ZIMMER BIOMET
Moving You Forward.™

Signature™ ONE Planner

V2 User Guide

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Introduction

This user guide provides instructions for the use of the Signature™ ONE Planner V2 software application for pre-operative planning of the shoulder joint through the virtual placement of the humerus and scapula implant components.

The output from the application will be used to create a corresponding planning report, and if ordered, Signature™ ONE Shoulder Guides (for scapula planning only) and/or a scapula Bone Model for intra-operative use to help replicate the pre-operative planning.

Zimmer Biomet Signature™ ONE Indications for Use

The Signature™ ONE System is indicated, based on patient-specific radiological images with identifiable placement anatomical landmarks, to assist in pre-operative planning and/or intra-operative guiding of surgical instruments for shoulder replacement surgical procedures on patients not precluded from being radiologically scanned.

The Signature™ ONE System is designed for use on a skeletally mature patient population. The targeted population has the same characteristics as the population that is suitable for the implants compatible with the Signature™ ONE System.

The Signature™ ONE System is to be used with the glenoid components of the following shoulder implant systems in accordance with their indications and contraindications: Zimmer® Trabecular Metal Reverse Plus® Shoulder, Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Comprehensive® Reverse Augmented Baseplates and Alliance® Glenoid System.

The Signature™ ONE System pre-operative planning is also compatible with the humeral components of the following shoulder implant systems in accordance with their indications and contraindications: Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, and Identity™ Shoulder System.

The Signature™ ONE System Guides and bone models are intended for single use only.

Zimmer Biomet Signature™ ONE Contraindications

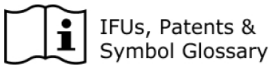
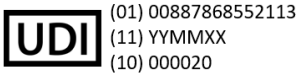
The Signature™ ONE System should not be used when the patient has metallic devices implanted that could interfere with the CT scan quality. Additionally, the Signature™ ONE System should not be used in cases where native bone is absent, or where a custom bone augment/graft will be used, on surfaces intended to mate with the Signature™ ONE Guides.

Notes:

- This manual concerns the Signature™ ONE Planner application for version 2.0 only.[1]
- Training is required prior to using the Signature™ ONE Planner application.
- The pre-operative plan is launched from the Zimmer Biomet portal, by selecting the applicable patient case.

1. The software version can be found in the About page of the One Planner.

Symbols

Pictogram	Description
	Federal law restricts this device to sale by or on the order of a physician
	Consult instructions for use
	Attention: Read all warnings and precautions in instructions for use
	UDI (Unique Device Identifier) where: (01) : Global Trade Item Number (GTIN) (11) : Production Date (YY: last two digit of product year, MM: Production month, XX: Production day) (10) : Lot Number
	Reference Number
	Batch code
	Manufacturer Information

These symbols can be found in the About page of the One Planner application.

Glossary

Term	Definition
2D Views	Includes the Coronal 2D view and the Transverse 2D view
Operator	Zimmer Biomet employee preparing the cases prior to surgeon plan review and approval
Planning Panels	SCAPULA planning panel and HUMERUS planning panel

Signature™ ONE Case ID

The Signature™ ONE case ID displayed in the planning application has 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. If guides are ordered for the case, the marking on the guides will be abbreviated due to space constraints.

Case ID example:
SAM123L50DD13UO

Printed on Pin Guide / Impactor Guide / Screw Guide / Rotational Guide: 123
Printed on Reamer Guide: SAM123L
Printed on Bone Model: SAM123L50DD13UO

S	AM	123	L	50	DD	13	U	O
1st letter of patient first name	First 2 letters of patient last name	Unique index assigned by ZB	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

Signature™ ONE Planner Bone Models

The application displays 3D bone models with osteophytes in the PREVIEW, HUMERUS and SCAPULA panels. However, in the JOINT and APPROVAL panels, the application displays 3D bone models with the osteophytes removed by operators.

If ordered, the PSI guides are designed from the scapula model with osteophytes.

PRE-OPERATIVE PLANNING

Upon launch, the application presents 3D models of the patient's scapula and humerus, with the operator-selected anatomical landmarks. The joint model displayed in the Preview panel is based on the CT images of the patient's entire scapula and proximal third of the humerus. Refer to Zimmer Biomet Signature™ ONE Shoulder CT Protocol for more details. The Preview panel also displays the reference axes and native version and inclination values (see Figure 1). For the scapula, a negative value of version indicates retroversion and a positive one indicates anteversion, whereas a negative value of inclination indicates inferior inclination and a positive one indicates superior inclination.

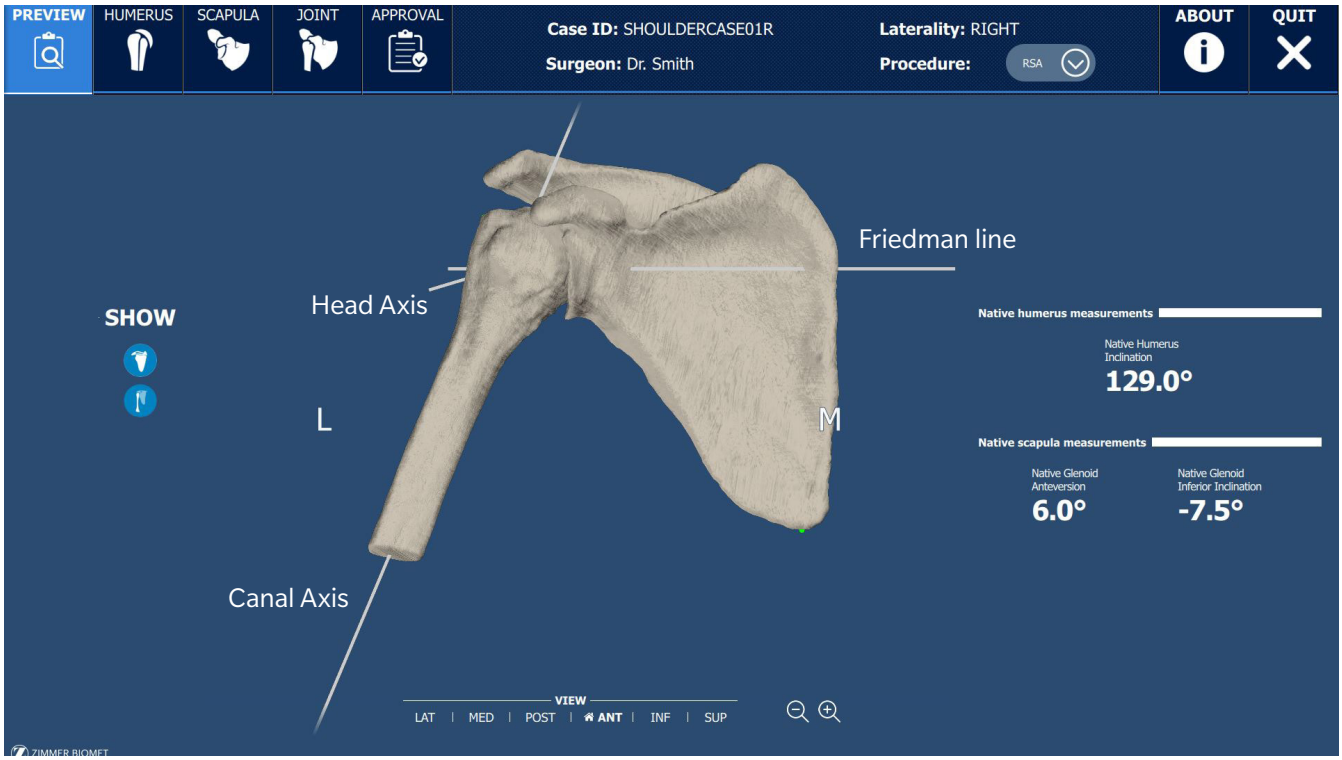


Figure 1 - Pre-plan view of the case seen when the application launches

For the scapula, these angles are based on the intersection of the scapula's anatomical planes and the scapular axis.

- The scapular axis is a line created between the center of the glenoid and the trigonum scapulae (intersection between the scapular spine and the medio-lateral border of the scapula). The scapular axis corresponds to the Friedman line.[1]

For the humerus, the angle is based on the humerus' anatomic neck plane and the humeral shaft axis.[2]

- The two humerus axes shown in Figure 1 are the canal axis[3] and the humeral head axis (vector normal to the anatomic neck plane).

Figure 2-left represents the scapular bone model in lateral view with the Glenoid center landmark and the rim landmarks. As shown in the Figure 2-right, these landmarks are used to calculate the glenoid plane and position the normal to the glenoid plane.

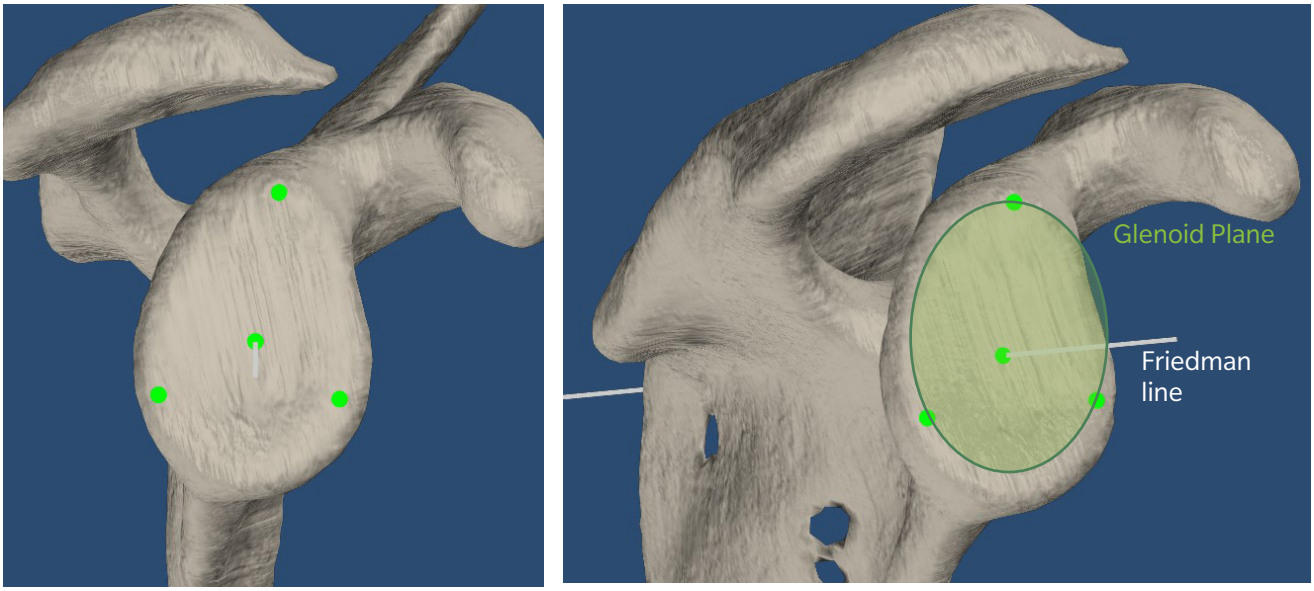


Figure 2 - Native glenoid landmarks (left), glenoid plane (right)

The native angles are defined as follows:

- The native glenoid version is the angle between the Friedman line and the vector normal to the glenoid plane projected onto the transverse plane. (Figure 3)

1. Friedman et al. The use of computerized tomography in the measurement of glenoid version. J Bone Joint Surg Am., 74 (1992), pp. 1032-1037.
2. Shaft axis is computed as the best fit line through the center of three cross sections of the cortical bone (outer diameter of the bone model). This axis is not displayed in the application.
3. Canal axis is computed as the best fit line through the center of three cross sections of the canal (inner diameter of the bone model).

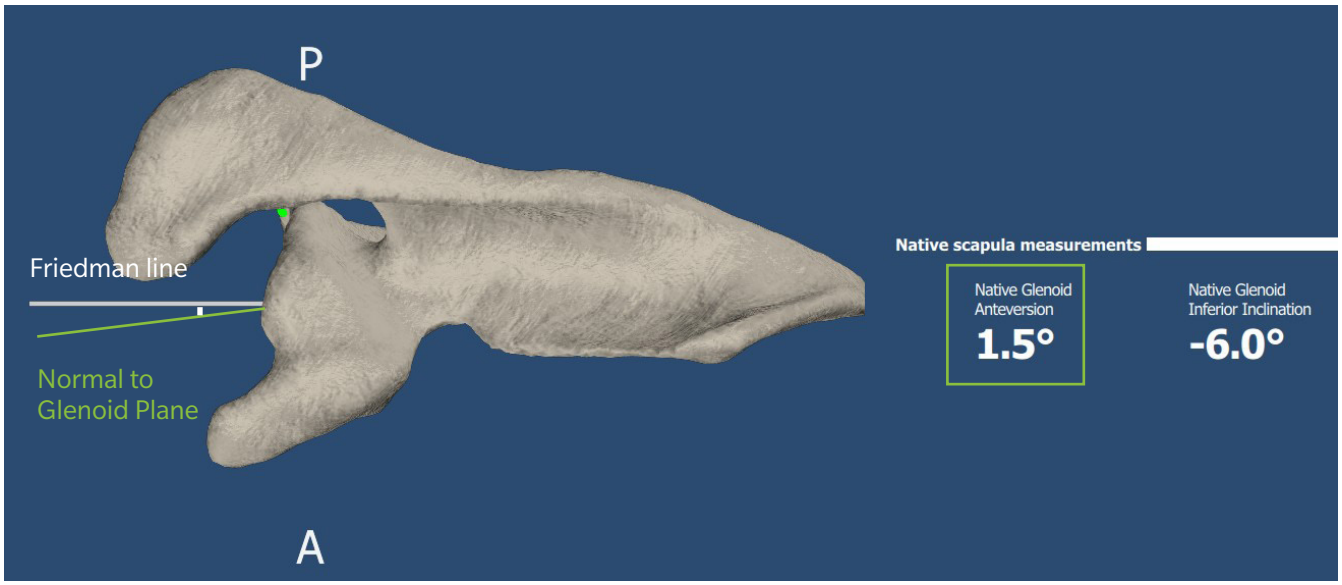


Figure 3 - Native glenoid version

- The native glenoid inclination is the angle between the Friedman line and the vector normal to the glenoid plane projected onto the coronal plane. (Figure 4)

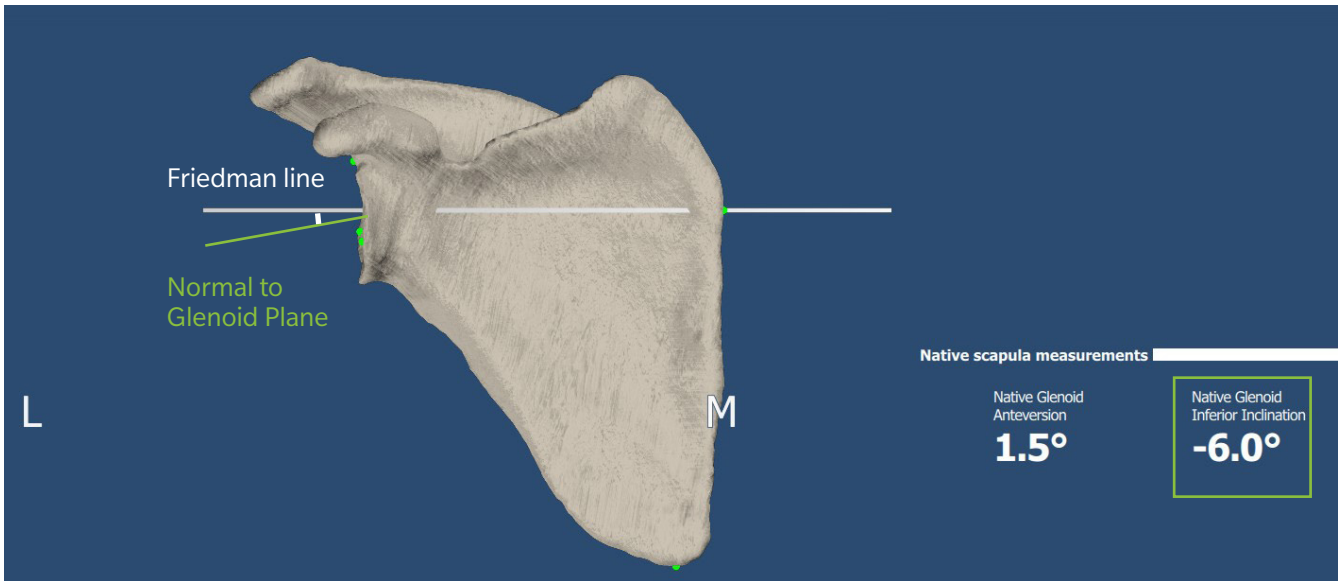


Figure 4 - Native glenoid inclination

- The native humerus inclination angle is defined as the angle between the humeral head axis (based on the anatomic neck) and the proximal humeral shaft axis. (Figure 5)

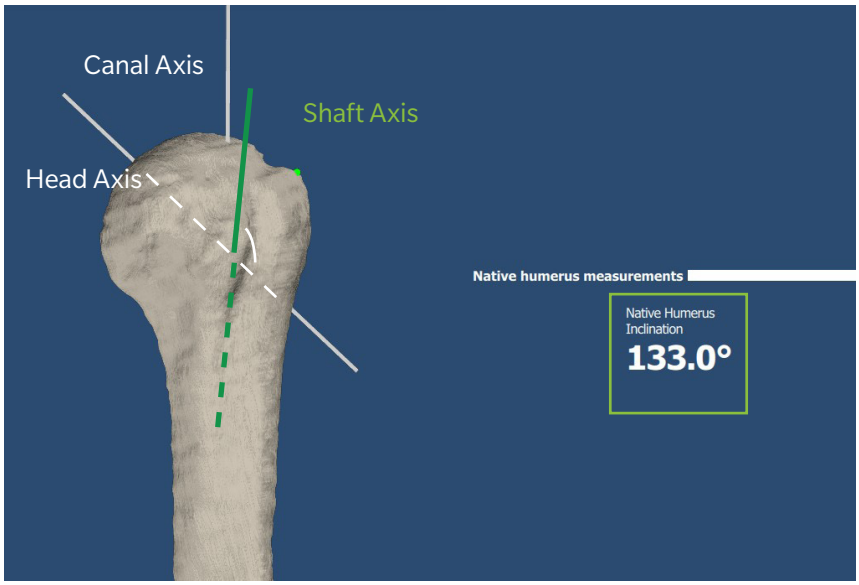


Figure 5 - Native humerus inclination

The controls shown in Figure 6 – left, allow to show or hide the humerus and/or scapula bone with their respective native measurement values.

The 3D model can be manipulated by left-click and dragged to rotate and right-click and dragged to translate, or by clicking on one of the 6 preset view buttons at the bottom of the screen (Figure 6 – center). The preset view with the home button resets the zoom and position of the humeral and scapula models to the default view.

The scroll wheel or the plus and minus buttons found on the right hand side of the views toolbar (Figure 6 – right) allow the user to zoom in or out of the humeral and scapula model.

Figure 6 - Humerus and scapula show/hide control (left), Preset views (center) and zoom buttons (right)

The top toolbar (Figure 7) displays the case ID, assigned surgeon, laterality and procedure, and provides controls to alternate between the following panels:

- Preview panel
- Humerus planning panel
- Scapula planning panel
- Joint panel, including the Joint Preview and ROM Evaluation sub-tabs
- Approval panel

The Procedure type can be toggled between TSA and RSA. This control is available in the preview panel, as well as the humerus and scapula planning panels.

The Quit button is always available to close the application with or without saving changes made to the plan. The About button displays relevant regulatory information applicable to the application.

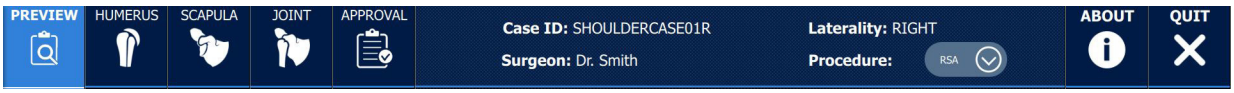


Figure 7 - Top toolbar of Signature™ ONE Planner application

General Planning

- **Component and Size Selection**
  In the Signature™ ONE Planner application, two types of selection menus are available: drop down menu and spinner control (Figure 8). For the drop down menu, when a component is selected the drop down menu shows all available options. After selecting the desired option, the selected option is displayed with blue background. Simply click anywhere else on the screen to accept the changes and close the drop down menu.

Figure 8 - Drop down menu (left), and spinner control (right)

When a component that has a spinner control is selected, in order to change its size, click on the left/right arrows to decrease/increase the component size to the next available size.

The selected and active component is displayed in blue in the 3D view and 2D views.

- **Camera Tool**
  The camera tool allows the freehand manipulation of the 3D model in the planning panels (Humerus and Scapula) and the Joint panel. The 3D model can be rotated by holding the left mouse button and can be dragged in the 3D scene by holding the right mouse button (Figure 9).

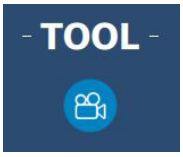


Figure 9 - Camera tool selected

- **Manipulator Tool**
  The manipulator tool allows to change the position and orientation of the selected implant component in the planning panels (when applicable). To activate it, click on the manipulator button in the tool menu (Figure 10).

Figure 10 - Manipulator tool selected

The manipulator tool is only available for the following implant components:

- In the HUMERUS panel, stem and head offset eccentricity
- In the SCAPULA panel, baseplate or glenoid, peripheral screws (for the TMR+ implant system) and glenosphere eccentricity

Once the implant manipulator is active, each button allows the **selected implant (in blue)** to move/rotate in a controlled direction.

Each click of a position arrow button (Figure 11-left) corresponds to a **translation movement of 0.5 mm,** whereas each click of a rotation arrow button (Figure 11-right) corresponds to **1 degree of rotation** in the 3D view or **0.5 degree of rotation** in the 2D views.

By pressing and holding down the mouse button the implant moves continuously and quicker, until the button is released.

Figure 11 - Implant position arrow (left) and implant rotation arrow (right)

Manipulation in the 3D view

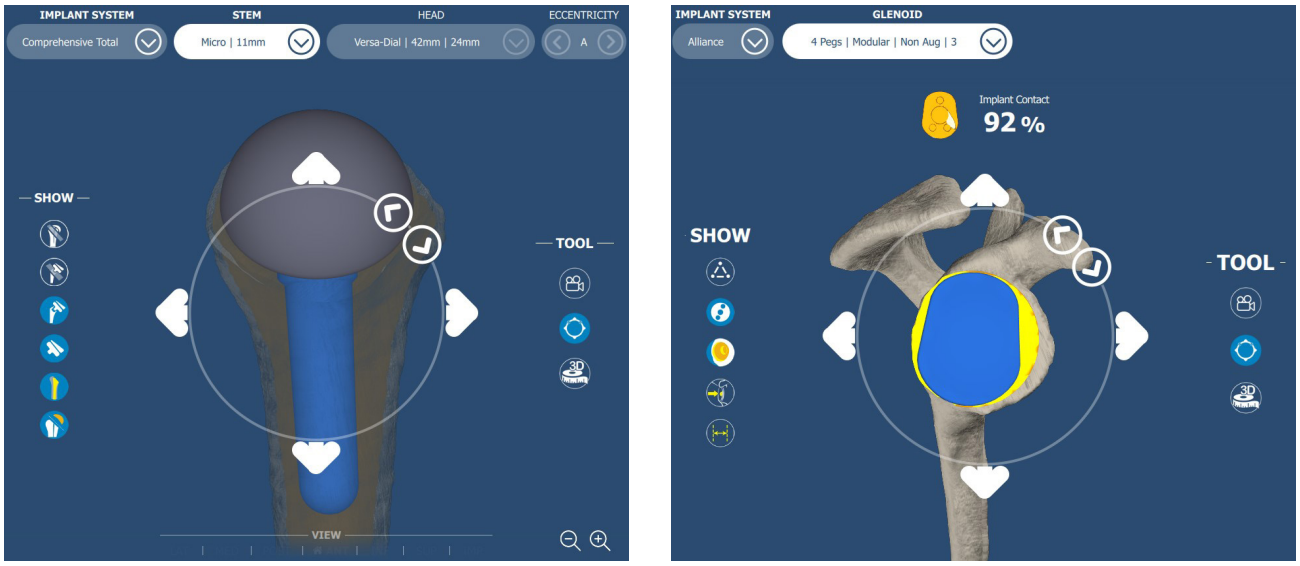


Figure 12 - Manipulator tool, Humerus stem positioning (left), and Glenoid component positioning (right)

In the 3D view, the four position arrows (Figure 11-left and Figure 12) allow the user to move the implant in anterior, posterior, inferior and superior.

Manipulation in the 2D view

Figure 13 - Stem is selected, allowing the user to show the manipulator in coronal view and move the implant

Figure 14 - Stem is selected, allowing the user to show the manipulator in transverse view and move the implant

A click on the top right view activates the manipulator in the coronal view (Figure 13) and a click on the bottom right view, when the superior view (SUP) is enabled, activates the transverse view manipulator (Figure 14).

The four position arrows allow the user to move the implant in superior, inferior, medial and lateral within the coronal view, and move in medial, lateral, anterior and posterior within the transverse view.

Within the coronal manipulator tool, the two rotation arrows allow adjustment of the implant **inclination** (Figure 13 and Figure 15). Within the transverse view, the implant **version** (or version offset from anatomical neck for the humerus) can also be adjusted with 0.5 degree of rotation per click (Figure 14 and Figure 16).

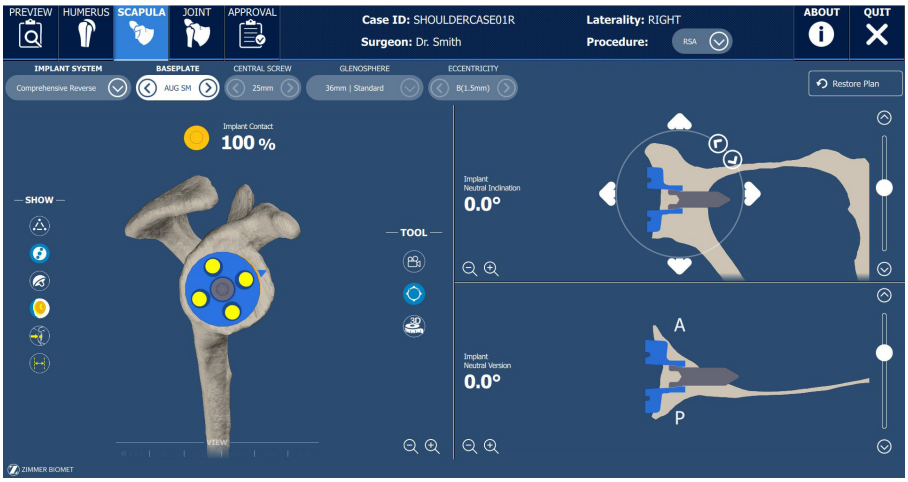


Figure 15 - Baseplate is selected, allowing the user to show the manipulator in the coronal view and move the implant

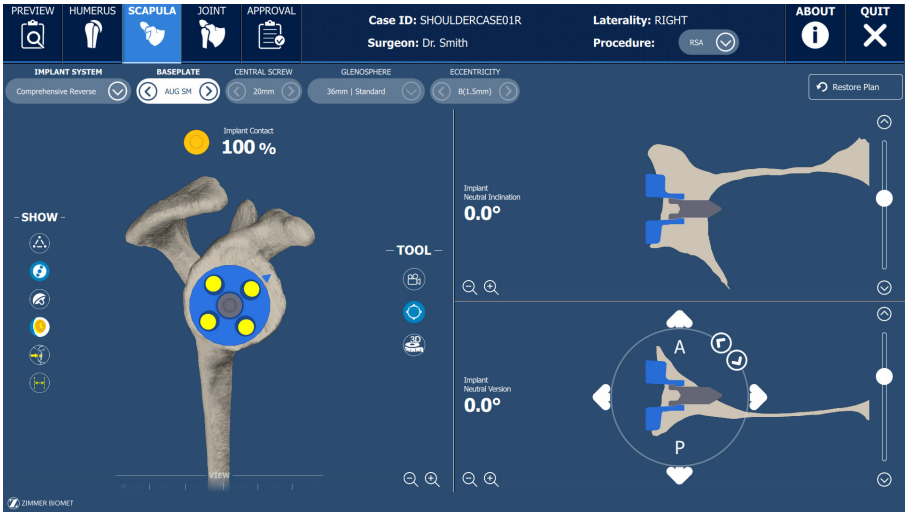


Figure 16 - Baseplate is selected, allowing the user to show the manipulator in the transverse view and move the implant

- **Scrolling in 2D views**
  In each 2D view, a scroll bar allows the user to navigate through the bone model and implant components. This can be done by using the scroll wheel while over the scroll bar, clicking and dragging the scroll bar or clicking on the arrows on either side of the scroll bar. (Figure 17)

  In the coronal view, scrolling up changes the view to a more posterior one and scrolling down changes the view to a more anterior one.

  In the transverse view, scrolling up moves the view superiorly and scrolling down moves the view inferiorly.

Figure 17 - Scrolling in 2D views

- **Measurement Tool**
  The 3D measurement tool allows taking of 3D distance measurements on the model in the 3D view and/or in a slice in the 2D views. The 3D measurement tool is available in the planning panels and JOINT panel. To activate it, click on the 3D measurement button in the tools menu (Figure 18 - left).

  Click on any of the shown models in the 3D or 2D views to place the first point at the desired location.
  Click again on any of the shown models in any view to place the second point at the desired location.

  The two selected points and the line between the two are displayed in all views. The 3D distance measurement is displayed in the 3D view in millimeters (mm) as per Figure 18 – right.

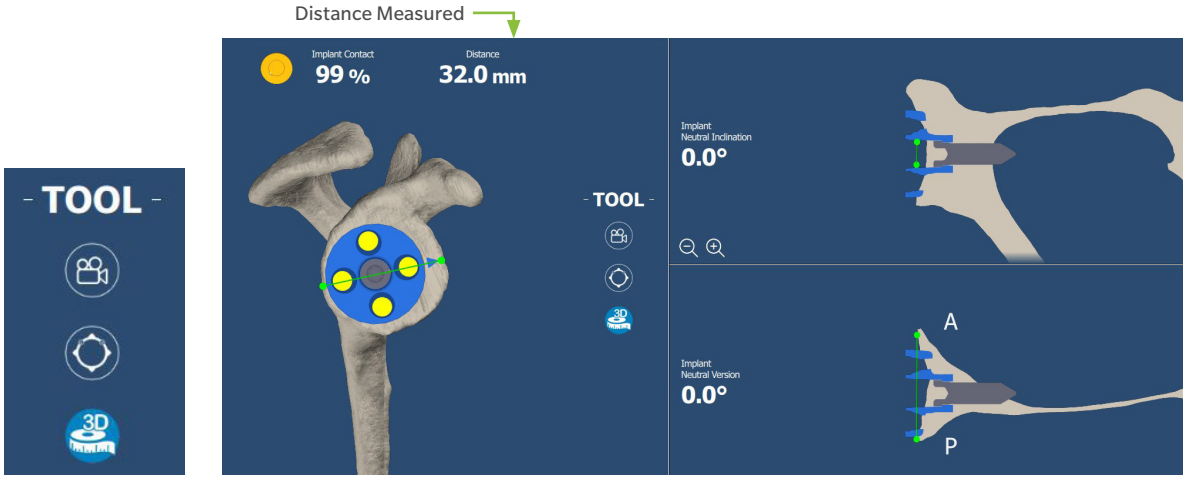


Figure 18 - Left: 3D measurement tool (bottom button, highlighted) to take 3D distance measurements. Right: 3D distance measurement shown on 3D model in the 3D view and in 2D views

- **Eccentricity Manipulation in 3D View**
  In the planning panels, the eccentricity manipulator allows the user to adjust the eccentric humerus' head component in TSA procedure and the eccentric glenosphere component in scapula RSA procedure planning.

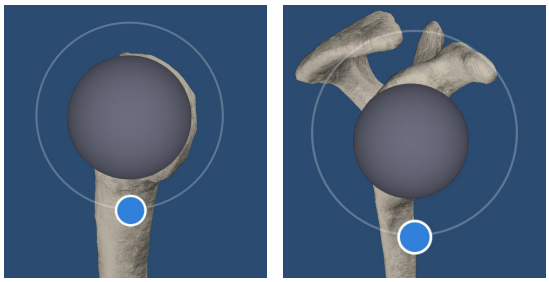


Figure 19 - Eccentricity manipulator on the humerus for TSA (left) and on the scapula for RSA (right)

Drag the blue circle shown in Figure 19 to adjust the eccentricity orientation.

- **Restore Plan**

  If the user wishes to restore the planning to the last saved plan, the user may click on the "Restore Plan" button on the top right. If no plans were saved by the surgeon, this button will restore the planning to the initial state provided by Zimmer Biomet.

  Note that the "Restore Plan" button will restore the plan for both HUMERUS and SCAPULA panels but only for the current procedure.

Humerus

This tab allows for planning of the humeral implant component types, sizes and positions. It is composed of the three views as shown in Figure 20 : a 3D view (left), a 2D coronal view, which is aligned with the anatomic neck (upper right), and a 2D transverse view (lower right).

Figure 20 - Humerus tab in the Signature™ ONE Planner application. 3D model view (on the left side), 2D coronal view (upper right) and 2D transverse view (lower right)

All sizes and lengths can be adjusted by using the drop down menu to select the appropriate size or by using the left/right arrows to decrease/increase the component size/offset (Figure 21).

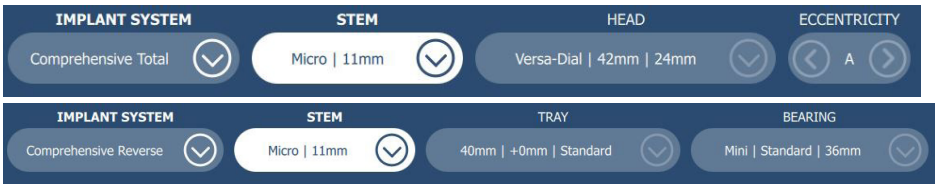


Figure 21 - Humerus implant selection and sizing menus for TSA (top) and RSA (bottom)

In the implant system drop down menu, only the implant brands for the selected procedure type are available (Figure 22).

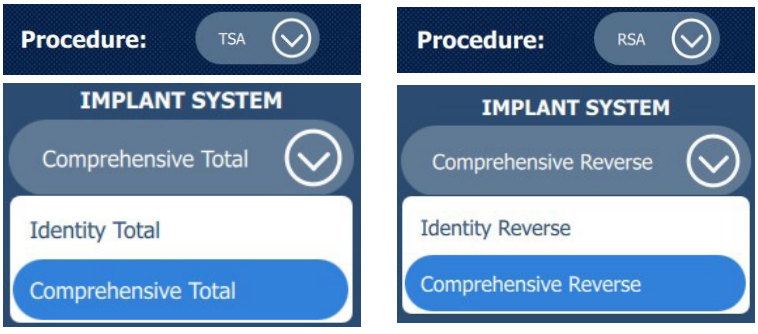


Figure 22 – Available Humerus implant systems (may vary per region), with selection in blue

The following parameters may be adjusted from the selection menus:

For Comprehensive Total:
- Stem length | size
- Head model | width | height
- Eccentricity offset

For Comprehensive Reverse:
- Stem length | size
- Tray diameter | offset | size
- Bearing model | offset | size

For Identity Total:
- Stem length | size
- Stem adapter size
- Head width | height
- Eccentricity offset

For Identity Reverse:
- Stem length | size
- Tray orientation | positioning | offset
- Bearing offset | size

The humerus stem drop down menu allows selection of stem component size and length (Figure 23).

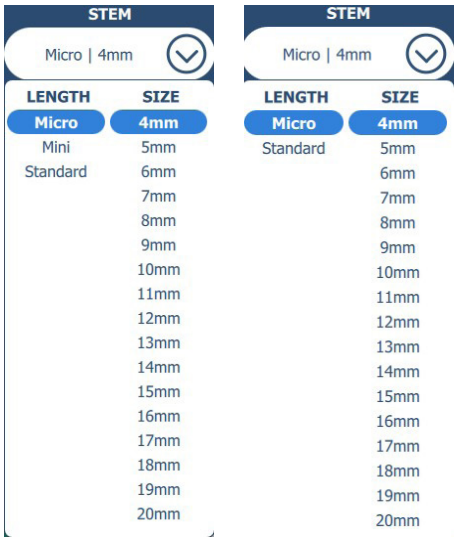


Figure 23 - Humerus stem selection, Comprehensive implant system (left) and Identity implant system (right)

In the RSA procedure, for Comprehensive Reverse, the tray drop down menu allows selection of tray components diameter, offset and size (Figure 24-left). For Identity Reverse, the tray options are orientation, positioning and offset (Figure 24-right).

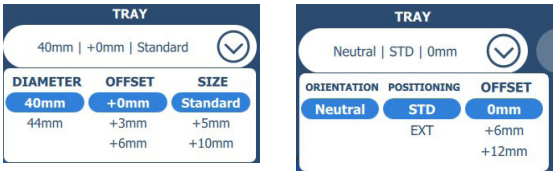


Figure 24 - Humerus tray selection, Comprehensive Reverse tray (left) and Identity Reverse tray (right)

After selecting the desired tray component, the user may click anywhere else on the screen to accept the changes and close the drop down menu. However, the selected tray diameter should be compatible with the bearing model. The incompatible components will be displayed in orange as shown in the Figure 25. Refer to the Incompatibility section for more details.

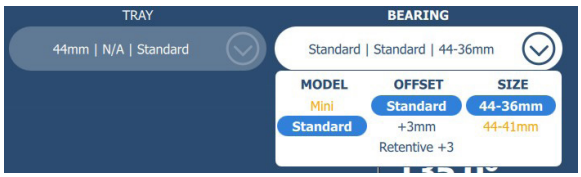


Figure 25 - Humerus Comprehensive Reverse bearing selection for 44mm tray

- **Display options – Humerus**
  The controls shown in Figure 26 allow showing or hiding of different humeral planning components.

Anatomic neck plane and axis, and greater tuberosity landmark

Cut plane and axis, canal axis, and implant COR (in TSA only)

Humeral assembly components

Humeral upstream components

Bone transparency

Bone cut

Figure 26 - Humerus show/hide controls

- **Transverse 2D view: Superior and Implant view toggle**
  In the bottom right 2D view, the toggle view button allows the user to change the transverse view from superior to implant view. The implant view (Figure 27-right) orients the 2D view in the same direction as the implant axis.

Figure 27 – Transverse view toggle; Superior view (left) and Implant view (right)

- **Stem Perforation**
  During the stem manipulation, it is possible to perforate the humeral cortical bone. Therefore, a visual indication and a message are displayed (Figure 28) when the humeral stem component may be perforating the humeral canal. However, this does not prevent the user from accessing other panels and approval of the plan is still allowed.

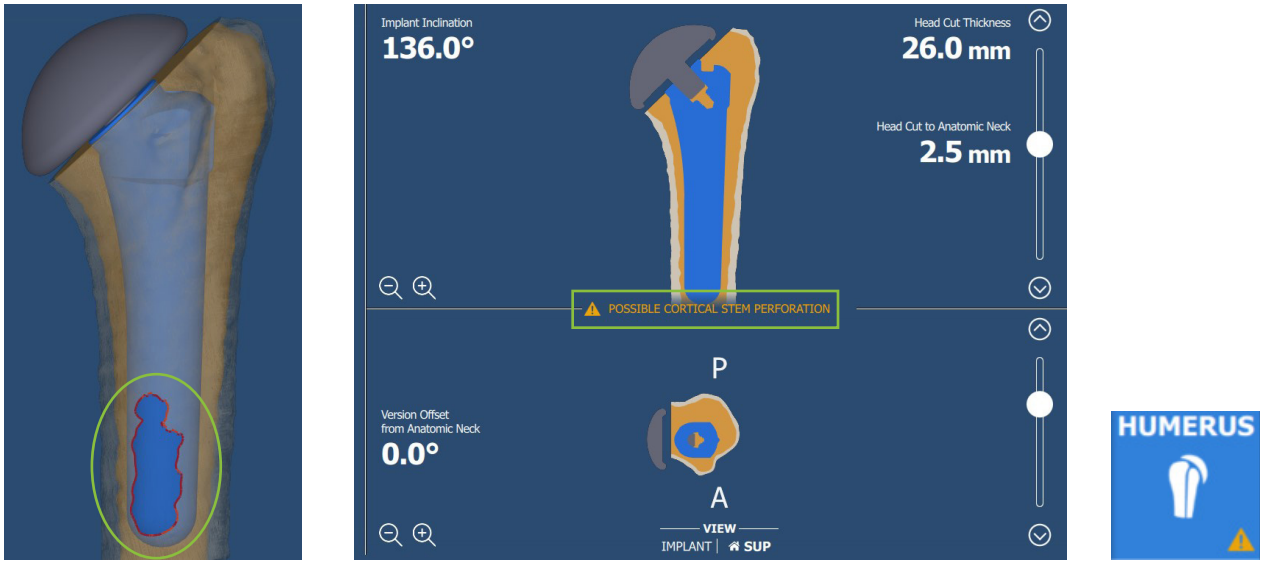


Figure 28 - Stem perforation; visual indication on the 3D model (left), stem perforation notification (center), visual indicator on HUMERUS panel tab (right)

- **Implant Inclination**
  Within the coronal view, the two rotation arrows contained in white circles allow adjustment of the implant inclination (i.e. humeral cut inclination), and the value indicates superior inclination in reference to the shaft axis.

- **Version Offset from Anatomic Neck**
  In the transverse plane, the humeral implant is by default orientated such that its **version is aligned with that of the anatomic neck plane.** To be more specific, the 0.0 degree of version offset from the anatomic neck is represented as the projected implant axis (green axis) parallel to the humeral axis (normal to the anatomic neck plane - white axis) in the transverse view, as seen in Figure 29.

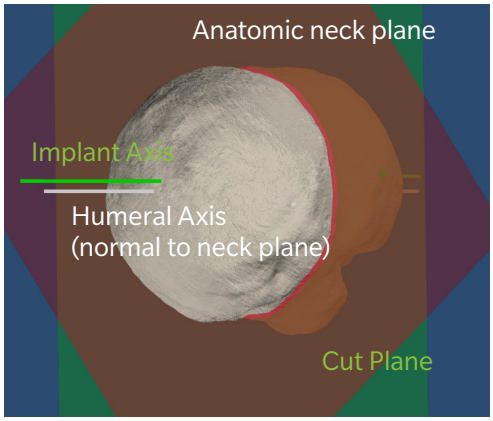


Figure 29 - Humeral version offset from anatomic neck in default position

In the transverse view, the version offset from anatomic neck will be negative when the implant is rotated posteriorly and positive when rotated anteriorly (Figure 30).

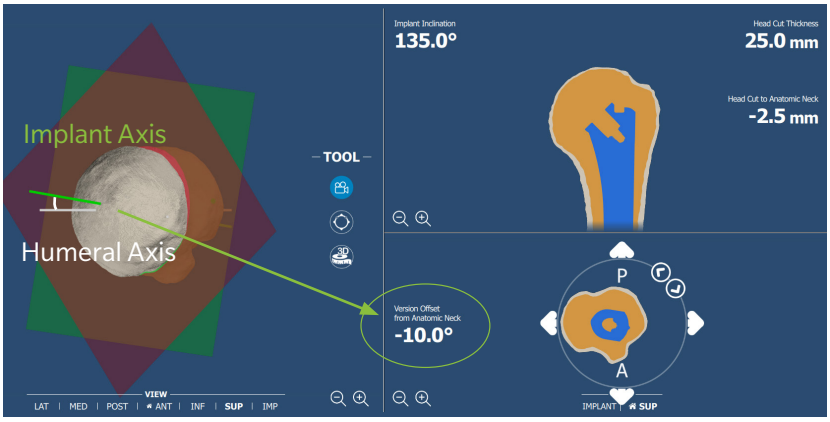


Figure 30 - Humeral version offset from anatomic neck, when the implant is rotated posteriorly in the transverse view

- **Implant rotation in the sagittal plane**
  In the 3D view, the humeral stem can be rotated in anterior/posterior in the sagittal plane. No value is provided for this adjustment, as this rotation is only used to align the stem with the canal axis.

- **Head Cut Thickness**
  The Head Cut Thickness represents the thickness of the humeral bone being resected. To be more specific, it is defined as the distance between the cut plane and the furthest point from the cut plane on the articular surface (Figure 31).

- **Head Cut to Anatomic Neck**
  The Head Cut to Anatomic Neck is defined as the distance between the anatomic neck plane and the cut plane following the direction of the humeral head axis (Figure 31).

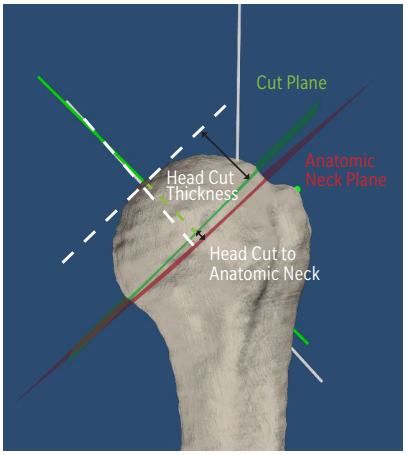


Figure 31 – Head Cut Thickness & Head Cut to Anatomic Neck distances

Scapula

This tab allows for planning of the glenoid implant component types and positions. It is composed of the three views as shown in Figure 32 : a 3D model view (on the left side), a 2D coronal view (upper right) and a 2D transverse view (lower right).

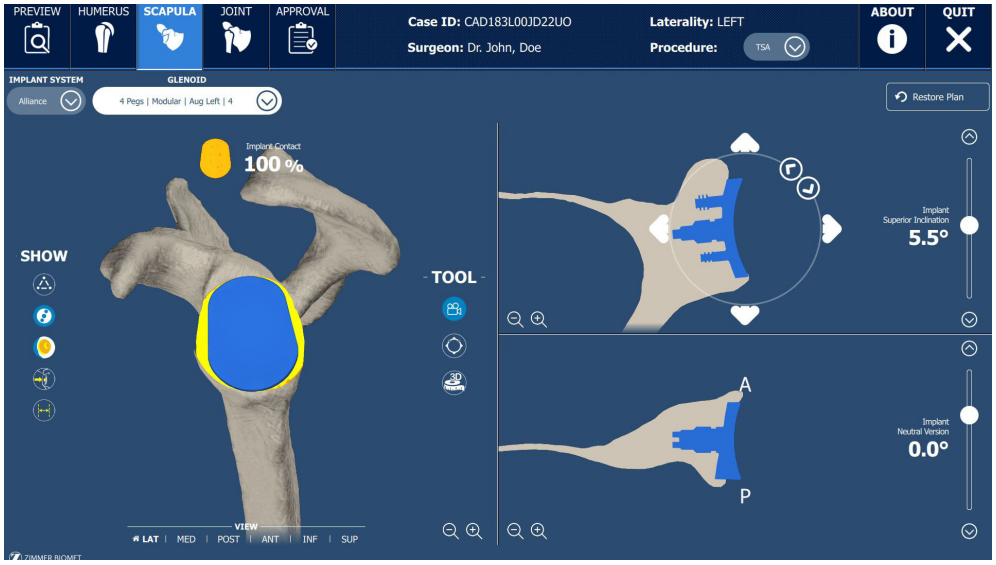


Figure 32 - Scapula tab in the Signature™ ONE Planner application. 3D model view (on the left side), 2D coronal view (upper right) and 2D transverse view (lower right)

All sizes and lengths can be adjusted by using the left/right arrows to decrease/increase the component size to the next applicable size (Figure 33), except for the Alliance Glenoid (TSA) and Glenosphere (RSA) components, where a drop down menu is used to select the appropriate size.

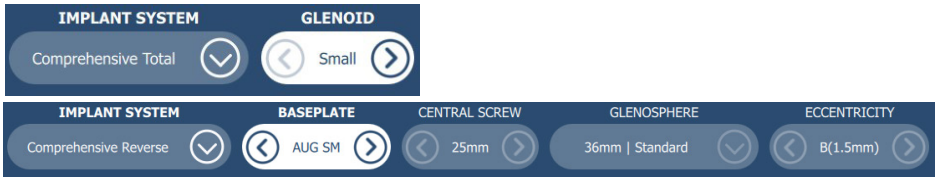


Figure 33 - Scapula implant selection and sizing menus for TSA (top) and RSA (bottom)

In the implant system drop down menu, only the implant brands for the selected procedure type are available (Figure 34).

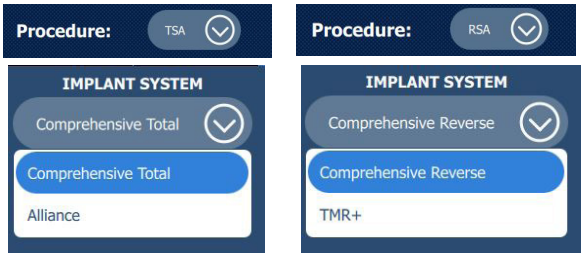


Figure 34 - Available Scapula implant systems (may vary per region), with selection in blue

The following parameters may be adjusted from the selection menus:

For Comprehensive Total:
- Glenoid Component size

For Alliance:
- Glenoid Component size

For Comprehensive Reverse:
- Baseplate/Augment size
- Central Screw length
- Glenosphere diameter | offset
- Eccentricity offset

For TMR+:
- Baseplate size
- Superior Screw length
- Inferior Screw length
- Glenosphere diameter | offset | eccentricity

The Alliance glenoid drop down menu allows selection of four glenoid component parameters (Figure 35):
- Number of pegs
- Peg type
- Augment option
- Glenoid Component size

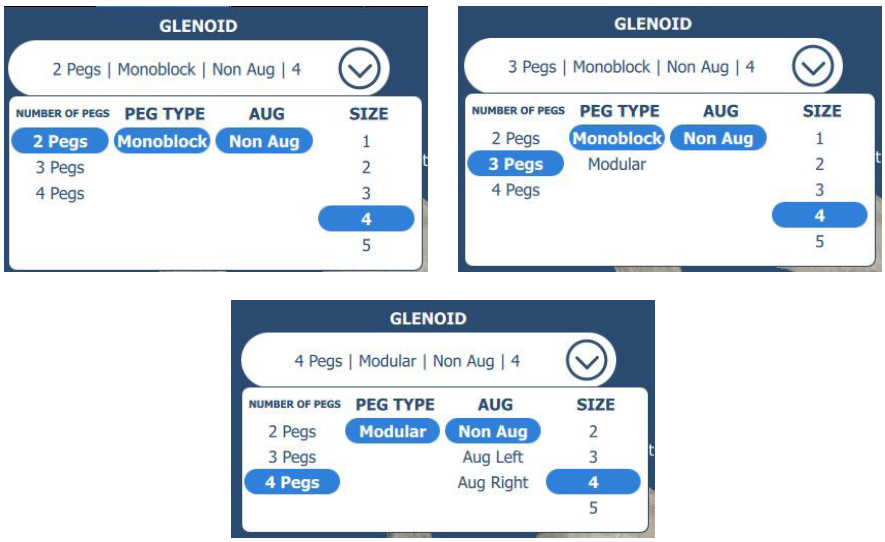


Figure 35 - Glenoid Component parameters for Alliance

The glenosphere drop down menu allows selection of three glenosphere parameters (Figure 36):
- Glenosphere diameter
- Medio-lateral offset
- Inferior eccentricity (for TMR+ only)

Figure 36 - Glenosphere sizing options for TMR+ (left) and Comprehensive Reverse (right)

After selecting the desired parameters for the glenoid component or glenosphere, click anywhere else on the screen to accept the changes and close the drop down menu.

- **Display options – Scapula**

  The controls shown in Figure 37 allow showing or hiding different scapula planning components. Note that depending on the procedure, the glenosphere display control may not be available.

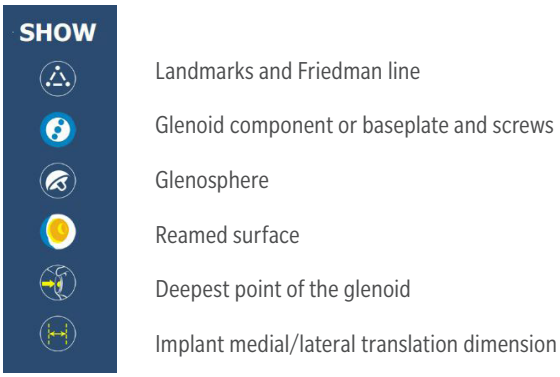


Figure 37 - Show/hide controls

The **Medial/Lateral Translation** of the implant can be displayed in the 2D views by clicking on its associated control in the Show/Hide menu (Figure 38). This value is rounded to 0.5 mm and is equal to the distance along the Friedman line between the most lateral point of the glenoid and the implant's backside.

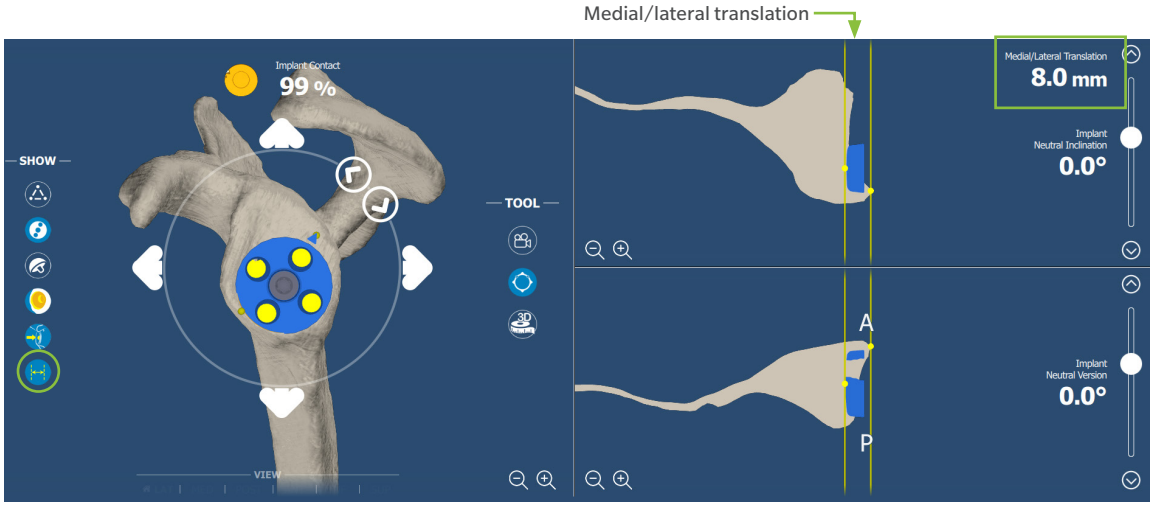


Figure 38 - Medial/Lateral Translation is shown (last button on the left is selected) and its value is displayed in the coronal view

The **Deepest point** of the glenoid indicates the most medial point of the glenoid surface based on the plane normal to the Friedman line. This point can be displayed to assist in the positioning of the augmented Comprehensive Reverse implant. If an augmented Comprehensive Reverse implant is selected, an arrow is provided to indicate the direction of the augment on the baseplate. At the surgeon's discretion, this arrow can be oriented to point towards the deepest point (Figure 39).

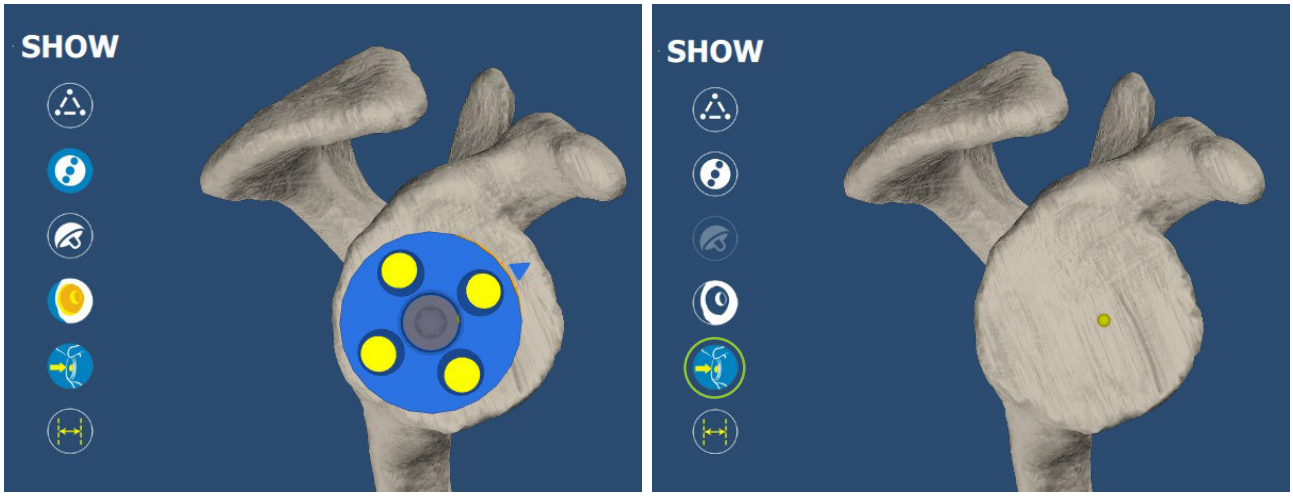


Figure 39 - Baseplate with the arrow indicating the augment direction (left); Deepest point landmark (right)

- **Baseplate/Glenoid Rotation, Inclination and Version**
  In the 3D view, the baseplate/glenoid rotates about the implant axis and the two arrows contained in white circles (Figure 11-right) allow rotation of the component with 1 degree of rotation per click. Furthermore, while the mouse button is held down, the rotation increment becomes larger.

  When the coronal manipulator is active, the two arrows contained in white circles allow adjustment of the baseplate or glenoid component **inclination,** with 0.5 degree of rotation per click.

  Within the transverse view, the baseplate or glenoid component **version** can also be adjusted with 0.5 degree of rotation per click. A negative number indicates retroversion and a positive one indicates anteversion.

- **Contact Percentage**
  Above the scapula, in the 3D view, the **percentage of contact** between the implant and the bone is displayed. This percentage corresponds to the area of the backside of the implant that is in contact with the glenoid over the total area of the backside of the implant.

- **Peripheral screws manipulator in the 2D views (for TMR+ only)**
  To change the size of one of the peripheral screws, select the desired screw on the implant selection and sizing menu, and click on the left/right arrows (Figure 40).

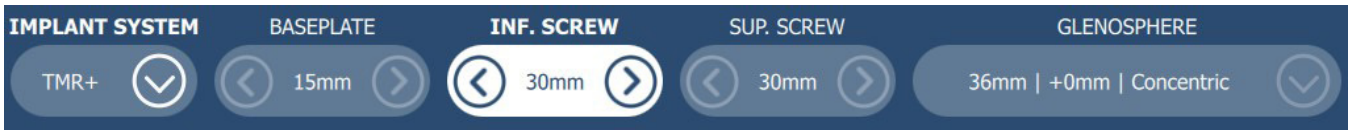


Figure 40 - Inferior screw is selected

If one of the peripheral screws is selected and the user clicks on one of the 2D views, a manipulator allowing angular adjustments of the screw is shown (Figure 41). The screw selected is highlighted in blue.

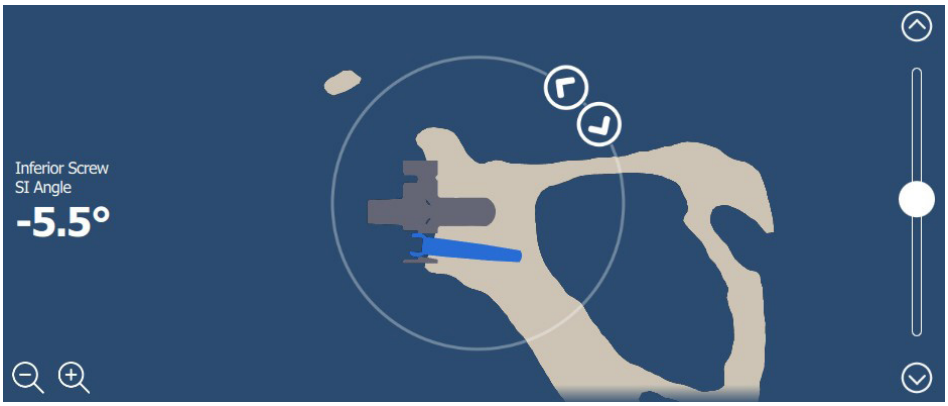


Figure 41 - Angular adjustment of the peripheral screws in the 2D views

The two arrows contained in white circles (Figure 41) allow adjustment of the peripheral screw angle. The current screw supero-inferior (SI) angle is displayed in the coronal 2D view, on the lateral side of the bone. The current screw antero-posterior (AP) angle is displayed in the transverse 2D view, on the lateral side of the bone.

The superior screw SI angle can be adjusted to values between 0° and 8° in 0.5° increments.

The inferior screw SI angle can be adjusted to values between 0° and -8° in 0.5° increments.

The superior screw AP angle can be adjusted to values between -8° and 8° in 0.5° increments.

The inferior screw AP angle can be adjusted to values between -8° and 8° in 0.5° increments.

The resulting angle of the AP and SI angles of each screw must be less than or equal to 8° total (Figure 42). If the screw reaches its angular limit, the control to change the angle in that direction will be disabled and increasing the angle in the other 2D view will also be disabled (Figure 43). A notification will be displayed, for example ⚠ INFERIOR SCREW ANGLES LIMIT REACHED, indicating which screw is at the maximum angle. To re-activate the angle controls blocked because of the reached limit, change the AP or SI angles that are permitted.

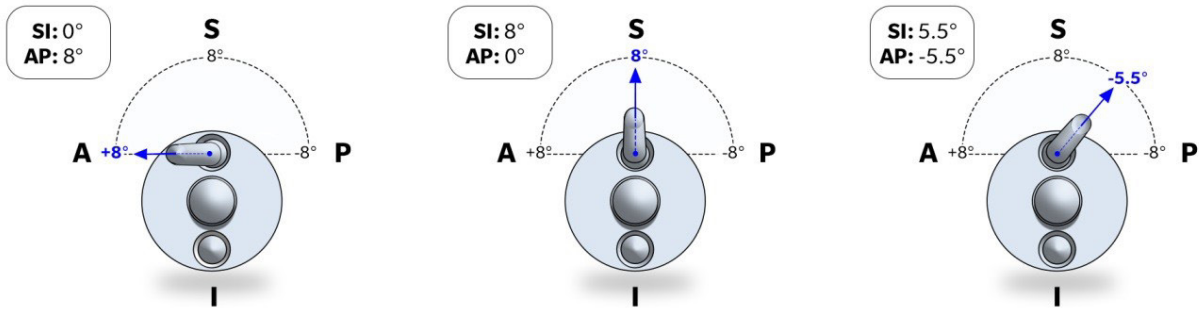
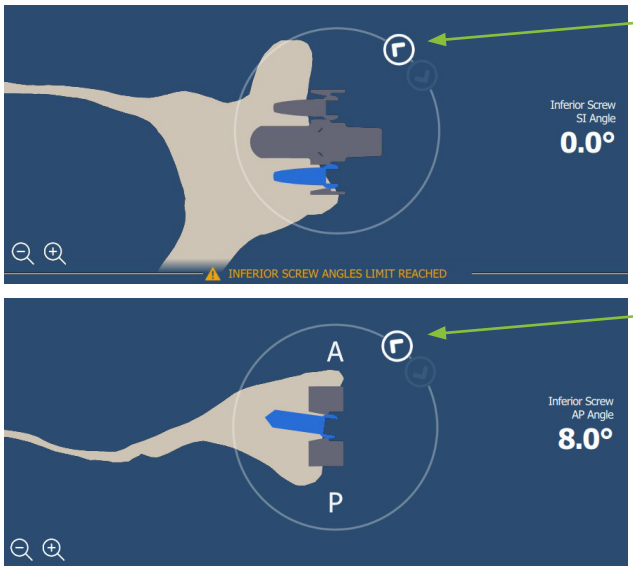


Figure 42 - Maximum angles of the peripheral screws in the implant



The inferior screw AP angle is at maximum value. The control to change the SI angle is blocked unless the inferior screw angle is brought further posterior.

The control to change the angle to a more anterior AP angle is blocked.

Figure 43 - Inferior Screw AP and SI angles at maximum, blocks the controls to further increase angles. A notification is displayed between the 2D views

- **Screws marked as incomplete**
  If the baseplate is moved after completing the screw placement, the screws are marked as incomplete ⚠ (Figure 44) in the application to ensure that their orientation and/or length is reviewed prior to approving the case.

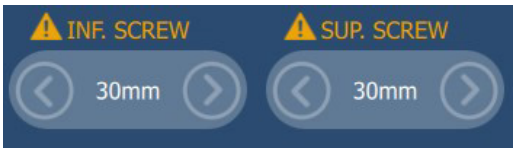


Figure 44 - Screws marked as incomplete

In this case, the JOINT and APPROVAL panels are disabled until the screws are reviewed.

Clicking on the screws selector to acknowledge that the screw length and orientation have been reviewed allows confirming the screws and enabling the JOINT and APPROVAL panels again.

Incompatibility

In order to access to the JOINT and APPROVAL panels, the selected implants in the planning panels must be compatible.

- **Implant component intra-incompatibility**
  Implant intra-incompatibility appears when the implants within one panel are not compatible. For the humeral Comprehensive Reverse implant system, some trays are not compatible with some bearings. If a component selector has multiple options, the incompatible options are visually identifiable in orange.

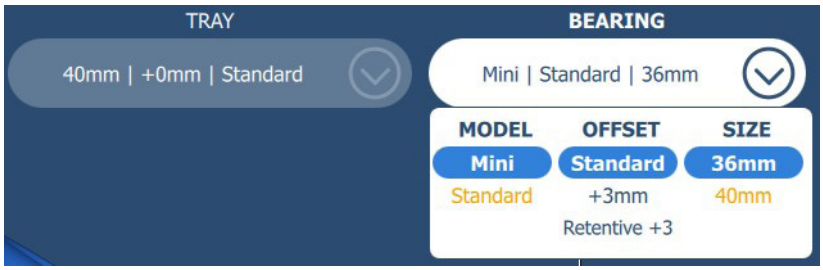


Figure 45 - Example of Humerus Comprehensive Reverse Bearing incompatibilities (in orange) with a 40mm Tray

If an incompatible option is selected, visual indicators will be displayed (Figure 46):

- On the HUMERUS panel tab, a notification symbol, ⚠
- On the incompatible components, a notification symbol, ⚠
- Below the implant system selector, a notification message that identifies the incompatible components.

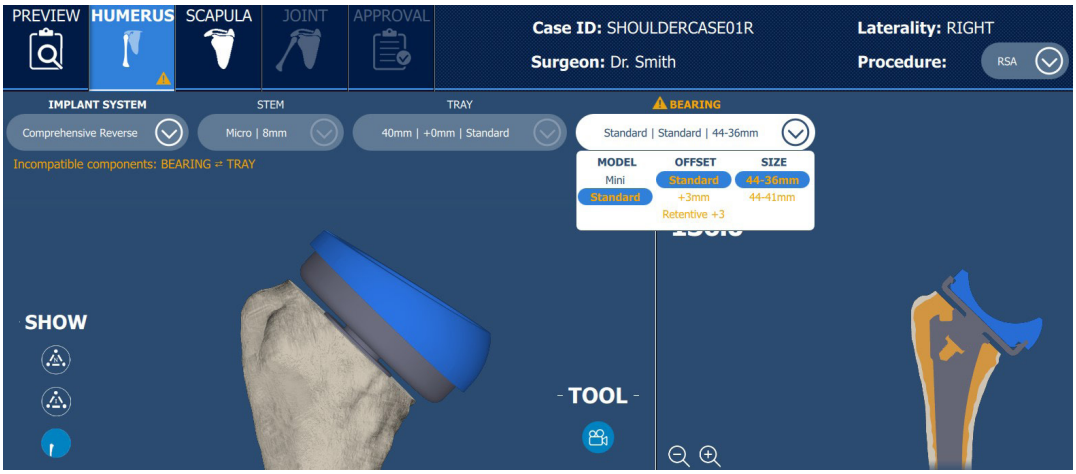
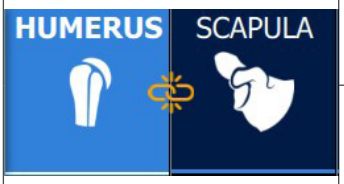


Figure 46 – Example of Humerus Comprehensive Reverse incompatibilities with a 40mm Tray and Standard Bearing

- **Implant component inter-incompatibility**
  Implant inter-incompatibility appears when the selected implants between the HUMERUS Panel and the SCAPULA Panel are not compatible with each other. For any implant components that are not compatible between the planning panels, the application displays the following visual indications:
  - Between the HUMERUS and SCAPULA panel tabs, a broken chain symbol ,
  - On the incompatible components, a notification symbol, ⚠
  - Below the implant system selector, a notification message that identifies the incompatible components.

The Signature™ ONE Planner application displays the associated visual indications for the selected surgical procedure and implant system (Table 1).

Table 1 - Incompatible implant components visual indications

Panel	Top toolbar indication	Notification message	Incompatible Component
HUMERUS Panel		Incompatible components: BEARING ⇄ GLENOSPHERE	BEARING
		Incompatible components: HEAD ⇄ GLENOID	HEAD
SCAPULA Panel		Incompatible components: GLENOSPHERE ⇄ BEARING	GLENOSPHERE
		Incompatible components: GLENOID ⇄ HEAD	GLENOID

To resolve the inter-incompatibility between the HUMERUS and SCAPULA panels, follow the visual indications in the respective planning panels and select a component that is compatible (not highlighted in orange).

Joint

Click on the JOINT tab button in the top toolbar when implant component planning (humerus and scapula) is completed. The JOINT panel has two sub-tabs: Joint Preview and ROM Evaluation.

Note that the JOINT panel/ROM evaluation is **optional** in the Signature™ One planning application flow, and provides supplementary information and estimations only (refer to Assumptions below).

- **Joint Preview sub-tab**
  The Joint Preview sub-tab displays the humerus and scapula with their implant components in 3D view and 2D views (Figure 47).

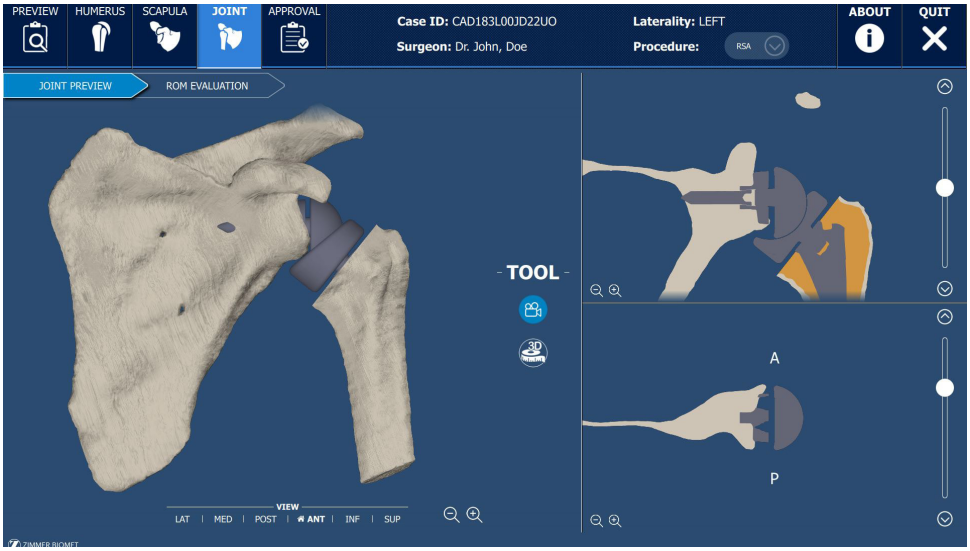


Figure 47 - Joint sub-tab: Joint Preview

- **Range of Motion (ROM) Evaluation sub-tab and Assumptions**
  The ROM evaluation sub-tab displays the humerus and scapula with their implant components in 3D view, as well as the Implant Values, Humeral Shift distances and Humerus Motions.

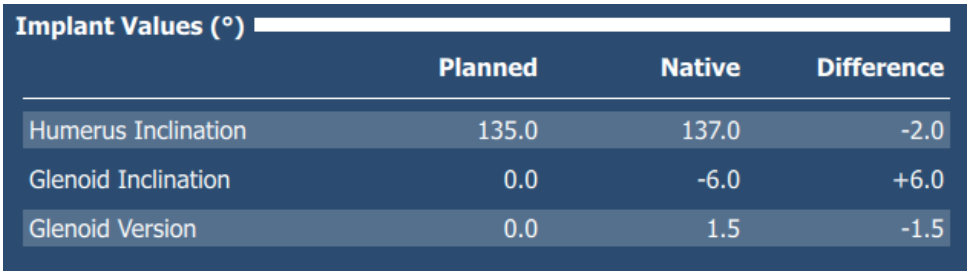
  Assumptions:
  As displayed in the UI (bottom right), it is to be noted that the Range of Motion (ROM) simulation assumes a rigid scapula with no soft tissue and models with osteophytes removed by operators (Figure 48).

  Note that during TSA planning simulations, the humeral motion is approximated as a rotation of the humeral head about a center of rotation, without any translation.

Figure 48 – Joint sub-tab: ROM evaluation

- **Implant Values**
  The Implant Values assessed are the following: Humerus inclination, Glenoid inclination and Glenoid version.

  Three values are displayed for each Implant Value. The first is the planned value (same as the implant angles in the planning panels). The second value is the native value (same as the measurements in the Preview panel), and the third value is the difference between the planned value and the native value (Figure 49).



Implant Values (°)

	Planned	Native	Difference
Humerus Inclination	135.0	137.0	-2.0
Glenoid Inclination	0.0	-6.0	+6.0
Glenoid Version	0.0	1.5	-1.5

Figure 49 - Implant values in ROM Evaluation sub-tab

- **Humeral Shift values**
  In the Humeral Shift section, the AP distance (Anteriorization), the ML distance (Lateralization) and the SI distance (Distalization) are displayed (Figure 50). These values are the result of the calculated distance between the **center of the native humeral head** and the **center of the native glenoid surface.** Refer to Figure 51 for a visualization of the humeral shift distances.

Same as the Implant Values, three values are displayed for each Humeral Shift distance (Figure 50). The first value is the absolute distance between the bones with the planned implant configuration. The second value is the native distance, and the third value is the difference between the planned bone positions and the native bone positions (the shift).

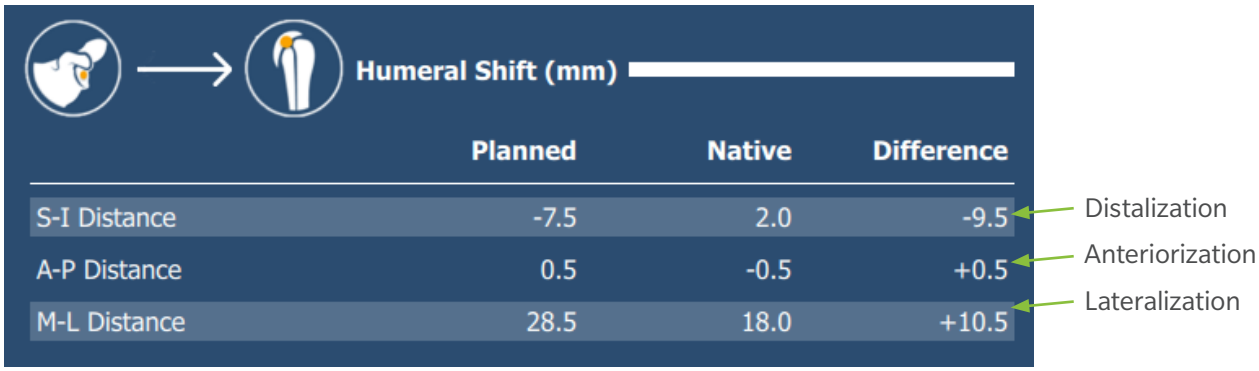


Figure 50 – Humeral Shift values in ROM Evaluation sub-tab

For instance, in Figure 50, it is shown that the M-L native distance (prior to planning) between the center of the native humeral head and the center of the native glenoid surface is 18.0 mm. The planned M-L distance between both centers after the placement of the implant components is 28.5 mm. Therefore, the difference between the planned M-L distance and native M-L distance shows that the joint was lateralized by 10.5 mm.

Refer to the following for the Planned and Native distances:

- A positive value refers to the Humeral Head Center being Superior/Anterior/Lateral relative to the Glenoid Center
- A negative value refers to the Humeral Head Center being Inferior/Posterior relative to the Glenoid Center

Refer to the following for the Humeral Shift (Difference) distances:

- A positive value refers to the shoulder joint having been shifted Superior/Anterior/Lateral relative to the native position.
- A negative value refers to the shoulder joint having been shifted Inferior/Posterior/Medial relative to the native position.

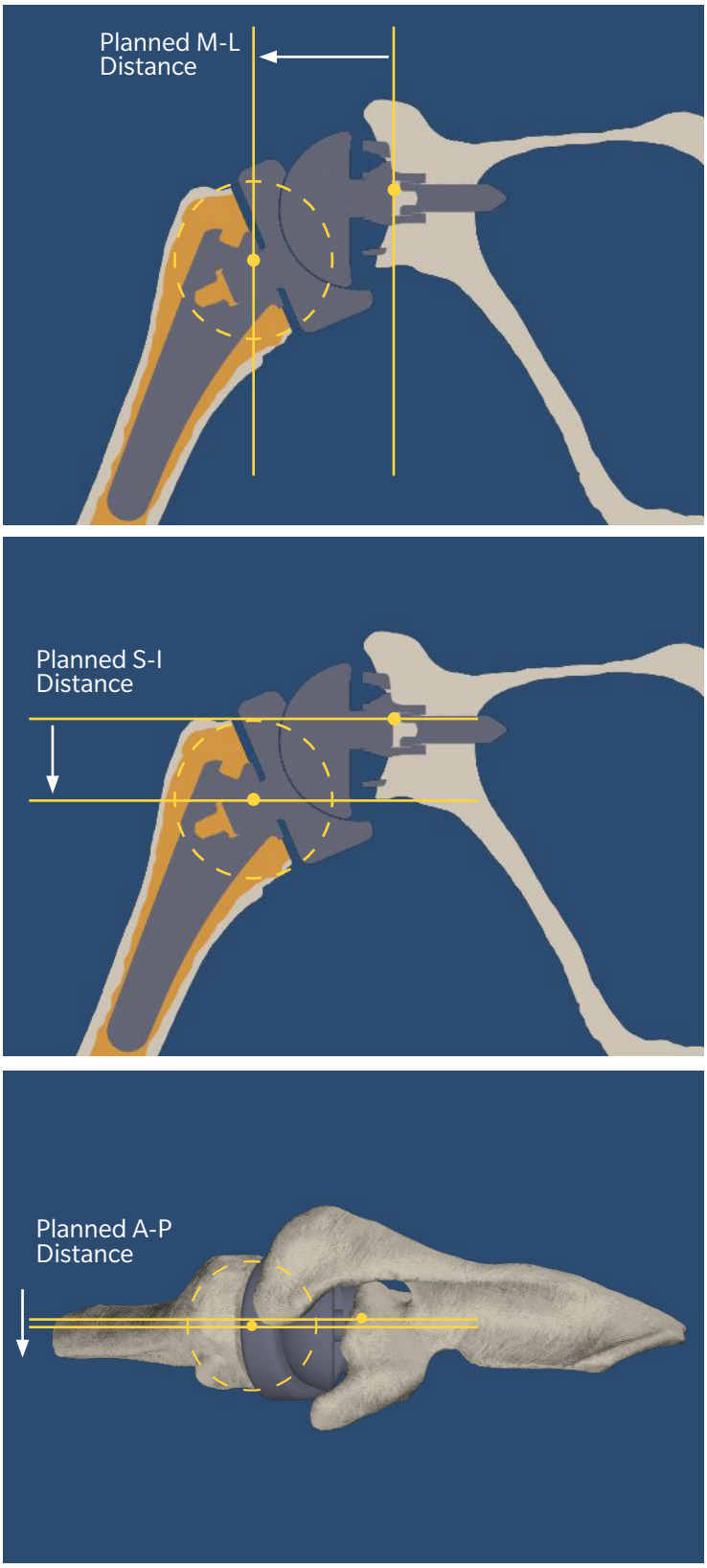


Figure 51: Visualization of the Humeral Shift distances between the Glenoid Center and the Humeral Head Center

- **Humerus Motions**
  In the Humerus Motions section, the glenohumeral motions with their range (angle) limits are displayed (Figure 52 and Table 2).

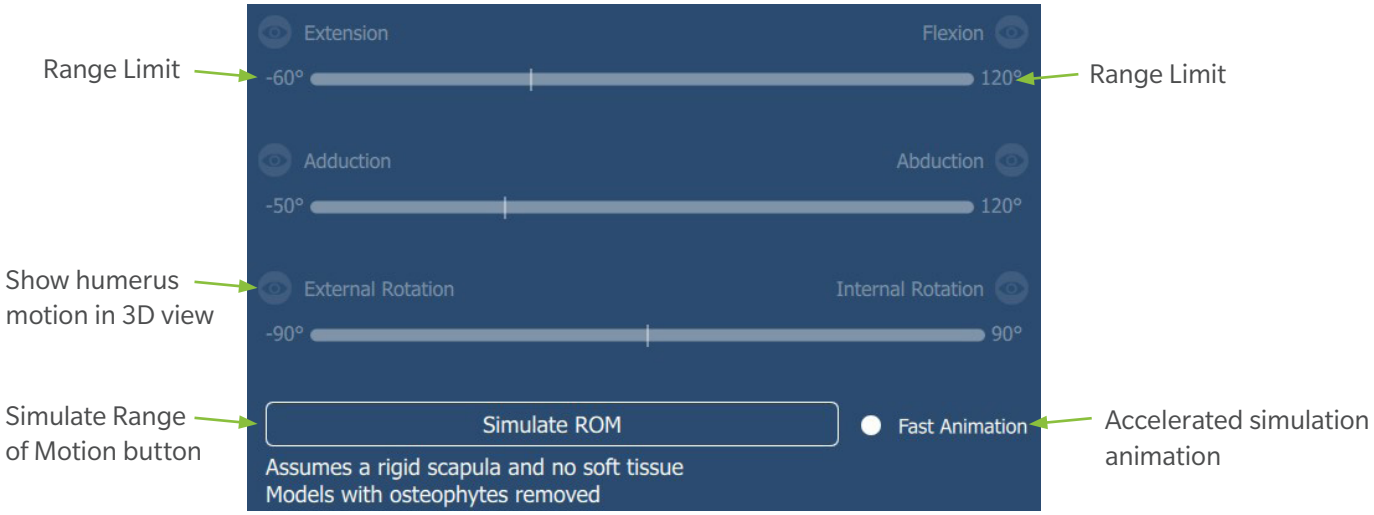


Figure 52 - Humerus Motions before ROM simulation

Table 2 - Glenohumeral motions and ROM maximum angles

Motion	Maximum Glenohumeral ROM (*)
Flexion is measured as a rotation of the humerus within the sagittal plane of the scapula in the anterior direction, starting from the shoulder joint's resting position.	120
Extension is measured as a rotation of the humerus within the sagittal plane in the posterior direction, starting from the shoulder joint's resting position.	60
Abduction is measured as a rotation of the humerus within the coronal plane of the scapula in the lateral direction, starting from the shoulder joint's resting position.	120
Adduction is measured as a rotation of the humerus within the coronal plane of the scapula in the medial direction, starting from the shoulder joint's resting position.	50
Internal Rotation is measured as a rotation of the humerus within the transverse plane of the scapula in the anterior direction, starting from the shoulder joint's resting position.	90
External Rotation is measured as a rotation of the humerus within the transverse plane of the scapula in the posterior direction, starting from the shoulder joint's resting position.	90

As mentioned in the Table 2, the humerus motions are started from the joint's resting position. During CT acquisition, the patient will be in supine with arms extended, and relaxed. Relaxed, being the point of greatest joint laxity. This will be the initial scanned position.

The application will then align the humerus to ensure that the native humeral head axis is within the frontal plane of the scapula. This will serve as the joint's resting position and initial reference point for humeral motions during the ROM simulation.

The **Simulate ROM** button will run the simulation of Range of Motion (ROM) with a **rigid scapula, no soft tissue** and **models without osteophytes.** During the ROM simulation, each humeral motion is performed until a collision (bony impingement or an implant contact) is detected. However, if no bony impingement or implant contact occurs, the humeral motions are stopped at their respective maximum range (Figure 53).

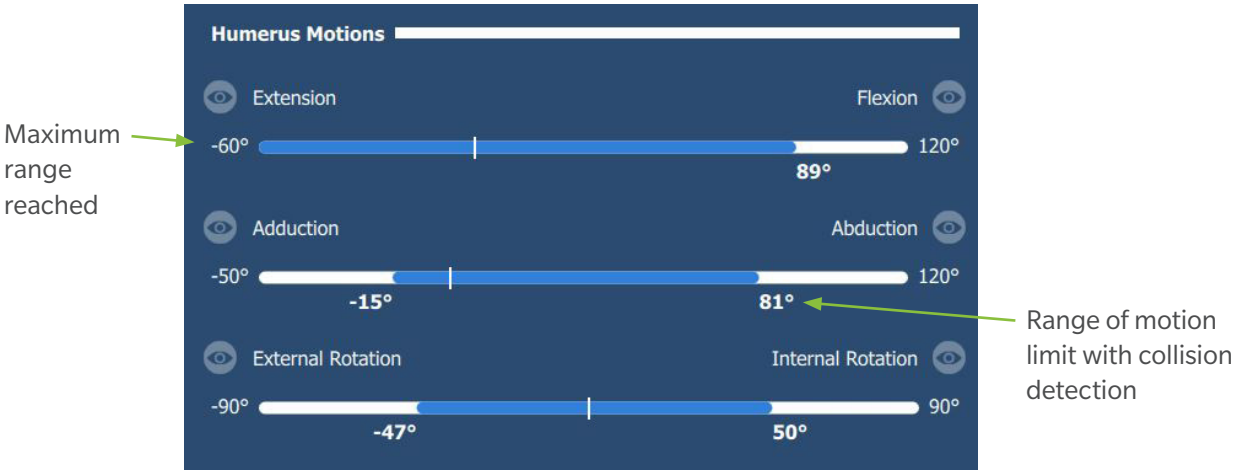


Figure 53 - Humerus motions after ROM simulation

- **ROM collision visualization**

  Each glenohumeral motion has an eye icon to visualize the position of the humerus bone and implant model (Figure 53).

  When the user clicks on the icon, it is highlighted and the detected collision (bony impingement and/or implant contact) is displayed in the 3D scene (Figure 54). The collision visualization appears in red (Figure 55).

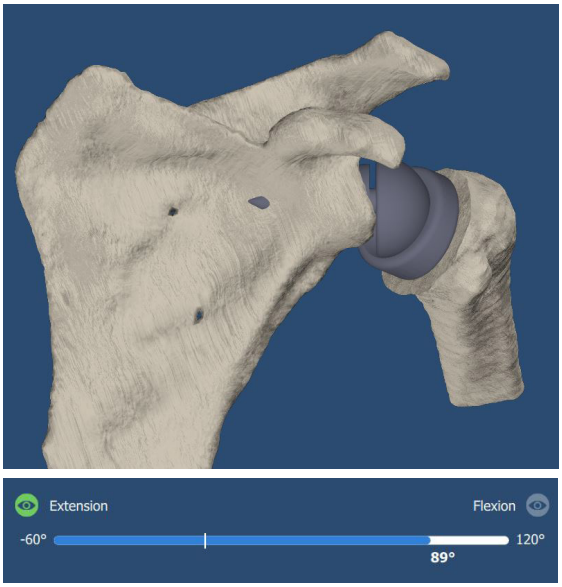


Figure 54 - Extension motion visualization without collision reaches the max 60° of extension

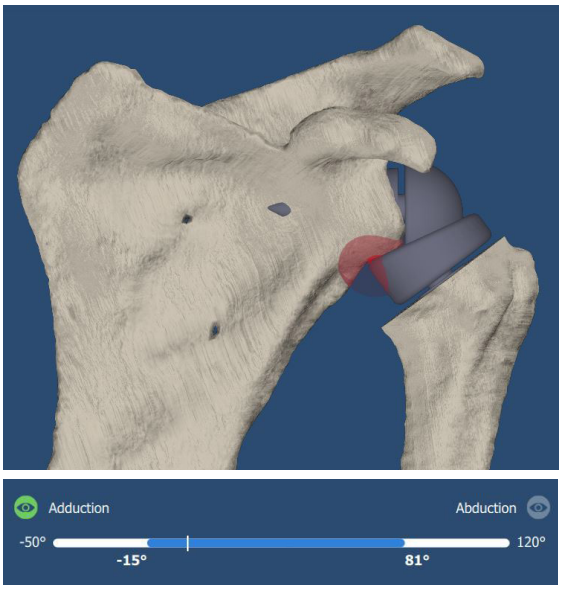


Figure 55 - Adduction motion visualization collision at 15° of adduction

Note: The joint's resting position is defined as the starting point of the ROM simulation. If impingement is detected in the joint's resting position, the ROM simulation will not be able to determine humerus motions and no ranges will be provided (zero degree values will be displayed) (Figure 56). In this scenario, the user should adjust component positioning to avoid impingement at the resting position.

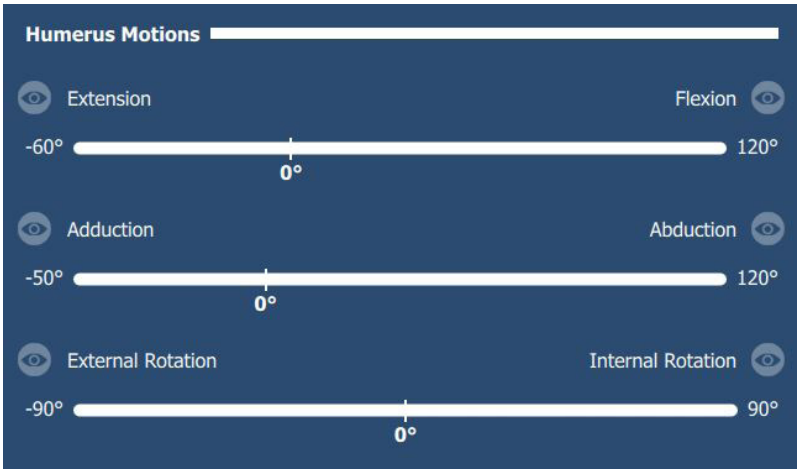


Figure 56 – ROM simulation result if there is impingement at resting position

Any changes in the planning panels will reset the humerus motion values in the ROM evaluation sub-tab and the notification symbol ⚠ will appear on the JOINT panel. Running the ROM simulation again will resolve the notification and will display the new values for the humerus motions.

Pre-Operative Review and Approval

Click on the **APPROVAL** tab button in the top toolbar when implant component modification is complete.

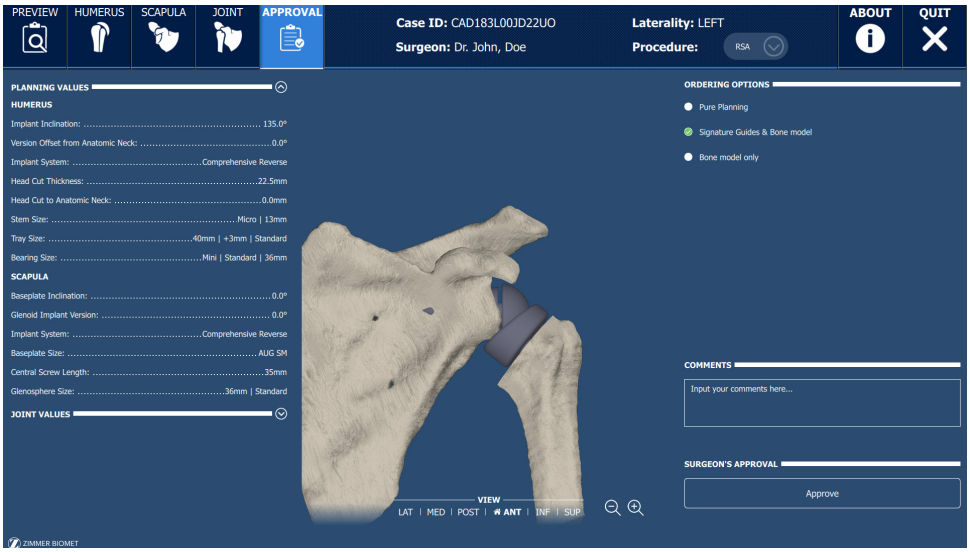


Figure 57 - Approval tab

In the middle of the screen is a 3D view of the humerus and scapula with their planned implant components, which can be manipulated in the 3D space (Figure 57).

The left side of the Approval tab presents a summary of implant components of the planning panels (angles, sizes and brands selected in the HUMERUS and SCAPULA panels) (Figure 57), and the JOINT panel values (Figure 58) in two collapsible menus.

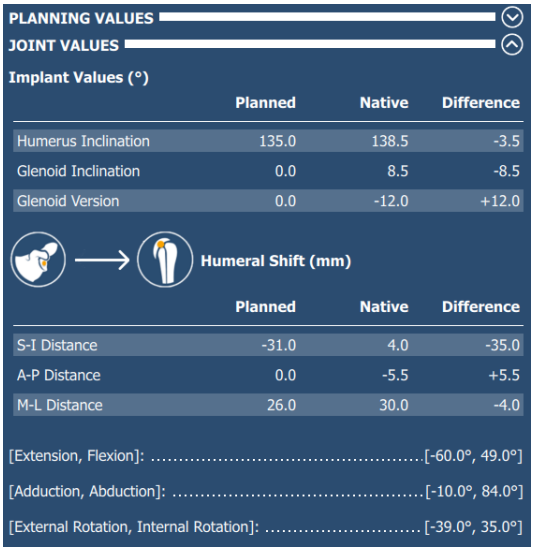


Figure 58 - Joint Values available in collapsible menu of Approval panel

On the right hand side of the screen is a comment box that can be used for any notes specific to the case. These notes will be included in the Surgical Planning Report (PDF file provided after approval).

In the **ordering options** section, the user has the following options:

- Pure Planning: Surgical Planning report is provided, without guides or bone model
- Guides and Bone Model: A pin guide, reaming guide, applicable impactor guide, applicable screw guide, applicable rotational guide and scapula bone model are manufactured based on the planning and shipped for the surgery
- Bone model only: The planning report is provided alongside a physical model of the reconstructed scapula bone.

For TMR+ cases, if the guides and bone model option is selected, the user must select a reaming option: either the Single Use or Reusable reamer (Figure 59).

Note that the selected reamer must be used in surgery. Otherwise, the provided reamer guide cannot be used in the surgery.

Figure 59 - Reamer options for TMR+ cases

When ready to **approve**, the user may click on the Approve button (Figure 57), at which point they will be prompted with a window asking to confirm the ordering options.

If the Comprehensive Reverse implant system is selected, the compatible reamer type is shown in the confirmation window. The only reamer supported is the Comprehensive Reverse reamer part number 110029136 (Figure 60).

After clicking the Confirm button, a window asking for the surgeon credentials (Figure 61) is shown. Once the credentials are entered and the Approve button is clicked, the plan is saved, sent for manufacturing and the application will close.

When the plan is saved or approved, the application will generate the Surgical Planning Report in .pdf format.

No changes can be made to the pre-operative plan after it has been approved. If the case is reopened in the Signature™ One planning application after the plan has been approved, the case will be in read-only mode.

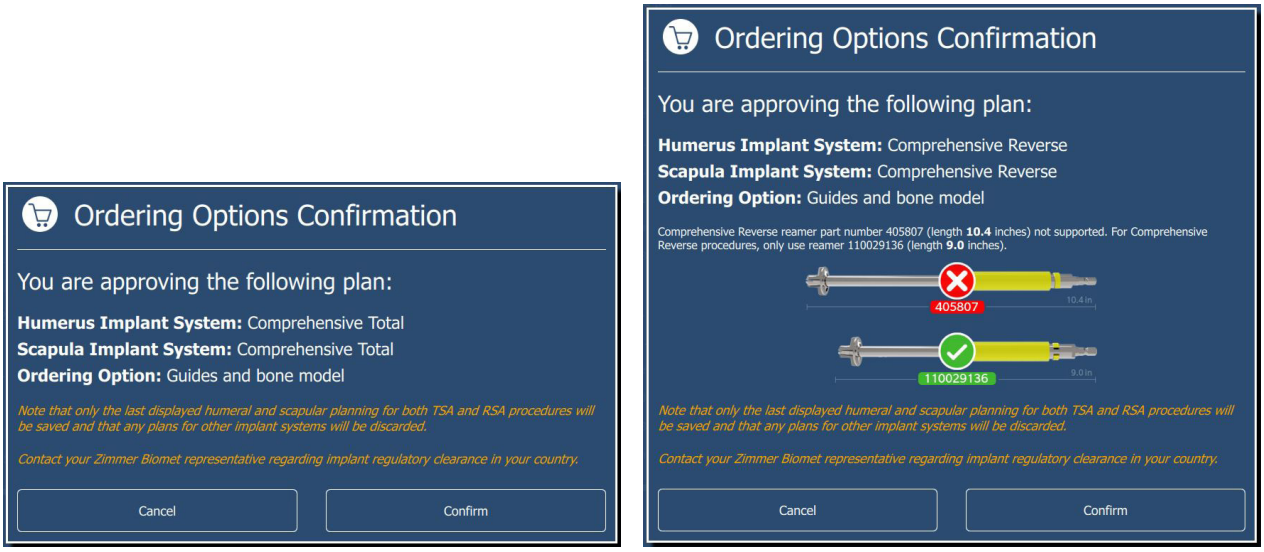


Figure 60 - Ordering Options Confirmation window for Comprehensive Total (left) and for Comprehensive Reverse (right).

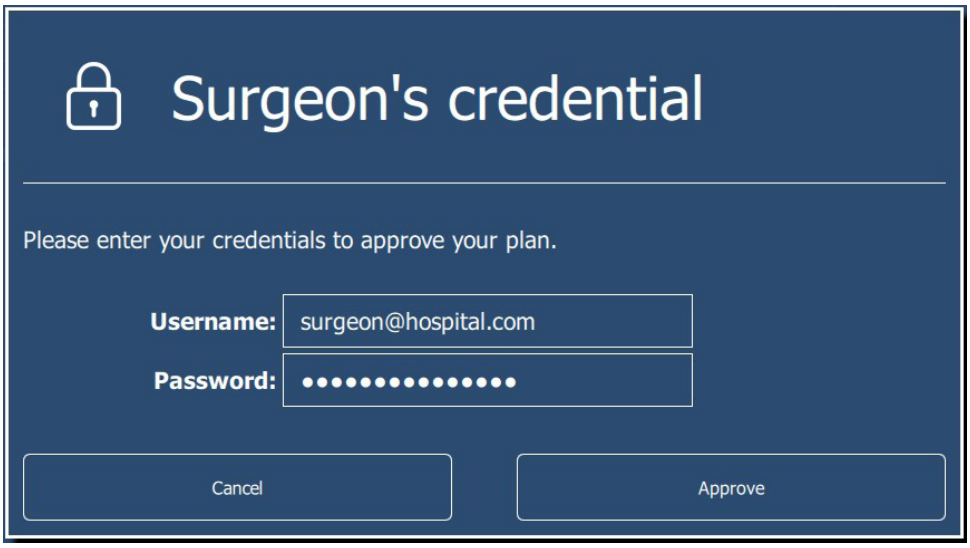


Figure 61 - Plan approval with credentials

Surgical Planning Report

The Surgical Planning Report document is a three page document that includes information on the Humerus and Scapula plans, as well as the Joint / ROM estimations.

Surgeon name, PSI Case ID, Operated Side, the Glenoid and Humerus preoperative Inclination, the Glenoid Version and glenoid Ordering Option are displayed in the General Information table.

The planned implant components sizing and orientation are displayed in the Component Planning table.

The Surgeon Comments can be found on the first page of the Surgical Planning Report.

Screenshots are provided on the Surgical Planning Report so the surgeon can confirm that the plan was reproduced correctly intra-operatively, such as the reaming shown on the reamed glenoid view for example.

See Appendix A for an example of a Surgical Planning Report.

Contact Information

Any Case Specific Question or Comment?

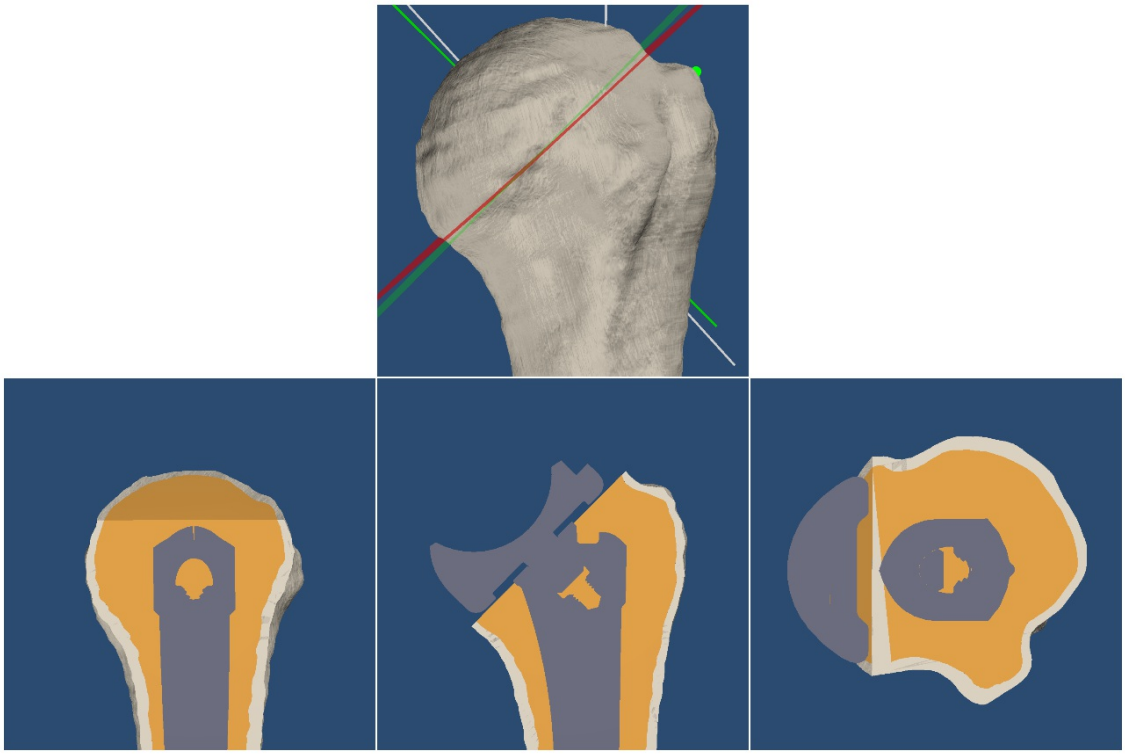
Contact Zimmer Biomet Customer Support as required for any case specific question that may arise during the review of the plan.

Customer Support
Phone: 1 (574) 371-3710
Email: PersonalizedSolutions@ZimmerBiomet.com

Appendix A – Surgical Planning Report

ZIMMER BIOMET

PATIENT SPECIFIC INSTRUMENTATION / SURGICAL PLANNING REPORT



GENERAL

Creation Date	2023-09-22 15:39:32
Surgeon	Dr. John, Doe
Signature Case ID	CAD183L00JD22UO
Patient Side	LEFT
Native Humerus Inclination	138.0°

HUMERAL COMPONENTS

Implant System	Comprehensive Reverse
Stem Size	Mini | 13mm
Tray Size	44mm | N/A | Standard
Bearing Size	Standard | Standard | 44-36mm
Implant Inclination	135.0°
Version Offset from Anatomic Neck	0.0°
Head Cut Thickness	22.5mm
Head Cut to Anatomic Neck	0.0mm

SURGEON COMMENTS

Comment here.

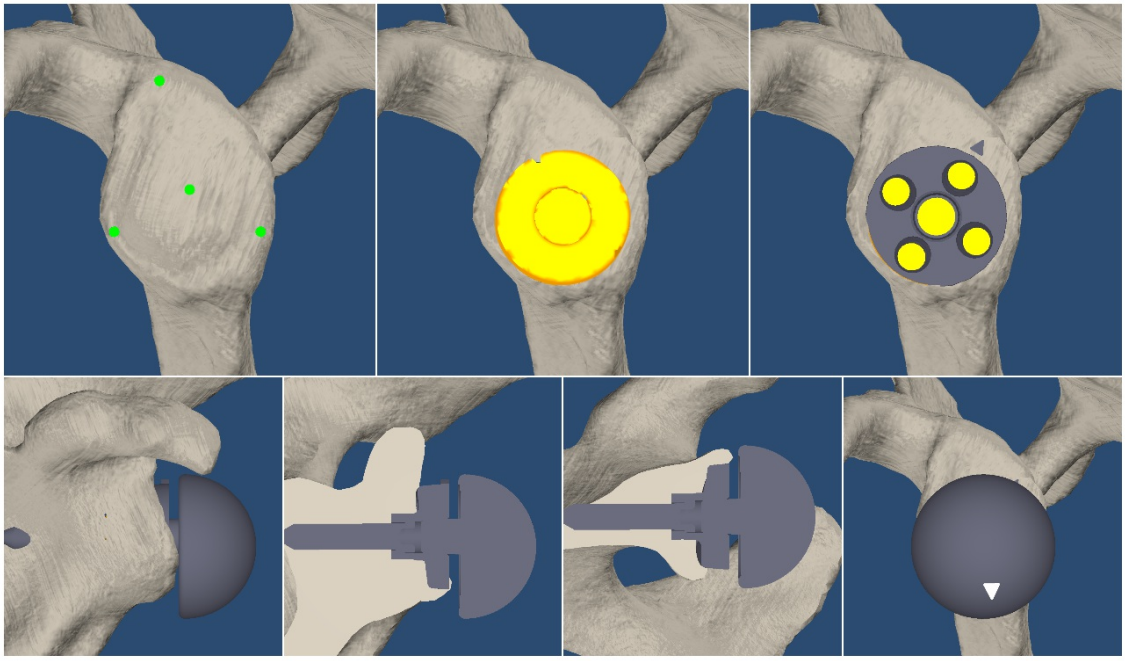
Approved by: N/A

Date: 2023-09-22 15:39:31 Eastern Daylight Time (YYYY-MM-DD)

Disclaimer: This Patient Specific Instruction Surgical Planning Report ("Report") must be approved by a licensed surgeon via Portal or paper. By approving this Report through Portal or via paper, you confirm that (i) you are a surgeon authorized by law to treat the patient identified in this Report, (ii) the data contained in the Report is accurate and corresponds with the patient indicated by the PSI case ID, (iii) you are solely responsible for the accuracy and completeness of all information in the Report, including ensuring that your patient is the patient identified in the Report and (iv) acknowledge and agree that Zimmer Biomet will not independently verify the information contained in the Report. This Report will be included with the PSI sent to you.

ZIMMER BIOMET

PATIENT SPECIFIC INSTRUMENTATION / SURGICAL PLANNING REPORT



GENERAL

Creation Date	2023-09-22 15:39:32
Surgeon	Dr. John, Doe
Signature Case ID	CAD183L00JD22UO
Patient Side	LEFT
Native Glenoid Version	-12.5°
Native Glenoid Inclination	9.0°
Guides ID	183
Ordering Option	Guides and bone model

GLENOID COMPONENT

Implant System	Comprehensive Reverse
Baseplate Size	AUG SM
Baseplate Inclination	0.0°
Baseplate Version	0.0°
Central Screw Length	35mm
Glenosphere Size	36mm | +3mm | C(2.5mm)
Implant Contact	100%

Comprehensive Reverse reamer part number 405807 (length **10.4** inches) not supported. For Comprehensive Reverse procedures, only use reamer 110029136 (length **9.0** inches).

Approved by: N/A

Date: 2023-09-22 15:39:31 Eastern Daylight Time (YYYY-MM-DD)

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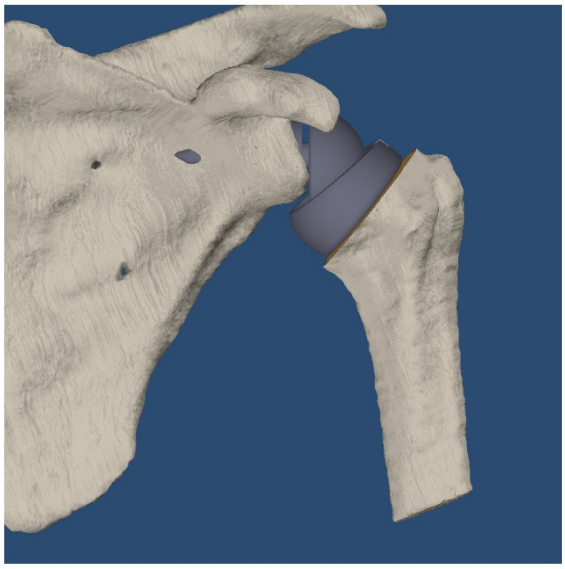
PATIENT SPECIFIC INSTRUMENTATION / SURGICAL PLANNING REPORT



GENERAL

Creation Date	2023-09-22 15:39:32
Surgeon	Dr. John, Doe
Signature Case ID	CAD183L00JD22UO
Patient Side	LEFT

HUMERUS MOTIONS *

Extension	Full range	-60°
Flexion	Impingement	73°
Adduction	Impingement	-16°
Abduction	Impingement	73°
External Rotation	Impingement	-50°
Internal Rotation	Impingement	48°

* Assumes a rigid scapula and no soft tissue
Models with osteophytes removed

HUMERAL SHIFT (mm)

	Planned	Native	Difference
S-I Distance	-26.0	4.0	-30.0
A-P Distance	1.0	-5.5	+6.5
M-L Distance	33.5	30.0	+3.0

Approved by: N/A

Date: 2023-09-22 15:39:31 Eastern Daylight Time (YYYY-MM-DD)

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