ONE Planner® Hip 3D

User Manual V1.0

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1. General Information

1.1 Conventions

This document employs the following conventions:

WARNING: This symbol is present when a warning alerts the user to a potential risk that can affect the outcome of the ONE Planner® Hip 3D results.

CAUTION: This symbol is present to prevent risk of use error.

REMARK: This symbol is present to provide a general observation or information related to procedures, events or practices that are recommended or essential for a successful operation.

1.2 ONE Planner® Hip 3D System Description

The ONE Planner® Hip 3D System is a web-based planning application used as pre-operative surgical planning software to assist the surgeon user in component selection, sizing and placement for primary total hip arthroplasty (THA). The system utilizes patient-specific 3D bone models from computed tomography (CT) scans with identifiable placement of anatomical landmarks and range of motion simulations, to assist the surgeon user in surgical case preparation.

The ONE Planner® Hip 3D System uses a Non-Device Medical Device Data System (MDDS) called the ZB*Edge*® Case Portal, which manages the creation and tracking of the surgical case. The user has access to ONE Planner® Hip 3D through a link in the portal.

The patient's pre-operative CT images can be transferred to Zimmer Biomet through various methods (e.g. PACS integration (Laurel Bridge) or manual upload through ZBEdge Case Portal).

1.3 Contact Customer Support

Phone: +X XXX-XXX-XXXX
Email: PersonalizedSolutions@ZimmerBiomet.com

1.4 Training

This application is a pre-operative planning assistance tool. It is not a replacement for the surgeon's expertise and experience. It should only be used by authorized surgeons trained in the use of the software by Zimmer Biomet or by personnel authorized by Zimmer Biomet.

1.5 Contraindications

ONE Planner® Hip 3D should not be used when the patient has metallic devices implanted that could interfere with the CT scan quality. ONE Planner® Hip 3D may not be suitable for use in case of: Hip pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum etc.). Hip replacement revision surgery. Contraindications of compatible hip implants can be found in Supported Implants in Appendix A.

1.6 Intended Use and Indications for Use

Intended Use:

ONE Planner® Hip 3D is intended to assist in pre-operative planning for hip replacement surgical procedures.

Indications for Use:

ONE Planner® Hip 3D is intended, based on radiological images with identifiable placement of anatomical landmarks, to assist in pre-operative planning for hip replacement surgical procedures.

ONE Planner® Hip 3D pre-operative surgical planning software is intended to assist orthopedic surgeons in component selection, sizing and placement for total hip arthroplasty. It is designed for use on a skeletally mature patient population, and the targeted population has the same characteristics as the population that is suitable for compatible implants (refer to Supported Implants in Section 8).

1.7 Disclosure of Residual Risks

All patient safety risks were effectively reduced to a low residual risk level. For a list of residual risks associated with the use of an implanted medical device, please review the IFU(s) of the associated implant(s). For further indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the Instructions for Use or contact the local representative; visit zimmerbiomet.com for additional product information. Check for country product clearances and reference product-specific Instructions for Use.

1.8 Restrictions For Use

The ONE Planner® Hip 3D System described in this User Manual should not be combined with other products or components unless such products or components are expressly recognized as compatible with the ONE Planner® Hip 3D System. The list of compatible implants is provided in section 8.1 Supported Implants.

1.9 Patents

Patents available online at zimmerbiomet.com/patents.

2. About This User Manual

This User Manual provides detailed information about the ONE Planner® Hip 3D System, which can be referred to as “the software” for the remainder of this document. For technical instructions about the software, please contact Zimmer Biomet’s Customer Service or one of its approved representatives.

2.1 Safety

2.1.1 Safety: Warnings, Cautions and Remarks

The correct use of the software implies that all operating staff are familiar with the Instructions for Use. Particular attention must be paid to the safety instructions related to people and the software.

Training and Use

The software must only be used after reading this User Manual and receiving the appropriate training. Please contact Zimmer Biomet’s Customer Service if the surgeon is unsure how to use the software.

The software must only be used for its intended use.

The login credentials for the software will only be provided after appropriate training.

Planner ONE Planner® Hip 3D is **not** to be used for the purpose of general diagnostic image viewing.

Planner ONE Planner® Hip 3D reports are intended for clinical experts only. The reports represent a simplified model of clinical reality and are **not** intended as a replacement for standard diagnostic methods. Medical and healthcare providers should exercise their independent clinical judgment.

Intended Operation Environment

The review and modification of the pre-operative plan by the user is performed on a desktop or laptop computer. This activity can be conducted anywhere: at home, at the physician’s office, in the hospital, etc.

ONE Planner® Hip 3D is not adapted for use on mobile devices.

Bright light (natural or artificial) shining directly on the user’s screen can affect the usage of ONE Planner® Hip 3D. Therefore, it is the user’s responsibility to use ONE Planner® Hip 3D in an environment that has appropriate conditions, including lighting.

3. Application Description

3.1 Overview

The ONE Planner® Hip 3D System is a web-based planning user interface application that aims to assist orthopedic surgeons in surgical case preparation, including hip joint preparation for primary total hip arthroplasty (THA).

To do so, the ONE Planner® Hip 3D System incorporates patient-specific 3D bone models from CT scans with identifiable anatomical landmarks and provides different features to assist the surgeon user in component selection, sizing and placement of the acetabular and femoral implant components.

3.2 System Requirements

3.2.1 Hardware System Requirements

ONE Planner® Hip 3D requires a minimum resolution of the screen on which it is being used.

Table 1: Screen Resolution Requirements and Recommendations

Dimension	Minimum	Recommended
Width	1024 pixels	1200 pixels
Height	640 pixels	825 pixels

ONE Planner® Hip 3D is not adapted for use on mobile devices.

When launching ONE Planner® Hip 3D on a screen with a lower resolution than the **minimum required**, an error message will be displayed. The user must use a larger window to continue using the software.

When launching ONE Planner® Hip 3D on a screen with a lower resolution than the **recommended** (but higher than the minimum required), an error message will be displayed. The user must acknowledge the message to continue using the software.

3.2.2 Internet Connection and Browser Requirements

ONE Planner® Hip 3D must be accessed via a browser. The following browsers are recommended:

- Google Chrome version 83 or newer
- Apple Safari version 13.1 or newer
- Mozilla Firefox version 78 or newer
- Microsoft Edge version 84 or newer

Internet Explorer (all versions) is **not** supported.

ONE Planner® Hip 3D does not require installation by the user; only a supported browser is required.

3.2.3 JavaScript and WebGL

JavaScript and WebGL browser features are required and need to be enabled.

3.2.4 Firewall

If the internet access of the user is determined by firewall preferences, the ONE Planner® Hip 3D domain will have to be whitelisted.

If the user cannot access ONE Planner® Hip 3D after the domain has been configured in the firewall on the user's device or network, the user should contact Customer Support.

3.2.5 Decommission and Disposal

For safe decommission and disposal of the surgeon's data, please contact Customer Support (see section 1.3).

3.2.6 Pre-operative Images

Zimmer Biomet declares that the provision of image data via the online platform will occur via an encrypted connection and that this transfer will meet the highest safety standards. Image data uploaded to Laurel Bridge Compass Portal will be de-identified by Zimmer Biomet Privacy Operators before use in the ONE Planner® Hip 3D planning environment.

ONE Planner® Hip 3D supports DICOM image data exclusively. No other type of imaging is supported.

If the user is unsure whether ONE Planner® Hip 3D can be used for the planning of the patient's pre-operative images, please contact Customer Support.

3.2.7 Glossary

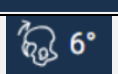
The following icons and abbreviations are used throughout the user interface of ONE Planner® Hip 3D and the Surgeon Report.

Table 2: Glossary of Abbreviations

Abbreviation	Description
AO	Acetabular Offset
AP	Anterior-Posterior
APP	Anterior Pelvic Plane
APT	Anterior Pelvic Tilt
ASIS	Anterior Superior Iliac Spine
CT	Computed Tomography
FO	Femoral Offset
GO	Global Offset
FPP	Functional Pelvic Plane
LLD	Leg Length Difference
MDDS	Medical Device Data System
ML	Medio-Lateral
OPH	ONE Planner® Hip
PI	Pelvic Incidence
S1	First Vertebra of the Sacrum
SPT	Spinopelvic tilt
SS	Sacral Slope
THA	Total Hip Arthroplasty
ZBCP	ZBEdge Case Portal

Table 3: Glossary of Icons

Icon	Description
	Menu
	Instructions for Use
	Language

	About
	Quit
	Finalize plan
	Undo
	Redo
	Operative side: Left side
	Operative side: Right side
	Gender: Female
	Gender: Male
	Case notes
	Close
	Save case notes
	Reset camera
	Access review screen
	Edit pelvic tilt (6 degrees, in this example)
	Access Pelvic Tilt panel/review lateral X-rays
	Access Cup panel / Edit cup
	Access Stem panel / Edit stem
	Decrease
	Increase
	Show planned implants / Post-op contralateral comparison
	Show native anatomy / Native contralateral comparison
	Bone Opacity toggle: opaque
	Bone Opacity toggle: transparent
	Reference planes / Slice toggle: display
	Reference planes / Slice toggle: hidden
	Cup size
	Liner type
	Liner orientation (only available for asymmetric liner types)
	Cup inclination
	Cup version
	Stem size
	Head size
	Head/Neck length

	Stem version
	Acetabular version
	Femoral version
	Combined native version
	Combined implant version
	Leg Length Difference
	Femoral Offset
	Global Offset
	Delta ipsilateral comparison
	120° Flexion
	50° Abduction
	15° Extension with 15° External rotation
	30° Internal rotation with 90° Flexion and 20° Abduction
	Implant visibility toggle: opaque
	Implant visibility toggle: hidden
	Implant visibility toggle: transparent
	Depth map visibility toggle: enabled
	Depth map visibility toggle: disabled
	Move shell inwards
	Move shell outwards
	View toggle: in 2D
	View toggle: in 3D
	Cut toggle: Step cut mode
	Cut toggle: Angled cut mode
	Implant visibility toggle: enabled
	Implant visibility toggle: disabled
Pelvic Tilt Panel	
	Invert image
	Brightness
	Contrast
	Manual
	Angle values
	Standing
	Sitting

	Supine
	Scene Element Hint
Surgeon Report	
	Percentage of cup in contact with bone
	Neck cut measurement: cut plane to Native Femoral Head Center
	Neck cut measurement: cut plane to Lesser Trochanter
	Neck cut measurement: cut plane to Greater Trochanter
	Neck cut measurement: cut plane to Saddle Point

4. ONE Planner Hip 3D Application

4.1 Launching ONE Planner® Hip 3D

ONE Planner® Hip 3D is accessible to the user through a button  in the ZBEdge Case Portal. When launching the ONE Planner® Hip 3D software for a case, a new tab in the internet browser will appear.

Due to security reasons, the user's session will be locked after 30 minutes of inactivity. All unsaved data is discarded. This may result in data loss. Therefore, make sure to always finalize a case immediately when the user's changes need to be saved for later access.

ONE Planner® Hip 3D does not automatically save the user's data. If ONE Planner® Hip 3D is closed without finalizing (e.g. closing the browser tab or due to a crash), any changes that have been made will be lost. The user's case will also remain locked for up to 30 minutes.

User preferences for the implant components (Family, Type) are entered through the ZBEdge Case Portal.

4.1.1 Error Handling

In case the user encounters errors with accessing ONE Planner® Hip 3D the user needs to close the tab/browser and relaunch ONE Planner® Hip 3D. If the error persists, the user must contact Customer Support.

4.2 ONE Planner® Hip 3D User Interface

4.2.1 ROSA Hip CT Warning

When a ROSA Hip patient case is opened, a message is displayed informing the user that the acetabular reaming depth defined during preoperative planning cannot be adjusted intraoperatively using the ROSA Hip application. This message must be acknowledged before proceeding with case planning to ensure awareness of this limitation (see Figure 1).

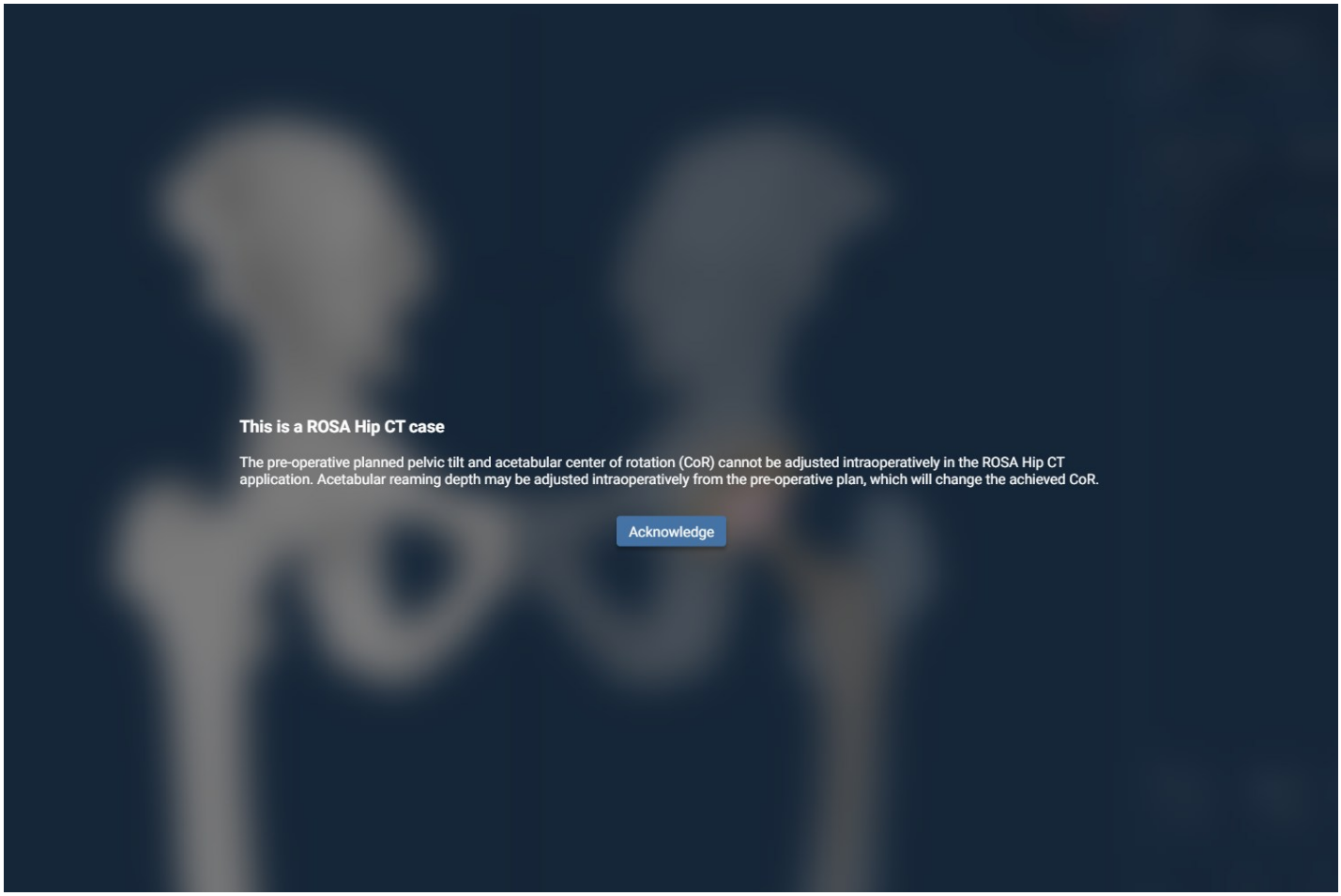


Figure 1: ROSA Hip CT Acknowledgment

4.2.2 Task Bar

The task bar remains accessible to the user in every panel of ONE Planner® Hip 3D (***Figure 2***).

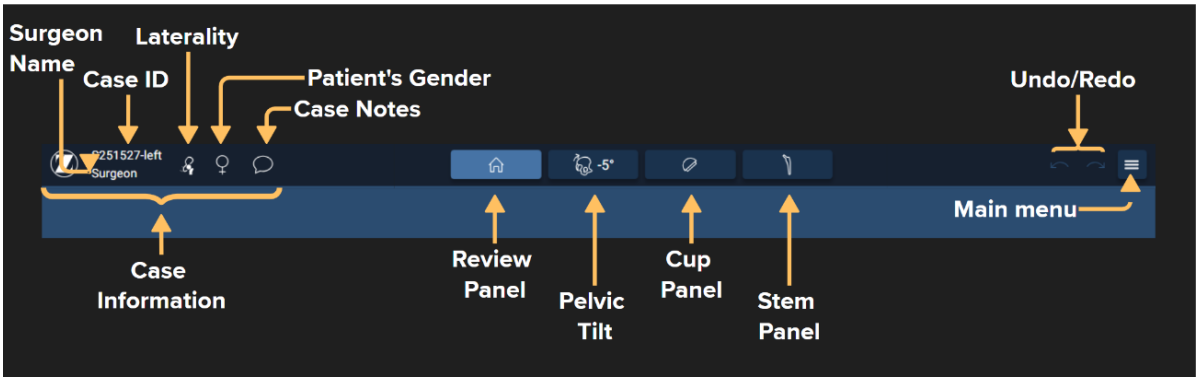


Figure 2: ONE Planner® Hip 3D Task Bar with Navigation Bar

4.2.3 Main Menu

The main menu allows the user to open the **Instructions for Use**, access the **About** box information, **Quit** the planner and **Finalize** the surgical plan (***Figure 3***). To access and close the main menu, use the buttons on the top right corner.

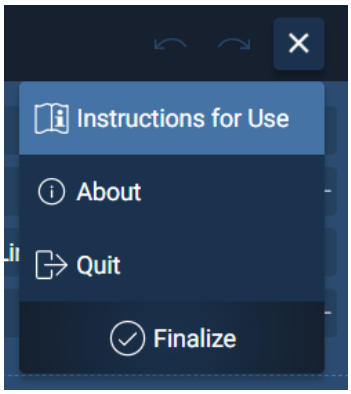


Figure 3: ONE Planner® Hip 3D General Menu

Instructions for Use

The Instructions for Use button will redirect the user to the Zimmer Biomet Electronic Labeling website, where the User Manual of ONE Planner® Hip 3D can be downloaded.

About

The About button will open the product label of ONE Planner® Hip 3D on the screen with information on the application version. To return to the Planning screen, click the close button.

Quit

The Quit button will open the menu allowing the user to discard, cancel or finalize the changes made to the current plan (***Figure* 4**). A report with the current plan will be presented to the user to verify the changes.

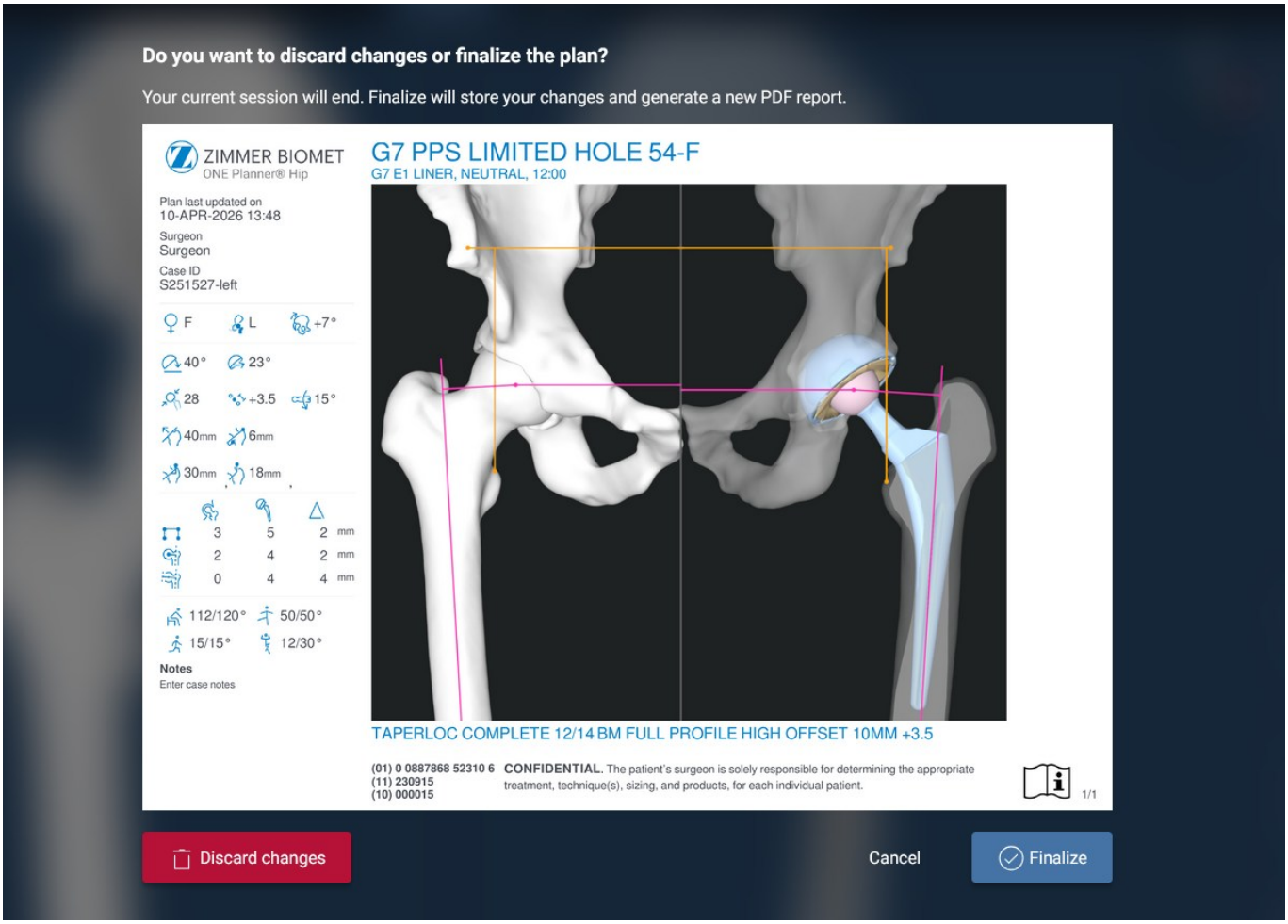


Figure 4:Quit Menu

If Discard is chosen, none of the planning changes made by the user will be saved.

ONE Planner® Hip 3D does not automatically save the surgeon's data. If it is closed without finalizing (e.g. closing the browser tab or due to a crash), any changes made will be lost. The case will also remain locked for up to 30 minutes.

After choosing Discard, the user can close the browser and exit ONE Planner® Hip 3D.

While the software is processing and applying changes (orange loading animation above the screen), the Finalize and Quit buttons will be disabled until the update is complete (**Figure *5***).

Finalize Plan

The Finalize button from the Main Menu will allow the user to finalize their surgical plan. Clicking on the finalize button will open a confirmation prompt to finalize the changes and generate a PDF report (Figure 4). ONE Planner® Hip 3D will then generate the Surgeon Report, as well as any machine-readable files for compatible systems, when applicable, that are available through ZBEdge Case Portal.

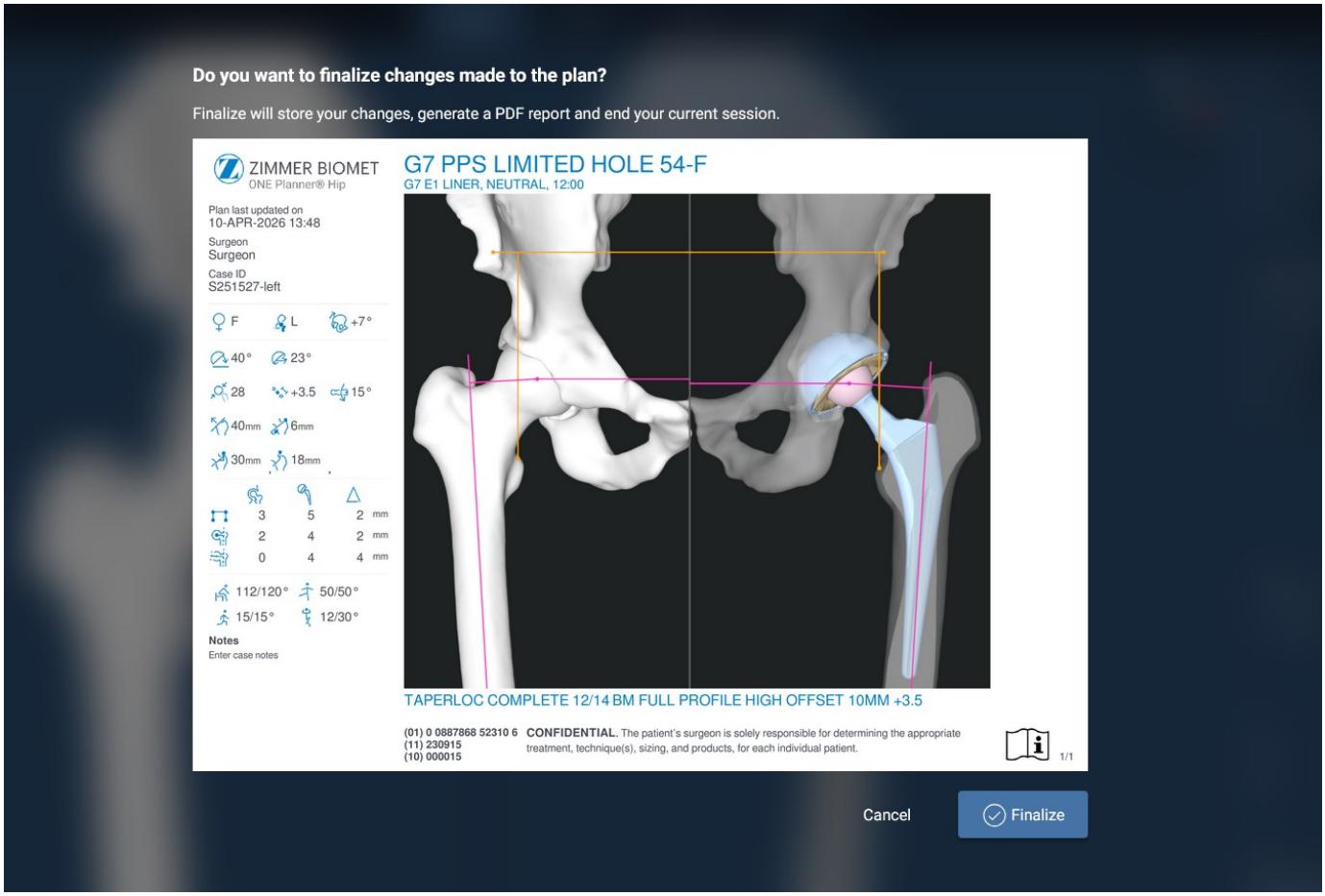


Figure 5: Finalize Plan Confirmation

- After finalizing, the user can close the browser to exit ONE Planner® Hip 3D.
- While the software is processing and applying changes (orange loading animation above the Task Bar), the Finalize and Quit buttons will be disabled until the update is complete (***Figure* 6**).

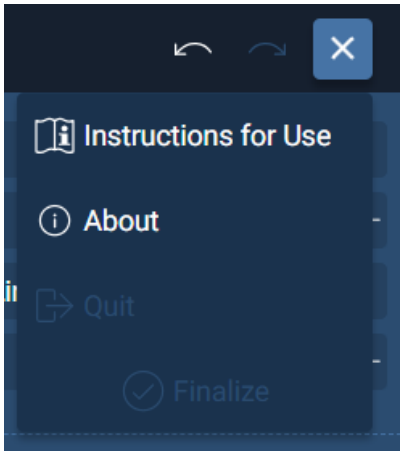


Figure 6: Finalize Plan Confirmation

Undo and Redo Buttons

The Undo and Redo buttons are located to the left of the main menu and allow the user to undo or redo previous action(s). See figure ***Figure* 7**.

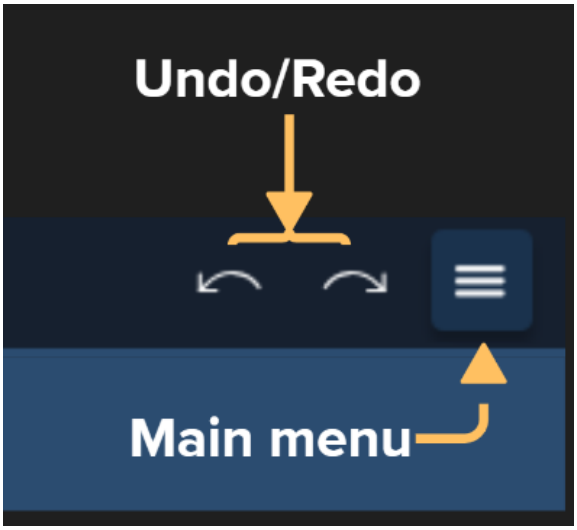


Figure 7: Undo Redo

Navigation Bar

The navigation bar allows the user to navigate to different panels in the application, such as the Review panel, the Pelvic Tilt panel, the Cup panel or the Stem panel. (see ***Figure 8***)

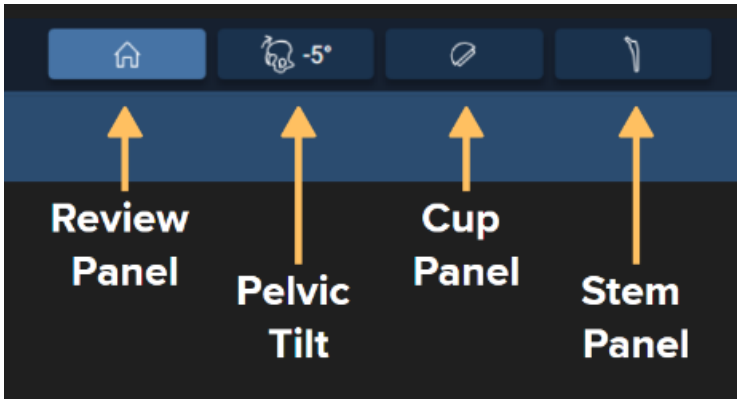


Figure 8: Navigation Bar

Resolution Warning

The system requires a minimum available screen size of 1024 x 640 at 100% scale. If these requirements are not satisfied, the application will display an error message. (see Figure 9)

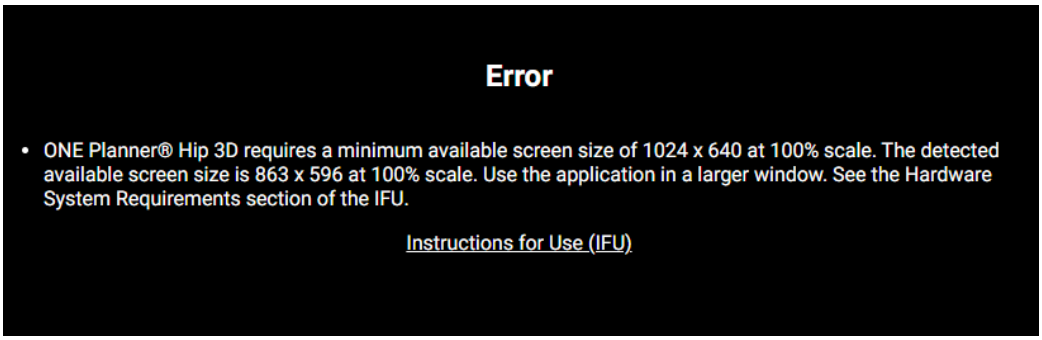


Figure 9: Screen Resolution Error Message

4.2.4 Case Information

Relevant case information is located in the Case Information menu. The case information is specific to the case that is visible in the window at that time. The information in this section is based on what the user entered during Case Creation in the ZBEdge Case Portal (***Figure 10***).

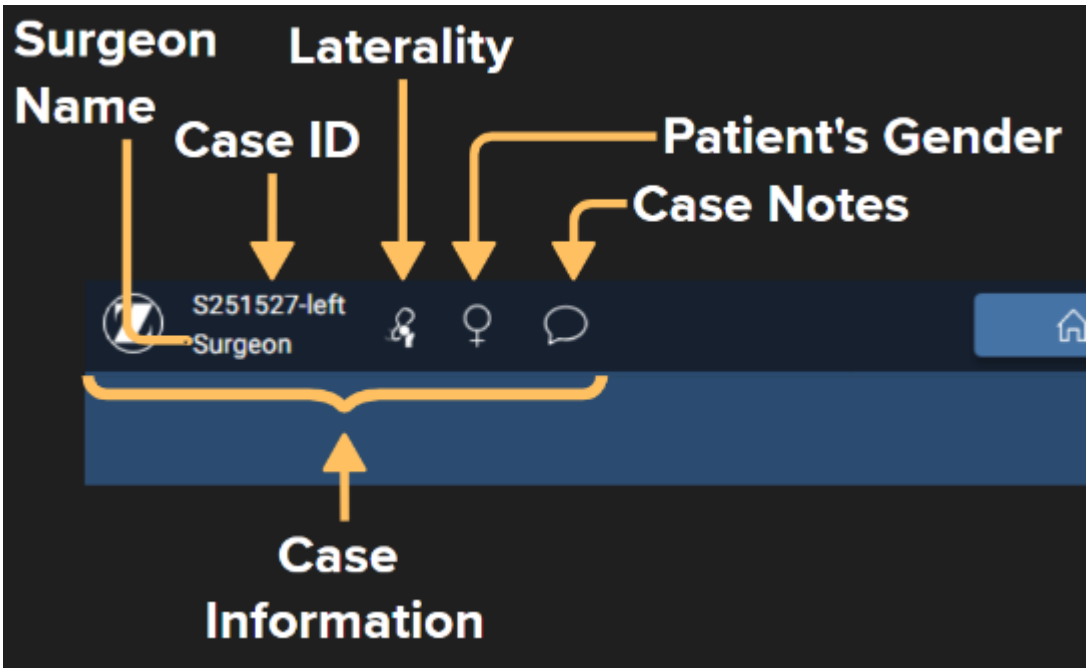


Figure 10: Case Information

Case ID

The patient's pseudonymized case ID is displayed at the top left of the window. The case ID is generated automatically from the patient case info during case creation in ZBEdge Case Portal. The case ID displayed in the planning application is 15 characters. Below is an example of a case ID for a patient with a first initial S and the first two letters of the last name AM, who is being operated on the left side.

Case ID*:* SAM123L50DD25UH

Table 4: Case ID Example

S	AM	123	L	50	DD	25	U	H
First letter of patient first name	First two letters of patient last name	Unique index assigned by Zimmer Biomet	Operated side (Left/ Right)	Last two digits of patient DOB	Surgeon initials	Year when the case was created	Region where the case ID originated	Code assigned on the technology

Case Laterality

The case laterality is displayed at the left side of the task bar, next to the case ID. This represents the user-selected side of the operative hip during case creation in ZBEdge Case Portal.

Patient Gender

The gender of the patient is displayed at the top left of the window next to the case laterality, and is the gender the user selected during case creation in ZBEdge Case Portal.

Surgeon Name

The surgeon's name (complete surname, complete first name) is displayed at the top left of the window, next to the patient's gender, and is the name the user entered during case creation in ZBEdge Case Portal.

Case Notes

The user can access the case notes (***Figure 11***) by clicking on the case notes icon located in the task bar, next to the surgeon's name. The case notes are optional; planning can proceed without them. When case notes are made and saved, they will be displayed in the ONE Planner® Hip 3D surgical plan PDF. If case notes are not saved, they do not appear in the surgical plan PDF.

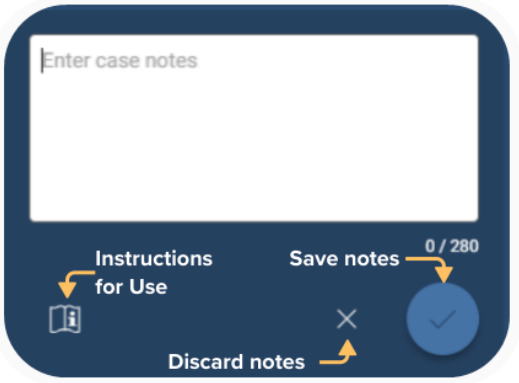


Figure 11: Case Notes

When accessing the case notes, the user can:

- Read the case notes
- Add, delete or edit the case notes
- Click on the Instructions for Use icon, which will redirect the user to the Zimmer Biomet Electronic Labeling website

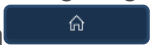
The user must save the case to keep the case notes. Unsaved notes will not appear in the Surgeon Report.

Case notes cannot contain patient names or any other patient sensitive data.

ONE Planner® Hip 3D cannot verify the contents of the case notes.

4.2.5 Accessing Panels

Access Review Panel

When navigating to a different panel, the user can return to the main Review panel by clicking the Review button  located in the center of the top navigation bar. Refer to section 4.2.6 for more information.

Access Pelvic Tilt Panel (if X-rays are provided)

The Pelvic Tilt panel can be accessed by clicking the Pelvic Tilt button  located in the

center of the top navigation bar and selecting the lateral X-ray button in the drop-down menu if the patient's pre-operative standing and sitting lateral X-rays **have been provided** for a case. Refer to section 4.2.9 Pelvic Tilt Panel for more information.

Access Cup Panel

The Cup panel can be accessed by clicking the Edit Cup button  located in the center of the top navigation bar. Refer to section 4.2.11 Cup Panel for more information.

Access Stem Panel

The Stem panel can be accessed by clicking the Edit Stem button located in the center of the top navigation bar. Refer to 4.2.12 for more information.

4.2.6 Review Panel

The Review panel is the first planning screen displayed when launching ONE Planner® Hip 3D (***Figure 12***) This panel displays a 3D reconstruction of the patient's pelvis (tilted to the patient's pelvic tilt measured from the CT scan) and femurs, generated from the provided CT scan images. It also displays the initially selected implant components based on the surgeon profile preferences (family and type), positioned on the reconstructed anatomy.

In the Review panel, implant components (i.e. cup, liner, stem, head) can be adjusted using the controllers on the planning side panel on the right side of the screen to instantly visualize how adjustments affect the Leg Length Difference and Offset measurements, as well as the patient's Range of Motion.

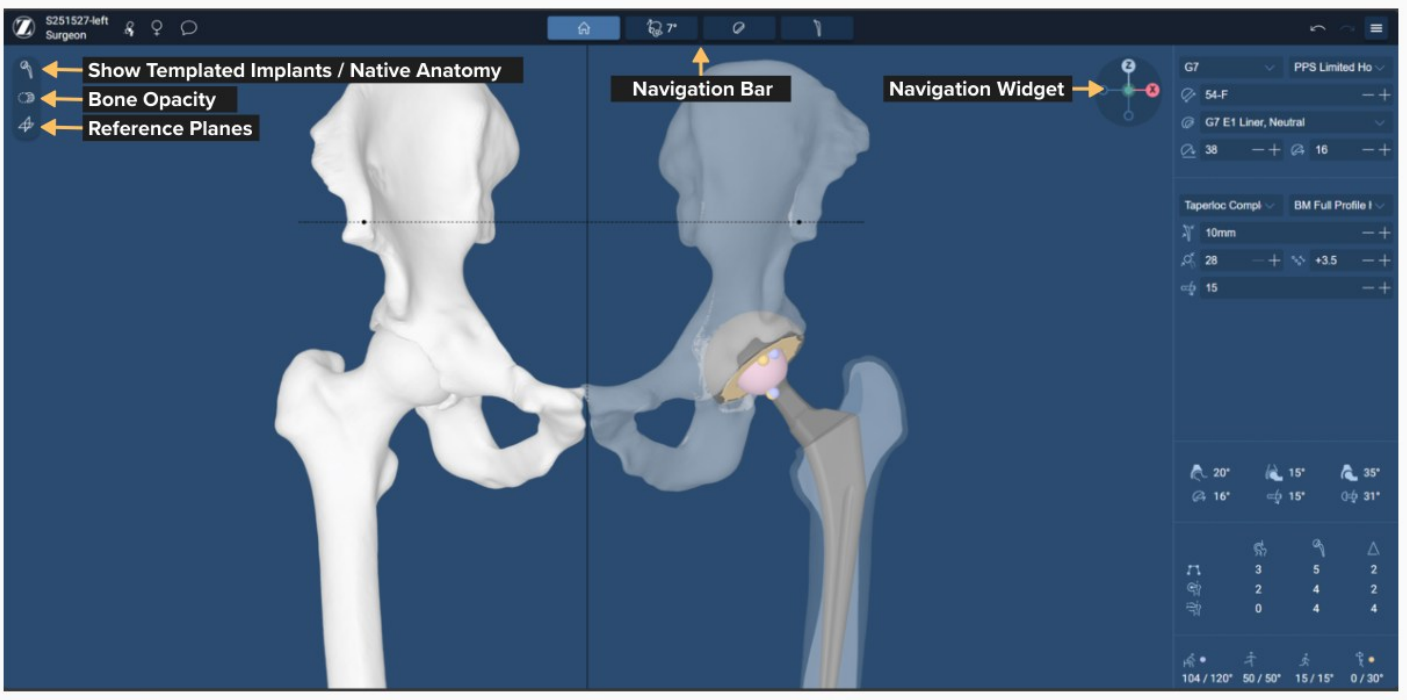


Figure 12: Review Panel

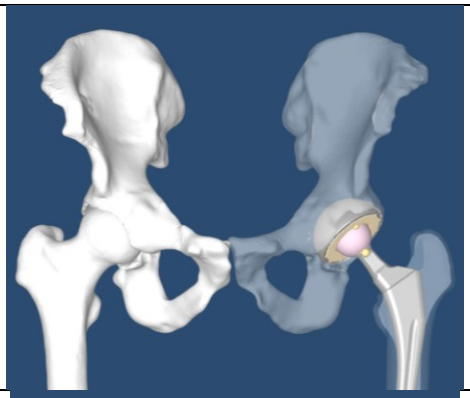
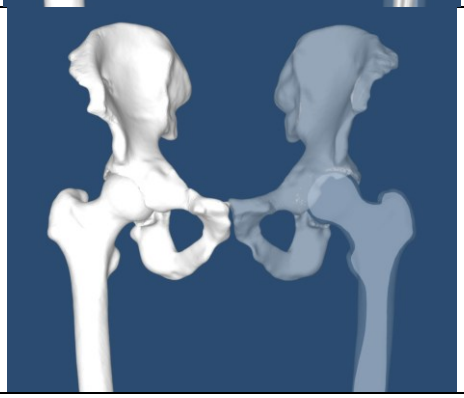
Show Templated Implants/Native Anatomy

Th show templated implants/native anatomy toggle (Table 5) allows the user to switch between:

- Displaying the 3D model of the currently planned implants
- Displaying the 3D model of the native reconstructed anatomy

When Show Native Anatomy mode is active, implant parameters cannot be modified, and Range of Motion animations will not be available; however, the native leg length difference and femoral offset measurements can still be available.

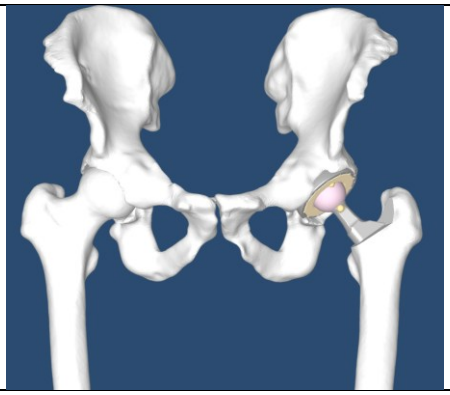
Table 5: Show Planned Implants/Native Anatomy Toggle - Review Panel

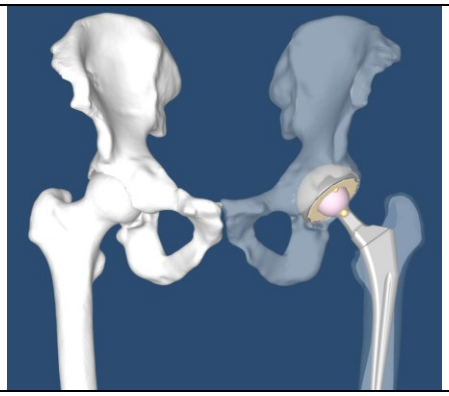
 When this icon is shown, the planned implants are displayed	
 When this icon is shown, the native anatomy is displayed	

Bone Opacity Toggle

The Bone Opacity toggle (Table 6) allows the user to enable or disable the transparency of the operated bone anatomy in the 3D view. Enabling the Bone Opacity toggle causes the bone to appear solid/opaque, while disabling opacity causes the bone on the operated side to be transparent, helping to visualize implant components or surrounding structures more clearly.

Table 6: Bone Opacity Toggle - Review Panel

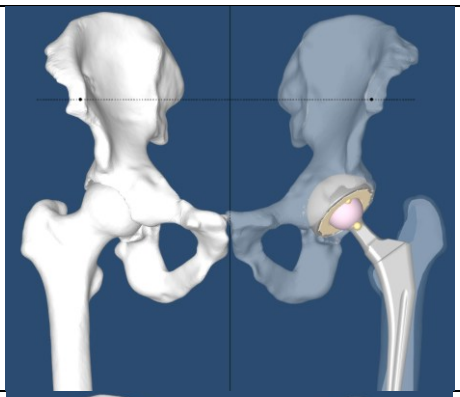
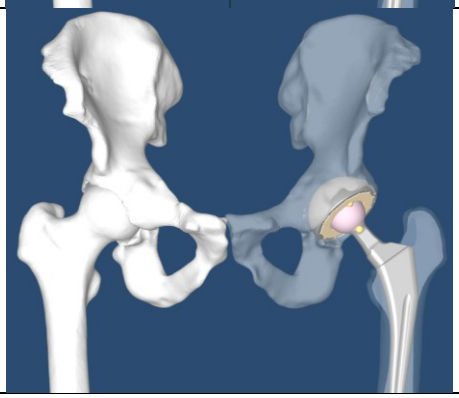
 When this icon is shown, the operated side is opaque	

When this icon is shown, the operated side is transparent	

Reference Planes Toggle

Activating the Reference Planes toggle (Table 7) highlights the reference landmarks and associated lines projected in this plane.

Table 7: Static Measurements Toggle - Review Panel

When this icon is shown, the reference planes are displayed	
When this icon is shown, the reference planes are hidden	

Navigation Widget

The Navigation Widget, located in the top-right corner of the 3D model views for the Review, Cup and Stem panels, displays color-coded X, Y and Z axes to orient the 3D model (***Figure* 13**). It allows the user to rotate the model and quickly switch between planar views by clicking on the X, Y, and Z axes. The orientation of the model can also be rotated by left-clicking and dragging the model.

Additionally, after modifying the 3D bone view, a Reset Camera button will appear under the Navigation Widget (***Figure* 13**), which restores the model to its original position and orientation.

Figure 13: Navigation Widget and Reset Camera Button

Planning Side Panel – on the Right Side of the Screen

The Planning Side Panel located on the right side of the screen of the ONE Planner® Hip 3D, provides the user with different tools and controls to refine and validate their surgical planning (***Figure 14***). The controls in this side panel allow the user to modify implant component selection and review key reference measurements to ensure accurate alignment. The cup liner and orientation can only be modified from the Review Panel.

Figure 14: Planning Side Panel on the Right Side of the screen

4.2.7 Pelvic Tilt

Pelvic Tilt

To support accurate implant alignment relative to the patient's functional pelvic orientation, ONE

Planner® Hip 3D displays the Pelvic Sagittal inclination angle, known as Pelvic Tilt during case planning. This value can be derived from imaging data or manually adjusted, depending on the information available for the patient. The initial Pelvic Tilt angle provided is based on the patient's supine position during the CT scan.

Pelvic Tilt Definition

Pelvic Tilt is calculated as the angle between two reference planes (***Figure 15***):

- **Functional Pelvic Plane (FPP)**

  A plane parallel to the CT table that passes through the bilateral anterior superior iliac spine (ASIS) points.

- **Anterior Pelvic Plane (APP)**

  A plane defined by the bilateral ASIS points and the midpoint of the pubic tubercles.

The Pelvic Tilt value displayed in the software represents the angular relationship between these two planes.

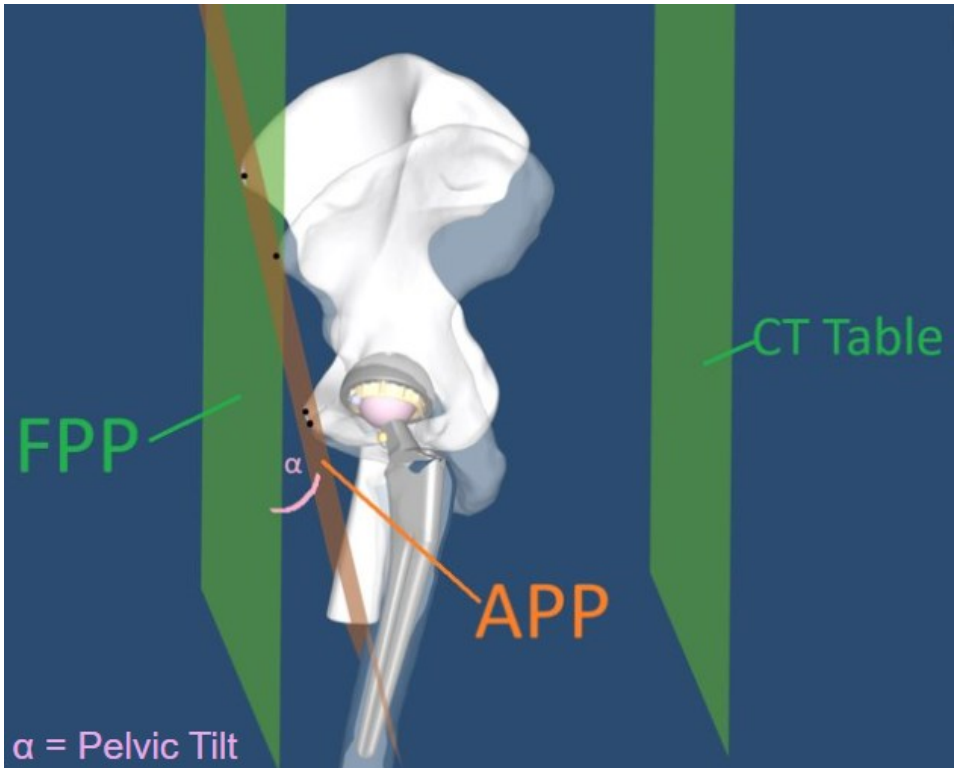


Figure 15: Pelvic Tilt Angle Reference Planes

Pelvic Tilt Modes for Case Planning

ONE Planner® Hip 3D supports three options that can be used for case planning: Supine, Standing, and Manual.

1. Supine Pelvic Tilt (Default)

- The initial Pelvic Tilt angle is automatically calculated from the patient's supine CT scan, reflecting pelvic tilt orientation during image acquisition

- This value serves as the default planning angle
- The user can reselect the value at any time by clicking the supine angle icon (see Figure 16)
- When standing and sitting lateral X-rays are available, the supine option is also accessible from the Pelvic Tilt panel (Refer to section 4.2.9)

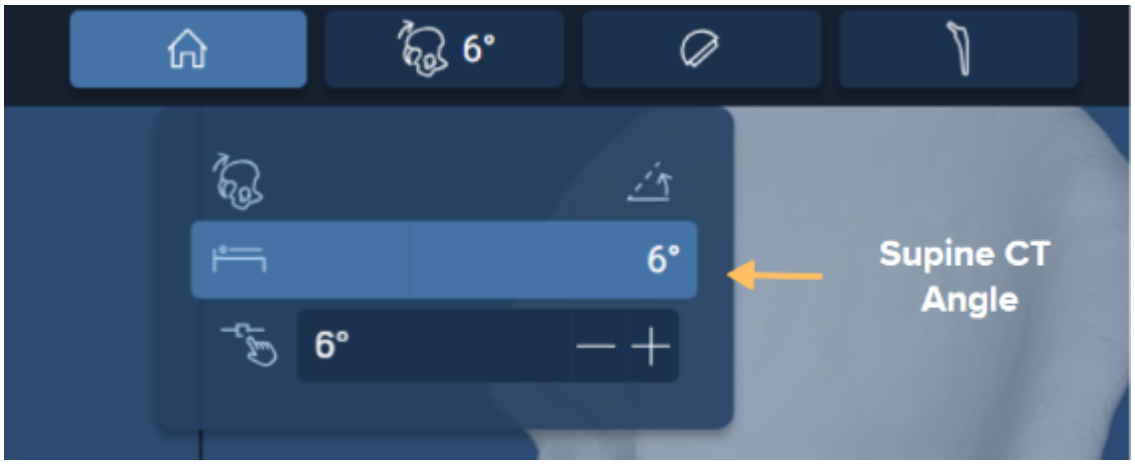


Figure 16: Selecting the Supine CT Pelvic Tilt Angle from the

2. Standing Pelvic Tilt

- When pre-operative standing and sitting lateral X-rays are provided, the application enables pelvic tilt values derived from functional positions (ex: standing)
- These values allow the user to plan implant orientation based on the patient's functional pelvic alignment rather than imaging position
- Standing (and sitting) pelvic tilt values are displayed and selectable within the Pelvic Tilt panel (Refer to section 4.2.9)

3. Manual Pelvic Tilt Adjustment

- If lateral X-rays are not available, the application provides a Pelvic Tilt Angle drop-down menu in the navigation bar of the Review panel (Figure ***17***).
- The user can manually adjust the Pelvic Tilt by:
    - Selecting a pre-defined value from the drop-down list, or
    - Incrementing or decrementing the angle using the plus (+) and minus (-) controls.
- Manual adjustment is also available in the Pelvic Tilt panel when standing and sitting X-rays are available. Allowing fine-tuning of any selected pelvic tilt value (Refer to section 4.2.9).

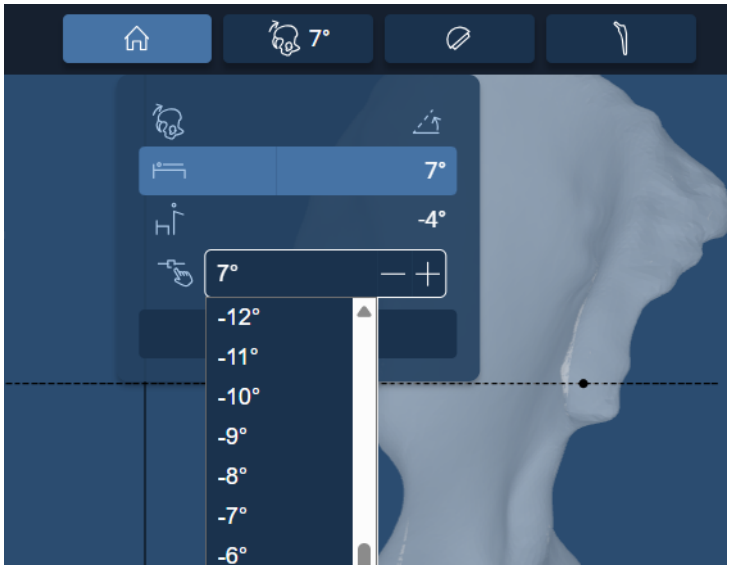


Figure **17***: Pelvic Tilt Angle Menu*

Access Pelvic Tilt Panel

If the patient's pre-operative standing and sitting lateral X-rays **have been provided** for a case, a Pelvic Tilt lateral X-ray button  is displayed in the Pelvic Tilt Angle drop-down menu on the navigation bar in the main Review panel, which will open the Pelvic Tilt panel (***Figure 18***). (refer to section 4.2.9 for more information about the Pelvic Tilt feature).

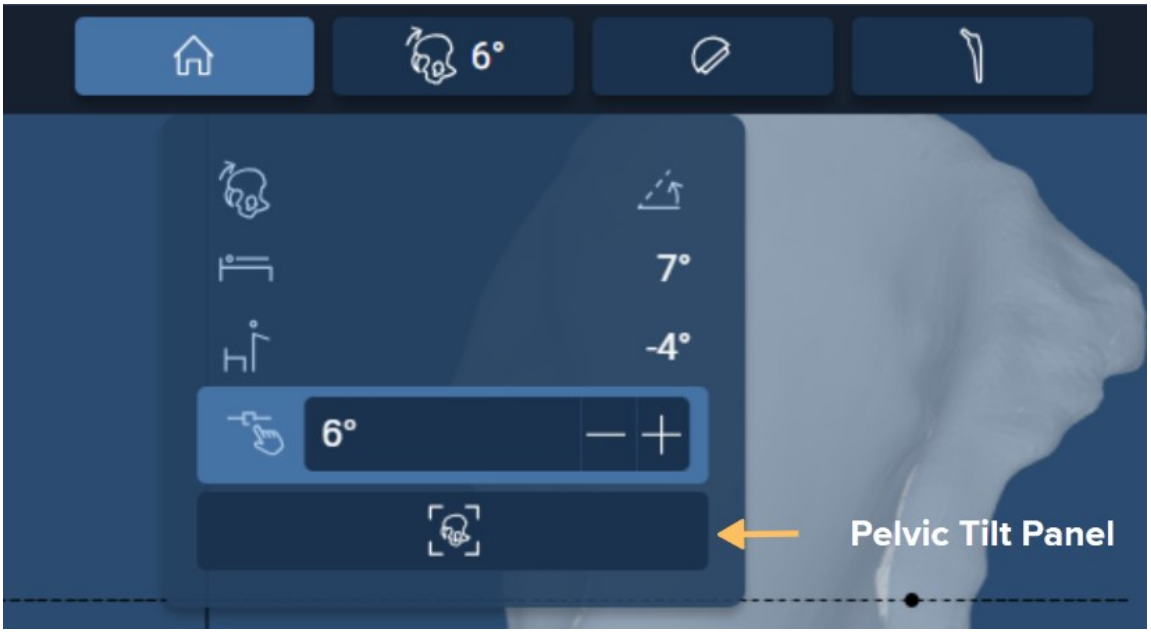


Figure 18: Access Pelvic Tilt Panel

4.2.8 Implant Components Menus and Controls

Cup and Liner Components

Cup Family and Type

Shows the current selected cup family and type and allows for the selection of other families and types of cup available from the dropdown menus, see Figure 19 and Figure 20.

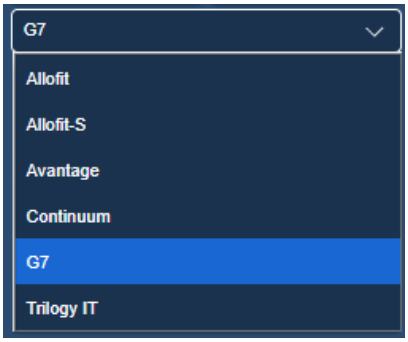


Figure 19: Cup Family Drop-down Menu

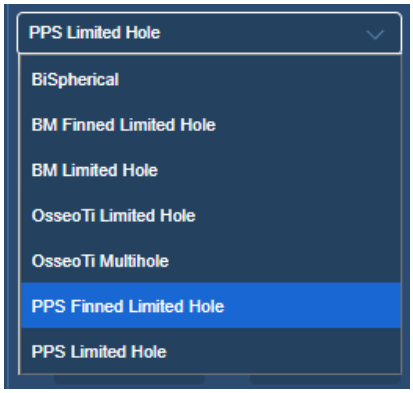


Figure 20: Cup Type Drop-down Menu

The software only provides access to implants that are cleared and approved for use with this software in the user's country.

The list of implants displayed on this menu does not imply availability in terms of stock supply with local distributors. Contact applicable distributors for information on stock availability.

Cup Size

Shows the size of the cup currently selected and allows for the adjustment of the size of the cup from the dropdown menu or by using the plus (+) and minus (-) buttons (Figure 21).

Figure 21: Cup Size Control

Liner Menu

Shows the current selected liner and allows for the selection of other liner types from the dropdown menu. Different liners are available depending on the selected family type (Figure 22).

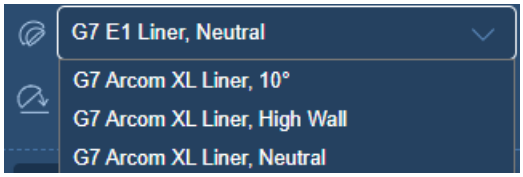


Figure 22: Liner Drop-down Menu

Liner Orientation

If the selected liner is asymmetric, the planner will present an additional selector to adjust the orientation of the liner, expressed in hour units on a clock-face reference system (e.g., 12 o'clock for vertical alignment). The clock reference perspective is defined by looking at the native femoral head along the acetabular axis The user can adjust the orientation of the cup from the drop-down menu or by using the plus (+) and minus (-) buttons (Figure 23.

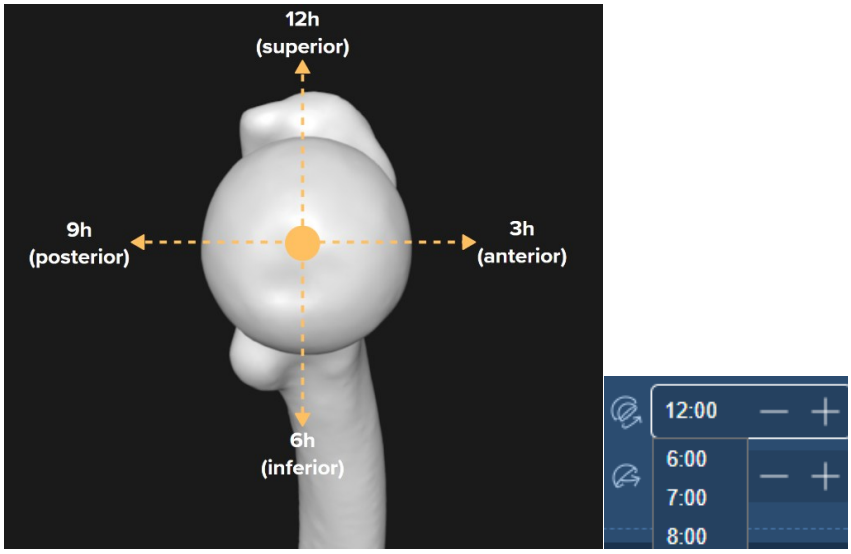


Figure 23: Liner Orientation Control

- 12:00 – Superior
- 03:00 – Anterior
- 06:00 – Inferior
- 09:00 – Posterior

Cup Inclination and Version

Displays the current inclination and version of the cup (in degrees), and allows for the adjustment of the cup angles from the drop-down menus or by using the plus (+) and minus (-) buttons (Figure 24 and 23). The inclination and version angles displayed are expressed in the radiographic coordinate system and are referenced to the FPP reference plane. Refer to Pelvic Tilt under section 4.2.6 for more information about this reference plane.

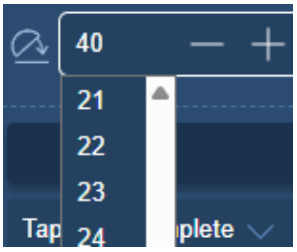


Figure 24: Cup Inclination Control

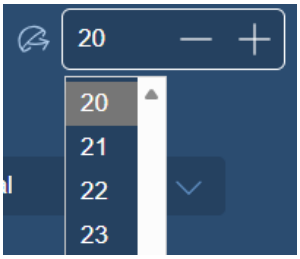


Figure 25: Cup Version Control

Stem Component

Stem Family and Type

Shows the current selected stem family and type, and allows for the selection of other families and stem types available from the drop-down menus (Figure 26 and Figure 27).

***Figure 26: Stem Family* Drop-down Menu**

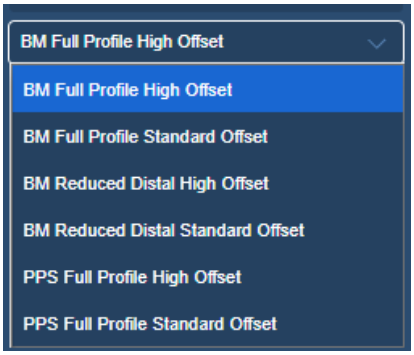


Figure 27: Stem Type Drop-down Menu

- The software only provides access to implants that are cleared and approved for use with this software in the user's country.
- The list of implants displayed on this menu does not imply availability in terms of stock supply with local distributors. Contact applicable distributors for information on stock availability.

Stem Size

Shows the current size of the stem and allows for the adjustment of the size of the stem from the drop-down menu or by using the plus (+) and minus (-) buttons (Figure 28).

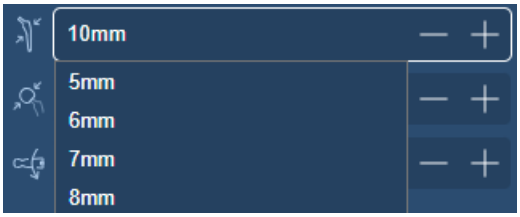


Figure 28: Stem Size Control

Head Size

Shows the current selected femoral head size and allows for the adjustment of the diameter from the drop-down menu or by using the plus (+) and minus (-) buttons (Figure 29).

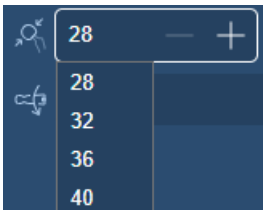


Figure 29: Femoral Head Diameter Control

Head/Neck Length

Shows the selected head/neck length of the stem and allows for the adjustment of the head/neck length from the drop-down menu or by using the plus (+) and minus (-) buttons (Figure 30).

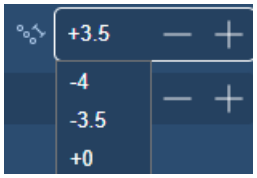


Figure 30: Head/Neck Length Control

Stem Version

Shows the current version of the stem (in degrees) and allows for the adjustment of the stem version from the drop-down menu or by using the plus (+) and minus (-) buttons (Figure 31).

Figure 31: Stem Version Control

Version Measurements

A table with pre-operative and post-operative version measurements in degrees is displayed in the lower section of the Planning Side Panel on the right side of the screen(***Figure* 32**).

- Pre-operative values: Displays the patient's
  - Native acetabular version
  - Native femoral version

- Combined version based on their anatomy

- Post-operative values: Displays the planned
  - Cup version
  - Stem version
  - Combined implant version according to the currently selected implant components

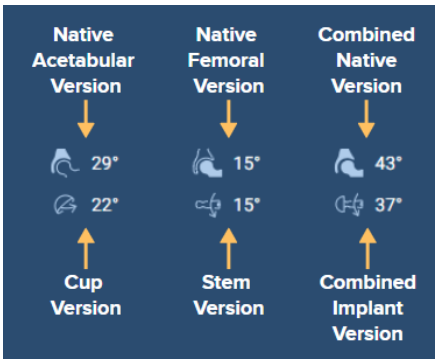


Figure 32: Version Measurements

Leg Length Difference and Offset Measurements

The Leg Length Difference and Offset Measurements table displays the calculated differences (deltas) between the ipsilateral and contralateral sides (***Figure* 33**). These measurements include Leg Length Difference and Femoral and Global Offset values:

- The first column of the table illustrates the native comparison of the Leg Length Difference, Femoral Offset and Global Offset in millimeters
- The second column of the table illustrates the implanted (post-operative) comparison in Leg Length Difference, Femoral Offset and Global Offset in millimeters after planning
- The third column of the table shows the delta ipsilateral values for Leg Length Difference, Femoral Offset and Global Offset in millimeters

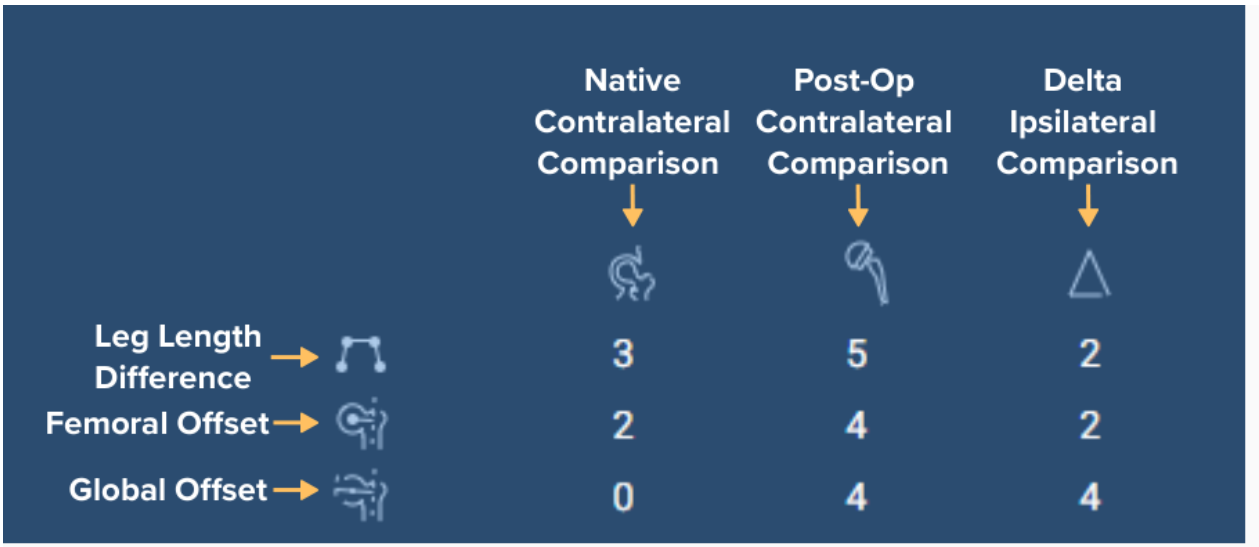


Figure 33: Leg Length Difference and Offset Measurements Table

Native Contralateral Comparison	Difference between the ipsilateral and contralateral sides before surgery *(Native Comparison = ipsilateral measurement - contralateral measurement)*
Post-Op Contralateral Comparison	Difference between the ipsilateral and contralateral sides after surgery, based on the current selected implant components and their position/orientation *(Implanted Comparison = ipsilateral measurement - contralateral measurement)*
Delta Ipsilateral Comparison	Difference (delta) between the native and the implanted measurements on the ipsilateral side *(Ipsilateral delta = Implanted Comparison - Native comparison)*

- Minor discrepancies may occasionally be observed in the delta values displayed in the table. These discrepancies are due to rounding and do not affect the underlying calculations or results.
- No raw distance measurements are provided; only the calculated difference values are displayed in this table. Rounding only occurs at the final step before display.

Leg Length Difference Measurement Method

The Leg Length Difference approximates the femoral length difference between the ipsilateral and contralateral sides of the patient. The Leg Length Difference reference points used are the ASIS on the pelvis and (top of/superior surface of) the Lesser Trochanter on each femur.

The Leg Length Difference is determined as follows: A transverse reference plane is generated at the two ASIS points (AP direction). The measurement on each side is made in the vertical direction (shortest distance) between the Lesser Trochanter landmark and the ASIS plane, and these lines represent the approximation of the femoral leg length. The Leg Length Difference is defined as the leg length on the operative/ipsilateral side minus the leg length on the contralateral side.

The user can display the reference lines for the Leg Length Difference in the Review panel by clicking on the top row of the Comparison Table, where the Leg Length Difference measurements are displayed (***Figure 34***). The reference lines displayed are accompanied by a label indicating whether the operated leg is shorter or longer than the contralateral side. Depending on the activated mode in the Show Planned Implants/Native Anatomy toggle, the reference lines will display either the native contralateral comparison value or the post-operative contralateral comparison value. To switch between these values, click on the Show Planned Implants / Native Anatomy icon toggle. Refer to section 4.2.6 for more information.

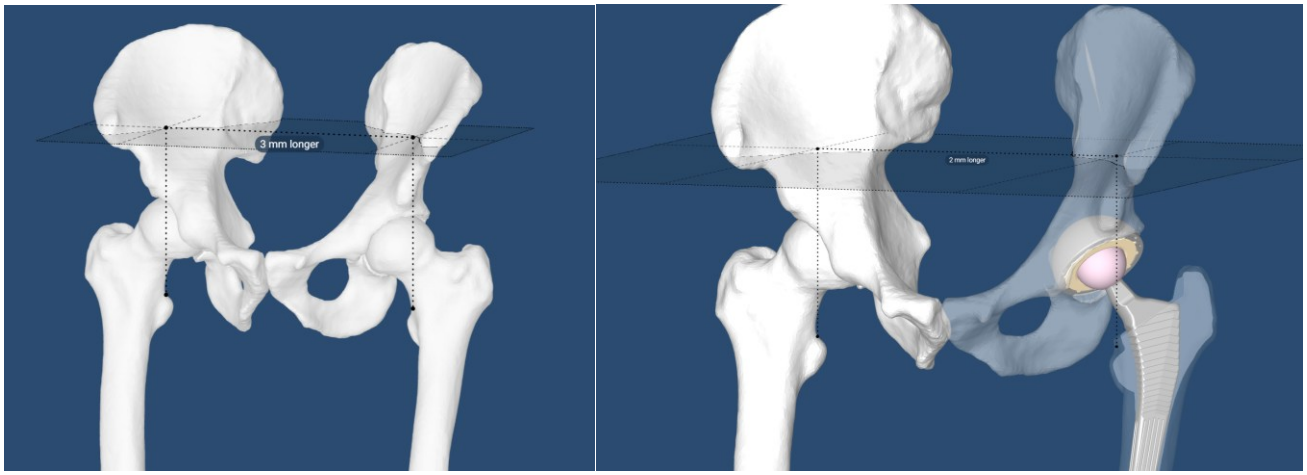


Figure 34: Leg Length Difference Reference Lines

Offset Measurement Method

ONE Planner® Hip 3D provides information on Femoral Offset (FO) and Global Offset (GO).

- The FO is calculated as the shortest distance between the femoral head center and the longitudinal axis of the femoral shaft. The FO Difference is defined as the ipsilateral FO minus the contralateral FO
- The GO is calculated as the sum of the FO and the Acetabular Offset (AO), where AO is the shortest distance (horizontal) between the femoral head center and the pubic symphysis plane (vertical plane parallel to the sagittal plane, originating at the pubic symphysis)

The user can display the reference planes for the Femoral, Acetabular and Global Offsets in the Review panel by clicking on the middle/bottom rows of the Measurements Table, where the Femoral and Global Offset measurements are displayed (***Figure 35***).

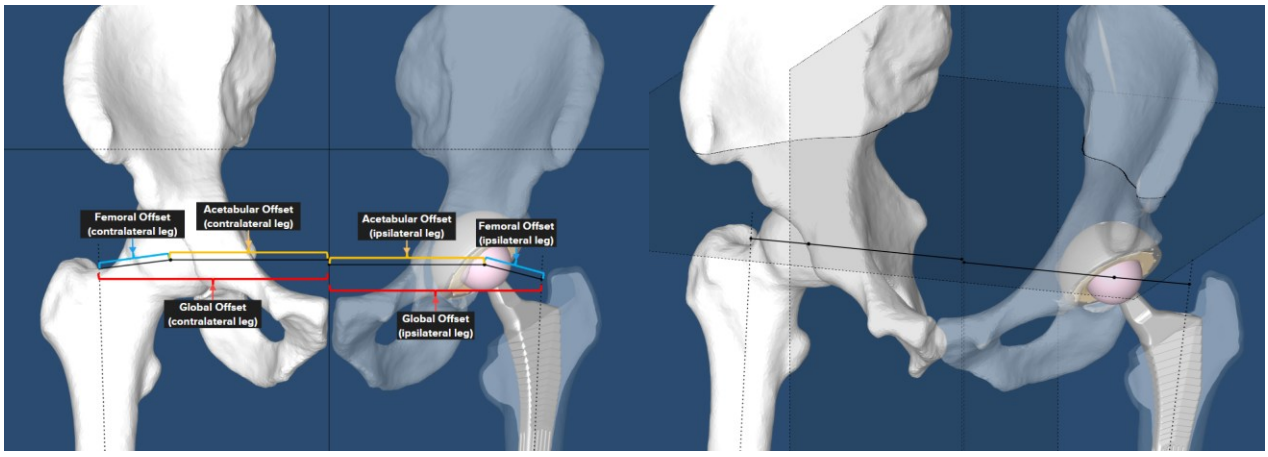


Figure 35: Femoral, Acetabular and Global Offset Reference Lines

Range of Motion (ROM) Simulation

ONE Planner® Hip 3D performs motion simulations to assist the user in identifying potential areas of impingement when selecting a specific implant combination. In the bottom right of the Planning Side Panel on the right side of the screen, the user will find the ROM Simulation ranges (based on a cadaveric

study published by Röling, Maarten A., et al.; 2015)[1].

Section 4.2.8 shows the maximum achievable angle (target end points) for the patient with the currently selected implant components for four motion tests: Flexion (120°), Abduction (50°), Extension with 15° of External Rotation and Internal Rotation with 90° of Flexion and 20° of Abduction.

Because the motion simulations do not take into account soft tissue constraints or potential osteophytes removal, motion beyond these end points may appear unrealistic and could incorrectly suggest joint hypermobility, which is beyond the capabilities of the motion simulation software.

Each motion pattern is represented by an icon. When a simulated motion is restricted due to impingement, the affected icon is highlighted with a colored sphere (refer to Table 8 and ***Figure* 36**). Below the icon, the planner displays the maximum angle the patient can reach in that position with the current plan (Displayed Values: *[maximum angle reached before impingement] / [maximum target range]*).

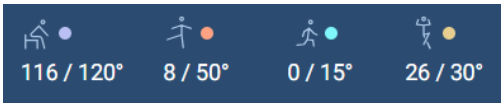


***Figure 36: Range of Motion* Icons Displaying *Impingement in all* Four *Motion* Simulations**

Table 8. Range of Motion Directions, Angles and Impingement Spheres

Motion Direction	Target Endpoint	Impingement Sphere
Flexion	120°	Lilac
Abduction	50°	Peach
Extension with 15° of External Rotation	15°	Blue
Internal Rotation with 90° of Flexion and 20° of Adduction	30°	Yellow

In the Review panel, the user can click any icon in the ROM Simulation area (Figure 34), to view an animation of the simulated movement of the patient's anatomy with the selected implant system. If impingement is detected, a colored sphere that corresponds to the affected motion will appear at the location of the impingement (refer to Table 8 and ***Figure* 36**).

When the Show Native Anatomy mode is active (refer to section 4.2.6), implant parameters cannot be modified, and Range of Motion animations will be unavailable.

4.2.9 Pelvic Tilt Panel

The Pelvic Tilt panel is only available when both the patient's pre-operative standing and sitting lateral

[1] Röling, Maarten A., et al. "A quantitative non-invasive assessment of femoroacetabular impingement with CT-based dynamic simulation - cadaveric validation study." BMC musculoskeletal disorders 16.1 (2015): 50.

X-ray images have been provided for the case. This panel allows the user to further analyze the Pelvic Tilt of the patient. When the X-rays are available, the Pelvic Tilt button is displayed on the Pelvic Tilt drop-down in the Review panel. Pressing this button will then open the Pelvic Tilt panel. (**Figure *37***).

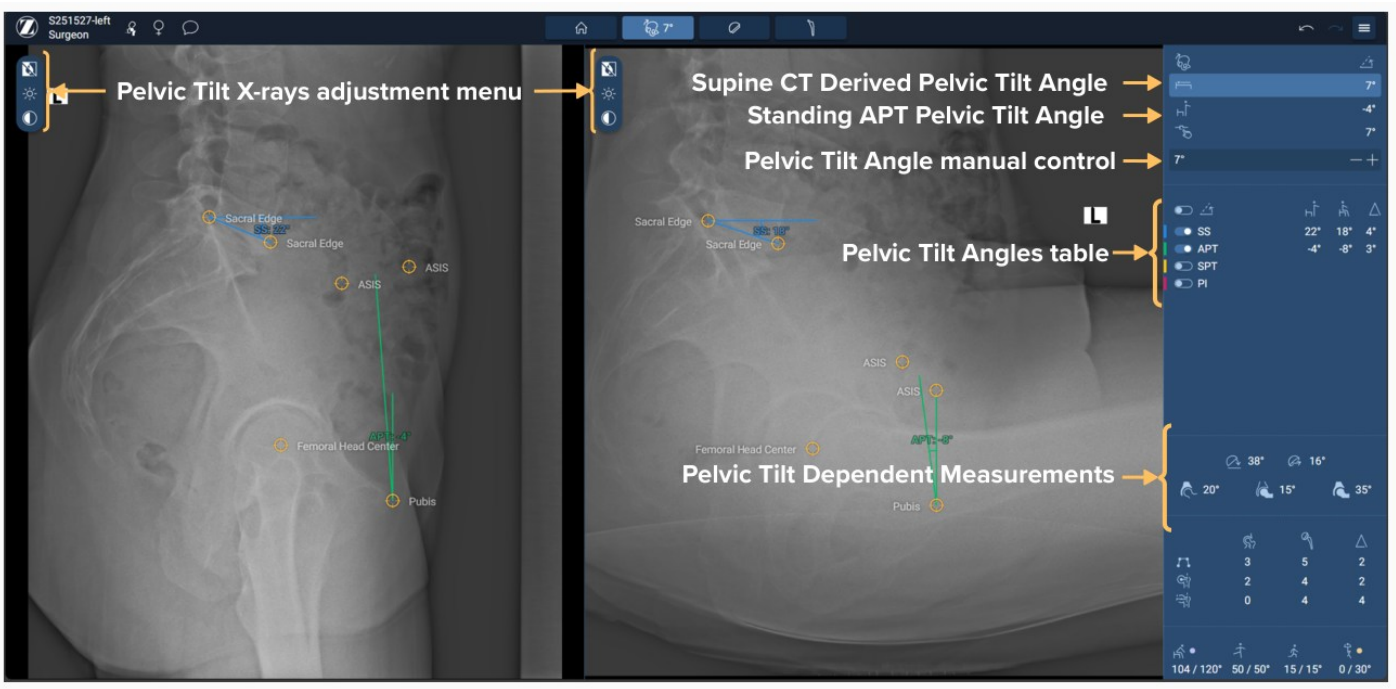


Figure 37: Pelvic Tilt *Panel*

X-ray Image Adjustment Menu

The brightness and contrast of the patient's pre-operative X-rays can be set from the X-ray Image Adjustments menu by adjusting the sliders (***Figure 38***). Adjustments can be performed for both sitting and standing lateral X-rays.

A toggle in the same menu allows for the inversion of the X-ray image, from either a black-to-white scale or a white-to-black scale. This can be performed for both the sitting and standing lateral X-rays.

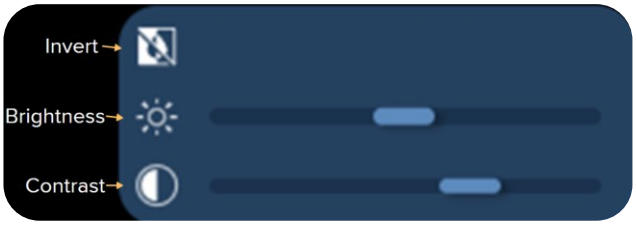


Figure 38: X-ray Image Adjustments Menu

Pelvic Tilt Angle Control

Similar to the Review panel, the Pelvic Tilt panel includes a Pelvic Tilt Angle Control to display the angle currently applied for case planning (***Figure 39***). The user can adjust the Pelvic Tilt Angle in three ways:

1. Manually

   Toggle left (towards Sync with Drop-down Field) by selecting a value from the drop-down list or using the plus (+) and minus (-) buttons (***Figure 39***)

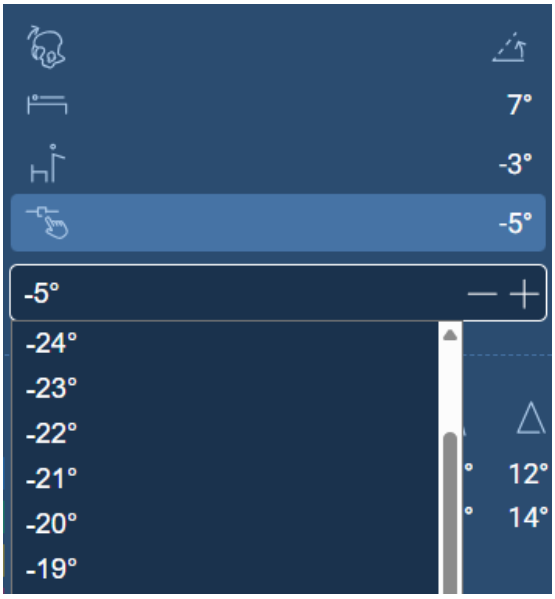


Figure 39: Pelvic Tilt Angle control with Manual Selection

2. Standing APT

To sync with the APT angle currently measured in the standing lateral X-ray image click on the standing APT Icon and angle (**Figure *40***)

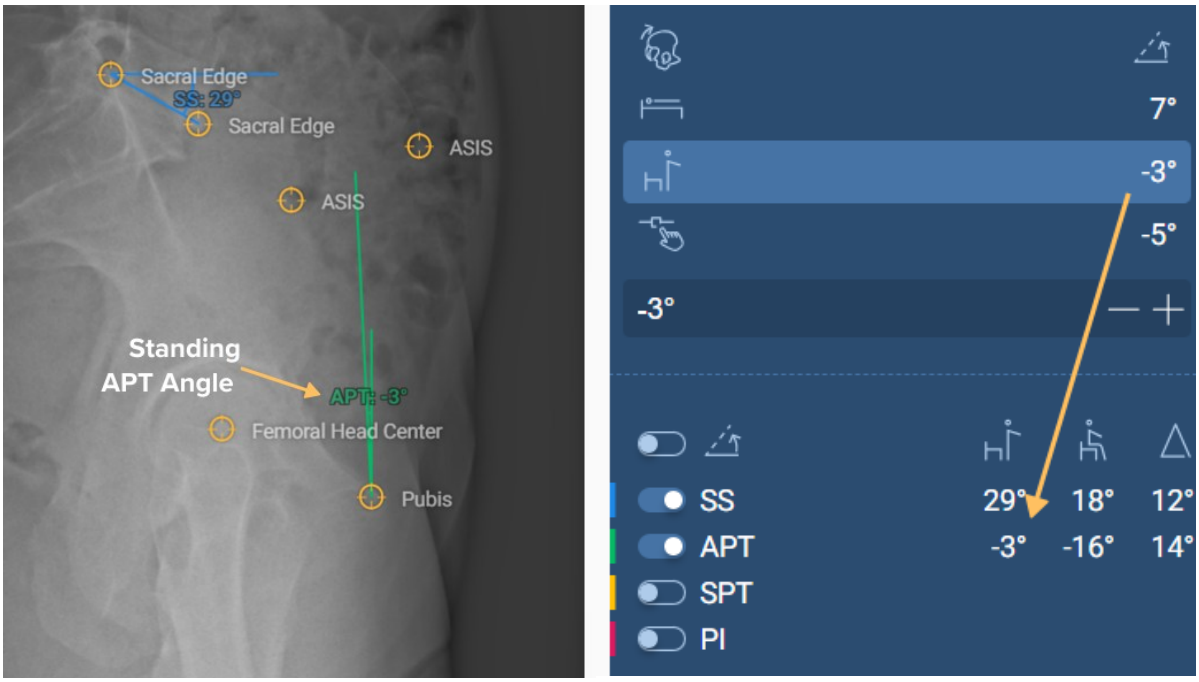


Figure 40: Pelvic Tilt Angle Control with Sync to APT Angle in X-ray Image

3. Supine CT

to sync with the Supine CT Angle, click on the Supine icon and angle (***Figure 41***)

Figure 41: Pelvic Tilt Angle Control with Sync to Supine CT Angle

Reference Points and Measurement Techniques

When first accessing the Pelvic Tilt panel, the patient's pre-operative sitting and standing lateral X-rays are displayed on the screen with the reference points placed corresponding to their anatomical placement (Figure 35).

- The Sacral Edge reference points are positioned along the superior surface of the S1 vertebrae in both the patient's pre-operative standing and sitting X-rays (two points in each X-ray)
- The ASIS reference points are positioned at the front of the coxae in the patient's pre-operative standing and sitting X-rays (two points in each X-ray)
- The Pubis reference points are positioned on the pubis of the coxae in both the patient's pre-operative standing and sitting X-ray (one point in each X-ray)
- The Femoral Head Center reference points are positioned at the center of the femoral head in both the patient's pre-operative standing and sitting X-rays (one point in each X-ray)

The reference points can be adjusted by the user by first selecting the landmark to expand the yellow target circle, and then holding and dragging the selected point to a different position.

The reference points (Sacral Edge, ASIS, Femoral Head Center and Pubis) are used to determine the following angles:

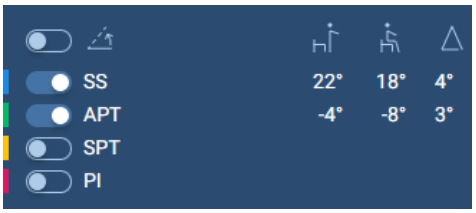
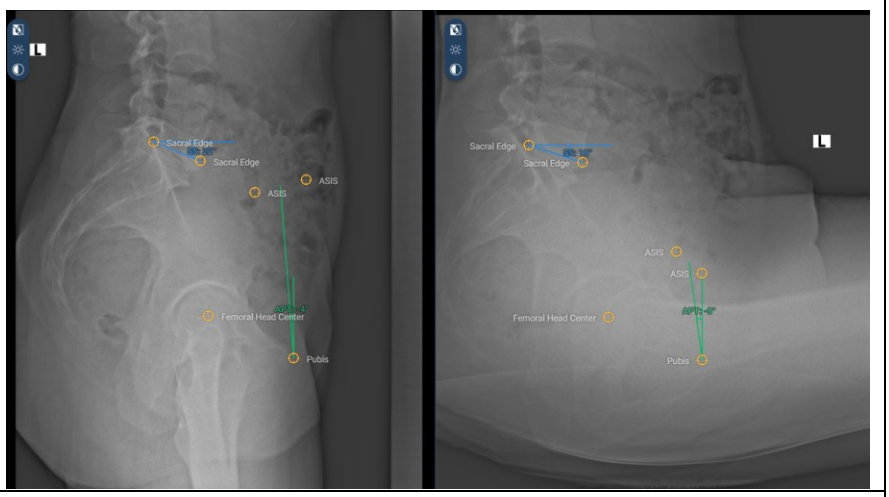
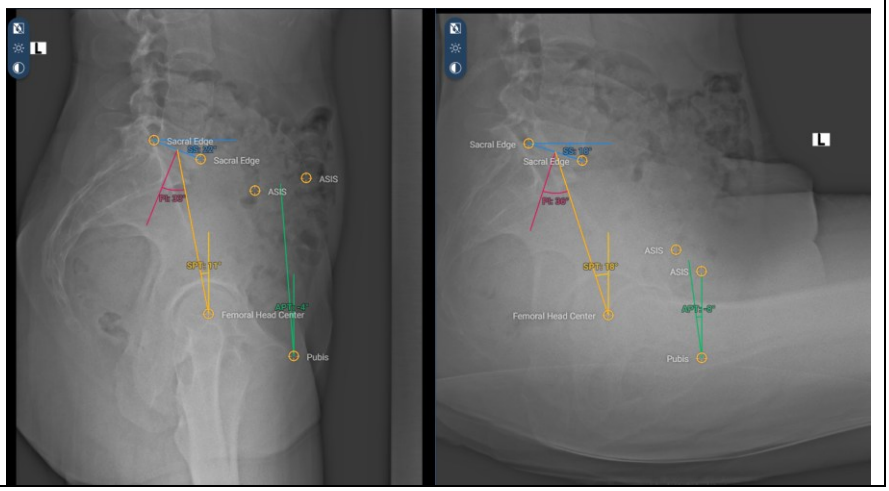
- SS – Sacral Slope: The angle between the Sacral Edge (blue line along the top of the S1 vertebra) and the line running parallel to the image's horizontal axis. The Sacral Slope determines the orientation of the lumbar spine
- APT – Anterior Pelvic Tilt: The angle between the line from the midpoint of the two ASIS points to the Pubis (indicated as a green line) and the line parallel to the image's vertical axis. The Anterior Pelvic Tilt defines the forward rotation of the pelvis in standing position
- SPT – Spinopelvic Tilt - The angle between the yellow line from the midpoint of the Sacral Edge to the Femoral Head Center and the yellow line parallel to the image's vertical axis. Spinopelvic Tilt denotes the spatial orientation of the pelvis
- PI – Pelvic Incidence - The angle between the line from the midpoint of the Sacral Edge perpendicular to the Sacral Edge (indicated by the red line) and the line connecting that midpoint to the center of the femoral head (on the side closest to the imaging source) from the midpoint

on the Sacral Edge (indicated by a yellow line). Pelvic Incidence is the algebraic sum of Sacral Slope and Spinopelvic Tilt

Pelvic Tilt Angles Table

Allows the user to toggle the visibility of the angles and displays the angles calculated and their numeric value for the PI, ST, SPT and APT (Figure 35 and Table 9). The angles are adjusted in real time if the user moves the reference points.

Table 9. Pelvic Tilt Angles Table

 Default Pelvic Tilt Angles Displayed (only SS and APT)	
 Pelvic Tilt Angles Toggles Enabled	

4.2.10 Implant Positioning with Directional Pad Widget

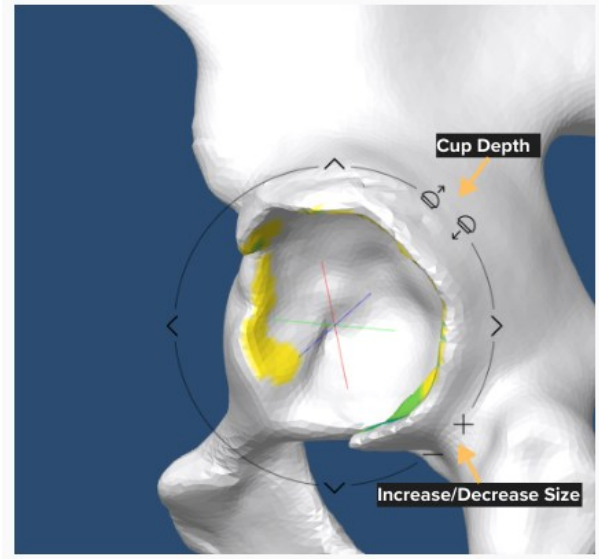
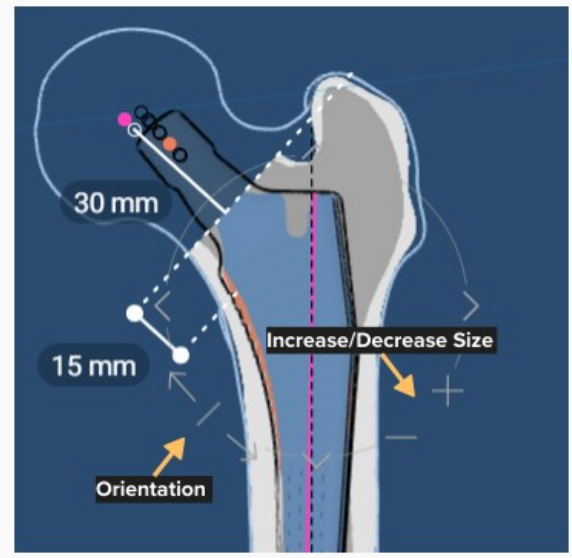
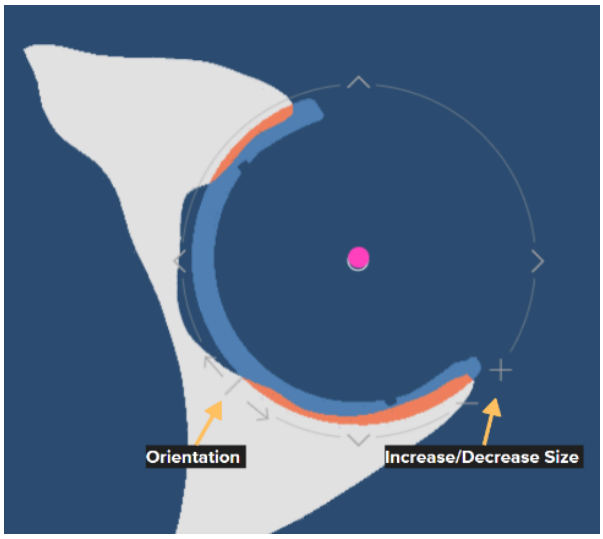
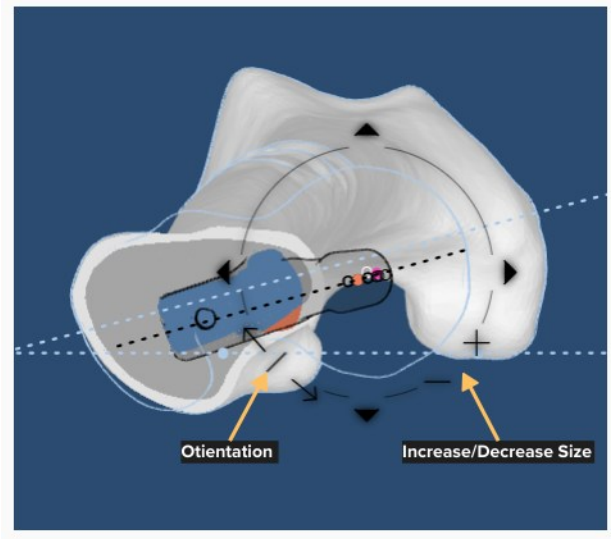
The Cup and Stem panels provide surgeons with precise control over the key components of hip planning. From these panels, the user can adjust critical parameters, including size, orientation and implant positioning, to ensure optimal fit and alignment for each patient's anatomy.

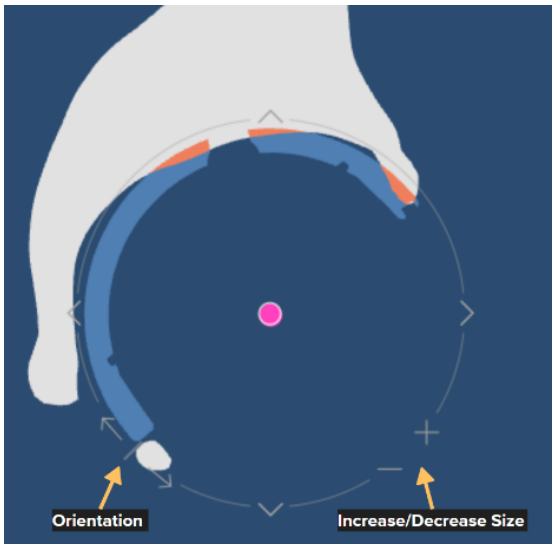
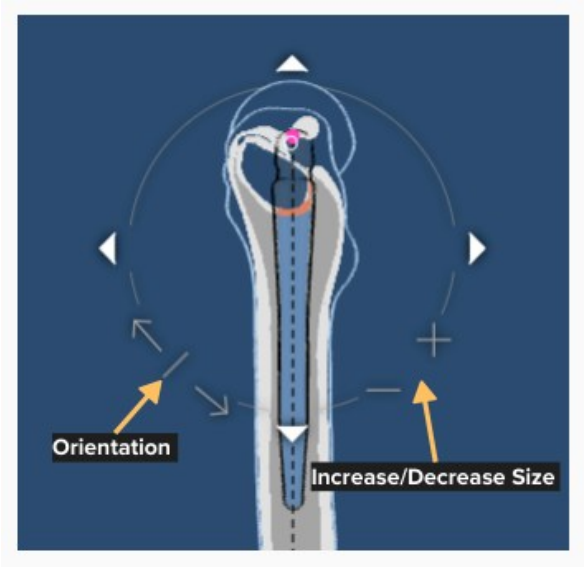
Directional Pad Widget

A Directional Pad (D-Pad) widget control is present in the Cup and Stem panels, allowing users to adjust the position and orientation of the implant components across different views (***Table* 10**). Using the directional arrows (up, down, left, right), users can reposition the cup or stem components within a specific view, while additional controls in the widget allow orientation adjustments in the corresponding panels.

To access the D-Pad widget, hover over the implant in any of the views seen in Table 10.

Table 10: Additional Controls in D-Pad Widget on Cup and Stem Panels

Cup Panel	Stem Panel
Frontal view (3D)	Anterior view (2D)
	
Axial view	Axial view
	

Radial slice view	Sagittal view
	

Increase/Decrease Size Button

The Increase/Decrease size button allows the user to increase (+) or reduce (-) the size of the cup or the stem implant component by **one size increment** (see different views in Table 10).

Orientation Controller

The Orientation Controller allows the user to adjust the version and inclination of the implant components.

- For the cup component, the user may modify both the version and inclination using the controller in the different views available
- For the stem component, the version is modified when the controller is used in the axial view. Note that other stem orientation adjustments – i.e. ML inclination/varus-valgus in the anterior view and AP inclination in the lateral view – can be made, but no associated values are provided

Orientation values can be changed by clicking the arrows for incremental adjustments (1 degree increment per click) or by clicking and holding the line between the arrows and dragging the mouse clockwise or counterclockwise for continuous adjustments. For reference on accessing the orientation controller, see different views in ***Table* 10**.

Cup Depth Controller

The Cup Depth Controller is available within the D-Pad widget exclusively in the 3D view of the Cup panel. This control allows users to adjust the depth of the cup within the acetabulum, by increasing or decreasing its position through incremental adjustments (**0.2mm increment** per click). For reference, see **Table *13***.

4.2.11 Cup Panel

The Cup panel is dedicated to configuring the acetabular component of the hip implant (***Figure* 42**). From this panel, surgeons can adjust parameters, including cup family, cup type, inclination, version and size, to achieve optimal coverage and alignment within the acetabulum.

The Cup panel displays three different views with real-time visualization, allowing fine-tuning of the implant positioning and assessment of the impact of each adjustment on the overall construct.

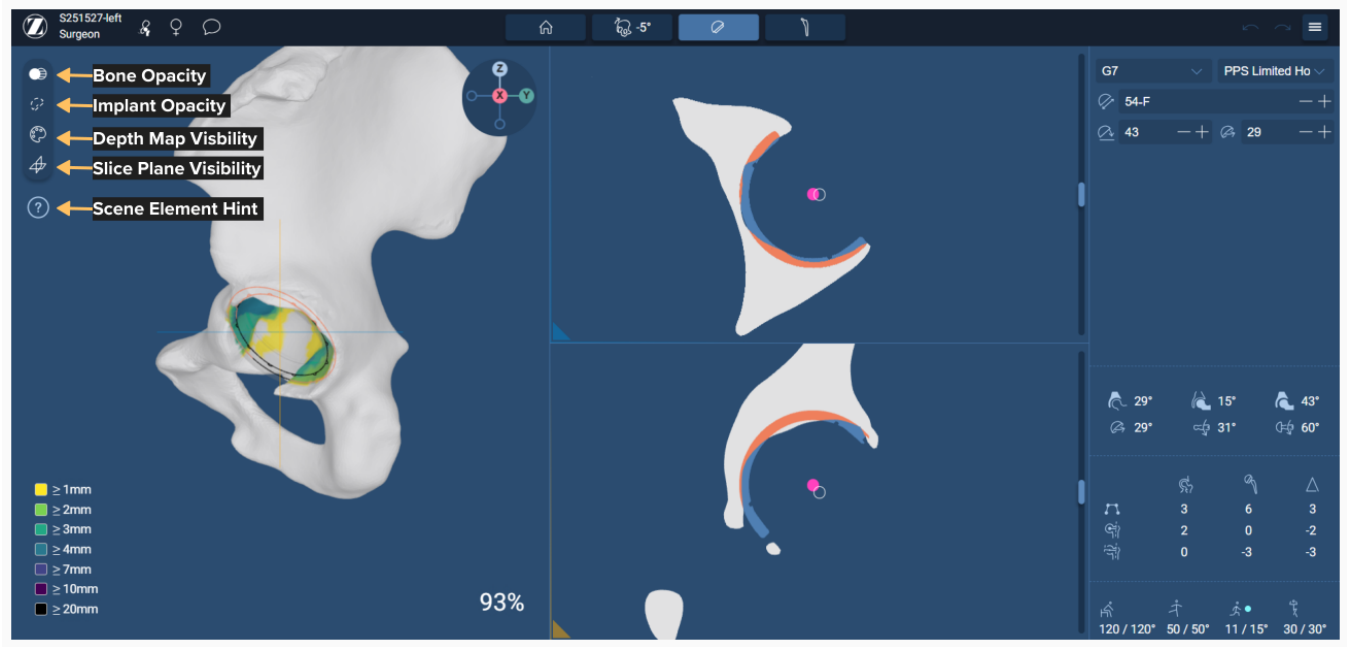


Figure 42: Cup Panel

Coxae 3D Model View

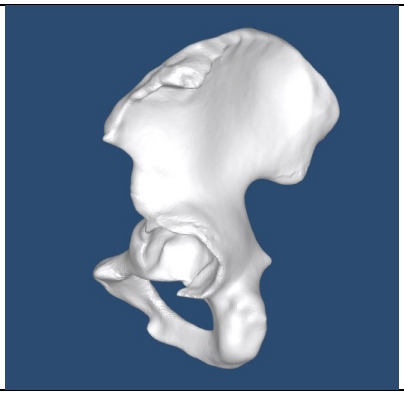
The Coxae 3D Model view on the left provides a visualization of the patient's reconstructed coxae, centered on the acetabulum of the operated side. This view allows surgeons to clearly assess the current positioning and orientation of the cup component within the acetabulum. It also enables interactive evaluation of implant contact with the bone and the depth of placement.

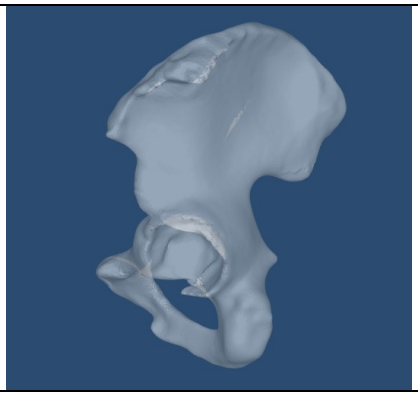
There are four toggles available in the Coxae 3D Model view:

1. Bone Opacity Toggle

This Bone Opacity toggle allows the user to affect the opacity of the operated acetabulum anatomy in the Coxae 3D Model view (Table 11). When the Bone Opacity toggle is enabled, the acetabulum bone appears opaque. When the toggle is disabled, the acetabulum bone is transparent, allowing the user to visualize the cup component or surrounding structures more clearly.

Table 11: Bone Opacity Toggle – Coxae 3D Model View

 When this icon is displayed, the bone is opaque		

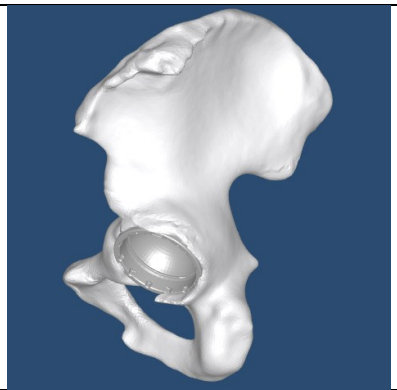
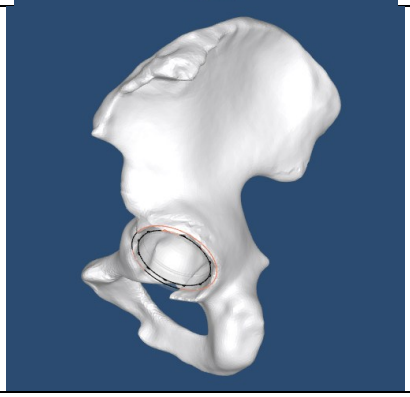
 When this icon is displayed, the bone is transparent	

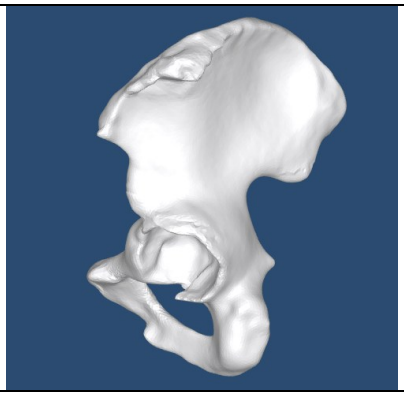
2. Implant Opacity Toggle

The Implant Opacity toggle controls how the cup component is displayed in the Coxae 3D Model view (Table 12). This feature offers three visualizations to assist the user with switching between different perspectives for better evaluation of implant placement and bone coverage:

- The cup displayed as an opaque model
- The cup displayed as a transparent model
- No cup is displayed. These options

Table 12: Implant Opacity in Cup Panel

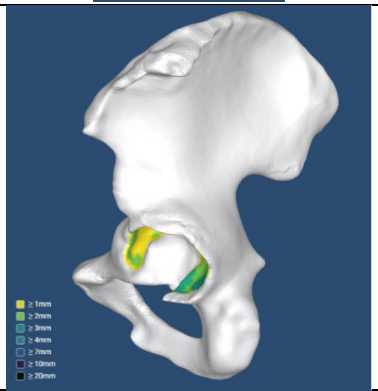
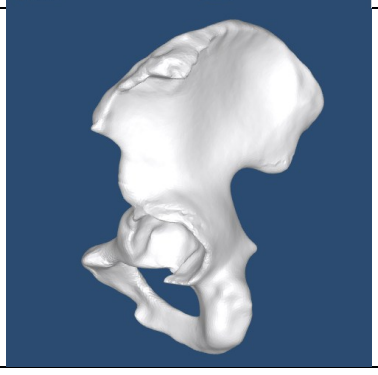
 When this icon is displayed, the cup component is opaque	
 When this icon is displayed, the cup component is transparent, an outline of the cup face is provided	

When this icon is displayed, the cup component is not displayed	

3. Depth Map Visibility

The Depth Map Visibility toggle provides a color-coded visualization of how deep the cup is positioned within the acetabulum (Table 13). When enabled, the 3D view displays a color gradient overlay on the bone surface, indicating areas of contact and penetration depth with a color scale that ranges from lighter to darker colors (first row of Table 13).

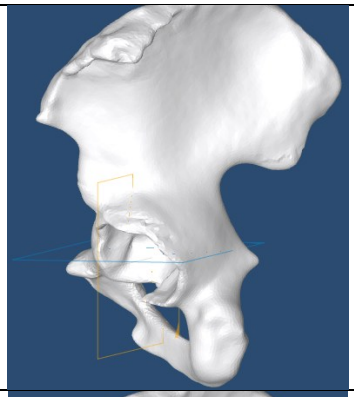
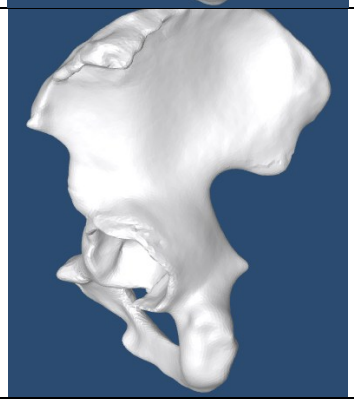
Table 13: Depth Map Visibility

Depth map legend	
When this icon is shown, the depth color map is displayed	
When this icon is shown, the depth color map is not displayed, the depth map legend is also hidden	

4. Axial and Radial Slices Plane Visibility Toggle

The Axial and Radial Slice Plane Visibility toggle toggles between the display of the current cross-sectional reference planes for the sagittal and axial views within the 3D model (Table 14). When enabled, the axial view is outlined in blue and the radial view in orange, visually linking the axial and radial slice reference plane to its corresponding view.

Table 14: Radial Slice Visibility Toggle

 When this icon is shown, the Axial and Radial Slice Reference Planes are displayed	
 When this icon is shown, the Axial and Radial Slice Reference Planes are not displayed	

Coxae 2D Slice View

The Coxae 2D Slice view displays an axial slice (outlined in blue) and a radial slice (outlined in gold) centered on the acetabulum (Table 14). Both can be moved by dragging the slider up or down, or by using the mouse scroll wheel on the view (***Figure* 43**). This visualization allows surgeons to evaluate cup positioning, depth and coverage from multiple angles without rotating the entire 3D model.

Each view represents a cross-section of the cup. Orange zones indicate areas of direct contact with the acetabulum and their depth. Additionally, the views show the femoral head center of rotation, represented by a white circle, and the post-operative center of rotation, represented by a pink circle.

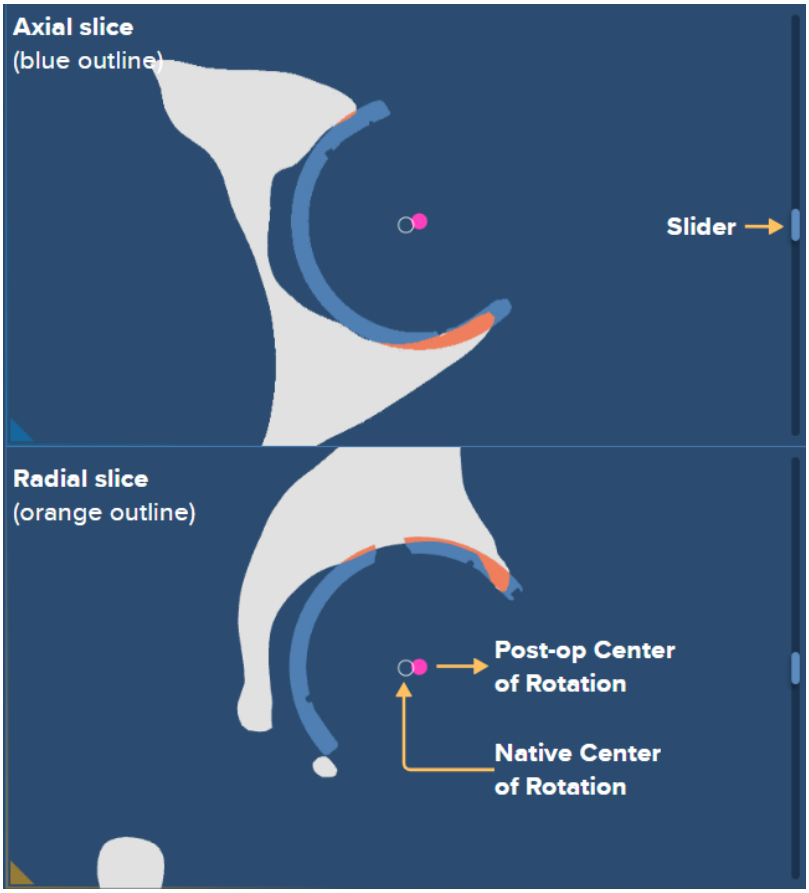


Figure 43: Axial and Radial View in Cup Panel

For other controls available in the Cup panel, refer to section 4.2.6.

Cup Coverage Percentage

The Cup Coverage Percentage tells the user the amount of the cup that is in contact with the patient's anatomy. This value is visible as a percentage on the Cup panel overview, on the bottom right of the Coxae 3D Model view (***Figure 44***).

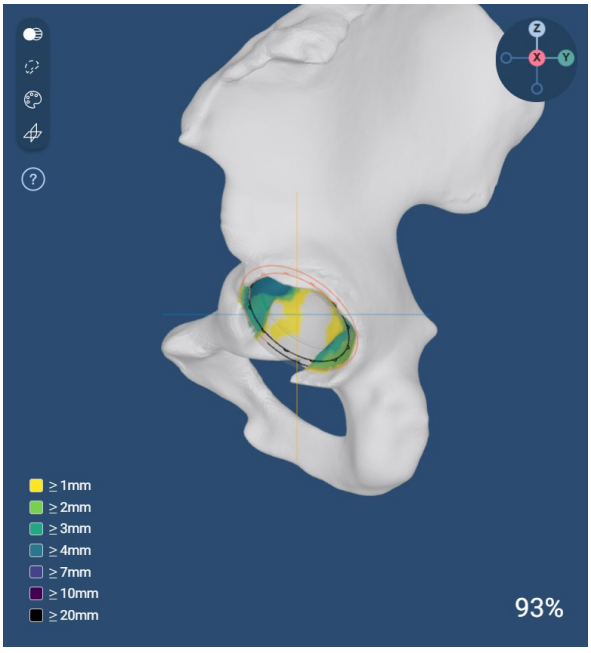


Figure 44: Cup Coverage Percentage

Scene Element Hint

Hovering over the question mark icon in the Coxae 3D Model view displays scene element hints. These hints explain the meaning of the graphical elements shown in the 2D and 3D Coxae views (Figure 45).

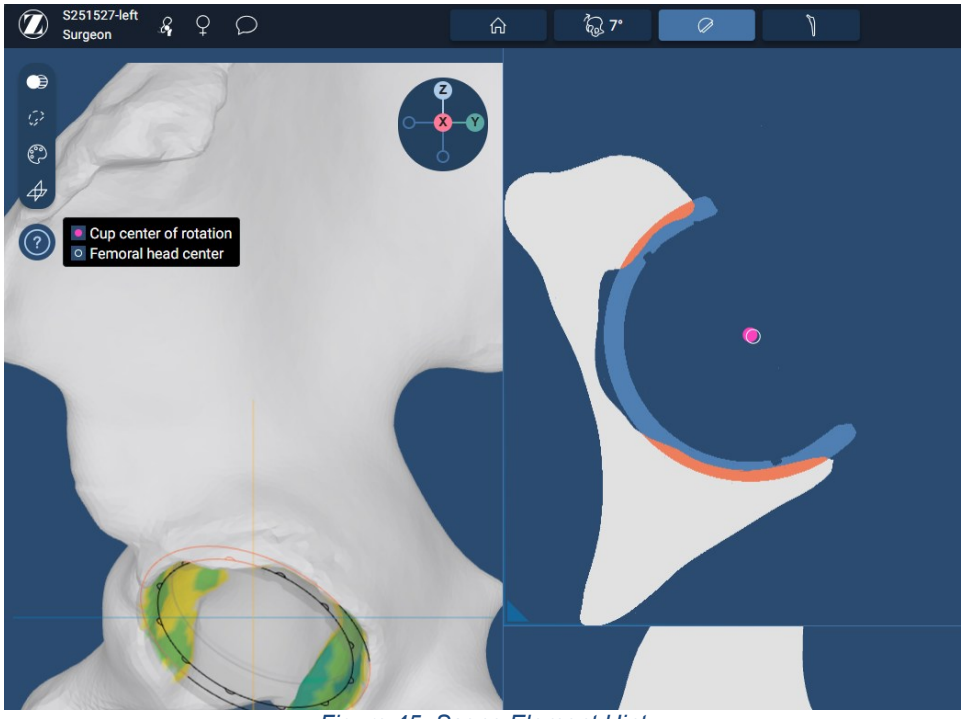


Figure 45: Scene Element Hint

4.2.12 Stem Panel

The Stem panel provides the tools and information necessary to plan and adjust the femoral component (***Figure* 46**). Within this panel, users can control stem positioning, orientation and sizing to achieve optimal alignment and stability.

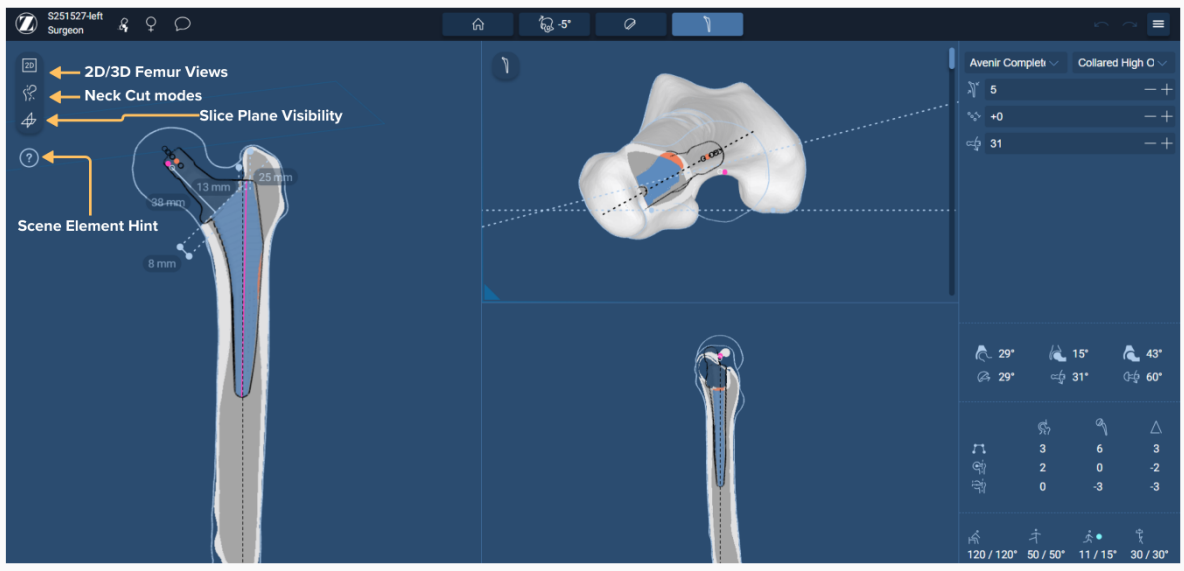
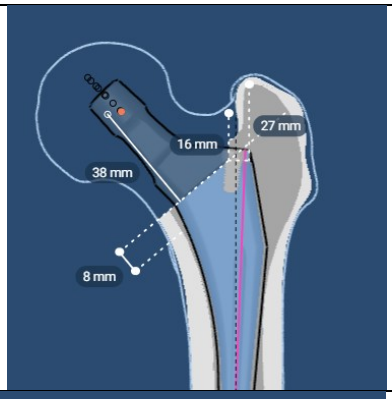
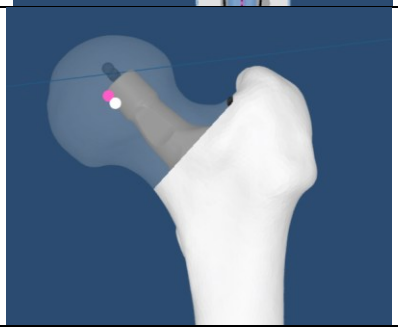


Figure 46: Stem Panel

Main Femur Frontal View

The Main Femur Frontal View is a toggle that allows the user to enable or disable the 2D view or 3D view of the femur and femoral stem (Table 15).

Table 15: Main Femur Frontal View in Stem Panel

 When this icon is displayed, the 2D View is enabled			
 When this icon is displayed, the 3D View is enabled			

Femur 2D View

When the Femur 2D View is enabled, measurements of the femoral neck cut are displayed. The user can adjust these measurements by dragging the position and orientation of the stem implant. The neck cut visualization is illustrated in ***Figure* 47** and Figure 48 for Step Cut mode.

The elements are represented in the Femur Anterior 2D View (***Figure* 47**):

- Stem Axis: Displayed as a solid pink line, while the Femur Canal Axis is displayed as a dashed black line
- Post-operative Center of Rotation: Displayed as a solid orange circle
- Cup Center of Rotation is displayed as a pink circle
- Native Femoral Head Center of Rotation is displayed as a white circle
- Lesser Trochanter Landmark is indicated by a dashed reference line parallel to the resection plane

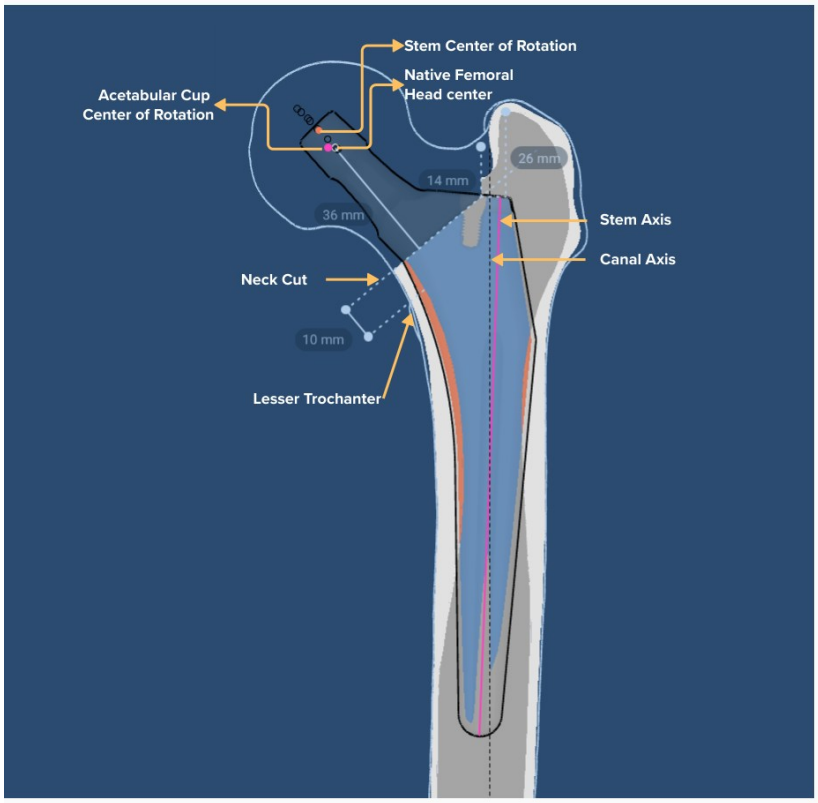


Figure 47: Reference Points in Main Femur Frontal 2D View (Step Cut Mode)

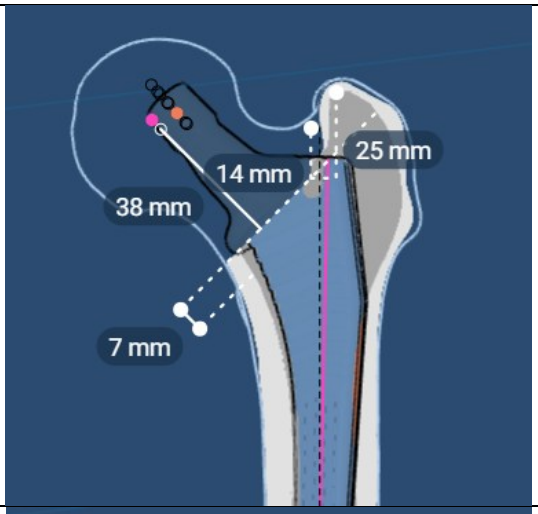
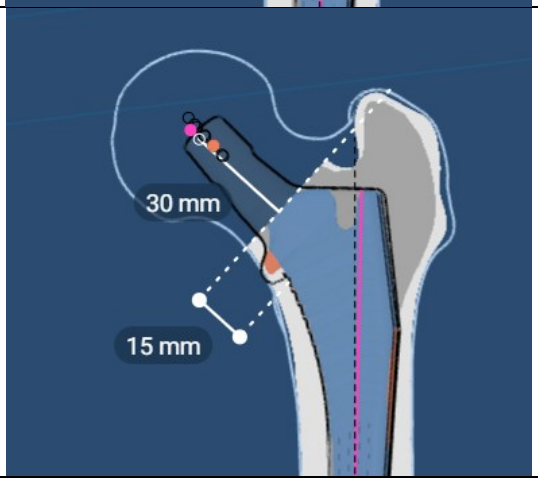
Cut Mode Toggle – Step 2D View

The Cut Mode toggle offers a clear and efficient way to switch between Step Cut mode and Angled Cut mode within the 2D viewer of the stem planner (Table 16).

In Step Cut mode, the ONE Planner Hip 3D software generates a stepped cut composed of a vertical section terminating at the Saddle Point, combined with a 45° cut aligned with the current neck cut position.

When Angled Cut mode is selected, the software displays an angled cut, ensuring that the planned cut remains within safe limits (at least 15 mm from the lesser trochanter) and does not extend into critical anatomical regions, such as the Greater Trochanter. If the resection line crosses the Saddle Point landmark or the neck cut becomes steeper, the software enforces a minimum distance of 15 mm between the resection plane and the Lesser Trochanter.

Table 16: Cut Modes

 When this icon is displayed, Step Cut mode is enabled	
 When this icon is displayed, Angled Cut mode is enabled	

Neck Cut Measurements in Step Cut Mode (2D)

When Step Cut mode is enabled, the Greater Trochanter and the Saddle Point landmarks are represented with solid white circles. Additionally, the following measurements (in millimeters) of the femoral neck cut are provided (Figure 48a):

- Distance between the cut plane and the Lesser Trochanter Landmark
- Distance between the cut plane and the Greater Trochanter Landmark
- Distance between the cut plane and the Saddle Point
- Distance between the cut plane and the Native Femoral Head Center

Neck Cut Measurements in Angled Cut Mode (2D)

When Angled Cut mode is enabled, only the following measurements (in millimeters) of the femoral neck cut are provided (Figure 48b):

- Distance between the cut plane and the Lesser Trochanter Landmark
- Distance between the cut plane and the Native Femoral Head Center

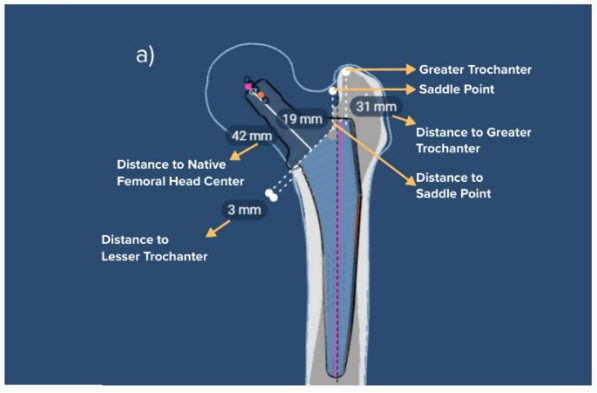


Figure 48a: Neck Cut Measurements - Step Cut Mode

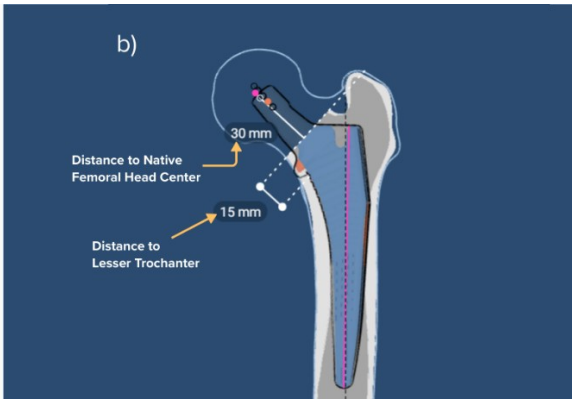
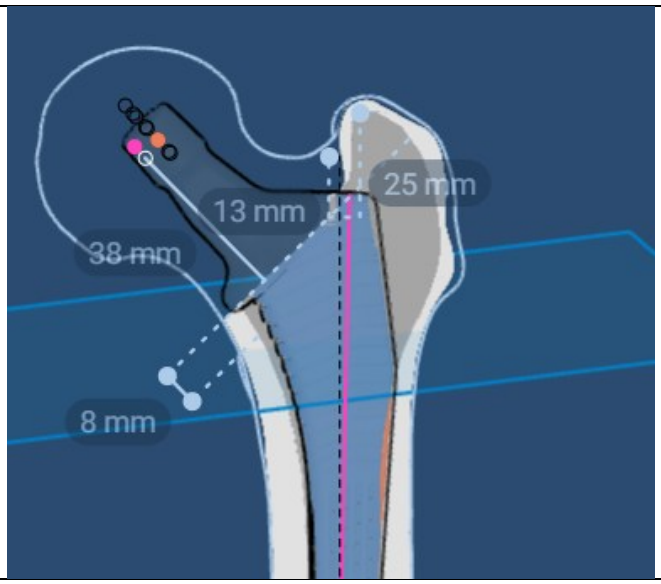


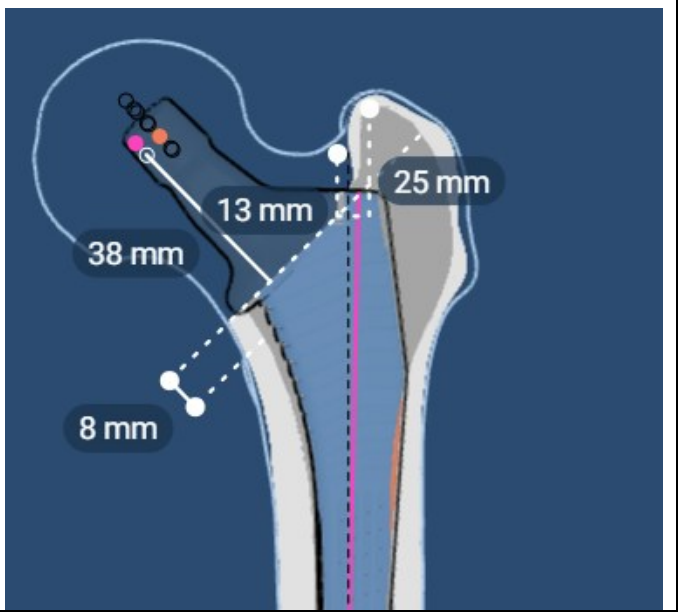
Figure 45b: Neck Cut Measurements - Angled Cut Mode

Axial Slice Plane Visibility

This toggle allows the user to show or hide the Axial Slice Plane in the Femur 2D view (Table 17). Toggling the Axial Slice Plane Visibility ON will display the plane.

Table 17: Slice Plane Visibility - Femur 2D View

 When this icon is displayed, the Axial Slice Plane is displayed	

 When this icon is displayed, the Axial Slice Plane is hidden	

Femur 3D View

When the Femur 3D View is enabled, the femur will appear less transparent/more solid and prominent. The reference points for the Saddle Point, Greater Trochanter and Lesser Trochanter landmarks will also be displayed (**Figure *49***).

- Anatomical reference points are represented by black circles
- Stem Center of Rotation is displayed as a solid orange circle
- Cup Center of Rotation is displayed as a pink circle
- Native Femoral Head Center is displayed as a white circle

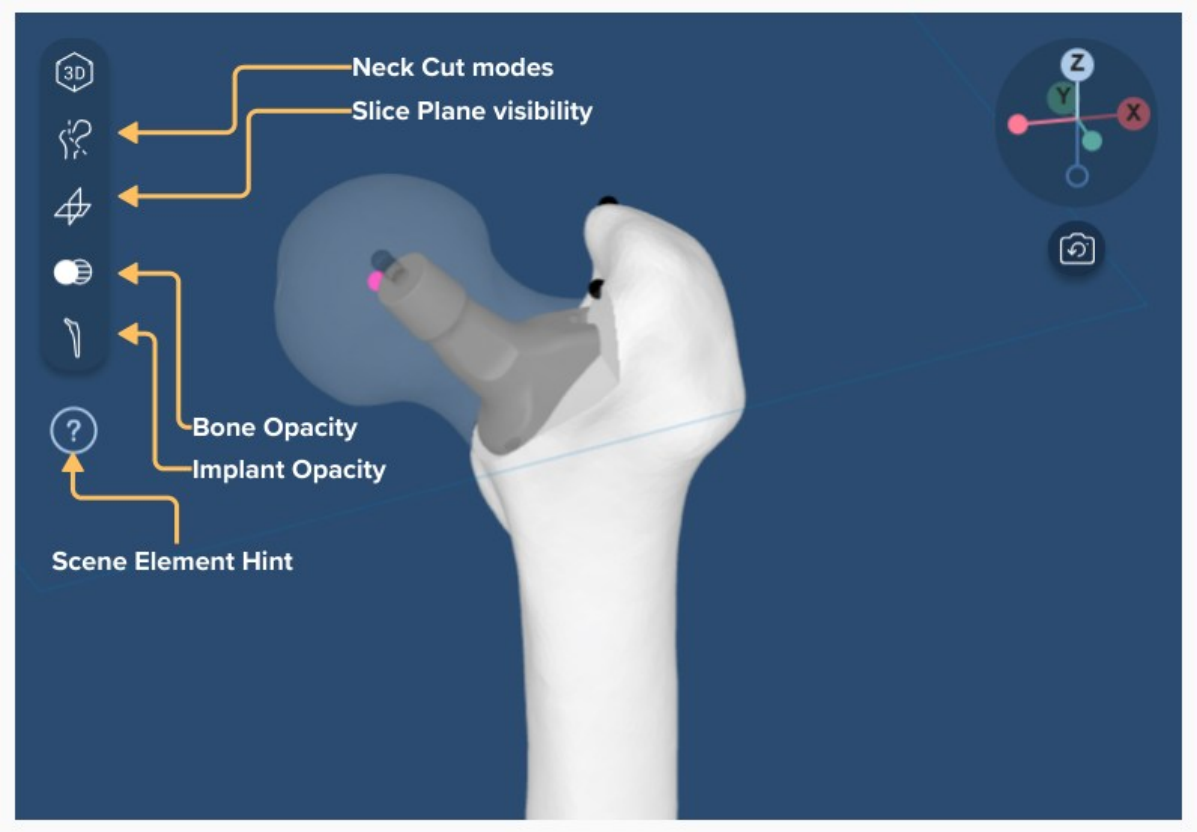


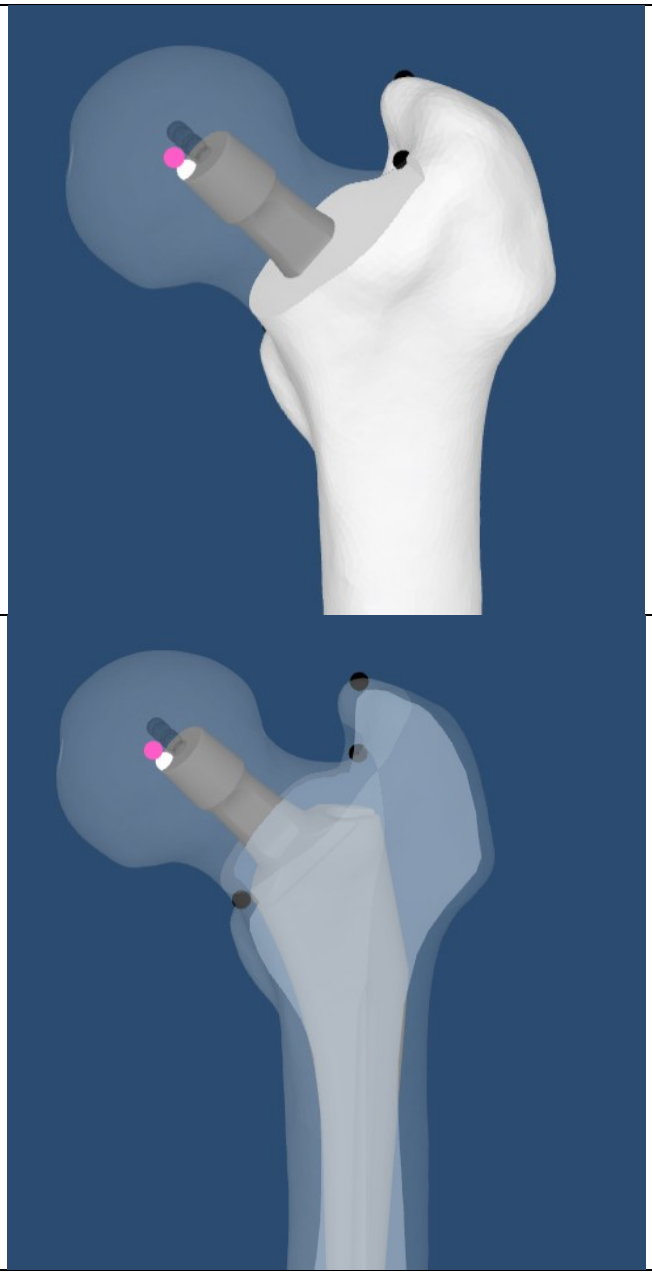
Figure 49: Femur 3D View in Stem Panel

There are four different toggles available in the Femur 3D View to visualize the femoral implant component.

1. Bone Opacity

This toggle allows the user to enable or disable the transparency of the operated femur anatomy in the Femur 3D view (Table 18). When the Bone Opacity toggle is enabled, the femur appears more solid and prominent. When the toggle is disabled, the femur appears transparent, allowing the user to visualize the stem or surrounding structures more clearly.

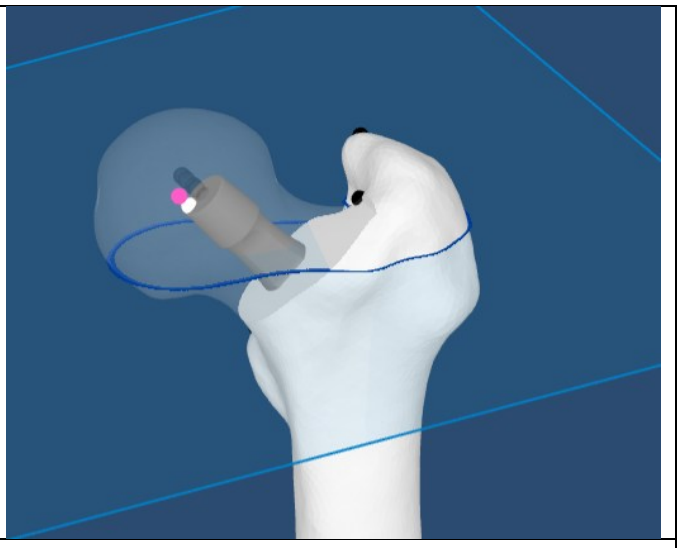
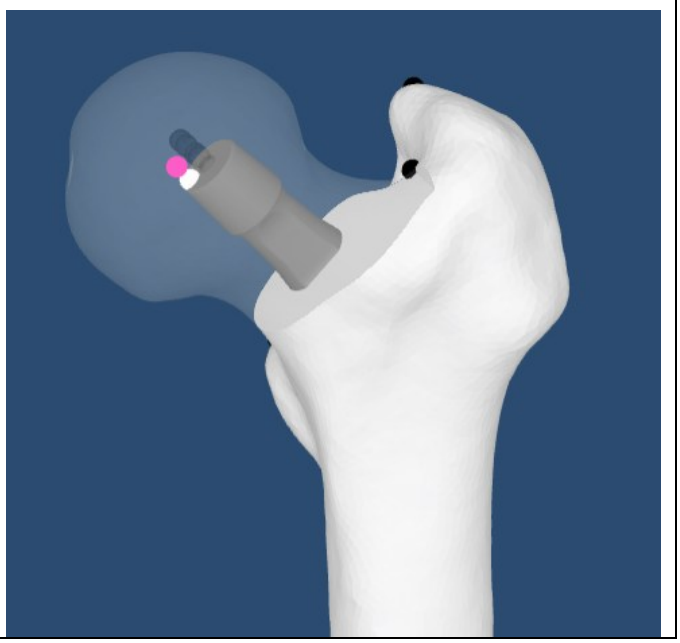
Table 18: Bone Opacity Toggle – Femur 3D View

 When this icon is displayed, the femur is opaque	
 When this icon is displayed, the femur is transparent	

2. Axial Slice Plane Visibility

This toggle allows the user to show or hide the Axial Slice Plane in the Femur 3D view (Table 19). Toggling the Axial Slice Plane Visibility ON will display the plane with an outline around the bone. The location of this plane on the 3D model aligns with the Axial Stem view ().

Table 19: Slice Plane Visibility - Femur 3D View

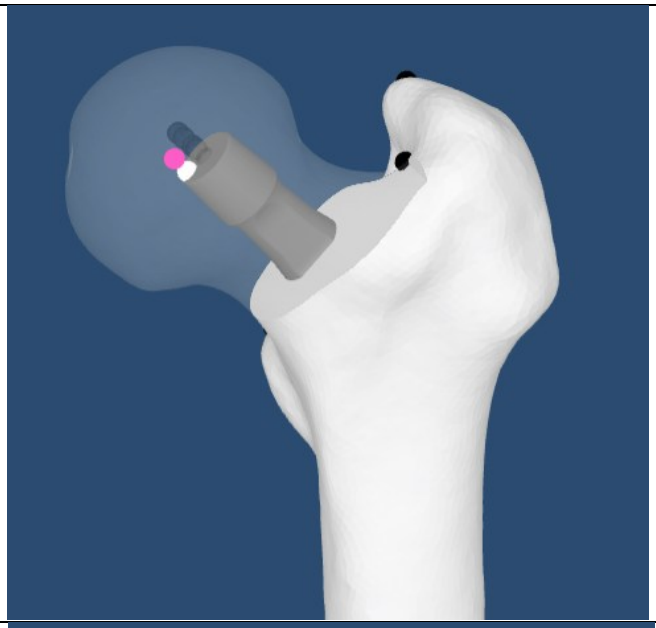
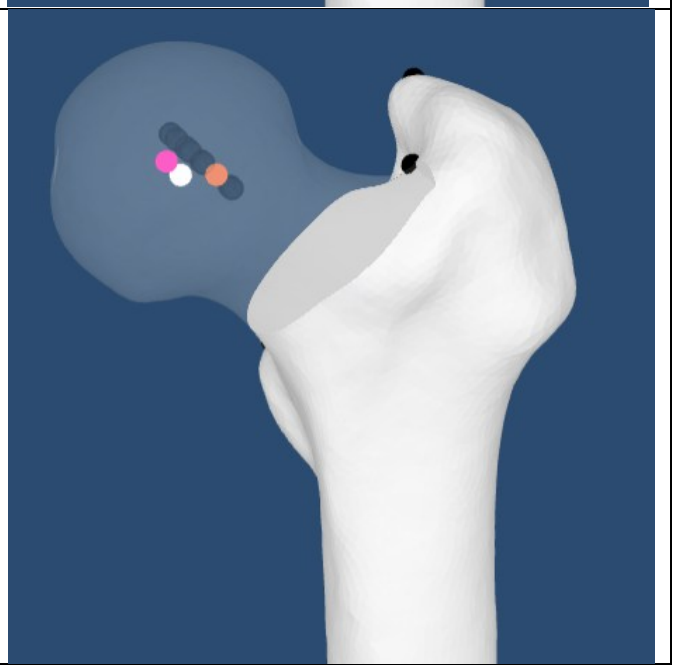
 When this icon is displayed, the Axial Slice Plane is displayed	
 When this icon is displayed, the Axial Slice Plane is hidden	

3. Implant Opacity

This toggle controls how the stem component is displayed in the Femur 3D view (Table 20). This feature offers two visualizations to switch between different perspectives for better evaluation of implant placement and bone coverage:

- Stem displayed as an opaque model
- No stem component displayed

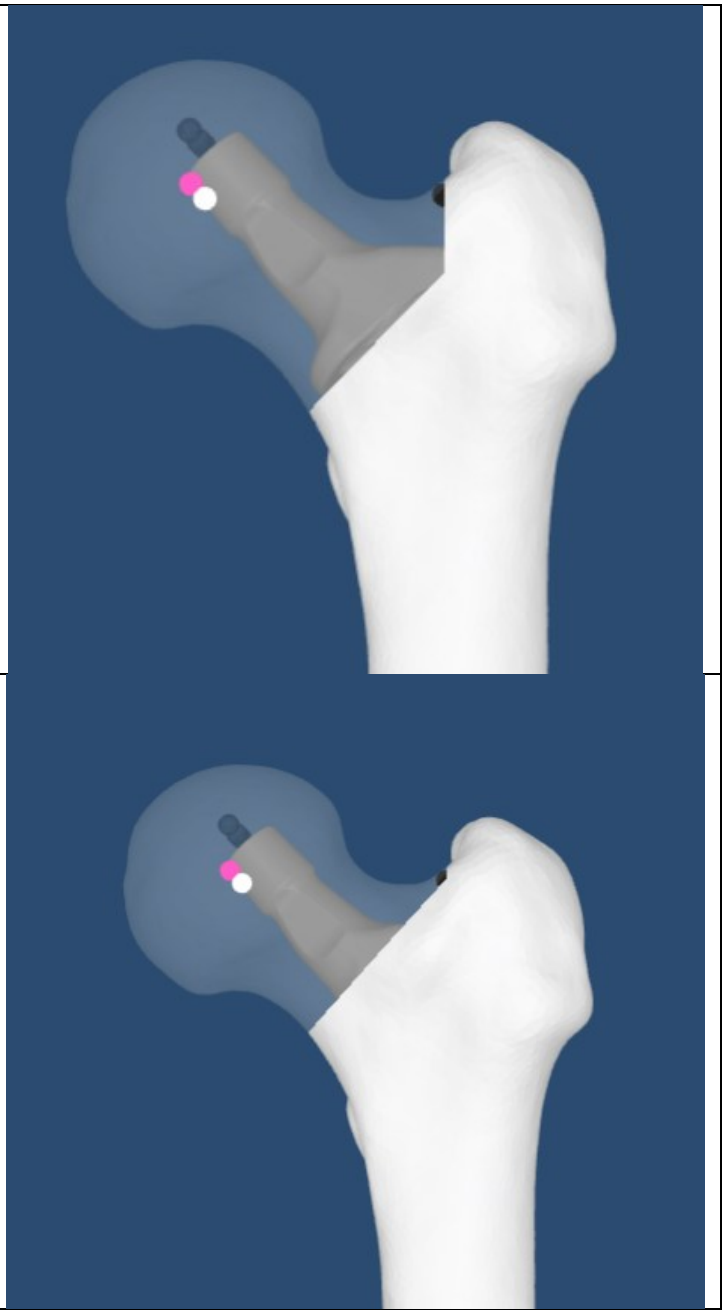
Table 20: Implant Opacity - Femur 3D View

 When this icon is displayed, the stem component is displayed	
 When this icon is displayed, the stem component is hidden	

4. Neck Cut Mode (3D)

The Neck Cut Mode toggle allows the user to switch between Step Cut mode and Angled Cut mode within the 3D viewer of the stem planner (Table 21).

Table 21: Neck Cut Mode - 3D View

 When this icon is displayed, the Step Cut Mode is enabled	
 When this icon is displayed, the Angled Cut Mode is enabled	

Axial and Sagittal Views

The Axial and Sagittal views in the Stem panel display sliced views of the femur. The slices shown in the Axial view can be traversed by moving the slider up or down or by using the mouse scroll wheel to move up or down (***Figure 50*** and ***Figure* 51**). This visualization allows the user to evaluate stem positioning and orientation from multiple angles without rotating the entire 3D model. Each view represents a cross-section of the stem, with orange zones to indicate areas of direct contact with the cortical bone of the femur.

The elements on the Axial view of the Stem panel are represented as follows (***Figure 50***):

- Stem Neck Axis is displayed as a black dashed line
- Native Femoral Version and the Posterior Condylar Line are displayed as two dashed blue lines. Together, they define the Native Femoral Version Angle

- Post-operative Stem Center of Rotation is displayed as a solid orange circle,
- Cup Center of Rotation is displayed as a pink circle
- Native Femoral Head Center of Rotation is displayed as a white circle
- Distal Femur Condyles are displayed as solid blue circles

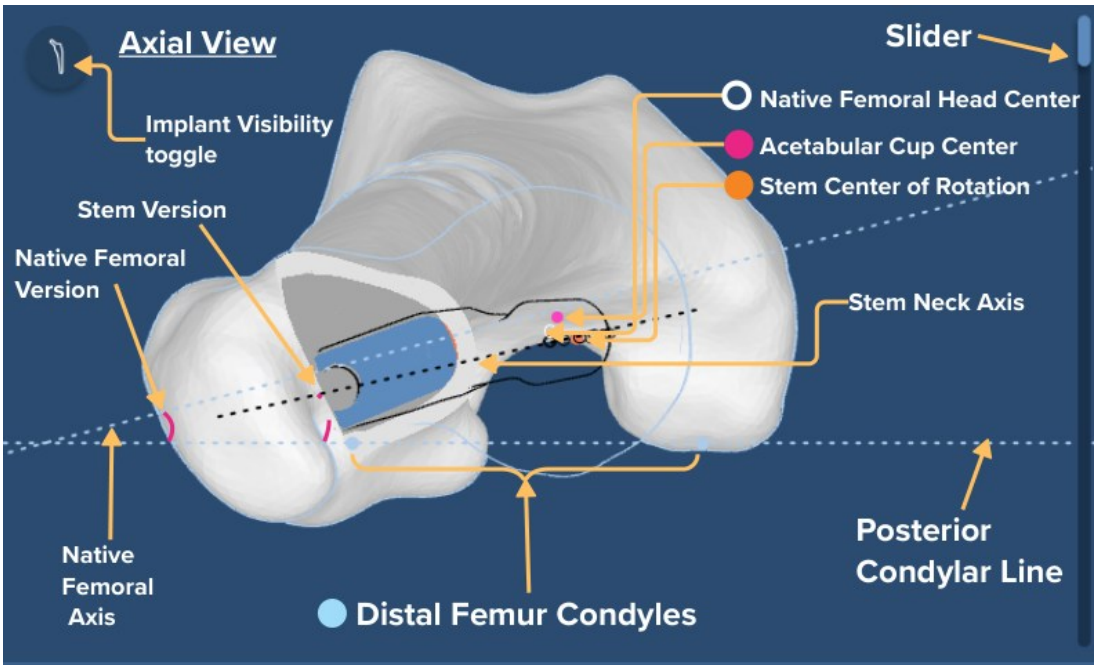


Figure 50: Axial View - Stem Panel

The elements on the Sagittal view of the Stem panel are represented as follows (***Figure* 51**):

- Femoral Canal axis is displayed as a black dashed line
- Native Femoral Head Center of Rotation is displayed as a white circle
- Acetabular Cup Center of Rotation is displayed as a pink circle

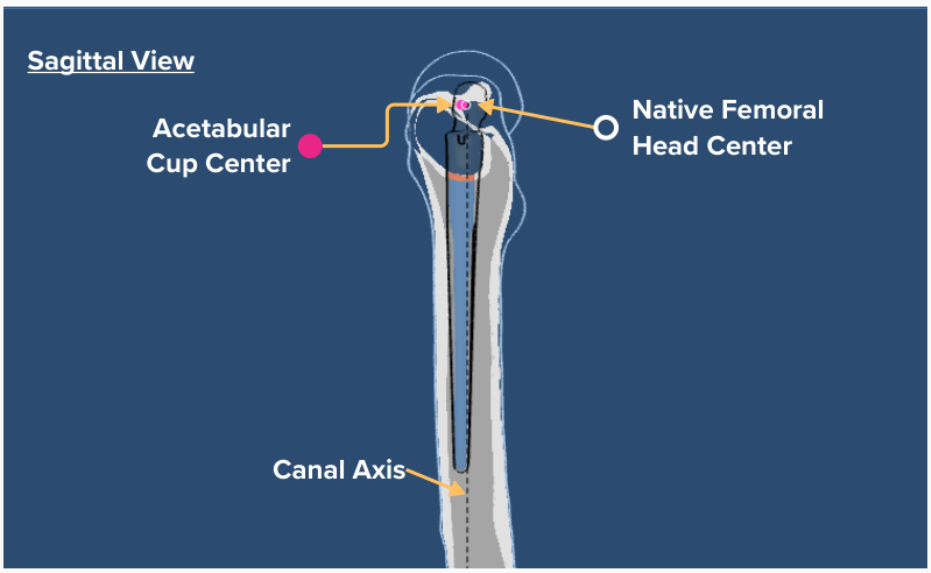


Figure 51: Sagittal View - Stem Panel

Scene Element Hint

Hovering over the question mark icon in the Femur view displays scene element hints. These hints explain the meaning of the graphical elements shown in the Femur 2D and 3D views (Figure 52 and Figure 53).

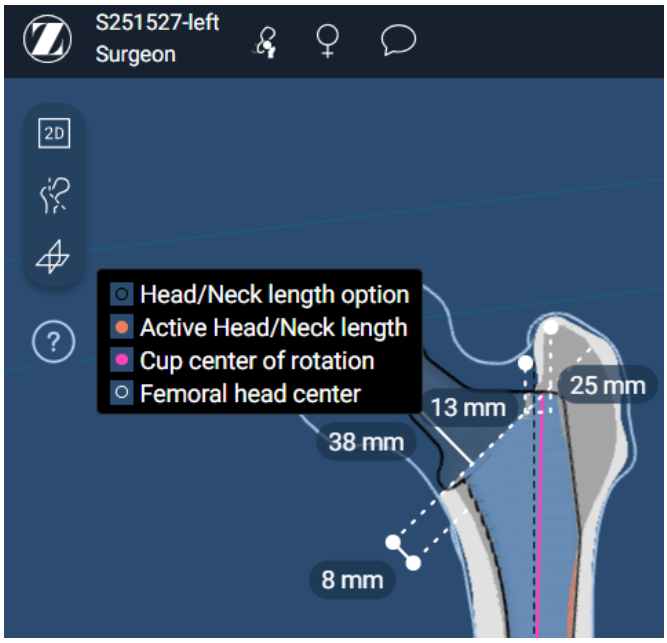


Figure 52: Femur 2D View Scene Element Hint Tool

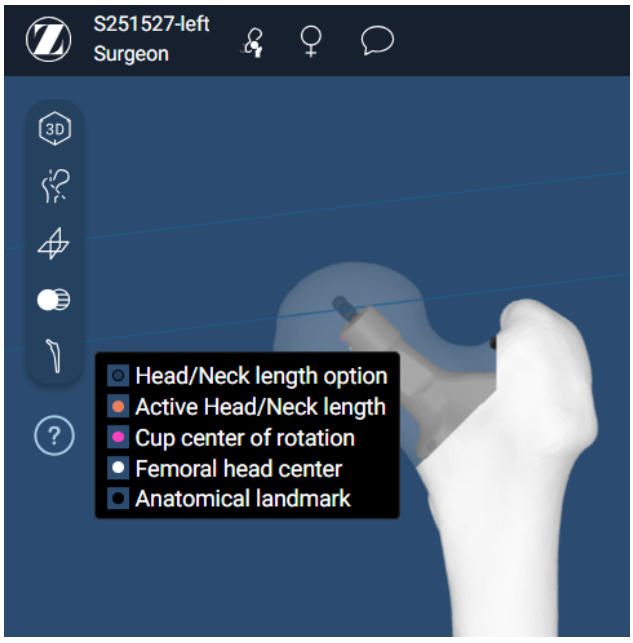


Figure 53: Femur 3D View Scene Element Hint Tool

5. Surgeon Report

5.1 Surgeon Report

When the user is finished manually adjusting the ONE Planner® Hip 3D plan, they must finalize the plan to generate the surgeon report (refer to section **Error! Reference source not found.**). After finalizing the plan, a PDF of the Surgeon Report will be generated. After generation, the report can be downloaded through the ZBEdge Case Portal.

After finalizing, close the internet browser tab to exit ONE Planner® Hip 3D.

5.1.1 Correcting a Finalized Plan

If the user reviews the Surgeon Report of a finalized plan and wants to make corrections to the plan, the user must reopen the surgical case in ONE Planner® Hip 3D from the ZBEdge Case portal. Once the user is finished adjusting the plan, the plan can be finalized and an updated Surgeon Report can be generated (refer to section 5.1).

5.1.2 Surgeon Report Content

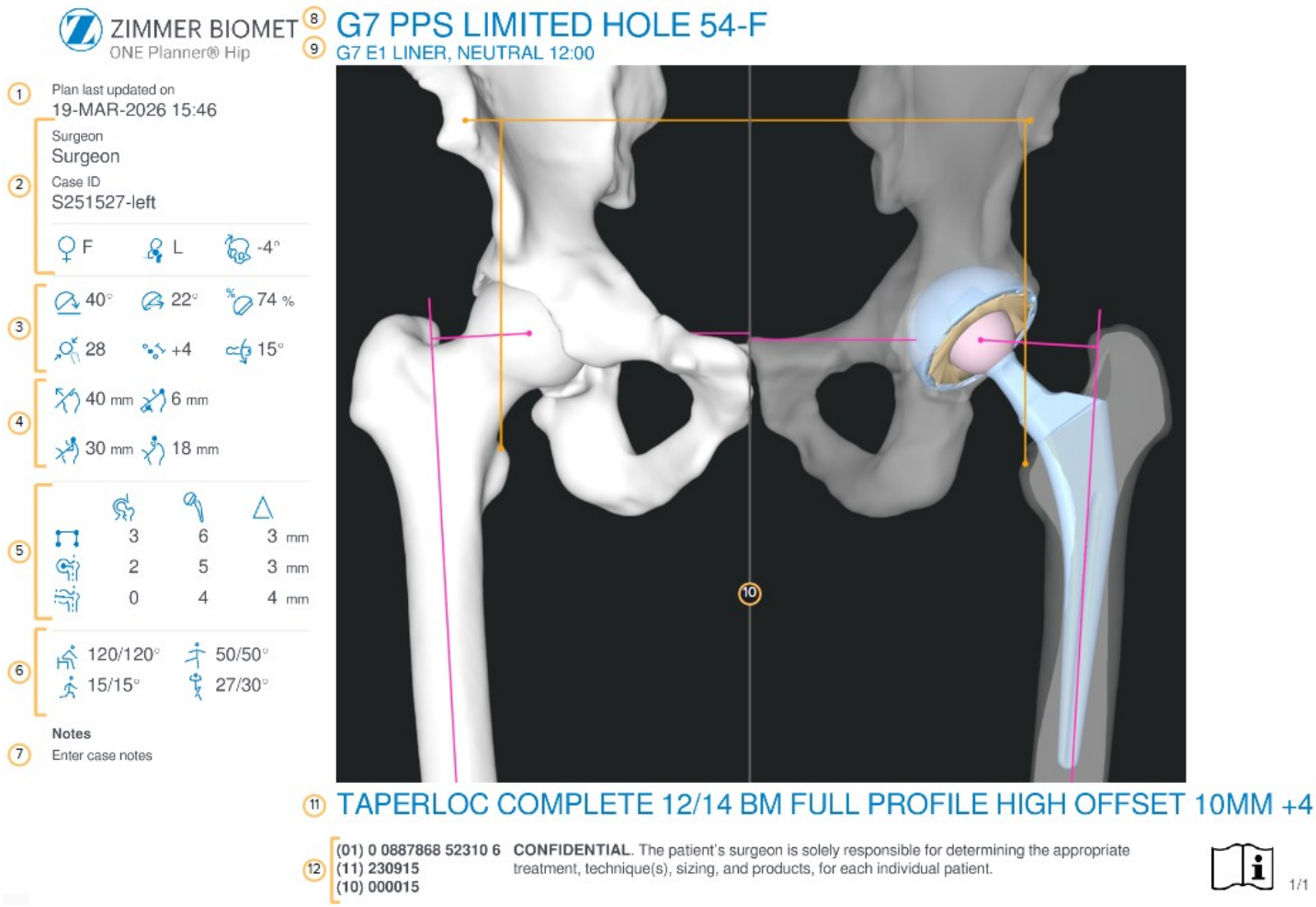


Figure 54: **Surgeon Report**

The content of the Surgeon Report includes:

1. Review Date: The last date that changes were made to the plan. Time displayed in the Surgeon Report is always in UTC time.

2. Case Data: Shows the case metadata that was provided to launch and plan the case.
   Case Data Legend:

   - Surgeon: Surgeon's name (complete surname, complete first name)
   - Case ID: Corresponding case management case ID
   - Gender: Corresponding patient gender selected during case creation
   - Operative Side: User-selected operative side during case creation
   - Pelvic Tilt Angle: Final Pelvic Tilt from planning

3. Implant Components and Configurations

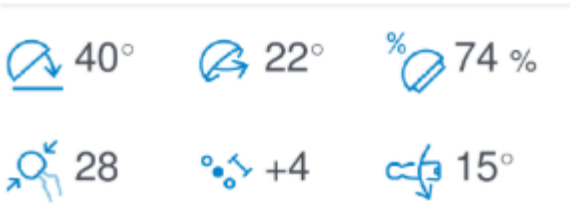


Figure 55. Implanted Components and Positions in Surgeon Report. Top row: Cup inclination, Cup version, Cup Coverage Percentage in Contact with Anatomy. Bottom Row: Femoral Head Diameter, Head/Neck Length and Femoral Version

4. Neck Cut Measurements: The neck cut distance set during planning. If Angled Cut mode was selected, only the first two distances apply.

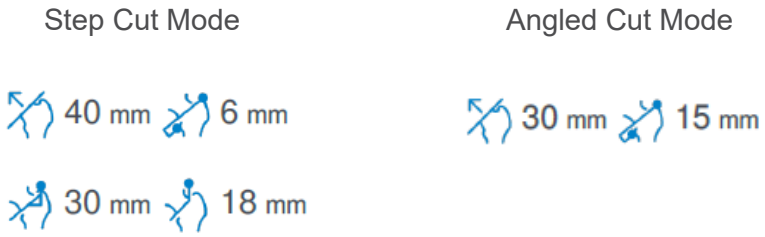


Figure 56: Neck Cut Distance Measurements in Surgeon report: Top row: Distance to Native Femoral Head Center, Distance to Lesser Trochanter. Bottom Row (only for Step Cut Mode): Distance to Greater Trochanter, Distance to Saddle Point.

5. Leg Length Difference and Offset Measurements: Displays the measurements that were performed during planning.
6. ROM Angles: The maximum achievable angle (in degrees) for the patient with the selected implant components.
7. Case Notes: Displays any case notes that were entered during planning.
8. Cup Information: Displays the planned cup family, type and size.
9. Liner Information: Displays the planned liner type and orientation (if applicable).
10. AP View Display: Displays the patient's planned 3D bone model in the AP (frontal) view.
11. Stem Information: Displays the planned stem family, type, size and head/neck length.
12. Product Label and Confidentiality Statement: Displays unique device indicator and Zimmer Biomet confidentiality statement.

6. Product Security Customer Control Considerations

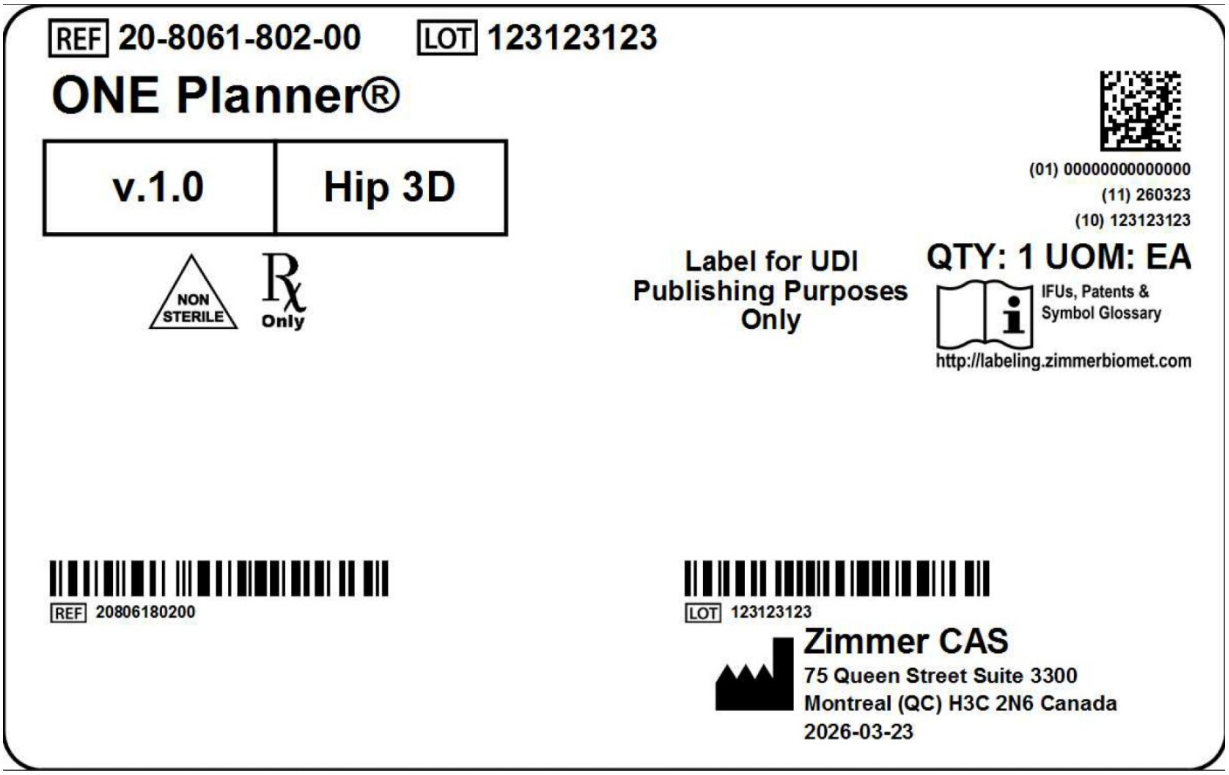
6.1 Cyber Security Controls

ONE Planner® Hip 3D functions as web-based planning tool. Access to OPH3D is restricted to use through the Case Manager application. Access to the software is restricted through user authentication mechanisms designed to ensure that only authorized users can access the application.

OPH3D is only accessible through an internet browser. Communication is limited to authenticated sessions between the client browser and designated backend services using standard web protocols. The system does not provide interfaces for communication with unauthorized external systems and no connectivity beyond what is necessary for normal operation of the application is required.

7.1 Labels and Symbols

The device labels affixed on the device components are detailed below. Bar codes and 2D Matrix are examples only.



* The countries list is not exhaustive and only provides examples where the platform could be used. Please contact your local support to determine availability in your region.

Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer and the manufacturing date
	General Caution Sign	Indicates to proceed with caution
Rx only	Prescription Only	Indicates that Federal law restricts this device to sale by or on the order of a physician
IFUs, Patents & Symbol Glossary http://labeling.zimmerbiomet.com	Consult Electronic Instructions for Use	Indicates the need for the user to consult the Instructions for Use available online at the website

		mentioned below the graphic
	Unique Device Identifier	Indicates the GTIN number, manufacturing date and software version
	Catalog Number	Indicates the manufacturer's catalog number to identify the medical device
	LOT Number	Indicates the batch code

8. Appendix A

8.1 Supported Implants

ONE Planner® Hip 3D is to be used with the following hip replacement systems per their indications and contraindications:

- G7® Acetabular system.
- iG7® Acetabular System
- Avenir® Hip System
- Avenir Complete® Hip System
- Fitmore® Hip Stem
- MS-30® Hip System
- iTaperloc® Complete Hip System
- Taperloc® Complete Hip System
- Taperloc® Complete Microplasty® Hip System
- Wagner SL Revision® Hip System
- Z1™ Hip System

Compatibility does not imply availability for use within the software. The software only provides access to implants that are cleared and approved for use with this software in the user's country.

Compatibility also does not imply availability in terms of stock supply with local distributors. Contact applicable distributors for information on stock availability.

Please visit ZimmerBiomet.com/ONEPlannerHip for additional information.

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5596.1-GLBL-en-Issue Date-YYYY-MM

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