will be shown on the tibia in blue. By recording the values, the software takes you into the next step.

In this step, it is possible to skip completely the distraction and the femoral planning steps by choosing the double forward arrow in the toolbar or the ring menu, or by doing a long footswitch press (see Chapter 4).



Data is recorded in this step using the same process as described for extension. As described in Chapter 4, it is always possible to redo these gap measurements (e.g., following a ligament release) using the software's back and delete functions.



#### Tip

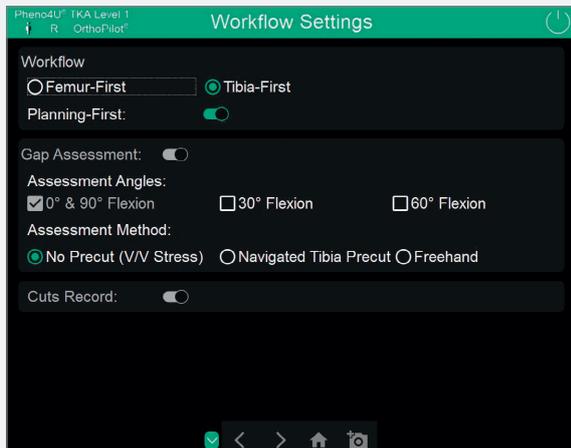
Gaps can additionally be recorded in  $30^\circ$  and  $60^\circ$  if selected in the settings (optional).

#### Note

After this step, please follow Chapters 11 ff.

# 10 | Planning First

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

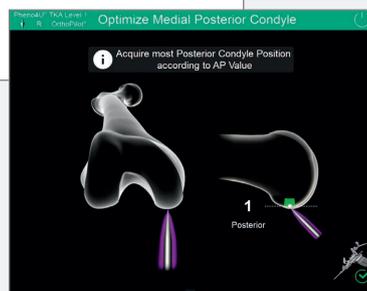
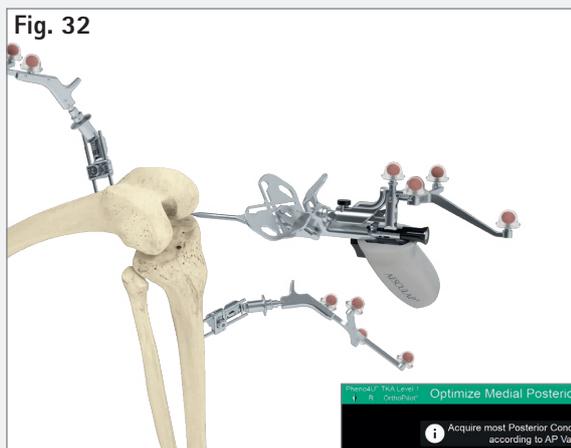


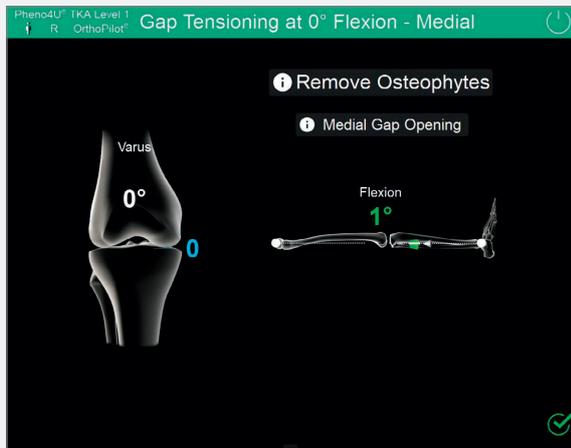
### 10.4 No precut (V/V stress) – optional

If the aim is to plan femur and tibia final cuts in the planning screen without any tibia resection, the no precut (V/V stress) option needs to be selected for gap assessment.

In this case Chapter 10.2 is completely skipped and after the last step of Chapter 7, the following step will be performed at first:

Before the gaps are measured this way, it is mandatory to **optimize** the initially recorded **posterior condyle** palpation both medial and lateral. Care needs to be taken to reconfirm the most posterior point on the medial and the lateral posterior condyle. The value on the screen shows, if there is a point still more posterior or more anterior compared to the initial palpation.





The gap tensioning at 0° flexion medial and lateral, will be measured by medial gap opening (valgus stress) and by lateral gap opening (varus stress).

The same applies for the other possible flexion angles of 30, 60° and the **gap tensioning at 90° flexion medial and lateral**. In order to record, the time-out function can be used by holding the gap open in a stable manner or by pressing the central pedal of the footswitch or the button of the Multitool.

The gap opening can be achieved by using manual varus and valgus stress or by using adequate instruments e.g. spacers (spoons) to hold the gap open.

Care needs to be taken to apply the desired force and take care to limit hip rotation during these steps.

The quality of the assessed gaps is in the users responsibility.

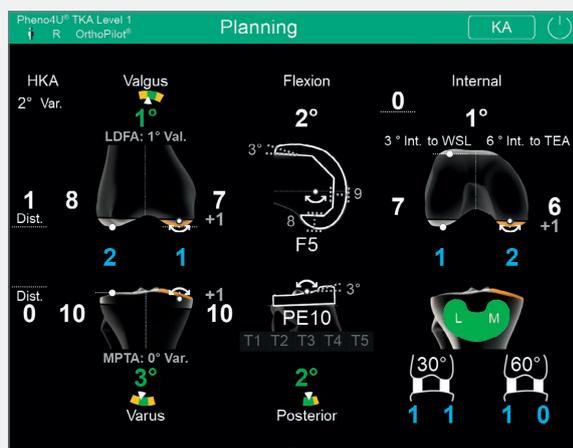


### Note

After this step, please follow Chapters 11 ff.

# 11 | Planning

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



### Note | Biomechanical corridor

The biomechanical corridor is implemented for the implants/ inserts VEGA System® PS, Columbus® DD, Columbus® UC, e.motion® Pro and e.motion® UC Pro considering the tibial-femoral contact mechanics (polyethylene wear and delamination and the resulting moments in the frontal and sagittal plane).

Please note that the simulation does not include third-body wear and implant component under- or oversizing in relation to the bone.

The biomechanical corridor is enabled and validated for patient weights ranging from 50 kg to 150 kg and within the range of 7° varus HKA to 6° valgus HKA. Outside of this validated range, the corridor will be grayed out.

Please note the instruction for use of the corresponding AESCULAP® knee systems (TA016100).

This corridor indicates whether the selected implant configuration – considering the planned alignment (varus/valgus, tibial slope), patient weight, implant type, and implant size – can withstand the resulting moments and contact pressure. The corridor for moments in the frontal and sagittal plane is shown in the frontal view in full extension and in the sagittal view, respectively. The pressure corridor is displayed in the frontal view with 90° flexion.

The corridor is split into three colors:

- The **green zone** represents the safe zone for the implant.
- To consider patient-related factors such as severe constitutional varus/valgus and soft tissue situation, the user may also work within the **yellow zone** if it is beneficial for the patient, but has to be aware that the corresponding constellation of parameters will get closer to the critical zone (red).
- It is not recommended to work in the **red zone** as there might be a risk of implant failure (extensive abrasive and adhesive wear, structural material fatigue and delamination, tibial and/or femoral component loosening).

The green and the yellow zones are covered under product liability.

### Planning

The following action buttons will appear on the screen as soon as any value is selected with the virtual mouse and are used for the following actions:

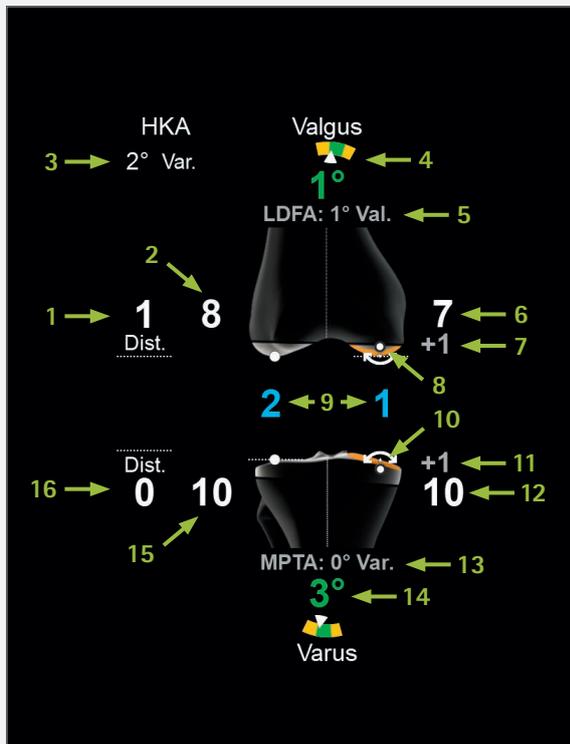
Button	Action
	Increase value displayed by one step
	Decrease value displayed by one step
	Turn angle value displayed by one step to the right
	Turn angle value displayed by one step to the left
	Increase single value displayed by one step
	Decrease single value displayed by one step
	Increase medial and lateral displayed values in parallel by one step
	Decrease medial and lateral displayed values in parallel by one step
	Change point of rotation in planning. Only visible when option "Points Of Rotation > Tunable" has been selected.

### Note

The corridor does not provide information regarding patient-specific kinematics, expected clinical outcomes, stability of the implant-bone interface, cement fixation of the implants, muscular and ligament situation (gap balancing), patient function and satisfaction, periprosthetic fractures and arthrofibrosis.

Please note that the contact mechanics of the patella-femoral joint is not considered in this software version.

The user is solely responsible for the careful consideration and accurate adjustment of all parameters in the planning screen as well as for conducting the surgery with the necessary quality. This includes, but is not limited to, bone cuts in general, the medial and lateral gaps in flexion and extension and implant size. Adjustments must be made based on the user's clinical expertise and experience.

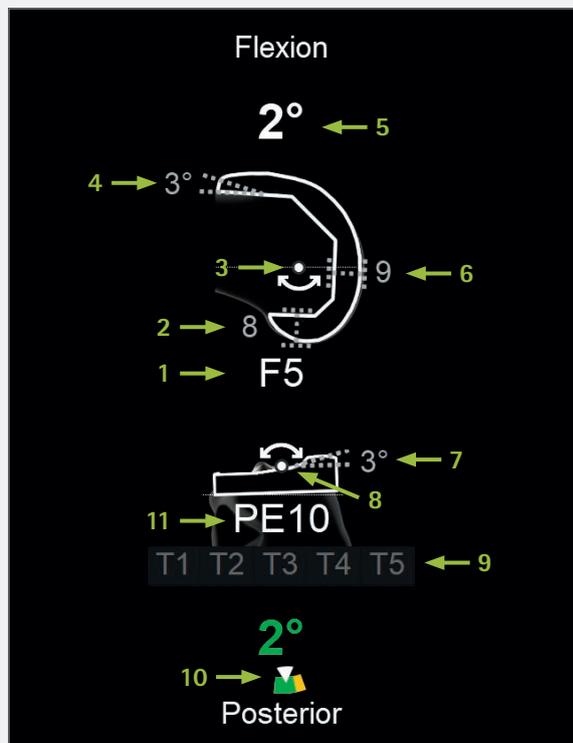


### In extension

- 1 Distalization or proximalization display of the femoral jointline in mm in relation to the most distal condyle
- 2 Lateral distal resection height in mm
- 3 Hip Knee Ankle – angle in degree (planned tibia cut – planned femur cut orientation)
- 4 Planned varus or valgus orientation of the femoral component in degree and in green, yellow or red according to the biomechanical safety corridor (see note)
- 5 Reminder value in grey of the LDFA angle from X-ray
- 6 Medial distal resection height in mm
- 7 Reminder value in grey number and orange area of how much mm defect compensation is considered on the femur
- 8 Current center of rotation of the femur indicated by white point and round arrow. Can be changed by pressing on it if activated (optional)
- 9 Remaining gaps lateral and medial in extension after planned implantation in current situation, clinically speaking, a negative gap value means stretching of the soft tissue (e.g., ligaments)
- 10 Current center of rotation of the tibia indicated by white point and round arrow. Can be changed by pressing on it if activated (optional)
- 11 Reminder value in grey number and orange area of how much mm defect compensation is considered on the tibia
- 12 Medial proximal tibia resection height in mm
- 13 Reminder value in grey of the MPTA angle from X-ray
- 14 Planned varus or valgus orientation of the tibial component in degree and in green, yellow or red according to the biomechanical safety corridor (see note)
- 15 Lateral proximal tibia resection height in mm
- 16 Distalization or proximalization display of the tibial jointline in mm in relation to the most proximal tibia palpation

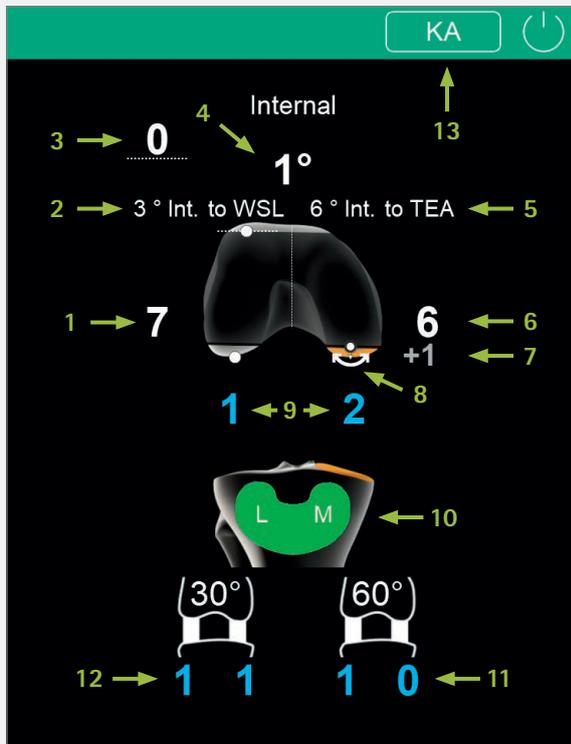
# 11 | Planning

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



### Display and control elements center

- 1 Size of the current femoral component
- 2 Reminder value in grey of the posterior implant thickness
- 3 Current center of rotation of the femur indicated by white point and round arrow, can be changed by pressing on it if activated (optional)
- 4 Reminder value in grey of the anterior inclination of the femoral shield in degree
- 5 Planned extension or flexion orientation of the femoral component in degree
- 6 Reminder value in grey of the distal implant thickness
- 7 Reminder value in grey about the amount of in-built slope in the tibia in degrees
- 8 Current center of rotation of the tibia indicated by white point and round arrow, can be changed by pressing on it if activated (optional)
- 9 Possible tibia size combinations to femur size
- 10 Anterior or posterior orientation of the tibia in degree and in green, yellow or red according to the biomechanical safety corridor (see note on p. 56)
- 11 Current height of polyethylene insert (including thickness of tibial baseplate) in mm



#### Different alignment MA, KA, rKA

If installed and selected in the options settings, within the planning screen, users can switch between the following alignment methods: Mechanical Alignment (MA), Kinematic Alignment (KA), and Restricted Kinematic Alignment (rKA). Each method adheres to its respective clinical application rules.

In MA, the planning proposal is based on 0° cuts in varus/valgus (HKA = 0°), the default femoral rotation is 0° (unless predefined differently in the option settings), the anterior cortex level is 0 mm and the smallest gap in extension is set to 0 mm remaining gap.

In KA, the cut levels are defined according to the implant components' thickness (unless predefined differently in defect compensation) and the orientation results thereof. The same applies to anterior cut level, rotation of femoral component, as well as remaining gaps.

In rKA, the cut levels are defined according to the implant components' thickness (unless predefined differently in defect compensation) and the orientation results thereof, but each individual cut is limited to max. 5° varus/valgus and a resulting HKA of max. 3° varus/valgus. Femur rotation, anterior cortex level, as well as remaining gaps are resulting.

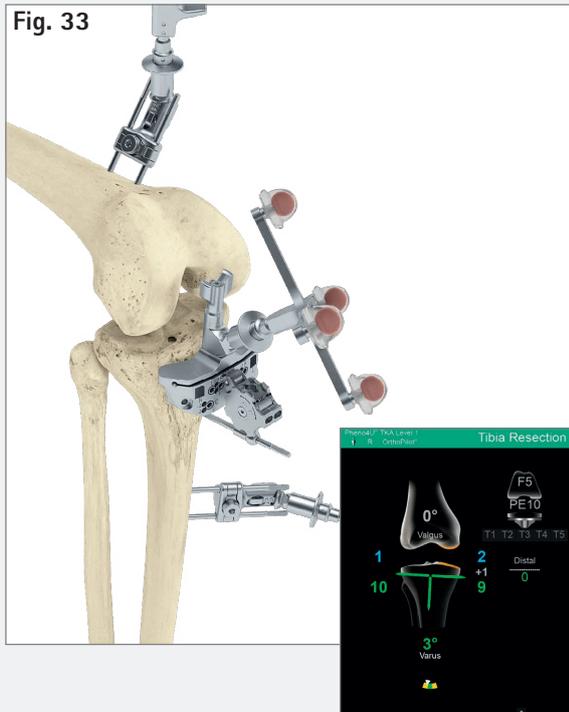
Changes to the values in the planning screen for each alignment method are automatically saved. If the user switches to a different alignment method and then returns to the initial method, the software will display the previously saved values for that initial alignment method.

#### In flexion

- 1 Posterior-lateral resection height in mm
- 2 Reminder value in grey of the rotation in degree to Whitesideline (optional)
- 3 Anterior resection height in relation to the anterior cortex point palpated (the location of the anterior femoral shield to that measured point). If the femoral shield would end up underneath that palpated point (notching), the number will turn red as well as if it would end up above that point (overstuffing).
- 4 Internal or external rotation of the femoral component in relation to the recorded posterior condyles
- 5 Reminder value in grey of the rotation in degree to transepicondylar axis (optional)
- 6 Posterior-medial resection height in mm
- 7 Reminder value in grey number and orange area of how much mm defect compensation is considered on the posterior femur
- 8 Current center of rotation of the femur indicated by white point and round arrow, can be changed by pressing on it if activated (optional)
- 9 Remaining gaps lateral and medial in 90° flexion after planned implantation in current situation, clinically speaking, a negative gap value means stretching of the soft tissue (e.g., ligaments)
- 10 Biomechanical safety corridor regarding contact pressure in green, yellow or red (see note on p. 56)
- 11 Remaining gaps lateral and medial in 60° flexion (optional) after planned implantation in current situation, clinically speaking, a negative gap value means stretching of the soft tissue (e.g., ligaments)
- 12 Remaining gaps lateral and medial in 30° flexion (optional) after planned implantation in current situation, clinically speaking, a negative gap value means stretching of the soft tissue (e.g., ligaments)
- 13 Button to switch the currently selected Alignment

# 12 | Execution of Plan and Final Steps

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



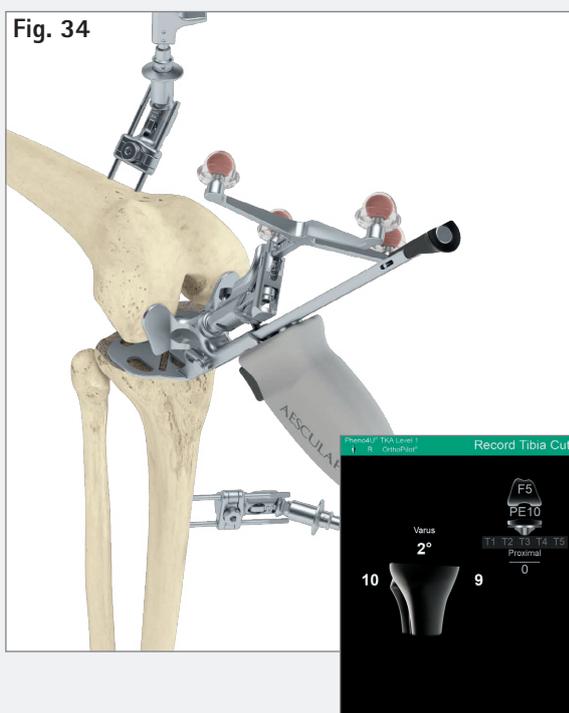
### Note

The order of the resections in this chapter is interchangeable and is defined in the option settings by selecting tibia or femur first.

### 12.1 Final tibia resection according to plan

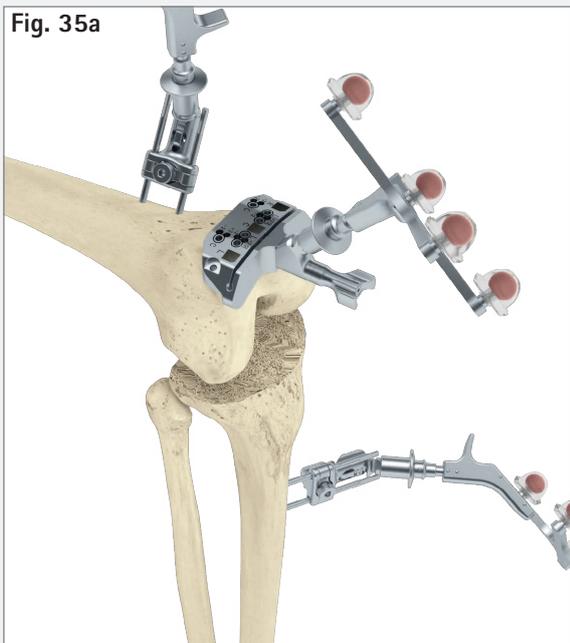
Attach the cutting block to the corresponding yellow transmitter. The precise resection plane in relation to the medial and lateral tibia reference points recorded, is determined by moving the cutting block in the proximal or distal direction.

Target values are the values selected during planning. For better orientation they are highlighted graphically as a green T-shaped outline. Once these values are attained in terms of varus/valgus angle, resection plane, and slope, the values will turn green. Another orientation aid for determining approximate resection height is the thickness of the tibial implant, which is displayed at the top of the screen in the middle. Users obtain additional information about the joint line shift in relation to the "condyle references" step (in the example shown: 0 mm).



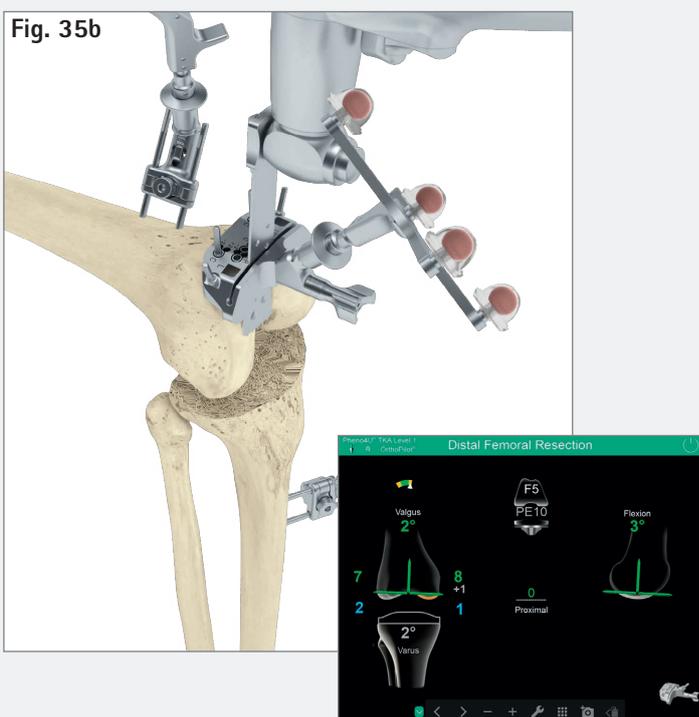
### 12.2 Record tibia cut

The tibia check plate of the Multitool (or tibia check plate NP617R/NP617RM) is used to check and record the tibial resection.



### 12.3 Distal femoral resection

Attach the distal femoral cutting block to the corresponding yellow transmitter. The precise resection plane in relation to the medial and lateral distal condyles recorded on the femur is determined by moving the cutting block in the proximal or distal direction. Target values are the values selected during femoral planning. For better orientation they are highlighted graphically as a green T-shaped outline. Once these values are attained in terms of varus/valgus angle, resection plane, and slope, the values will turn green. Another orientation aid for determining approximate resection height is the distal thickness of the femoral implant, which is displayed at the top of the screen in the middle. Users obtain additional information about the joint line shift in relation to the "condyle references" step (in the example shown: 0 mm).



#### Tip

Users also have the option of using an alignment instrument (NP1018R) to assist with IQ cutting block alignment. Start by connecting the alignment instrument to the cutting block (with attached FS626R and corresponding transmitter (FS633 or FS636)) using the correct interface, and then anchoring it at a resection height of around 10 mm (proximal to the femoral joint line) using a headless screw pin. Rotate around the screw pin to adjust varus/valgus settings. Adjust to the desired resection height (+/- 4 mm) and tibial slope (+/- 8°) manually using the two adjustment knobs or screwdriver NP618R.

#### Tip

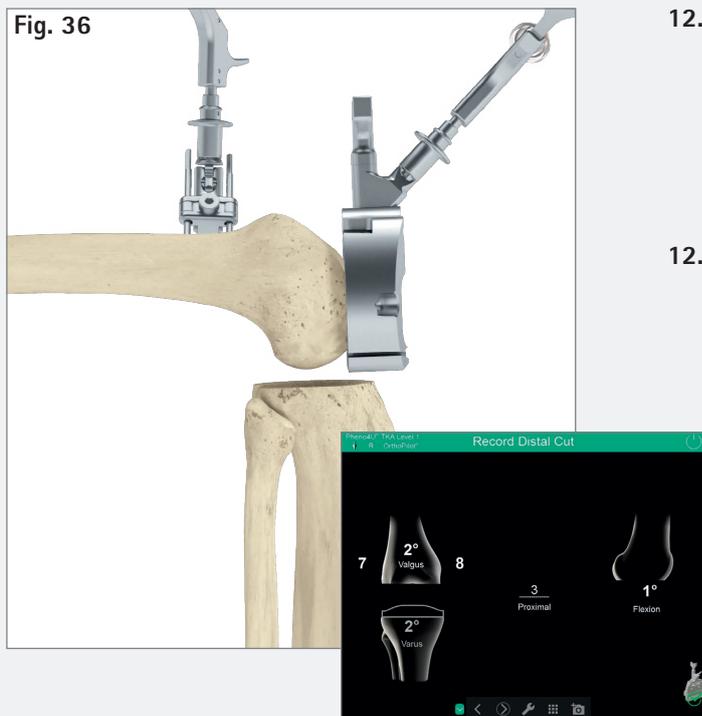
To prevent contamination of the marker spheres on the transmitters, it is advisable to either remove the transmitters or cover them until the resection is finished.

#### Note

For next step follow chapter 8.9 distal femoral resection until 8.13 tibia rotation navigation.

# 12 | Execution of Plan and Final Steps

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

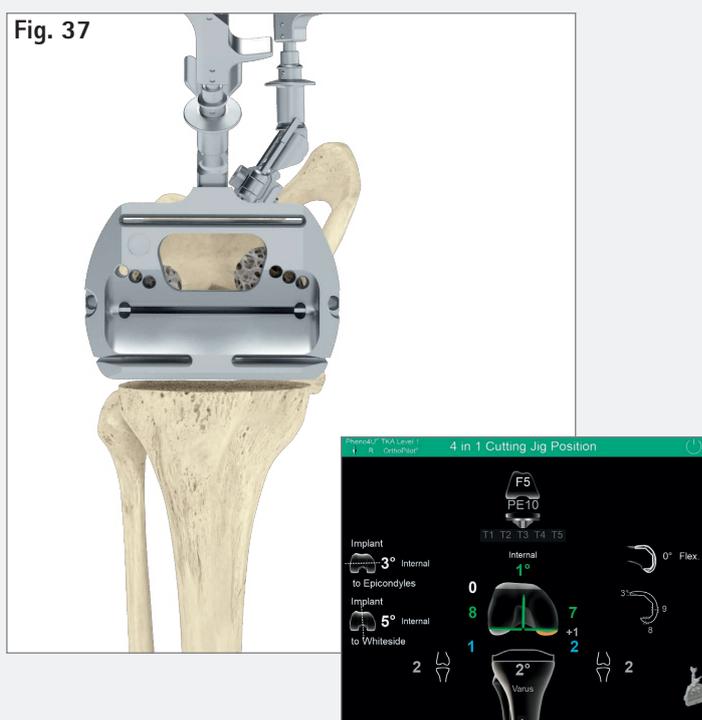


### 12.4 Checking distal resection

After completing the distal femoral resection, check the resection plane using the corresponding 4-in-1 cutting block with adapter FS626R and transmitter (FS633 or FS636).

### 12.5 Setting rotation and A/P positioning

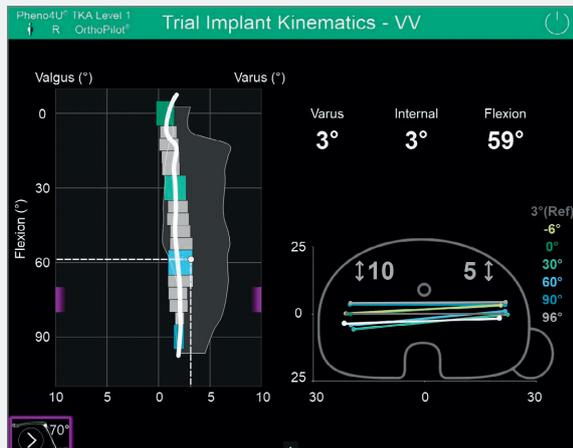
Rotation and A/P position is set using the 4-in-1 cutting blocks. The rotation value is displayed in relation to the recorded posterior condyles. The A/P position in relation to the anterior cortex as well as the posterior cutting height and the resultant remaining gaps in flexion are displayed. Once the desired rotation position has been attained, the corresponding cutting block for the femoral size plus transmitter FS633 or FS636 can be fixed by two distal pins and two pins from the medial and lateral side through the convergent pin holes. After that, proceed with resections: first anterior, then posterior, then chamfer. Prior to the chamfer cuts the distal pins need to be removed. After completing the resections, proceed with implantation – starting with trial implants, and then moving to final implants.



### Tip

The rotation value is displayed in relation to the recorded posterior condyles. Regarding rotation, users have the option of running a comparison to the palpated epicondyles (optional, see Chapter 7.4) and/or the Whiteside line (optional, see Chapter 8.4). The corresponding information will be displayed at the left edge of the screen. In addition to the planned femoral size, the screen will display possible tibial implant combinations based on the prosthesis system selected. The slope and/or extension/flexion angle of the distal resection will also be shown on the right-hand side of the screen. The femoral size can be adjusted at this stage if desired.

# 13 | Implant Kinematics

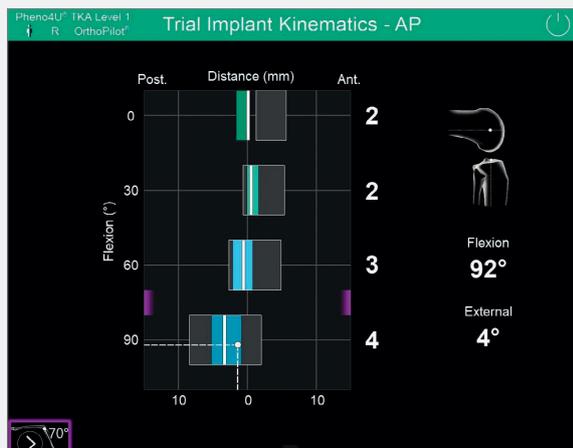


At the end of the surgery, the kinematics with trial implants as a minimum mandatory is recorded. Optionally the kinematics with the final implants in place can be recorded, as well as the kinematics with final implant after closure of the capsule.

The **grey area** in the background is the laxity recorded initially according to the option settings either before the incision, before cuts native or before cuts without ACL.

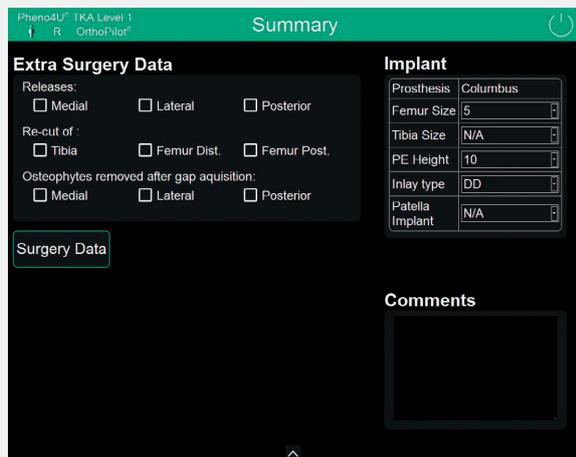
The reference for the Pinskerova-view on the right side of the screen is the same as for the first kinematics measurement.

Optionally, also the **AP-shift** kinematics can be recorded.



# 14 | Summary

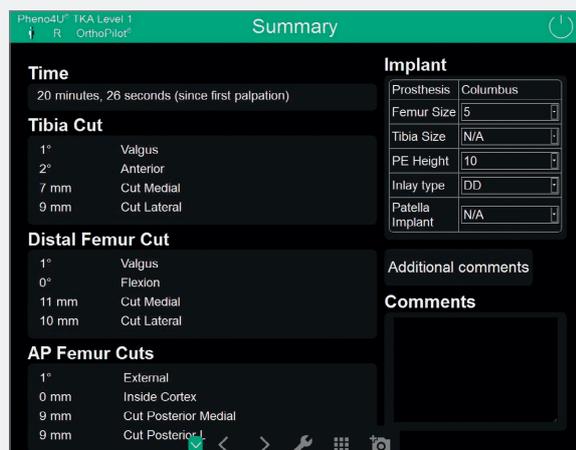
## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1



### Summary

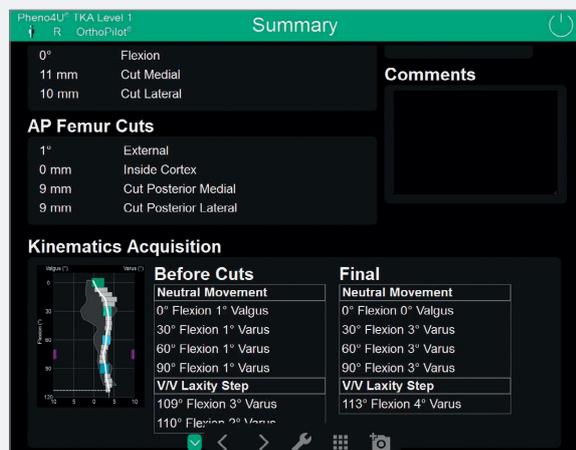
The summary screen offers additional possibilities in the **extra surgery data** section to document performed releases, recuts or osteophytes removal.

In the **implant** section, besides the planned implant, deviations of that can be documented as well as additional information, e.g. tibia size and patella implant. By activating the button **surgery data**, more data concerning the current operation can be retrieved, e.g. **time** needed, detailed information about **tibia cut**, **distal femur cut** and **AP femur cuts**.



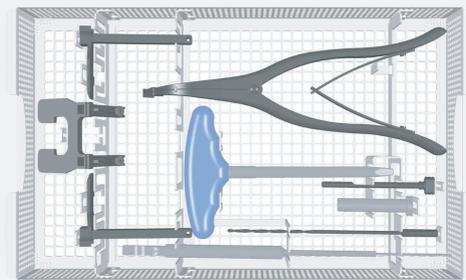
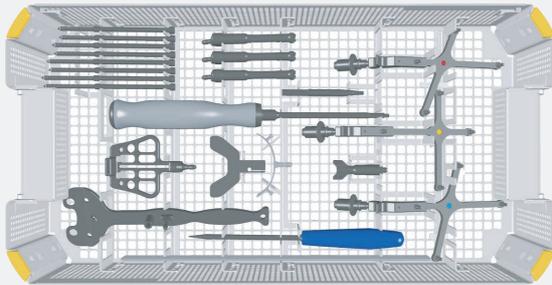
By scrolling down on the same screen, more information about the **kinematic acquisition** can be gathered as graphical element as well as tables. Comparing last available neutral and laxity (VV) curves to the ones at the beginning, e.g. here: Final implant kinematics compared to kinematics recorded before cuts.

A comment field on the right hand side offers the possibility to add important comments to the case.



# 15 | Instruments Overview

## 15.1 OrthoPilot® TKA Aesculap Reset® – IQ navigation instruments



### OrthoPilot® TKA navigation instruments NP138

NP139R	OrthoPilot® TKA tray navigation instr.	1
JA455R	Lid for Aesculap OrthoTray® DIN w/o handle	1
FS604	OrthoPilot® straight pointer	1
FS633	OrthoPilot® passive transmitter (yellow)	1
FS634	OrthoPilot® passive transmitter (blue)	1
FS635	OrthoPilot® passive transmitter (red)	1
NE358R	Screw driver bit torx T20/AF3.5	1
NP619R	OrthoPilot® transmitter mounting sleeve	3
NP620R	OrthoPilot® bicortical screw 30 mm	2
NP621R	OrthoPilot® bicortical screw 35 mm	2
NP622R	OrthoPilot® bicortical screw 40 mm	2
NP623R	OrthoPilot® bicortical screw 45 mm	2
FS626R	IQ OrthoPilot® TKA RB-adapter modular	1
NS320R	IQ navigated femoral alignment block	1
NQ958R	MIOS® Y-footplate f/alignment block	1
NS423R	IQ screw driver SW3.5	1
TA020007	User manual for knee-instruments	1

TF149	Graphic template f/NP139R (NP138)	1
NE750R	e.motion® PS/REV femur-tibia-distractor	1
NP609R	Femorotibial gap distractor for NP604R	1
NP616R	Bicortical screw drill guide 3.2/100 mm	1
NP615R	Bicortical screw drill bit 3.2 mm dia.	1
NP617RM	OrthoPilot® tibial checking plate modif.	1

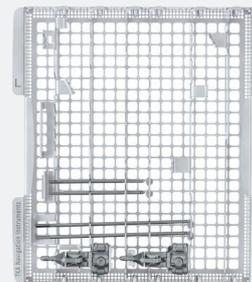
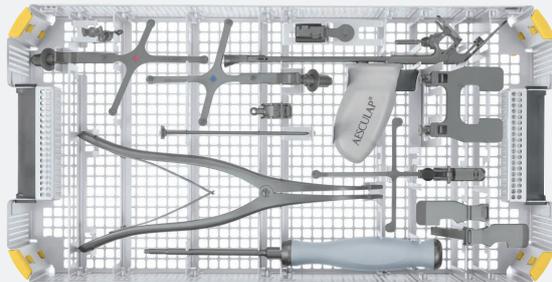
### Optional

NM743	OrthoPilot® elastic foot strap	1
NM769R	OrthoPilot® transmitter foot plate	1
NP281R	OrthoPilot® screw length gauge	1
NQ940R	MIOS® handle f/tissue protection sleeve	1
NQ941R	MIOS® tissue prot. sleeve f/Rigid Body	1

# 15 | Instruments Overview

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

### 15.2 OrthoPilot® TKA Aesculap Reset® – IQ navigation instrument Multitool, 2-pin fixation

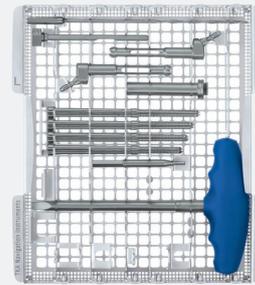
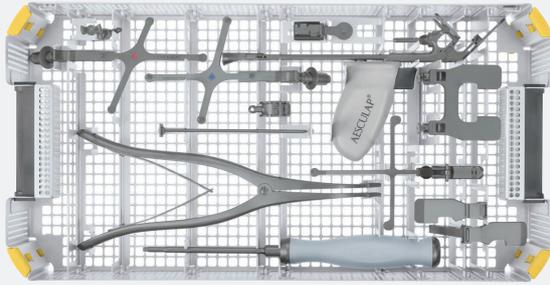


IQ set navig. instr. Multitool/monocort. NP1000		
JA455R	Lid for Aesculap OrthoTray® DIN w/o handle	1
NP1001R	IQ tray navigation instruments	1
TF277	Packing stencil f/NP1001R (NP1000)	1
FS634	OrthoPilot® passive transmitter (blue)	1
FS635	OrthoPilot® passive transmitter (red)	1
NS423R	IQ screw driver SW3.5	1
FS640	OrthoPilot® TKA Multitool	1
FS636	OrthoPilot® pass. click transmitter yellow	1
NP609R	Femorotibial gap distractor for NP604R	1
NE750R	e.motion® PS/REV femur-tibia-distractor	1
FS626R	IQ OrthoPilot® TKA RB-adapter modular	1
NP1016R	2-pin transmitter fixation element	2
NP1012R	Pin f/2-pin transm. fixati. D 3.2 mm WL 70 mm	4
NP1013R	Pin f/2-pin transm. fixat. D 3.2 mm WL 120 mm	2
NP618R	RB screw driver on motor	1
TA015999	IFU instrument set navigation	1

Optional		
NP1018R	IQ alignm. instr. f/femur/tibia cutt. guide	1
TF272	Graphic template f/NP1001R (NP1000)	1
TA014010	IFU for aluminium graphic templates	1
NP1017R	IQ navigation adapter f/tibia rotation	1
NP1013R	Pin f/2-pin transm. fixat. D 3.2 mm WL 120 mm	1

Alternative		
NP605R	Femur-tibia-distract. FCPS w/force contr.	1

### 15.3 OrthoPilot® TKA Aesculap Reset® – IQ navigation instrument Multitool, bicortical fixation



#### IQ set navig. instr. Multitool/bicortical NP1002

JA455R	Lid for Aesculap OrthoTray® DIN w/o handle	1
NP1001R	IQ tray navigation instruments	1
TF278	Packing stencil f/NP1001R (NP1002)	1
FS634	OrthoPilot® passive transmitter (blue)	1
FS635	OrthoPilot® passive transmitter (red)	1
NS423R	IQ screw driver SW3.5	1
FS640	OrthoPilot® TKA Multitool	1
FS636	OrthoPilot® pass. click transmitter yellow	1
NP609R	Femorotibial gap distractor for NP604R	1
NE750R	e.motion® PS/REV femur-tibia-distractor	1
NP1013R	Pin f/2-pin transm. fixat. D 3.2 mm WL 120 mm	1
NP615R	Bicortical screw drill bit 3.2 mm dia.	1
NP616R	Bicortical screw drill guide 3.2/100 mm	1
NP619R	OrthoPilot® transmitter mounting sleeve	2
NP621R	OrthoPilot® bicortical screw 35 mm	2
NP622R	OrthoPilot® bicortical screw 40 mm	2

NP623R	OrthoPilot® bicortical screw 45 mm	2
NP624R	OrthoPilot® bicortical screw 50 mm	2
NP618R	RB screw driver on motor	1
TA015999	IFU instrument set navigation	1

#### Optional

NP1018R	IQ alignm. instr. f/femur/tibia cutt. guide	1
FS626R	IQ OrthoPilot® TKA RB-adapter modular	1
TF273	Graphic template f/NP1001R (NP1002)	1
TA014010	IFU for aluminium graphic templates	1
NP1017R	IQ navigation adapter f/tibia rotation	1
NQ941R	MIOS® tissue prot. sleeve f/Rigid Body	1
NQ940R	MIOS® handle f/tissue protection sleeve	1

#### Alternative

NP605R	Femur-tibia-distract. FCPS w/force contr.	1
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# 16 | Software and Consumables

## AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

### 16.1 OrthoPilot® Software

#### Software module

FS241	OrthoPilot® Software Pheno4U® TKA Level 1
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### 16.2 Disposables

#### Passive marker spheres

FS616	OrthoPilot® dispos. passive marker sterile
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FS618SU	OrthoPilot® cap single-use markers
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### 16.3 Consumables

#### Instruments care oil

JG600	STERILIT® I oil spray
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JG598	STERILIT® I drip feed oiler
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#### Note

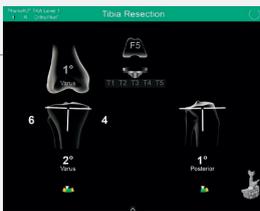
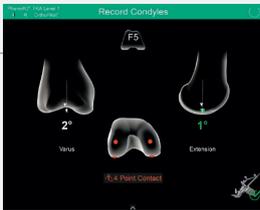
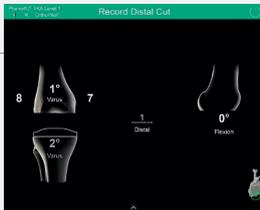
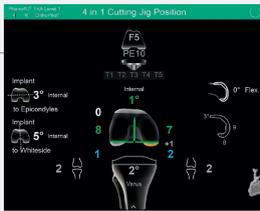
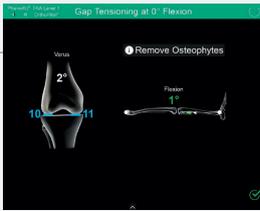
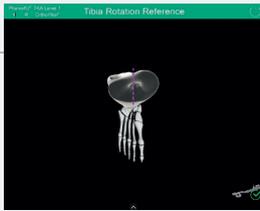
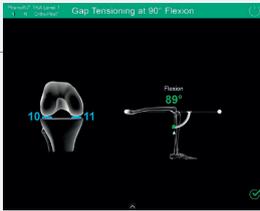
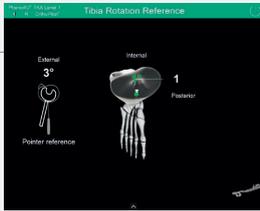
Prior to function checks, lubricate moving parts (e.g. joints, pusher components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: AESCULAP® STERILIT® oil spray JG600 or STERILIT® drip lubricator JG598).



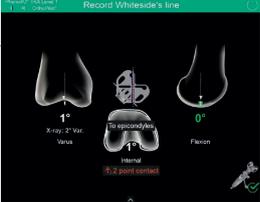
# 17 | Workflow Overview

AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

## 17.1 Tibia first with gap management – specific steps

- |   |   |  |    |  |                                      |
|---|---|--|----|--|--------------------------------------|
| 1 |    | Planning tibia cut   | 7  |    | Femoral planning                     |
| 2 |   | Recording tibia cut  | 8  |   | Planning distal femoral resection    |
| 3 |  | Registering distal and posterior condyles (condyle references) | 9  |  | Registering femoral resection        |
| 4 |  | Optimizing anterior cortex point                               | 10 |  | Positioning 4-in-1 cutting block     |
| 5 |  | Recording extension gap  | 11 |  | Tibia rotation reference (optional)  |
| 6 |  | Recording flexion gap  | 12 |  | Tibia rotation navigation (optional) |

## 17.2 Femur first – specific steps

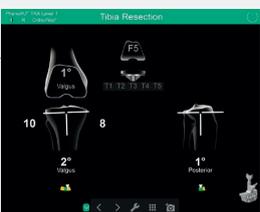
**1**  Recording Whiteside line

**2**  Optimizing anterior cortex point

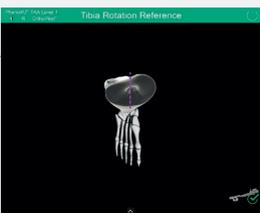
**3**  Planning distal femoral resection

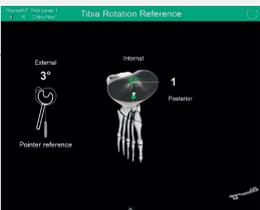
**4**  Registering femoral resection

**5**  Positioning 4-in-1 cutting block

**6**  Planning tibial resection

**7**  Registering tibial resection

**8**  Tibia rotation reference (optional)

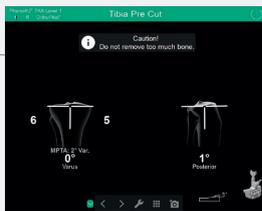
**9**  Tibia rotation navigation (optional)

# 17 | Workflow Overview

AESCULAP® OrthoPilot® Pheno4U® TKA Level 1

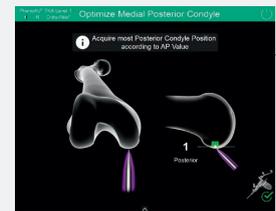
## 17.3 Planning first – specific steps

1a



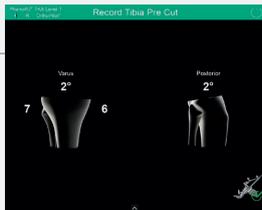
Tibia precut – optional

Optimize medial posterior condyle



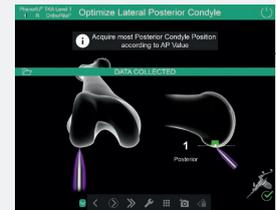
1b

2a



Record Tibia precut

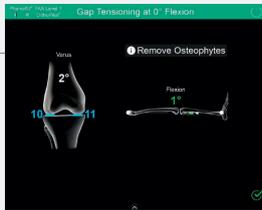
Optimize lateral posterior condyle



2b

OR

3a



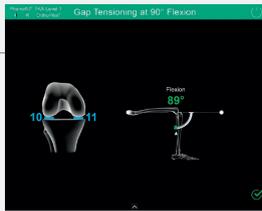
Recording extension gap

Gap tensioning at 0° medial and lateral (V/V-stress)



3b

4a



Recording flexion gap

Gap tensioning at 90° medial and lateral (V/V-stress)



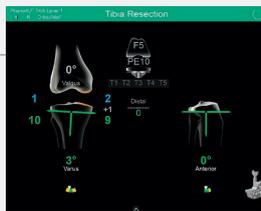
4b

5



Planning

6



Tibia resection

7



Record tibia cut

8



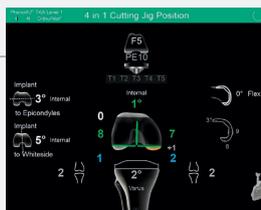
Distal femoral resection

9



Registering femoral resection

10



Position 4-in-1 cutting block

# AESCULAP<sup>®</sup> – a B.Braun brand

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Manufacturer acc. to MDD 93/42/EEC

NDI-marker:

NDI | 103 Randall Drive | Waterloo | Ontario | Canada

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