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SurgiCase Knee Planner

Software User Manual

Version 3.3

CE
0120

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Table of contents

1 Introduction

The SurgiCase Knee Planner allows the surgeon to simulate the placement of knee components in a total knee replacement (TKA) surgery and in a partial knee replacement (PKA) surgery. This simulation is based on three-dimensional models of the patient's anatomy that are derived from medical imaging data (MRI or CT for TKA, MRI for PKA).

Using the SurgiCase Knee Planner, the surgeon can inspect a default pre-operative plan that is generated by Materialise, adjust planning parameters as desired, and approve the plan.

The approved pre-operative plan will then be used by Materialise to design and produce TKA or PKA guides using additive manufacturing. Finally, the patient-specific knee guides will be used during surgery to determine the exact drill and pin positions to accurately position the knee implant according to the pre-operative simulated plan.

For indications for use, contraindications, precautions, warnings and possible adverse effects please refer to the Instructions For Use (IFU) of the device.

2 Installation

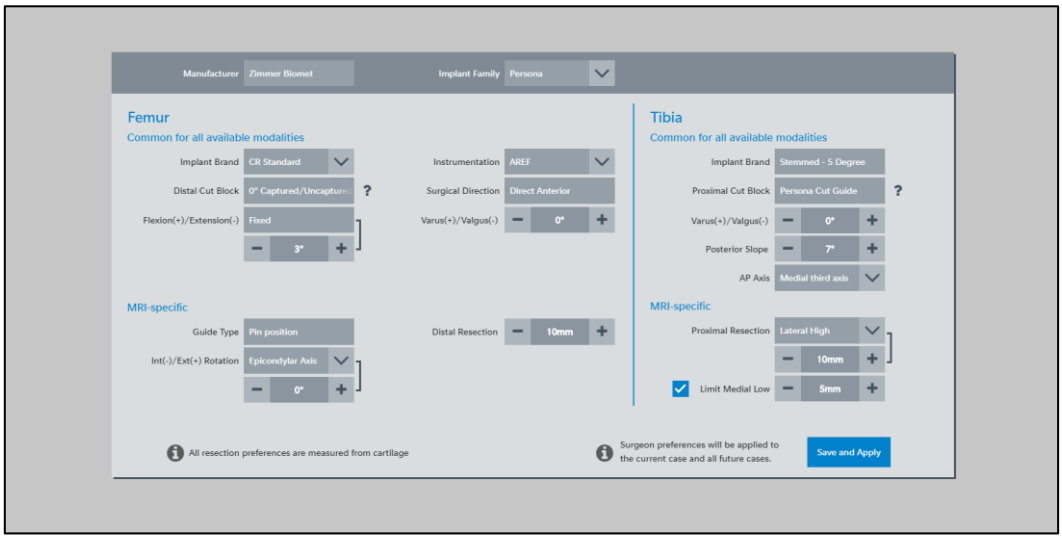
No installation is required to use the SurgiCase Knee Planner. The SurgiCase Knee Planner is web-based interactive software which can be launched from an internet browser. For more information regarding browser compatibility, please refer to Section 5.

The SurgiCase Knee Planner is accessible via Zimmer Biomet's Drive Case Management System (DCMS) by clicking on the SurgiCase Knee Planner link within the patient's case details.

3 Knee planning preferences

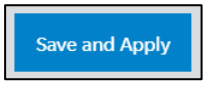
3.1 First time usage

Upon opening the first TKA MRI case, the first TKA CT case or the first PKA case, a surgeon will each time be required to fill in the surgical preferences window:



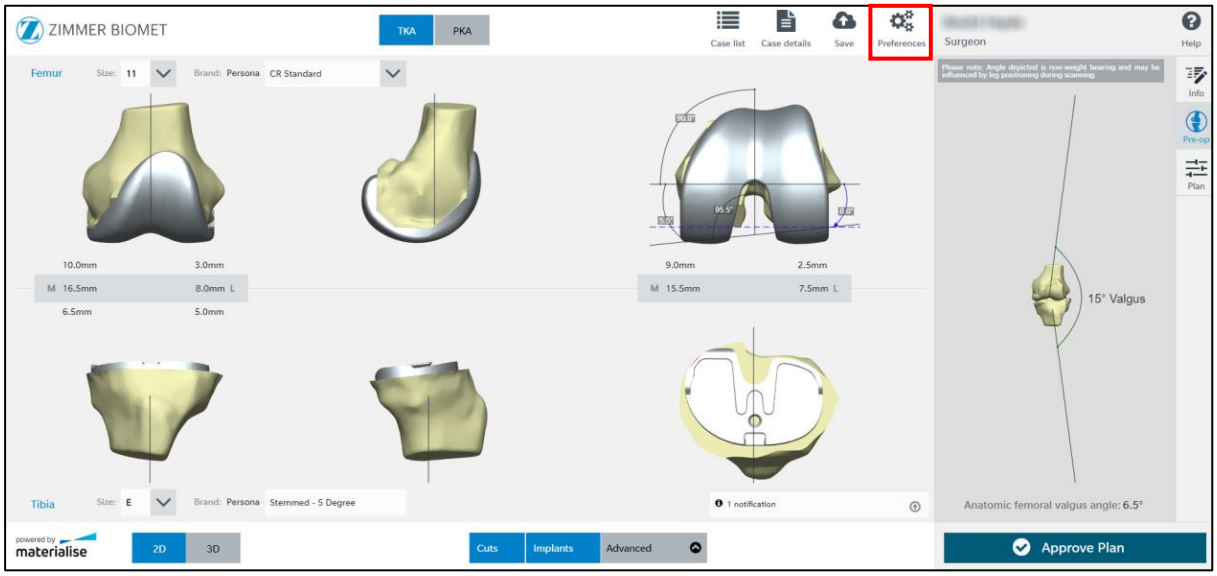
This screen contains the surgeon's desired default planning parameters and instrumentation for the current knee replacement surgery. These planning parameters will be used to compute a default surgery plan for the first (and all upcoming plans) for the associated knee replacement surgery.

After reviewing (and/or updating) the preferences press the 'save and apply' button to continue:



3.2 Updating preferences

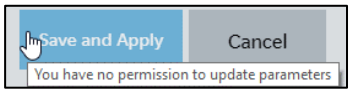
At any moment, the preferences can be from the main screen by pressing the Preferences button in the top menu of the Planner.



The selection of available preferences will depend on the surgery procedure (TKA versus PKA). An overview is given in sections 3.3 and 3.4. To exit the preferences window press either of the two buttons:

Please note that pressing 'save and apply' will result in these changes to be applied to the present and all upcoming cases. They will not retro-actively be applied for previously approved (and potentially shipped) cases.

Also note that only some users will have permissions to change the surgical preferences. In case permissions are not granted, the save and apply button will be deactivated.

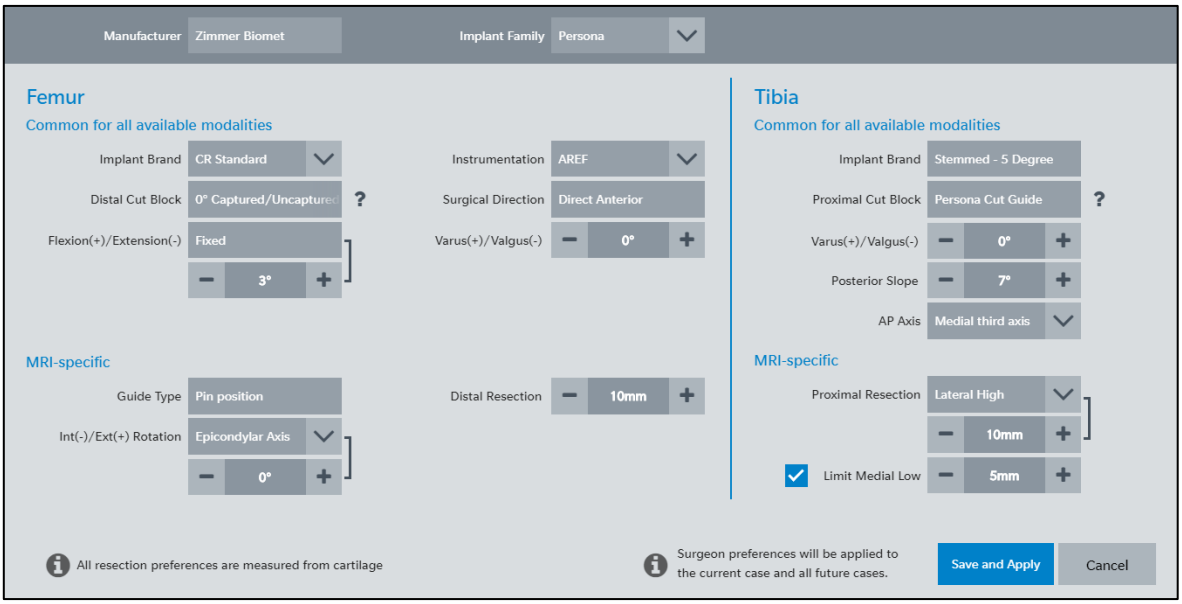


3.3 TKA preferences

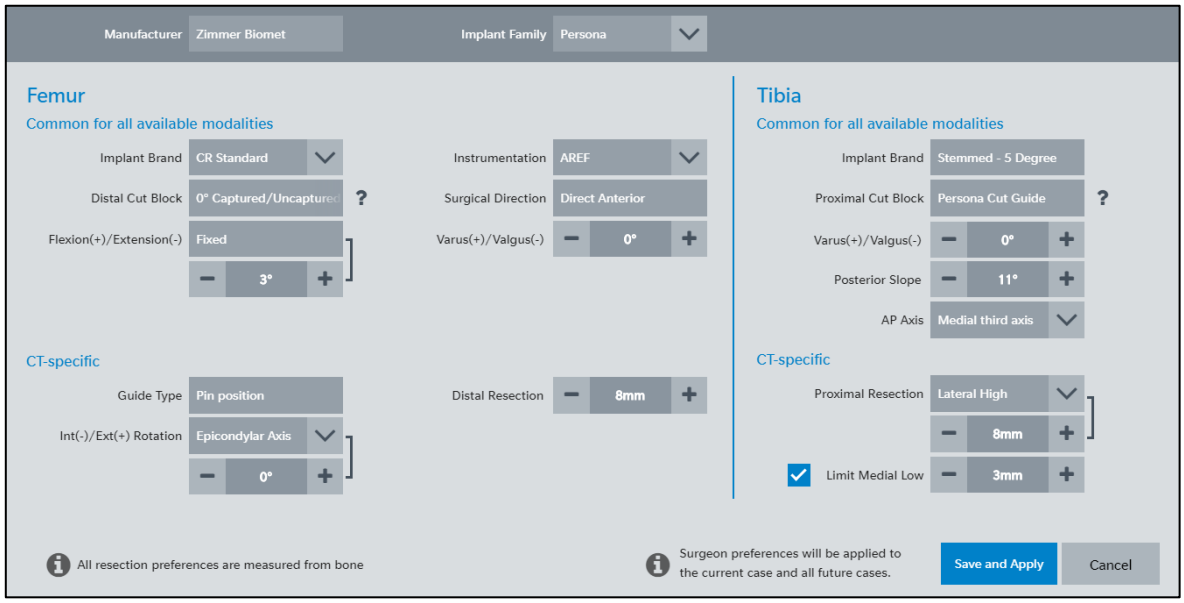
The TKA preferences window is divided horizontally into a femur and tibia section, and vertically into two sections depending on the modality. The top section labeled as 'Common for MRI and CT' contains instrumentation and planning preferences that are shared between MRI and CT cases. This implies that changes made in this section when opening an MRI case will carry over to the current and future MRI and CT cases; and vice versa, changes made in this section when opening a CT case will carry over to future CT and MRI cases.

The bottom section labeled as MRI-specific (when opening an MRI case) will only carry over to the current and future MRI cases, or when labeled as CT-specific only carry over to the current and future CT cases.

Please note that some TKA implant families may not be available depending on the hospital country of the specific case.

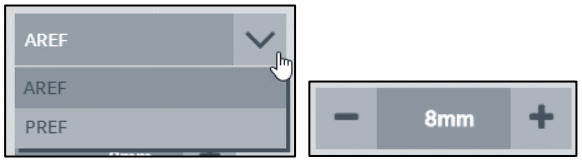


Example TKA MRI preferences window



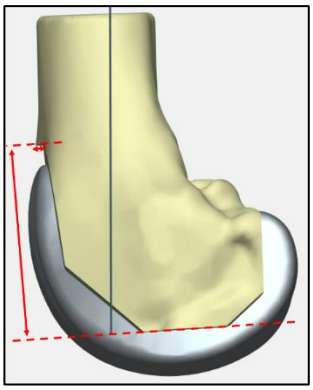
Example TKA CT preferences window

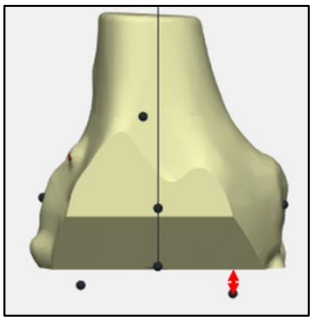
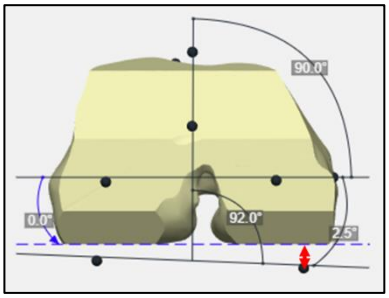
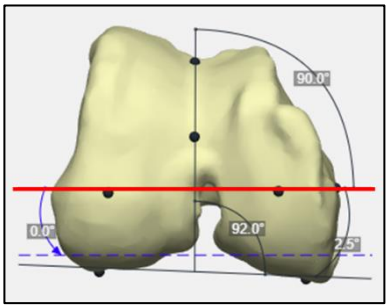
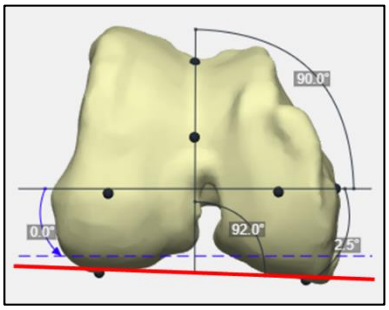
Only preferences which have a dropdown menu or a '+/-' control can be changed. Other preferences are pre-filled and cannot be changed since there is only one option.

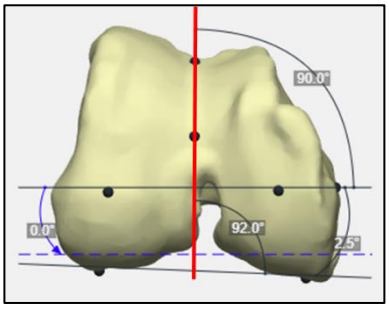
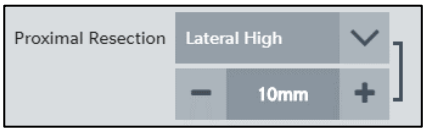
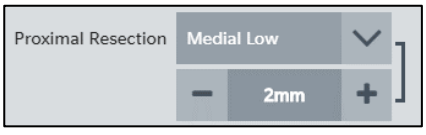


When multiple cutblocks are available for a given implant family, an information sheet with item numbers and cutblock pictures is accessible by clicking on the associated help button in the preferences window:

The following preferences can be set by the surgeon:

Preference	Description
GENERAL	
Implant Family	Preferred implant family
FEMUR (Common for MRI and CT)	
Implant Brand	Preferred femur implant brand. Available options depend on the implant family.
Instrumentation	Instrumentation used during surgery (Options only for Persona) AREF or PREF (Options only for NexGen) Standard or Posterior Referencing
Distal Cut Block	Distal cut block used. Choices depend on implant family.
Surgical Direction	Approach of distal femoral cutblock. (Options only for Vanguard) **Direct Anterior** or **Anteromedial**
Varus(+)/Valgus(-)	Default varus/valgus value.
Allowed Notch **(only available for posterior referencing cutblocks)**	The default femur implant size will be selected in such a way that that the femoral notch will remain under the indicated allowed notch. Setting a positive allowed notch implies that some default plans might have a femoral notch that satisfies this condition. Femoral notch is calculated at a position based on the tip of the AP sizer instrumentation from conventional surgical technique. 
Flexion(+)/Extension(-) **> Method**	**Dynamic** (only available for Posterior referencing cutblocks) or **Fixed** option. When fixed flexion is selected, the indicated flexion value is used together with the allowed notch to calculate the femur implant size. When dynamic flexion is selected, then the femur implant size is calculated by optimizing for implant flexion and allowed notch.
Flexion(+)/Extension(-) **> Value**	(Only when Fixed is selected) The number of degrees of flexion or extension.
FEMUR (MRI or CT-specific)	
Guide Type	(Options only for Vanguard/Vanguard Mobile) **Pin positioning** or **Cut-through guide**.

Preference	Description
Distal Resection	Default distal resection. The distal resection is measured from the most distal of the medial and lateral distal cartilage/bone points (for MRI/CT respectively). 
Posterior Resection	Default posterior resection. The posterior resection is measured from the posterior medial cartilage/bone point (for MRI/CT respectively). 
Int(-)/Ext(+) Rotation > Reference Axis	The reference axis used for defining the femoral implant rotation: - **Epicondylar axis** (MRI and CT): between the medial and lateral epicondylar landmarks.  - **Posterior condylar axis** (MRI and CT): between the posterior medial and lateral bone references. This axis is defined from bone (for MRI and CT) to avoid a possible influence of diseased posterior condyles. 

Preference	Description
	- **Whiteside's line** (MRI only): between the anterior point and middle notch point. 
Int(-)/Ext(+) Rotation > Value	The number of degrees of femoral rotation from the selected rotation reference axis.
TIBIA (Common for MRI and CT)	
Implant Brand	Preferred tibia implant brand. Choices depend on the selected implant family.
Proximal Cut Block	Proximal cut block used. Choices depend on the selected implant family.
Varus(+)/Valgus(-)	Default varus/valgus angles in degrees.
Posterior Slope	Default posterior slope of the tibia implant in degrees.
AP Axis	The reference AP axis used for defining the tibia implant rotation: - **Medial third axis:** from the medial third tuberosity to the center of the posterior sulcus. - **Transverse AP axis** (i.e. the Cobbs axis): defined as the perpendicular bisector of the axis connecting the medial and lateral plateau center points.
TIBIA (MRI or CT-specific)	
Proximal Resection > Reference	Reference to measure the amount of proximal resection: - **Lateral high** point, i.e. the most proximal point in the center area of the lateral plateau. - **Medial low** point, i.e. the most distal point in the center area of the medial plateau.
> Value	The amount of tibia resection from the proximal resection reference.  
> Optional limit from medial low	(Only available when Lateral High is selected as a proximal resection reference) The medial resection can be limited to a certain resection if desired. 

3.3.1 Femur TKA planning philosophy: anterior or posterior referencing

The SurgiCase Knee Planner supports anterior and posterior referencing. Options available based on the selected implant family femur instrumentation set.

Implant family	Femur instrumentation set	Femur planning philosophy
Persona	AREF	Anterior referencing
Persona	PREF	Posterior referencing
NexGen	Standard	Anterior referencing
NexGen	Posterior Referencing (PRI)	Posterior referencing
NK-Flex	NK-Flex MIS	Posterior referencing
Vanguard	PREF	Posterior referencing
Vanguard Mobile	PREF	Posterior referencing

Anterior referencing:

- The femoral implant is positioned anteriorly along the anterior cortex point. The size is mimicking the AP sizer.
- Femur dynamic flexion option in the preference menu is not available
- Posterior resection option in the preference menu is not available
- Posterior resection option in the planning menu is not available (see section 4.4). Instead the option A/P shift is available, measuring how much the implant is shifted in the AP direction with respect to the anterior cortex point (i.e. the amount of notching in mm)

Posterior referencing:

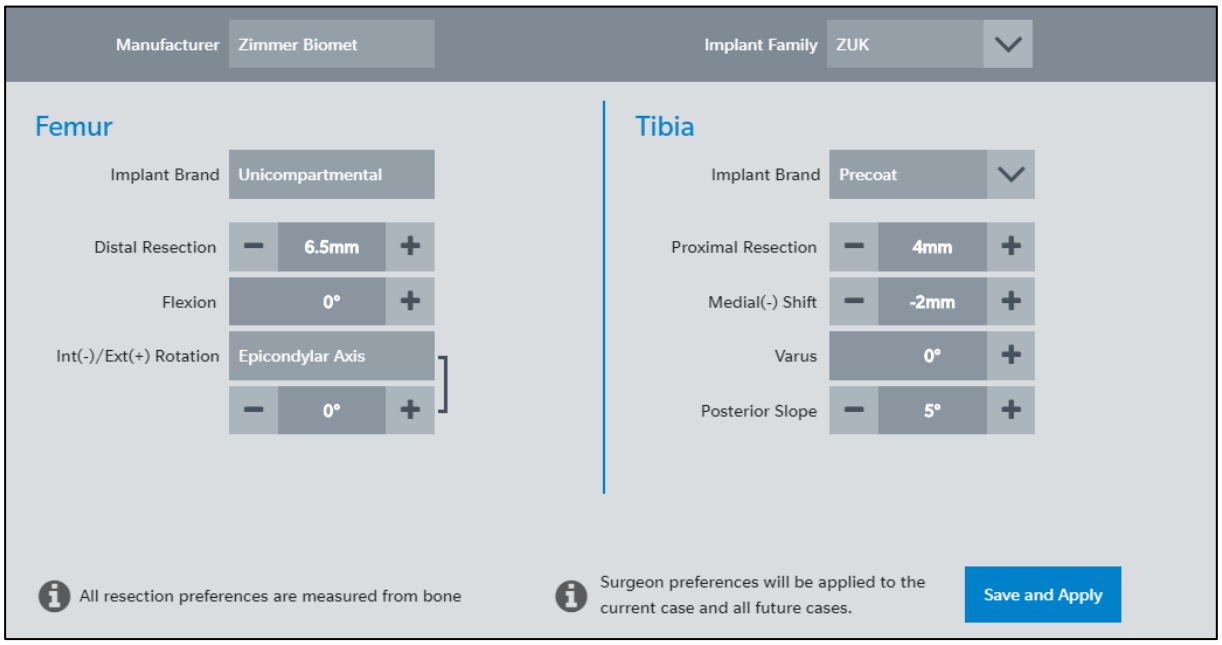
- The default femur size and position will be determined as the plan optimized for the specified implant flexion and allowed notch with the specified amount of posterior resection.
- The posterior resection option in the preference menu is available.
- The posterior resection option in the planning menu is available (see section 4.4) and measures how posterior resection is taken with respect to the medial most posterior point.

Note: For TKA, the default planning is referencing the mechanical axis. This is unlike conventional instrumentation in which the surgeon must intra-operatively determine the anatomic to mechanical axis adjustment using instruments such as the intramedullary rod. Therefore, consider specific deformities when adjusting varus or valgus.

3.4 PKA preferences

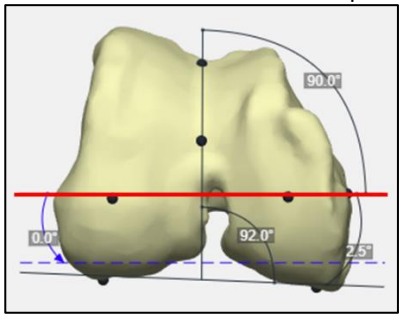
The PKA preferences window is divided horizontally into a femur and tibia section. The available options depend on the selected implant family. Please note that some PKA implant families may not be available depending on the hospital country and surgeon trainings.

3.4.1 PKA ZUK



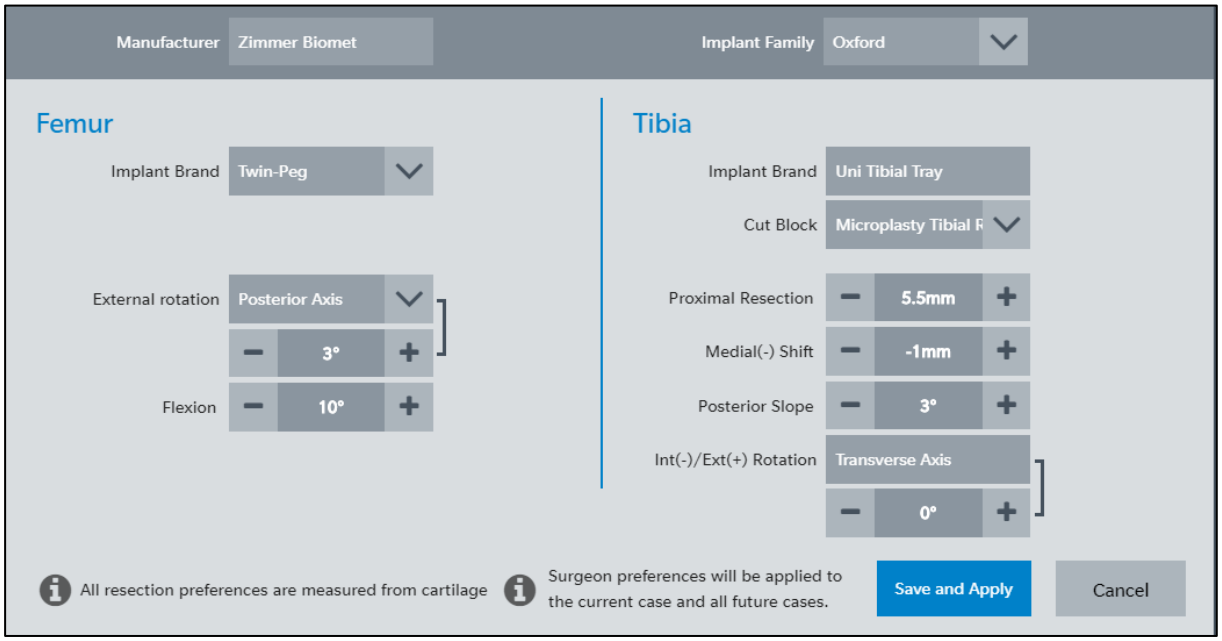
Example PKA ZUK preferences window

The following preferences can be set by the surgeon:

Preference	Description
FEMUR	
Implant Brand	(Only 1 option for ZUK) Preferred femur implant brand.
Distal Bone Resection	Default distal resection. The distal resection is measured from the most distal point **on bone** on the medial condyle. Note: Resections measurements from cartilage are provided in the 2D view (see section 4.3)
Flexion	Default flexion value Note: only flexion is allowed.
Ext(+) Rotation > Reference Axis	The reference axis used for defining the femoral implant rotation. (Only 1 option for ZUK): - Epicondylar axis: between the medial and lateral epicondylar points. 

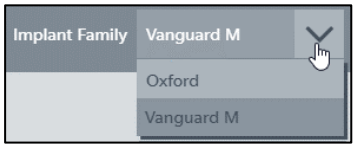
Preference	Description
Ext(+) Rotation > Value	The amount of femoral rotation from the selected rotation reference axis.
TIBIA	
Implant Brand	Preferred tibia implant brand. Choices depend on the selected implant family.
Proximal Bone Resection	Default proximal resection. The proximal resection is measured from the most distal point (medial low) **on bone** on the medial condyle. Note: Resections measurements from cartilage are provided in the 2D view (see section 4.3).
Medial(-) Shift	Default tibia implant shift measured from the tibial high spine point. *Note: only negative values are allowed, representing that the implant is shifted away medially from the tibial high spine point.*
Varus(+)/Valgus(-)	Default varus/valgus value
Posterior Slope	Default posterior slope

3.4.2 PKA Oxford / PKA Vanguard M

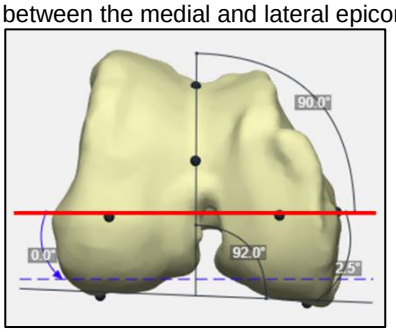


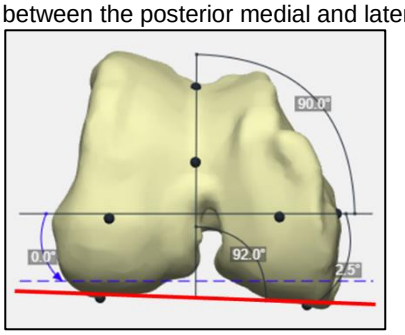
Example PKA Oxford preferences window

Oxford or Vanguard M implant family can be selected by using the implant family dropdown menu:



The following preferences can be set by the surgeon:

Preference	Default	Description
FEMUR		
Implant Brand		Preferred femur implant brand. Available options depend on the selected implant family.
Flexion		Default flexion value Note: only flexion is allowed.
Ext(+) Rotation > Reference Axis		The reference axis used for defining the femoral implant rotation: - **Epicondylar axis**: between the medial and lateral epicondylar landmarks. 

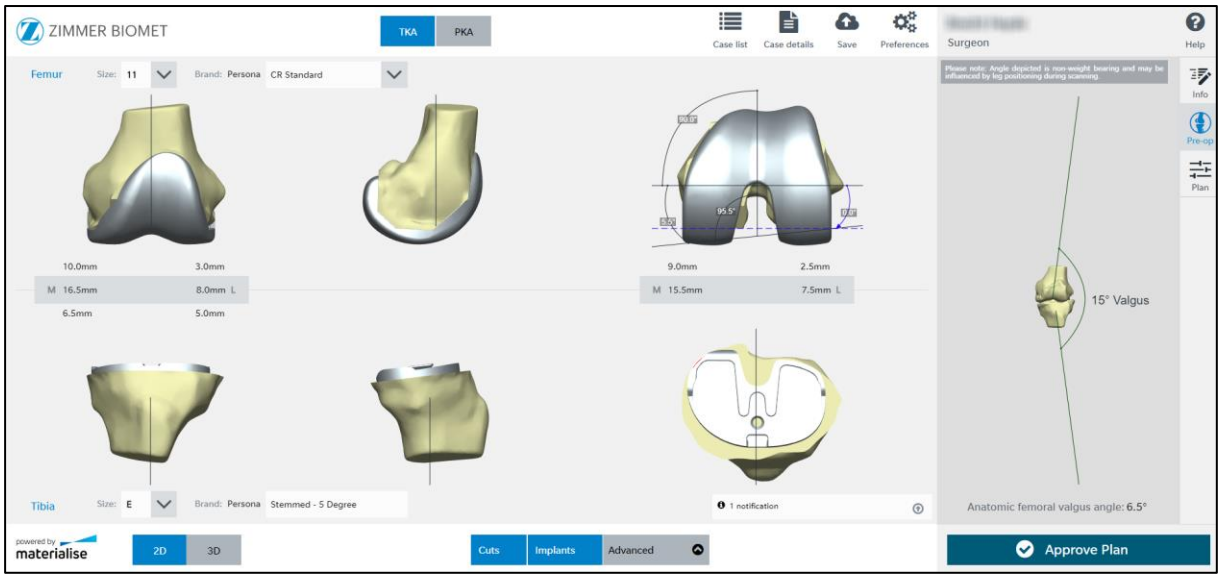
Preference	Default Description
	- **Posterior condylar axis**: between the posterior medial and lateral bone references.  This axis is defined from bone to avoid a possible influence of diseased posterior condyles.
Ext(+) Rotation > Value	The amount of femoral rotation from the selected rotation reference axis.
TIBIA	
Implant Brand	(Only 1 option for Oxford) Preferred tibia implant brand.
Cut Block	Proximal cut block used. Choices depend on the selected implant family.
Proximal Resection	Default proximal resection. The proximal resection is measured from the most distal point (medial low) **on bone** on the medial condyle. Note: Resections measurements from cartilage are provided in the 2D view (see section 4.3).
Medial(-) Shift	Default tibia implant shift measured from the tibial high spine point. *Note: only negative values are allowed, representing that the implant is shifted away medially from the tibial high spine point.*
Posterior Slope	Default posterior slope
Int(-)/Ext(+) Rotation > Reference Axis	The reference AP axis used for defining the tibial implant rotation. (Only 1 option for Oxford): - **Transverse AP axis**: defined as the perpendicular bisector of the axis connecting the medial and lateral plateau center points.
Int(-)/Ext(+) Rotation > Value	The amount of tibial implant rotation from the selected rotation reference axis.

4 SurgiCase Knee Planner functionality

The SurgiCase Knee Planner is accessible via Zimmer Biomet's Drive Case Management System (DCMS) by clicking on the SurgiCase Knee Planner link within the patient's case details. It provides an adapted user interface that displays all data necessary to complete the pre-operative planning for a specific case.

The user interface of the SurgiCase Knee Planner consists of several dedicated functional areas explained in more detail in the next sections:

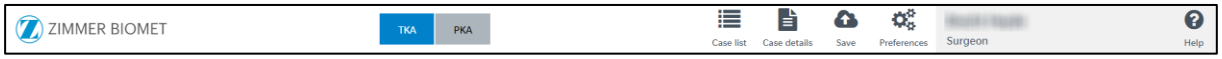
- Top menu
- Main viewing area visualization options
- Side bar
    - Case Info and Notes
    - Pre-op View
    - Femur and Tibia Implant planning options
- Case Approval



Default SurgiCase Knee Planner view on opening a case

4.1 Planner top menu

The top menu provides information on the user currently logged in the system and links to access the Case Details or the full Case List via Zimmer Biomet's Drive Case Management System (DCMS).

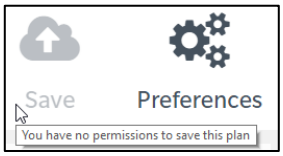
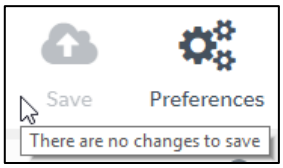
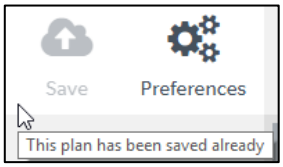


4.1.1 Case saving

Saving the current state of the plan can be done after any changes have been made by clicking the save button in the top menu of the application.

Please note that saving a plan is not enough to order a guide. Only upon case approval (see section 4.9), the case will be processed further.

Case saving is disabled when:

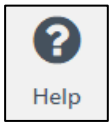
Scenario	Icon
The user has no permissions to make changes to the plan	
There are no changes to be saved	
The plan has already been saved	

4.1.2 Access to surgical Preferences

The preferences can be changed at any moment by pressing the Preferences button in the top menu of the Planner. See section 3 for more details.

4.1.3 Help

More information about the application, including the software version and this manual, can be accessed through the help menu:



4.1.4 Access to case list and case details

The user can at any moment return to Zimmer Biomet's Drive Case Management System (DCMS) by clicking on the Case list and Case details icons:

4.1.5 Switching surgery procedures

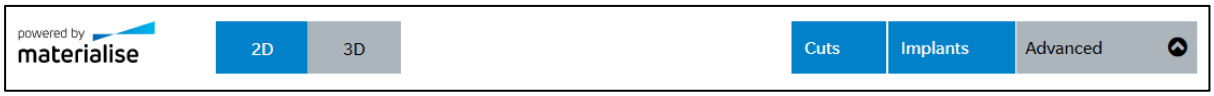
The user can switch between TKA and PKA procedures by clicking the associated buttons:

Please note that switching procedures is not be available for your case when:

- The case is based on CT images
- The procedure is not available in the hospital country
- Surgeon training for the procedure has not been registered in DCMS

4.2 Visualization options area

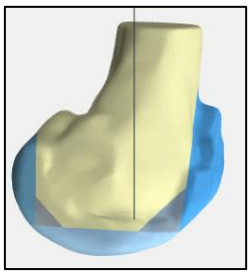
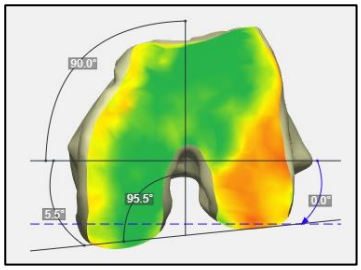
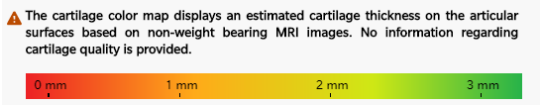
The visualization options allow to define what is visualized in the View area. Visualized items are highlighted in blue and are selected and deselected by clicking the respective buttons.

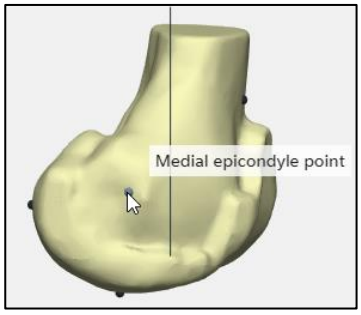
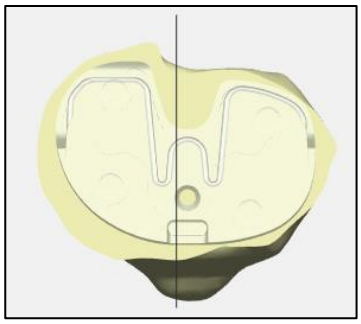
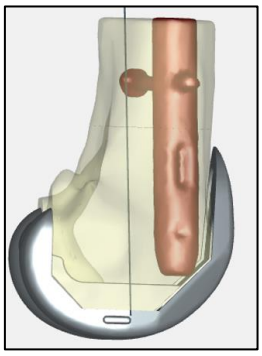


Pre-operative planning can be visualized in a 2D mode with preset views or in a 3D mode with full rotation/translation control.

By default, the implants are shown on the resected bones.

In both modes, cut bone surfaces and implants can be visualized or hidden. By hovering the mouse over the advanced button, more visualization options become available.

Visualization option	Effect	Description
Colored resections		When cuts are hidden, the resected parts are shown in colors corresponding to the distal, anterior, posterior cuts (for the femur), and the proximal cut (for the tibia)
Cartilage (Only for MRI)		Bones are visualized with an overlaying heat map representing the amount of cartilage as indicated by the associated legend.  Red colored areas indicate areas without cartilage. Green colored areas correspond to areas with more than 2mm of cartilage.

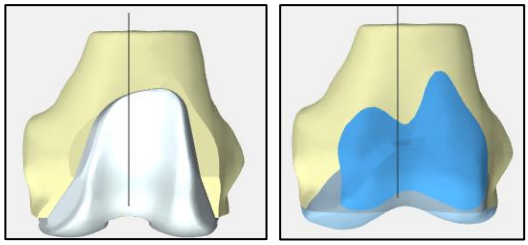
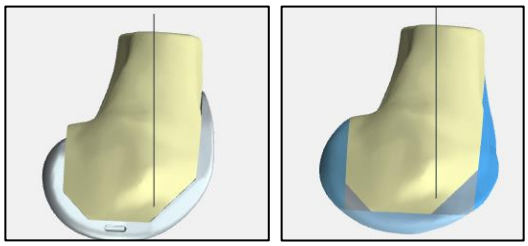
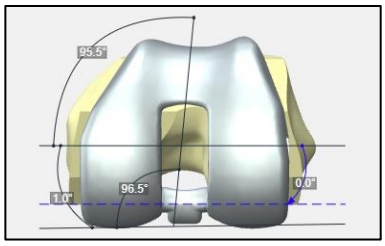
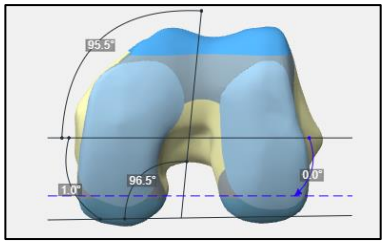
Visualization option	Effect	Description
Landmarks		Anatomical landmarks which are used to define axes and resection references are visualized. The names of the landmarks can be shown by mouse hovering or by finger tapping (on a touch device). Note: showing landmarks can be useful to visualize where the resection measurements are calculated from.
Implant Transparency		Implants become transparent. Bone and metal (only for CT cases when metal is present) can be seen through the implant.
Bone Transparency		Bones become transparent. Any implants or (in case of CT) any potential metal inside the bone can be seen through the bone.

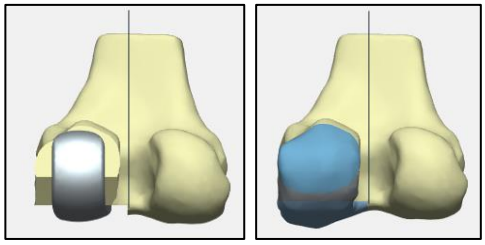
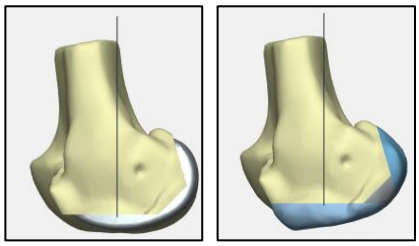
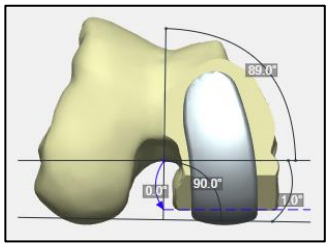
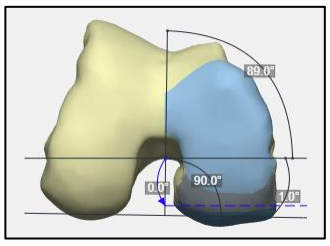
4.3 View area

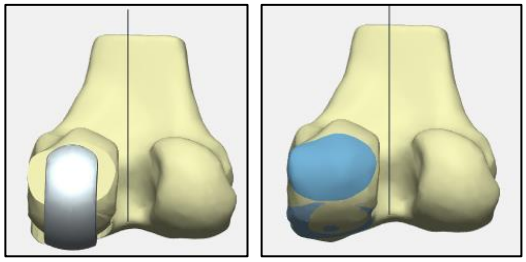
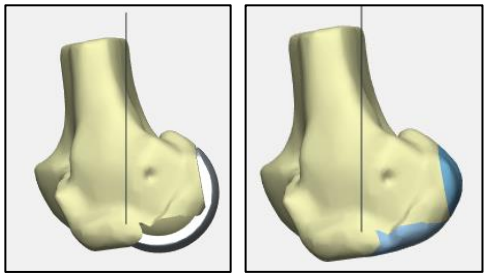
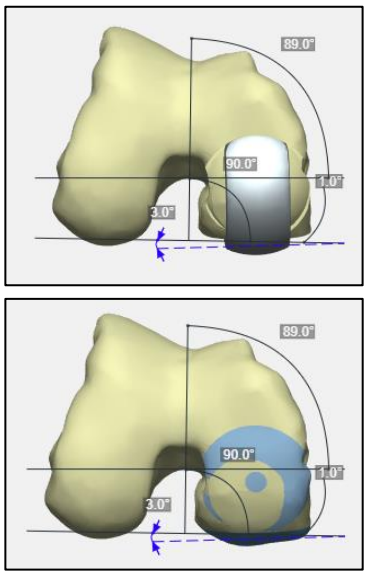
There are two modes to visualize a pre-operative planning: 2D and 3D mode, which can be selected from the Visualization options area.

The 2D view consists of predefined views aligned with each of the anatomical planes and the mechanical axes, providing easy access to resection measurements and angles of particular interest for the planned procedure. All views and measurements update instantly with any changes made to the plan.

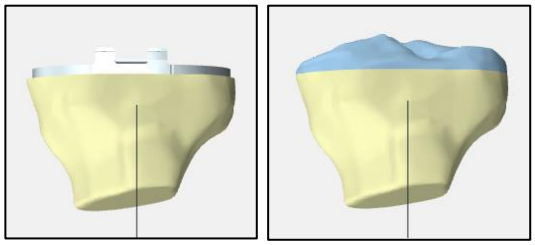
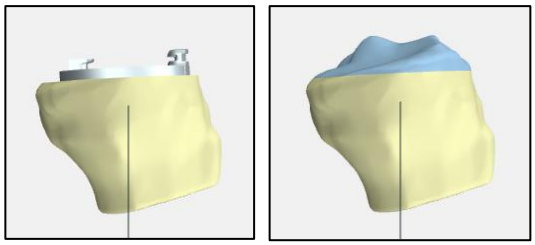
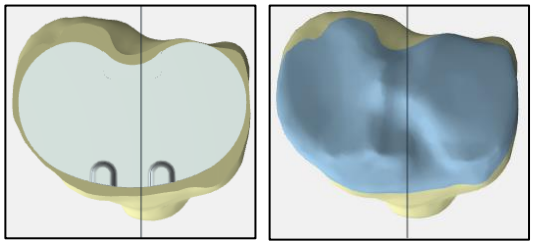
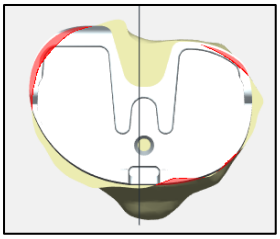
4.3.1 Femoral 2D view

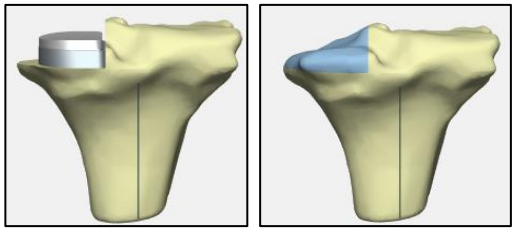
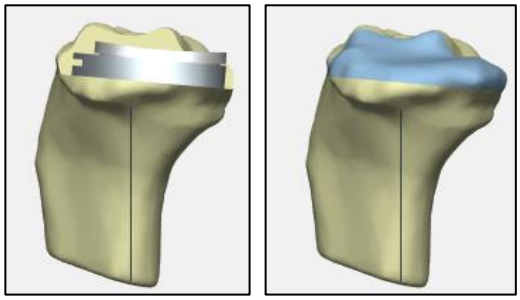
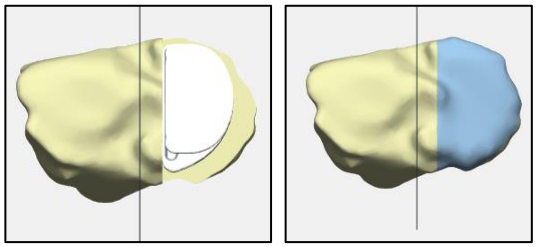
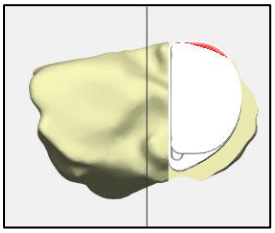
Orientation	Description	Example
TKA		
Coronal view	Through femur mechanical axis (middle notch to femoral head point) Parallel to epicondylar axis Femur mechanical axis is shown with a black line.	
Sagittal view	Through femur mechanical axis (middle notch to femoral head point) Perpendicular to coronal view Femur mechanical axis is shown with a black line.	
Axial view	Perpendicular to femur mechanical axis (middle notch to femoral head point). Shows the angles between: - Posterior and epicondylar - Posterior and femur AP axis - Epicondylar and femur AP axis All angles are rounded to 0.5° accuracy. Blue dotted line represents the intersection between the posterior cut plane and the posterior chamfer cut plane. Blue arrow shows the angle between the chosen reference axis (in the preferences) and the posterior cut.	 

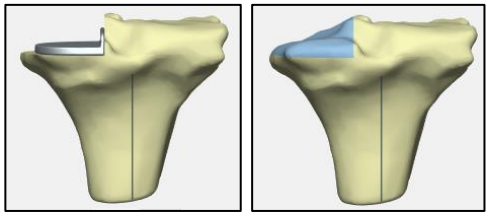
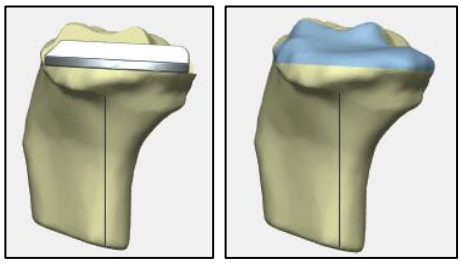
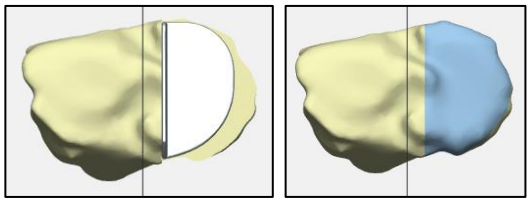
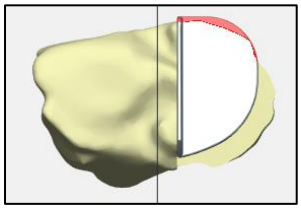
Orientation	Description	Example
PKA ZUK		
Coronal view (from posterior side)	Through femur mechanical axis (middle notch to femoral head point) Parallel to epicondylar axis Femur mechanical axis is shown with a black line.	
Sagittal view	Through femur mechanical axis (middle notch to femoral head point) Perpendicular to coronal view Femur mechanical axis is shown with a black line.	
Axial view	Perpendicular to femur mechanical axis (middle notch to femoral head point). Shows the angles between: - Posterior and epicondylar - Posterior and femur AP axis - Epicondylar and femur AP axis All angles are rounded to 0.5° accuracy. Blue dotted line represents the intersection between the posterior cut plane and the posterior chamfer cut plane. Blue arrow shows the angle between the chosen reference axis (epicondylar only for ZUK) and the posterior cut.	 

Orientation	Description	Example
PKA Oxford / Vanguard M		
Coronal view (from posterior side)	Through femur mechanical axis (middle notch to femoral head point) Parallel to epicondylar axis Femur mechanical axis is shown with a black line.	
Sagittal view	Through femur mechanical axis (middle notch to femoral head point) Perpendicular to coronal view Femur mechanical axis is shown with a black line.	
Axial view	Perpendicular to femur mechanical axis (middle notch to femoral head point). Shows the angles between: - Posterior and epicondylar - Posterior and femur AP axis - Epicondylar and femur AP axis All angles are rounded to 0.5° accuracy. Blue dotted line represents the intersection between the posterior cut plane and the distal cut plane. Blue arrow shows the angle between the chosen reference axis (in the preferences) and the posterior cut.	

4.3.2 Tibial 2D view

Orientation	Description	Example
TKA		
Coronal view	Through tibia mechanical axis (proximal to distal tibia point) Perpendicular to tibia sagittal plane Tibia mechanical axis is shown with a black line.	
Sagittal view	Through tibia mechanical axis (proximal to distal tibia point) Parallel to reference tibia AP axis (indicated in preferences) Tibia mechanical axis is shown with a black line.	
Axial view	Perpendicular to tibia mechanical axis (proximal to distal tibia point) The reference tibia AP axis (Medial third axis or Transverse axis) is visualized with a black line.	
Implant overhang	The area where the tibia implant hangs over the proximal cut plane or where the implant is not supported by bone is shown in red.	

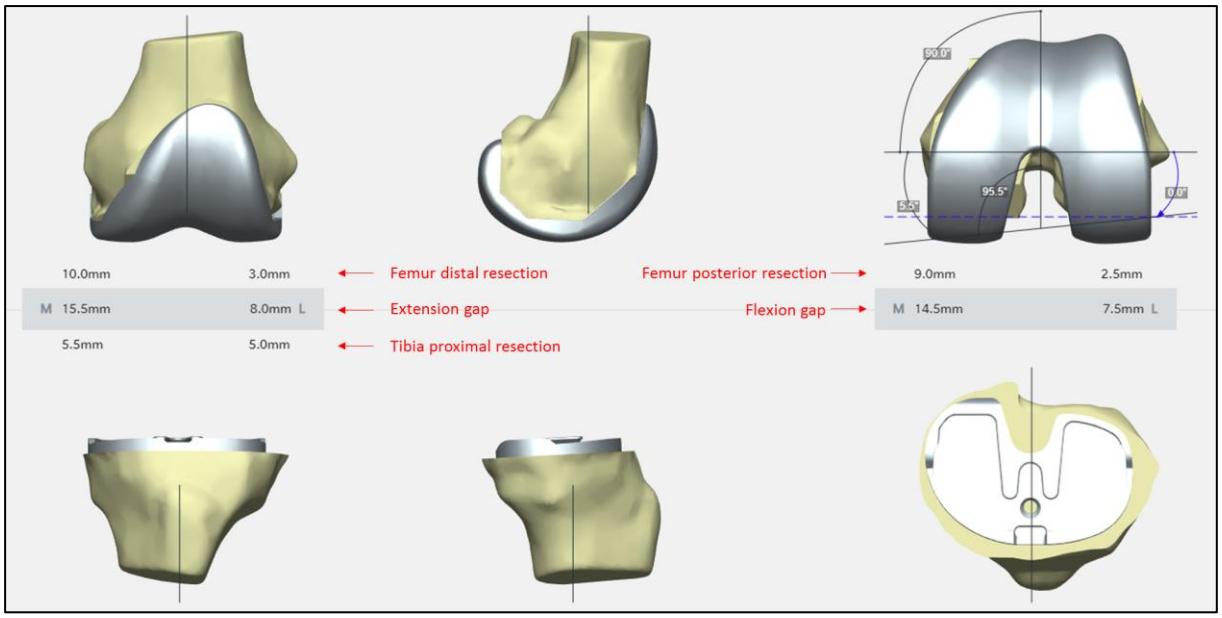
Orientation	Description	Example
PKA ZUK		
Coronal view	Through tibia mechanical axis (proximal to distal tibia point) Perpendicular to tibia sagittal plane Tibia mechanical axis is shown with a black line.	
Sagittal view	Through tibia mechanical axis (proximal to distal tibia point) Parallel to reference tibia AP axis (indicated in preferences) Tibia mechanical axis is shown with a black line.	
Axial view	Perpendicular to tibia mechanical axis (proximal to distal tibia point) The Transverse axis is visualized with a black line.	
Implant overhang	The area where the tibia implant hangs over the proximal cut plane or where the implant is not supported by bone is shown in red.	

Orientation	Description	Example
PKA Oxford / Vanguard M		
Coronal view	Through tibia mechanical axis (proximal to distal tibia point) Perpendicular to tibia sagittal plane Tibia mechanical axis is shown with a black line.	
Sagittal view	Through tibia mechanical axis (proximal to distal tibia point) Parallel to reference tibia AP axis (indicated in preferences) Tibia mechanical axis is shown with a black line.	
Axial view	Perpendicular to tibia mechanical axis (proximal to distal tibia point) The Transverse axis is visualized with a black line.	
Implant overhang	The area where the tibia implant hangs over the proximal cut plane or where the implant is not supported by bone is shown in red.	

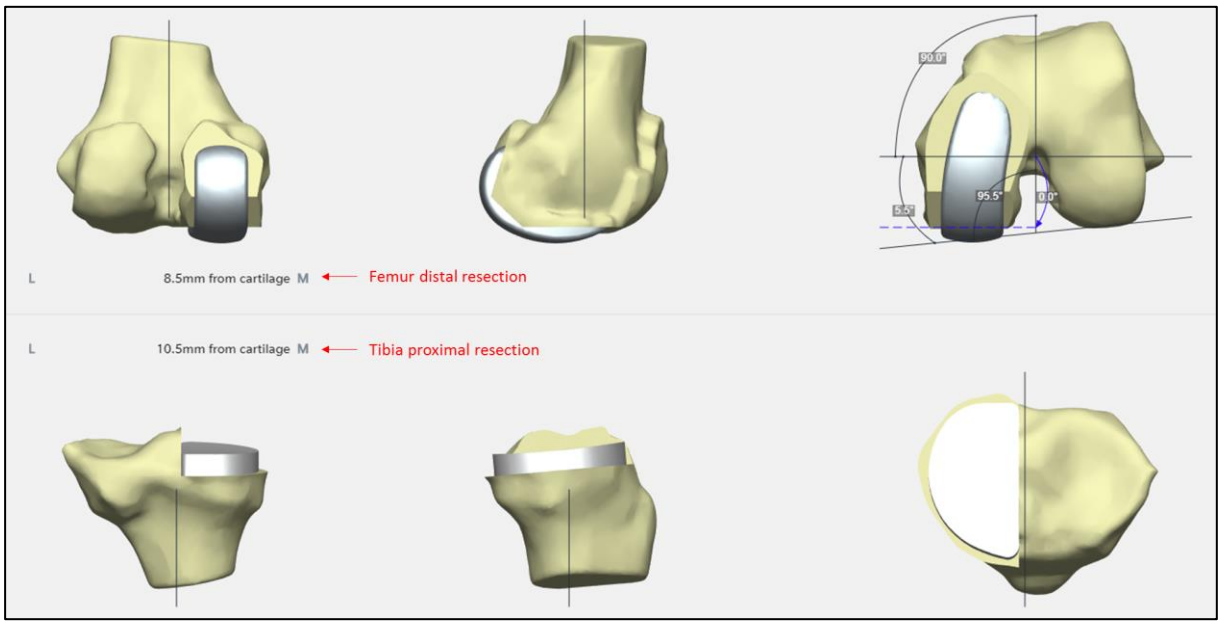
4.3.3 Resection/gap measurements on 2D view

All resection measurements are measured perpendicular to the cut surface, measured from cartilage and include the saw blade thickness. The *M* and *L* references depict which measurement is medial or lateral. All measurements are rounded to 0.5mm accuracy. For TKA, the total flexion and extension gap is shown in the middle between these respective measurements.

TKA

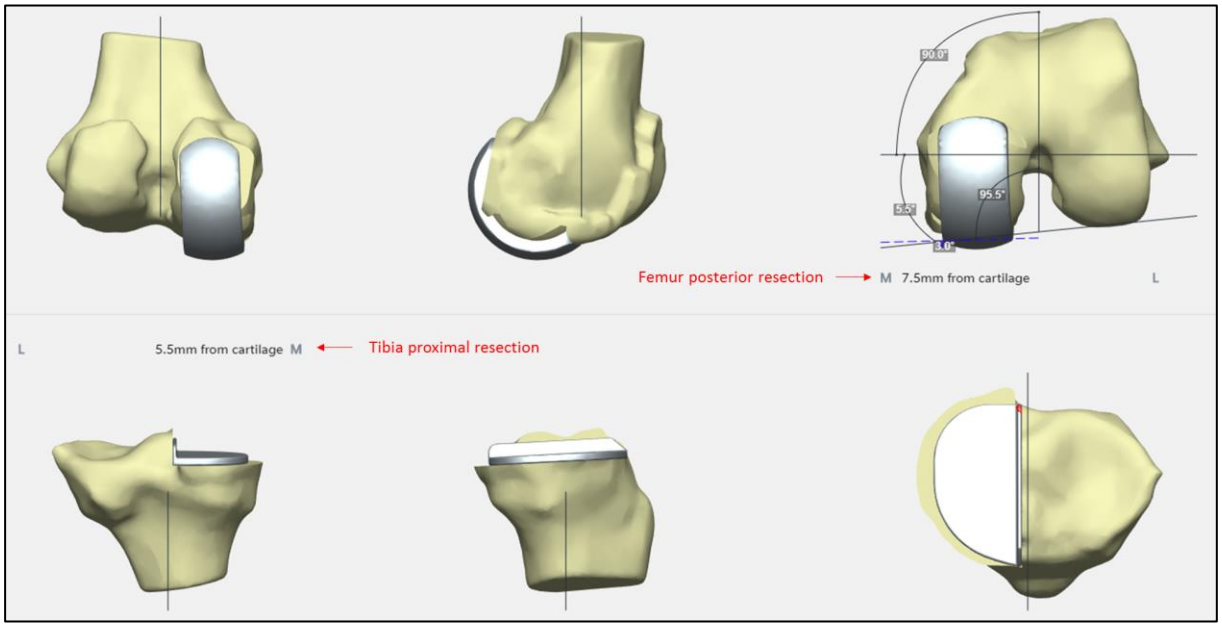


PKA ZUK

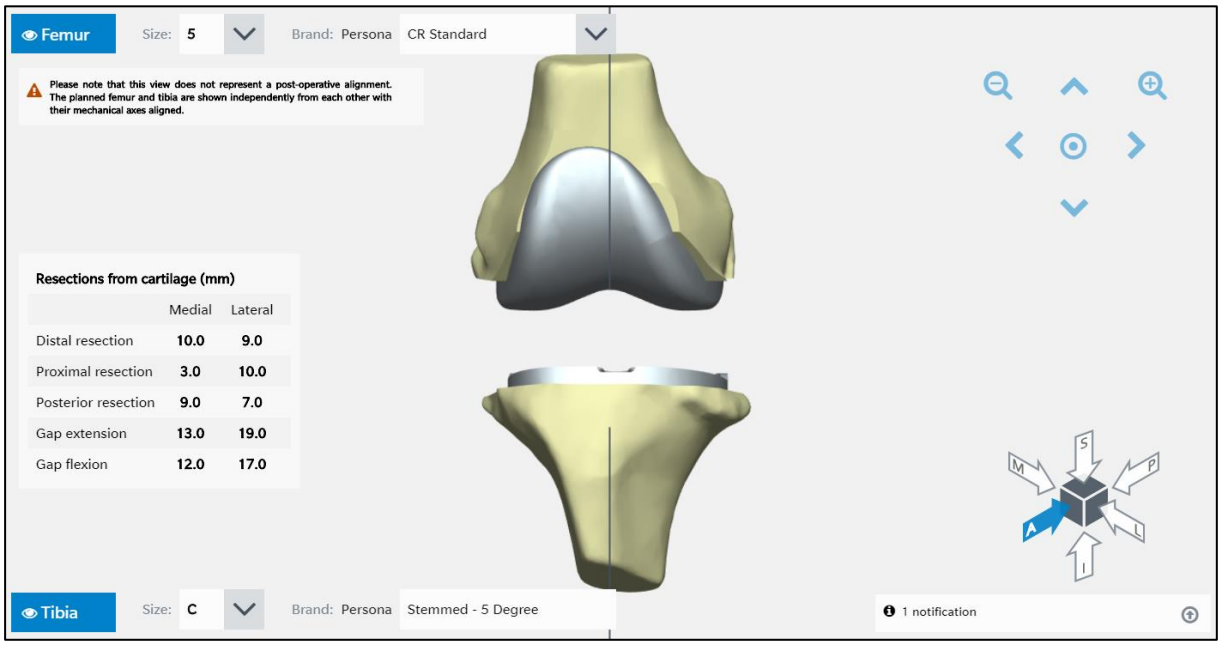


Please note that the resections are shown from cartilage, whereas the planning parameters are defined from bone.

PKA Oxford / Vanguard M



4.3.4 3D view



The 3D view displays the femur and tibia separately or together. The surgeon can (de)activate either of them by clicking the femur and tibia buttons on the top left and bottom left side of the 3D view respectively. The same advanced visualization options are available in the 3D view as in the 2D view (see section 4.2).

The 3D view can be manipulated as follows:

- Models can be rotated by holding down the right mouse button and moving the mouse in the desired rotation direction (one finger movement on mobile device). The mouse icon changes into

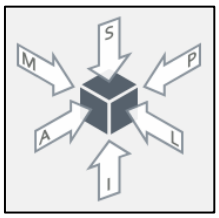
- Models can be translated by pressing the mouse scroll wheel and moving the mouse in the desired direction (3 fingers movement on mobile device). Alternatively one can press shift together with the left mouse button. The mouse icon changes into

- Zooming can be achieved by rotating the mouse scroll wheel up and down (pinching with 2 fingers on mobile device).
  The mouse icon remains unchanged.

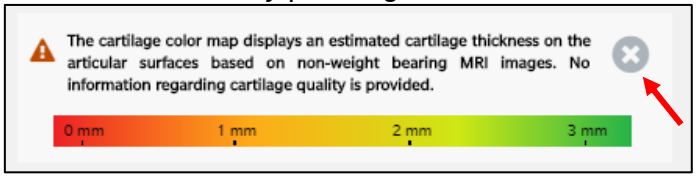
- The same operations can also be done by using the viewing controls:

  To reset the view to its default position, press the circle/dotted button in the center of the viewing controls.

- One can quickly switch between default views corresponding to the anterior/posterior, medial/lateral and inferior/superior view by clicking on the corresponding arrows on the quick-view icon.

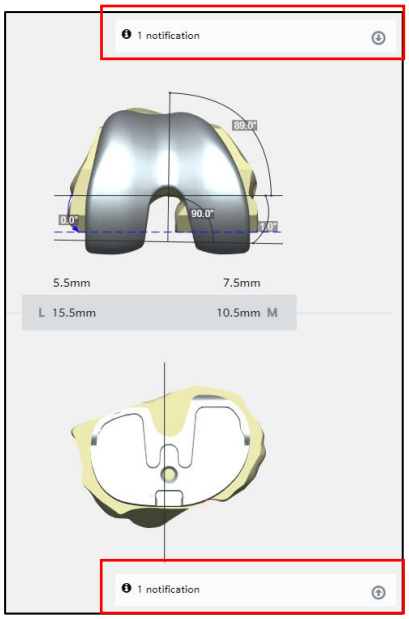


Note: When the cartilage colormap overlay is shown in this view (Advanced > Cartilage, see section 2.4), the legend can be hidden by pressing the associated “Close” button.



4.3.5 Notifications

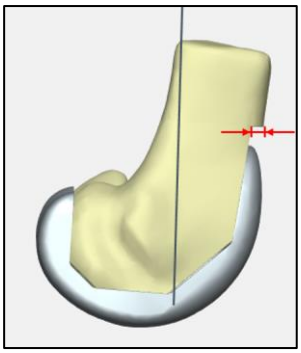
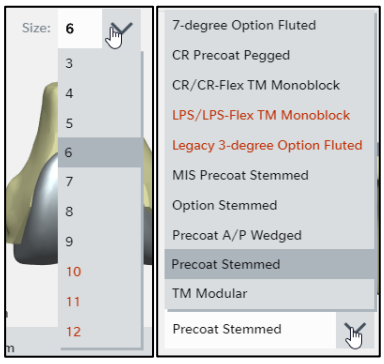
In case there are any notifications present for the plan they are shown on the top right or bottom right side in the view area for the femur and tibia respectively.

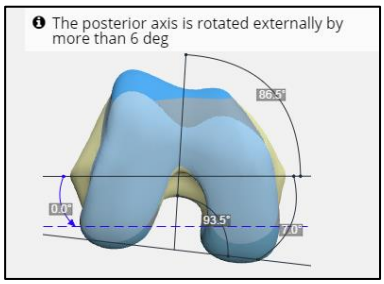


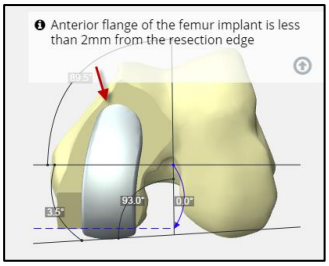
When multiple notifications are present, they can be collapsed by clicking the arrow at the bottom right of the notification area.

Two types of notifications exist:

- Warnings that block approval (shown in orange with an exclamation mark)
- Informative warnings that do not block approval (shown in black with an information sign)

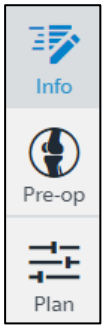
Notification	Explanation	Blocking approval
TKA		
Potential notch	This notification is shown if the sawblade does not exit the femur bone model on the anterior side resulting in a bone defect (notch) in the anterior femoral cortex.  When this notification is displayed, it demonstrates a *potential* risk for an anterior femoral notch. This can be verified on the sagittal and coronal femoral 2D views and on the 3D view. Attempting to approve a case with a potential notch will result in a notification being shown on the case approval window, to explicitly verify that the surgeons would like to proceed as such with the surgical plan.	No
Selected implant sizes or brands are not compatible, please consider changing femur/implant size.	In case the chosen femoral implant size or brand is incompatible with the chosen tibial implant size or brand, this notification will be shown (both for femur and tibia). Until compatible sizes or brands are chosen, approval of the case will be prohibited. Incompatible sizes and/or brands are highlighted in red in the size and/or brand parameters on the 2D view 	Yes

Notification	Explanation	Blocking approval
Rotation notification	A notification is shown in case the femur is - Rotated internally - Rotated externally by more than 6°  This notification is shown for convenience to ensure that unusual femur anatomies can immediately be taken into account when planning the surgery.	No
Tibia implant overhang	A notification is shown when the tibia implant hangs over the tibia proximal bone cut.	No
Femur/tibia implant collision with existing metal parts	(Only for CT cases) when the femur/tibia implant collides with existing metal parts. The metal parts are visualized in red and can be made more visible by making the bone and/or the implant transparent.	No
Pin collision is detected	This warning is shown when there is a potential collision detected between: - Femoral distal pins and the medial anterior pin; or - Femoral distal pins and the lateral anterior pin; or - Tibia rotation pins and the medial fixation pin; or - Tibia rotation pins and the lateral fixation pin It is recommended to take this into account intra-operatively: - (For femur) removing the medial/lateral pin prior to drilling the distal pins - (For tibia) removing the medial/lateral pin prior to drilling the anterior pins These warnings and recommendations will also be shown on the planning report.	No
Vanguard Select	If Vanguard Select has been chosen for this case, a warning will be shown to indicate that the implant shown in the SurgiCase Knee Planner and on the surgical PDF report is a standard line component and may not fully represent the final Vanguard Select design.	No
PKA		
The pre-operative mechanical alignment indicates a valgus knee	This warning is to inform that the patient has a valgus knee, which might be a contra-indication for certain partial knee implants	No
Risk of contacting ACL	Shown if the tibia sagittal cut plane is less than 2mm from the medial spine point.	No

Notification	Explanation	Blocking approval
Tibia implant overhang	A notification is shown when the tibia implant hangs over the tibia proximal bone cut.	No
Anterior flange of the femur is less than 2mm from the resection edge	(ZUK only) Shown to indicate there is a risk of patella impingement on the prosthesis. 	No
The current selected alignment may lead to edge loading. Please consider changing the operative parameters	(ZUK only) Shown to indicate that the simulated post-op position (visible when switching to the 3D view) is at more than 8 deg varus or valgus with risk of edge loading. Please note that this warning is based on a simulation based on the original non-weight bearing scan.	No
The distal resection is proximal to the femoral notch	(ZUK only) Shown when the femoral distal cut is more than 1mm proximal than the middle notch point and a sagittal cut might be required.	No
Pin collision is detected	(ZUK only) This warning is shown when there is a potential collision detected between: - Femoral rotation pins and the medial fixation pin; or - Femoral rotation pins and the lateral fixation pin It is recommended to take this into account intra-operatively by removing the medial/lateral fixation pin prior to drilling the rotation pins. These warnings and recommendations will also be shown on the planning report.	No

4.4 Side bar

The side bar conveniently allows switching between several functional areas of the planner by clicking on the appropriate tabs: Info, Pre-op or Plan.

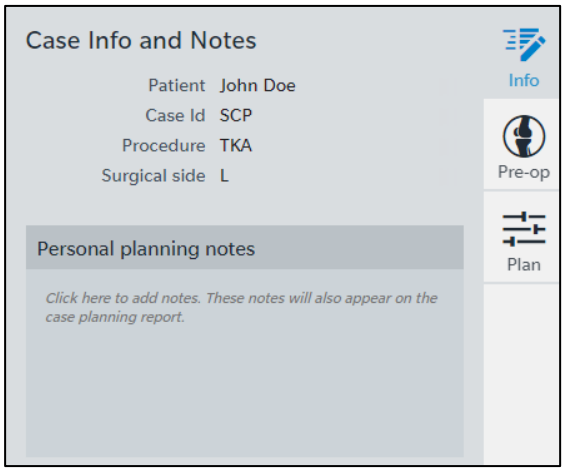


4.4.1 Info tab

Some limited Case information is provided in the Case Info panel. For more case details refer to the Case Details button in the top menu which returns to Zimmer Biomet's Drive Case Management System (DCMS) for more details.

In the bottom section of this panel Personal Planning Notes can be added related to this particular case. These will appear on the Case Planning report shipped with the guides.

Please note that these are personal notes for the surgeon, and are not suitable for providing feedback to Materialise and/or Zimmer Biomet.

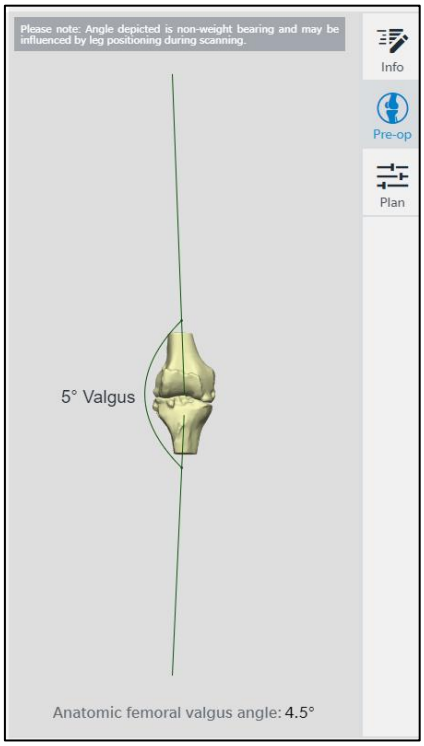


4.4.2 Pre-op tab

The Pre-op view is opened by default when opening a case. It provides information on the pre-operatives varus/valgus condition of the patient based on the patient's MRI or CT images.

The anatomic femoral valgus angle (being the angle between the femur mechanical and anatomical axis) is also shown at the bottom of this view.

It is important to note that this view is a non-weight bearing depiction based on the patient's MRI or CT scan.



4.4.3 Planning tab

The planning tab provides convenient access to further fine tune the default plan. For more information on the options, the user is referred to section 3.3 and 3.4.

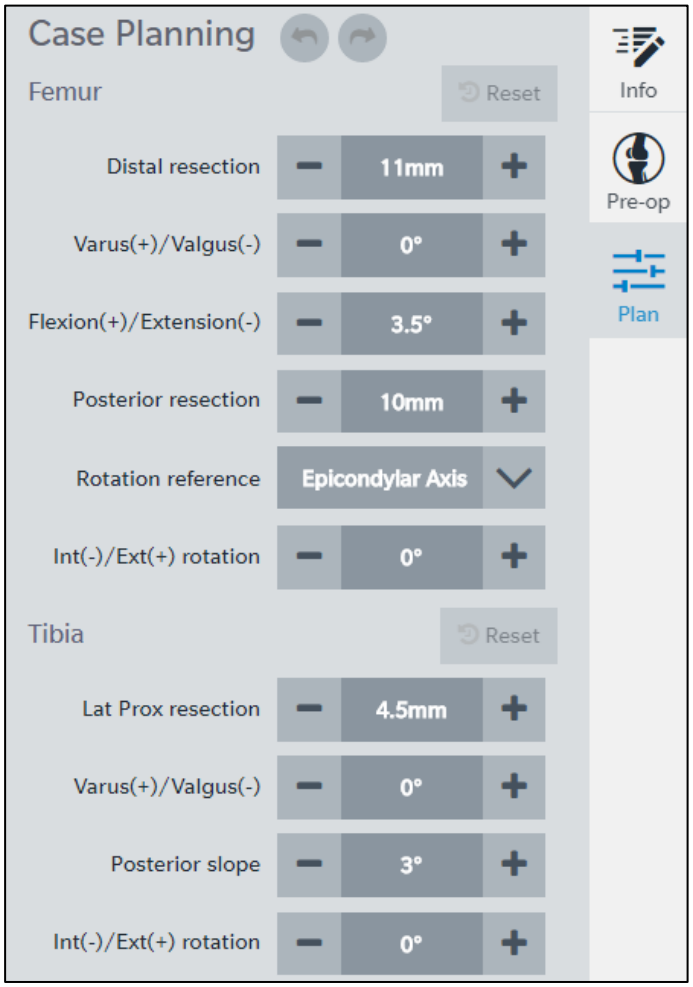
Implants can be repositioned by adjusting any of the parameters present in the Femur or Tibia pane. Any parameter changes will be reflected immediately in the view area with updated cuts/measurements etc. While the views are being updated, this is indicated by a loading indicator in the view area, also the fine tune options are disabled shortly until all views are up to date.

At any moment in time the plan can reverted to its default by clicking on the reset button. This can be done independently for the femur and the tibia.

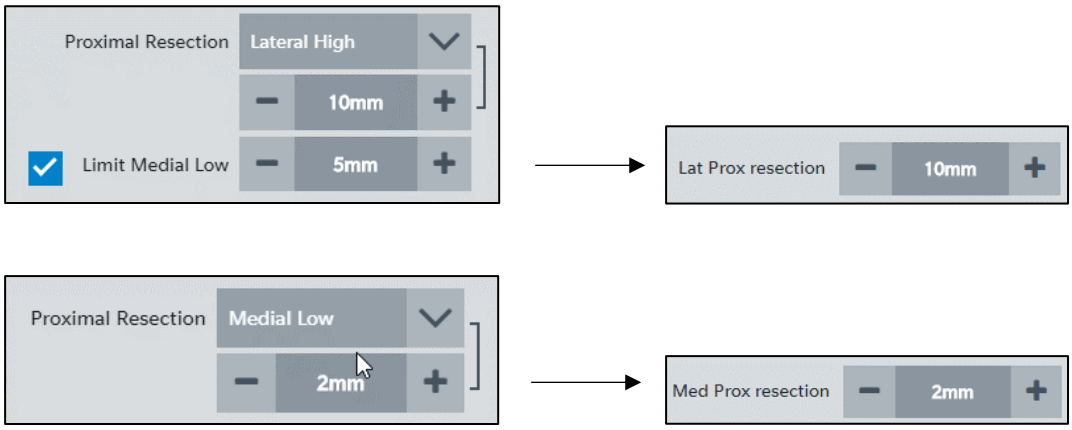
The last change to the plan can be undone/redone by clicking on the undo/redo buttons.

The planning tab has a different layout based on the currently active procedure.

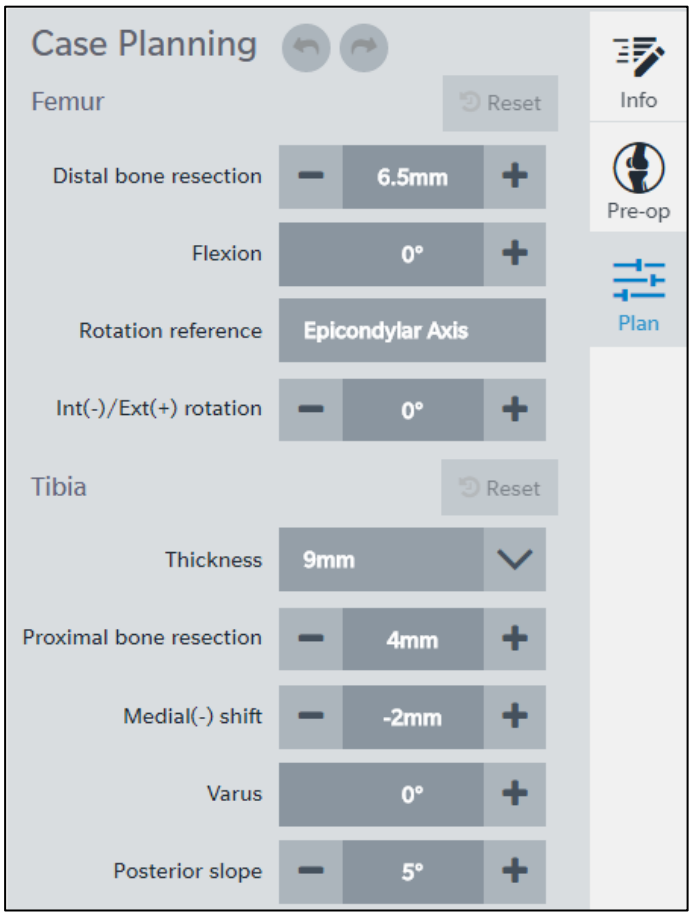
TKA



Note that the label and the value of the tibia proximal resection changes depending on the tibia preferences:

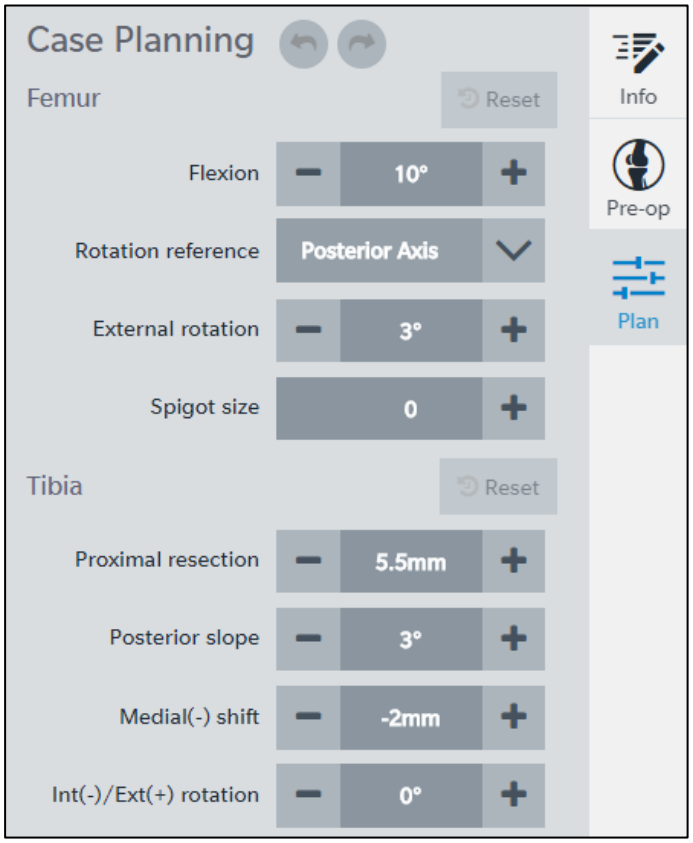


PKA ZUK



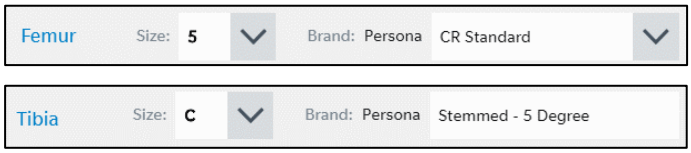
Note that the resection controls in the planning menu (for both the femur and the tibia) are measured with respect to bone.

PKA Oxford / Vanguard M

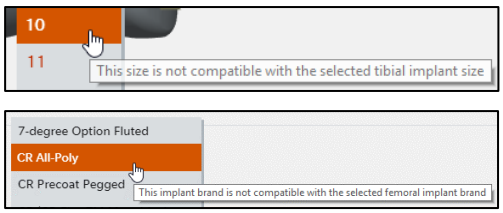


4.5 Implant brand and size selection

The femur/tibia implant brand and size can be modified from the main view, both in 2D and 3D viewing modes:



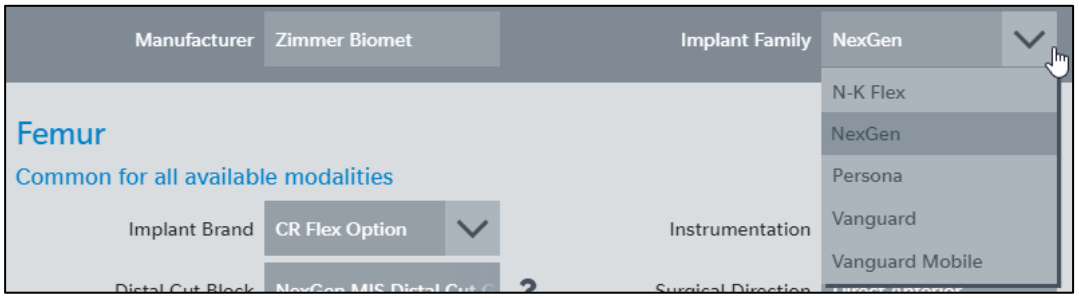
Incompatible brands or sizes are indicated in orange in the brand/size dropdown menu, a warning appears in the notification area (see section 4.3.5), and a tooltip appears when hovering over an incompatible brand/size:



When an incompatible implant brand or size is chosen plan saving or plan approval will no longer be allowed.

4.6 Implant family switching

The implant family can only be switched from within the preference menu. After selecting save and apply, the plan will be recalculated. Note that all future cases will be opened with this new implant family.

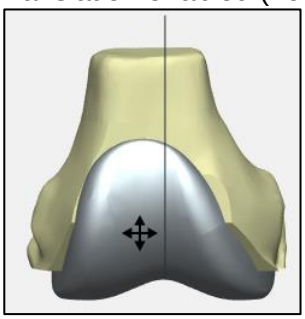
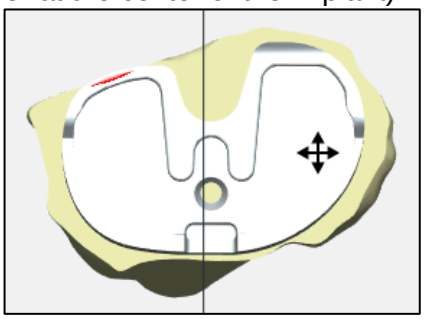


4.7 Interactive implant positioning

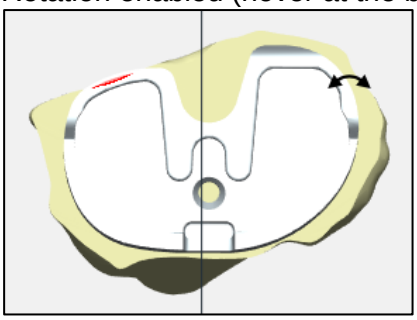
When the implants are shown in the 2D and 3D view, they can be repositioned interactively within the current cut plane.

When repositioning is possible, the mouse indicator changes when hovering over the implant:

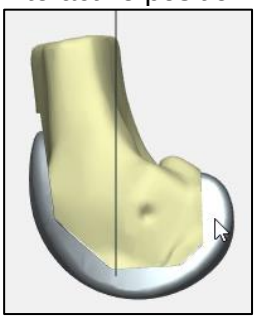
- Translation enabled (hover at the center of the implant):

- Rotation enabled (hover at the border of the implant):



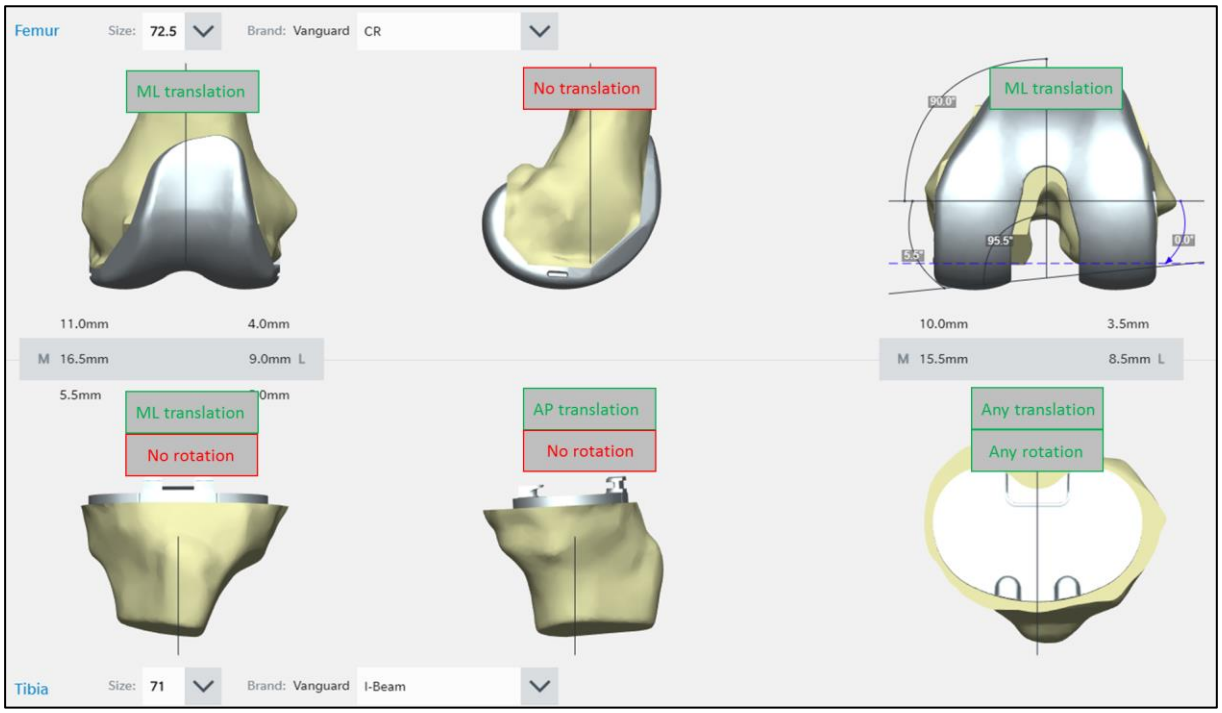
- Interactive positioning disabled (normal mouse indicator):



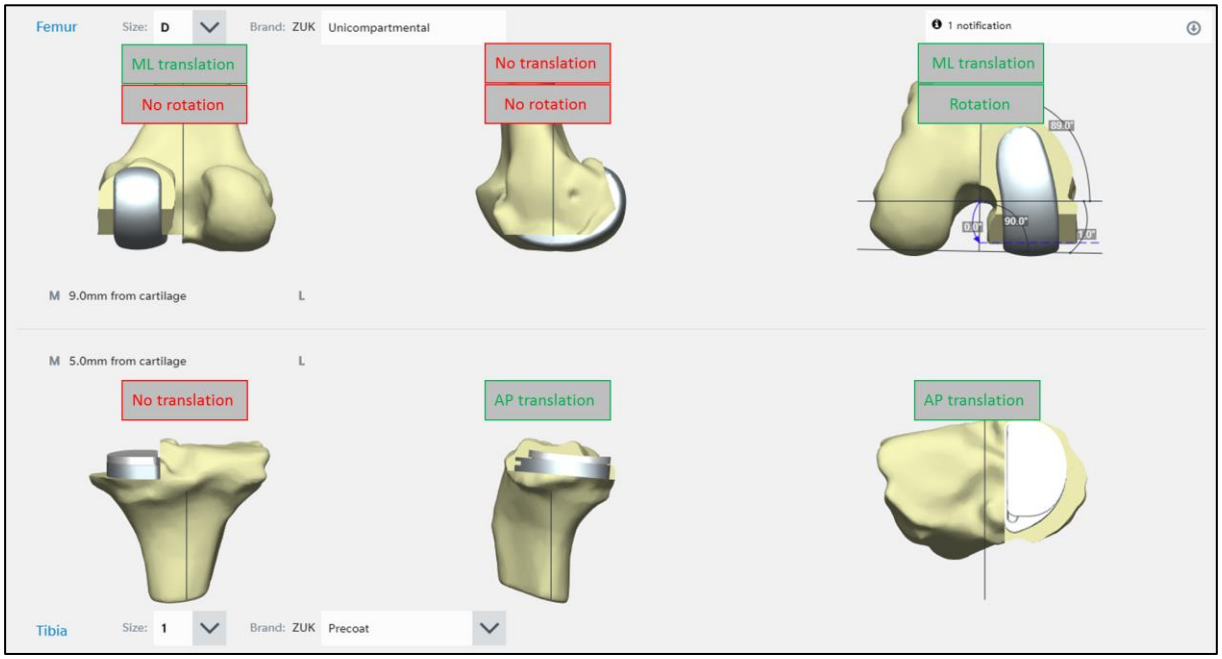
To reposition the implant, left click the implant and drag the mouse. The implant will become transparent to help repositioning.

The available interactive options depend on the current procedure and the view.

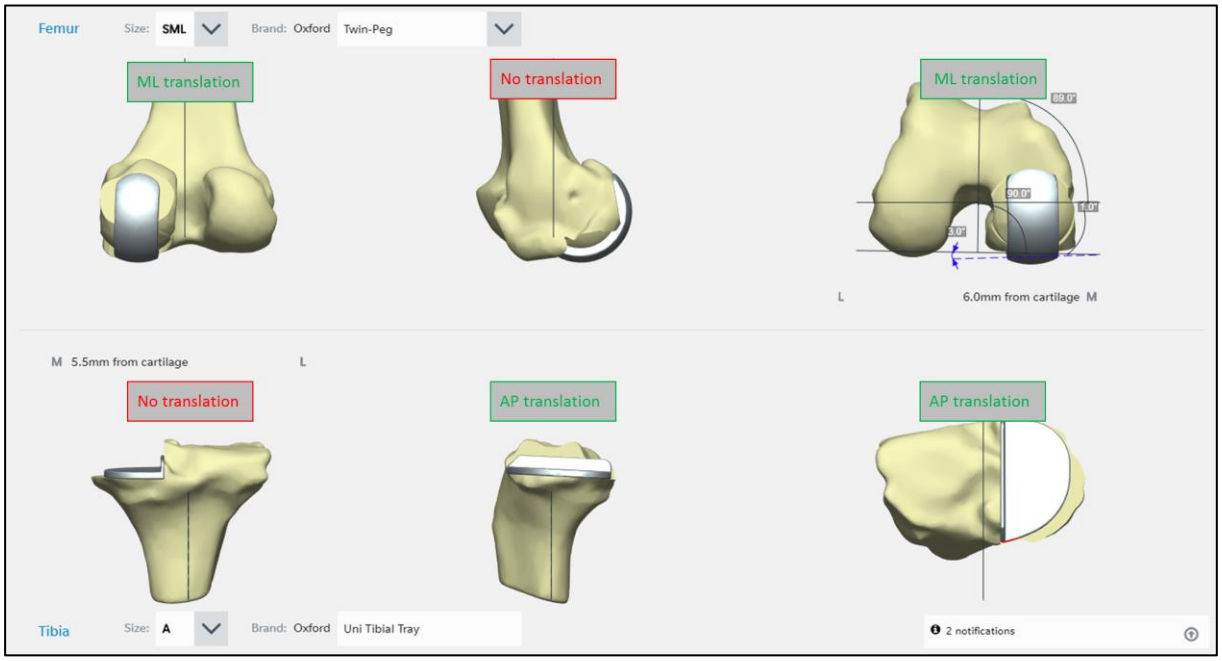
2D view - TKA



2D view - PKA ZUK



2D view - PKA Oxford / Vanguard M



3D view

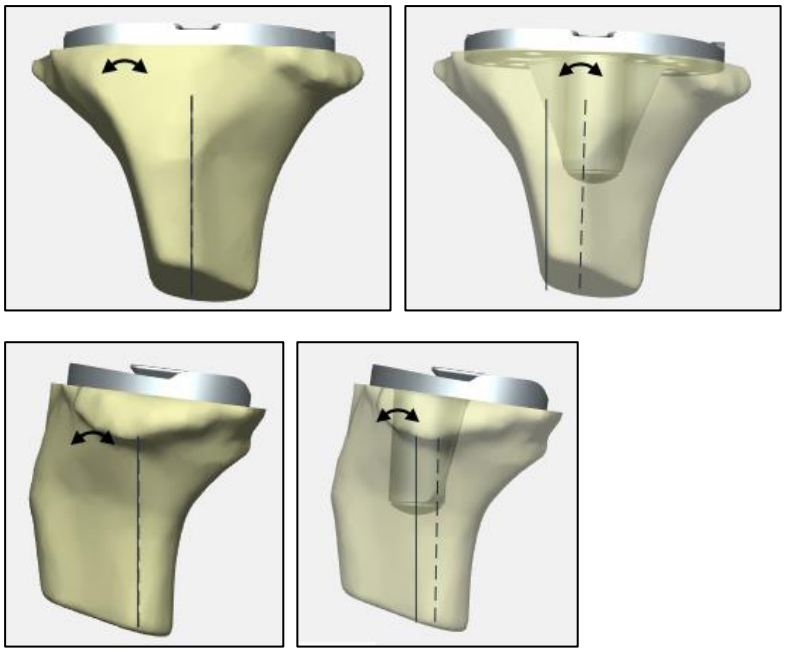
Interactive positioning in the 3D view depends on the orientation of the model. If the implants are viewed from the side then only translation in the direction parallel to the view is possible. If it is viewed in a more oblique fashion, then any translation/rotation is possible because its position can more accurately be assessed from this view.

4.8 Interactive tibia mechanical axis positioning

Note: this feature is only available in Japan

The tibia mechanical axis is defined in the Surgicase Knee Planner as the axis between the distal and the proximal tibia point. For certain anatomies the surgeon may want to reposition the tibia mechanical axis in the proximal area.

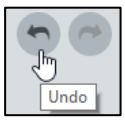
Repositioning can be done in the tibia coronal and sagittal 2D view by clicking on the tibia bone and dragging the mouse cursor left/right. The mouse cursor icon will be updated when this mode is active. The tibia bone will also become transparent to help reposition the axis. The tibia mechanical axis can be changed only in the 2D coronal and sagittal view:



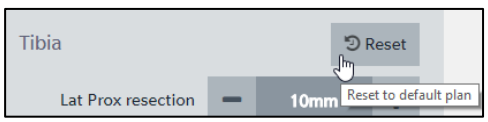
The original mechanical axis will be shown as a dotted line for referencing purposes. The new mechanical axis will be shown as a full line.

Note that the distal point of the mechanical axis is not changed with this operation. Also note that the current planning parameters of the tibia implant (e.g. varus/valgus) will be kept after repositioning the tibia mechanical axis.

Reverting the mechanical axis back to its default can be done by pressing the Undo Button in the planning menu. Note that any subsequent tuning steps since the mechanical axis was changed will need to be undone as well.

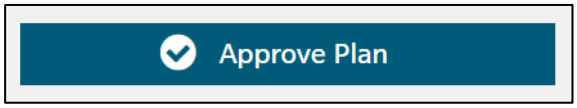


The tibia mechanical axis and the tibia plan can be reset completely by pressing the Reset Button.

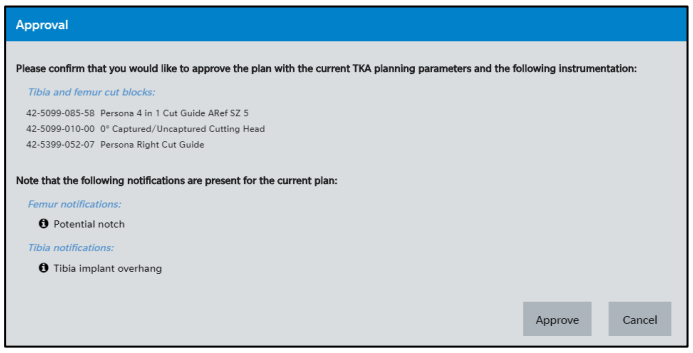


4.9 Case approving

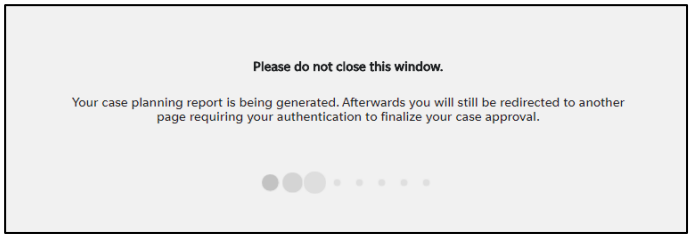
When the user is satisfied with all planning parameters, the case needs to be explicitly approved in the planner. This is done by clicking on the “Approve Plan” button in the bottom right.



This will take you to the planning approval confirmation screen, which provides an overview of the selected surgical instrumentation and the potential notifications in the surgical plan.



Pressing approve in this window will first save any unsaved planning parameters (see section 4.8) and then redirect the user to another page for a digital signature.



It is important to note that the browser should not be closed until redirection is complete and a digital signature is provided. Otherwise the case will not continue towards guide design.

Case approval is not available in the following scenarios:

- The user has no permissions to approve the plan:

- There is a notification blocking approval (for example incompatible implant sizes/brands):

- The case has already been approved:

4.10 Backward compatibility

To ensure compatibility of older files, approved cases are always opened in the version in which they were approved. A warning will be shown to inform that a case is opened in an older version of the software. Functionality in this ‘compatibility mode’ version may differ from the most recent version of the software.

5 System requirements

No installation is required to use the SurgiCase Knee Planner. The SurgiCase Knee Planner is web based software which is accessed through an internet browser. It is accessible via the case details of a specific case on the Medical Device Data System it is integrated with.

5.1 Minimal requirements

Operating Systems

The following operating systems are supported:

- Latest version of iOS
- Latest version of Mac OS
- Windows® 7 Service Pack 1 (SP1) (32-bit or 64-bit)
- Windows 10

Browsers

Browser with WebGL support and WebGL enabled.

The following browsers are supported by the SurgiCase Knee Planner per operating system:

- Google Chrome on Windows, Mac OS X
- Microsoft IE on Windows OS desktop
- Microsoft Edge on Windows OS desktop
- Mozilla Firefox on Windows OS desktop
- Apple Safari on Mac OS X, iOS Oss

Cookies support

Internet Connection

3G or higher

Application Window Resolution

WXGA or higher

Screen size

7 inches or more

Memory

2 GB RAM or more

CPU

Dual Core processor or better

Graphic Card

Please refer to the following list describing black/white list of graphic cards:

https://www.khronos.org/webgl/wiki/BlacklistsAndWhitelists

5.2 Device Lifetime

The SurgiCase Knee Planner is web based software deployed on servers fully controlled by Materialise. Materialise can at each time revoke or update the software with a new version.

The medical device has no predefined lifetime of the use of the device, instead, the device must be used according to the defined "system requirements" specified above.

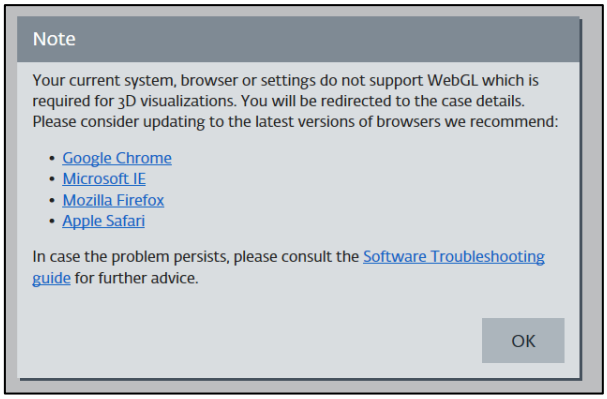
Since the software will not degrade in performance over time, its lifetime is determined by the business services which require the SurgiCase Knee Planner usage.

6 Troubleshooting

6.1 WebGL is not working

6.1.1 WebGL is not supported by your browser

In case WebGL is not supported, the SurgiCase Knee Planner will provide the following note:



In general you can check using the following link whether your browser supports WebGL: https://get.webgl.org/

In case your browser supports WebGL you should see the following when accessing the above link and you should be able to use the SurgiCase Knee Planner:

In case your browser does not support WebGL you will see something like this:

Ensure to upgrade to the latest version of your browser.

6.1.2 Enabling WebGL for your browser

In case you have the latest version of one of the recommended browsers above and WebGL is still not supported, follow the instructions below depending on your current browser.

Chrome

First, enable hardware acceleration:

- Go to chrome://settings
- Click the **+ Show advanced settings** button
- In the **System** section, ensure the **Use hardware acceleration when available** checkbox is checked (you'll need to relaunch Chrome for any changes to take effect)

Then enable WebGL:

- Go to chrome://flags
- Ensure that **Disable WebGL** is not activated (you'll need to relaunch Chrome for any changes to take effect)

Then inspect the status of WebGL:

- Go to chrome://gpu
- Inspect the **WebGL** item in the **Graphics Feature Status** list. The status will be one of the following:
  - *Hardware accelerated* — WebGL is enabled and hardware-accelerated (running on the graphics card).
  - *Software only, hardware acceleration unavailable* — WebGL is enabled, but running in software. See here for more info: "For software rendering of WebGL, Chrome uses SwiftShader, a software GL rasterizer."
  - *Unavailable* — WebGL is not available in hardware or software.

If the status is not "Hardware accelerated", then the **Problems Detected** list (below the the **Graphics Feature Status** list) may explain why hardware acceleration is unavailable.

Please ensure to always work with updated graphics drivers.

Firefox

First, enable WebGL:

- Go to about:config
- Search for webgl.disabled
- Ensure that its value is false (any changes take effect immediately without relaunching Firefox)

Then inspect the status of WebGL:

- Go to about:support
- Inspect the **WebGL Renderer** row in the **Graphics** table:
  - If the status contains a graphics card manufacturer, model and driver (eg: "NVIDIA Corporation -- NVIDIA GeForce GT 650M OpenGL Engine"), then WebGL is enabled.

- If the status is something like "Blocked for your graphics card because of unresolved driver issues" or "Blocked for your graphics driver version", then your graphics card/driver is blacklisted.

Please ensure to always work with updated graphics drivers.

Safari

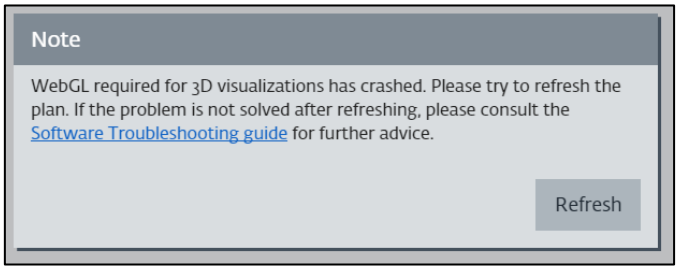
- Go to Safari's **Preferences**
- Select the **Advanced** tab
- Ensure that the **Show Develop menu in menu bar** checkbox is checked
- In Safari's **Develop** menu, ensure that **Enable WebGL** is checked

6.1.3 Upgrading graphics drivers

In case the above actions did not resolve the issue and WebGL is still not supported, it might be due to outdated graphics drivers. It is recommended to upgrade the graphics driver.

6.1.4 WebGL crashing

In case WebGL is crashing during a session with SurgiCase Knee Planner, the following notifications will be shown:



The issue can typically be resolved by refreshing your browser (e.g. by pressing F5). If this did not resolve the issue, restart your browser and access the case again.

It is advised to not open too many cases simultaneously in different tabs. WebGL may crash as you may be running out of memory on your computer.

6.2 Internet Explorer: Slow interaction with 3D models

When the interaction with the 3D models is slow, or when there is a lag between mouse movement and model movement, go to Options > Internet Options > Advanced Tab and verify the following settings:

- Accelerated graphics > Use software rendering instead of GPU rendering
  - Turn this option off by unticking the checkbox
- Browsing > Disable script debugging (Internet Explorer)
  - Turn this option on by ticking the checkbox
- Browsing > Disable script debugging (Other)
  - Turn this option on by ticking the checkbox

7 Contact information

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