Signature™ ONE Planner
User Guide

807.001 rev C

Issue Date 2022-01

Contents

INTRODUCTION

This user guide provides instructions for the use of the Signature™ ONE Planner software application for the placement of the glenoid implant components Zimmer® Trabecular Metal™ Reverse Plus Shoulder, Comprehensive® Total Shoulder System, Comprehensive® Reverse Shoulder System, Comprehensive® Reverse Augmented Baseplates and Alliance™ Glenoid System; the output of which will be used to create corresponding planning, Signature™ ONE Shoulder Guides and/or Bone Model for intra-operative use to help replicate this planning.

Zimmer Biomet Signature™ ONE Indication 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 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 Guides and bone model 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 1.2 (may vary from version 1.0)[*].
- Training is required prior using the Signature™ ONE Planner application.
- The pre-operative plan is launched from the Zimmer Biomet portal, selecting the applicable patient case.

[*] 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
	Refer to instruction manual/booklet
	Consult instructions for use
	Attention: Read all warnings and precautions in instructions for use

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

Signature™ ONE case ID

The Signature™ ONE case ID displayed in the planning application can be either 8 or 15 characters, based on region. Figure 1 shows an example 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 and bone models will be abbreviated on the guides due to space as shown.

15 characters example: SAM123L50DD13UO

Printed on Pin Guide / Impactor Guide / Screw 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 Zimmer Biomet	Operated side (Left/ Right)	Last two digits of the Year of patients DOB	Surgeon initials	Year when the case created	Region where the case ID originated	Code assigned on the technology

8 characters example: SAM1234L

Printed on Pin Guide / Impactor Guide / Screw Guide: 123
Printed on Reamer Guide: SAM1234L
Printed on Bone Model: SAM1234L

S	AM	1234	L
1st letter of patient first name	First 2 letters of patient last name	Unique index assigned by Zimmer Biomet	Operated side (Left/ Right)

Figure 1 – Signature™ ONE Case ID

PRE-OPERATIVE PLANNING

Upon launch, the application presents a 3D model of the patient's scapula, with the operator-selected scapular landmarks and the scapular axis as well as the native glenoid version and inclination (see Figure 2). A negative number for the version indicates retroversion and a positive one indicates anteversion. A negative number for the inclination indicates inferior inclination and a positive one indicates superior inclination.

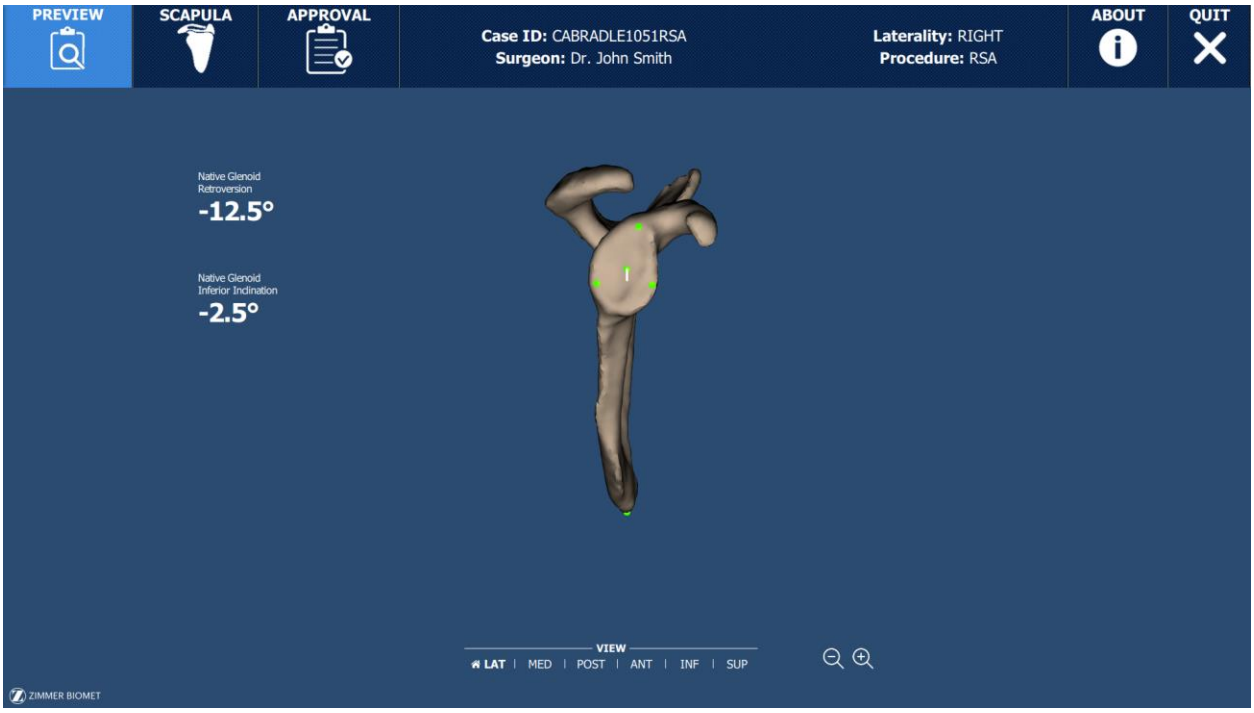


Figure 2 - Pre-plan view of the case seen when the application launches

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 scapula (intersection between the scapular spine and the medio-lateral border of the scapula). The scapular axis corresponds to the Friedman line[†].

The native angles are defined as:

- The native glenoid version is the angle between the Friedman line and the vector normal to the glenoid plane projected onto the transverse plane.
- The native glenoid inclination is the angle between the Friedman line and the vector normal to the glenoid plane projected onto the coronal plane.

[†] Friedman et al. The use of computerized tomography in the measurement of glenoid version. J Bone Joint Surg Am., 74 (1992), pp. 1032-1037.

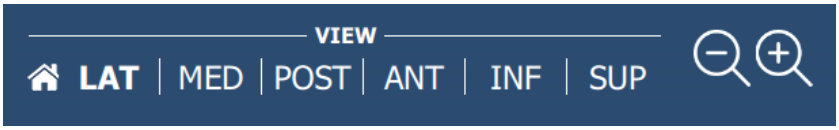


Figure 3 - Preset views and zoom buttons

The 3D model can be manipulated by clicking and dragging, or by clicking on one of the 6 preset view buttons at the bottom of the screen (Figure 3). The home button on the left hand side of the views toolbar resets the zoom and position of the scapula model to where it was when the application launched, which is the lateral view. The scroll wheel or the plus and minus buttons found on the right hand side of the views toolbar allow the user to zoom in or out of the scapula model.

Finally, the top toolbar displays the procedure, laterality, assigned surgeon and case ID and provides controls to go the next step of the application (Figure 4).

Figure 4 - Top toolbar of Signature™ ONE Planner application (Note: figure content may differ from version 1.0)

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. In the OnePlanner version 1.0 available in Europe, a language button allows the user to change the language of the application.

Click on the scapula button in the top toolbar to proceed to the next step.

Position the implant components on the scapula

This tab allows for planning of the implant component types and positions. It is composed of the three views as shown in Figure 5: a 3D model view (on the left side), a 2D coronal view (upper right and a 2D transverse view (lower right).

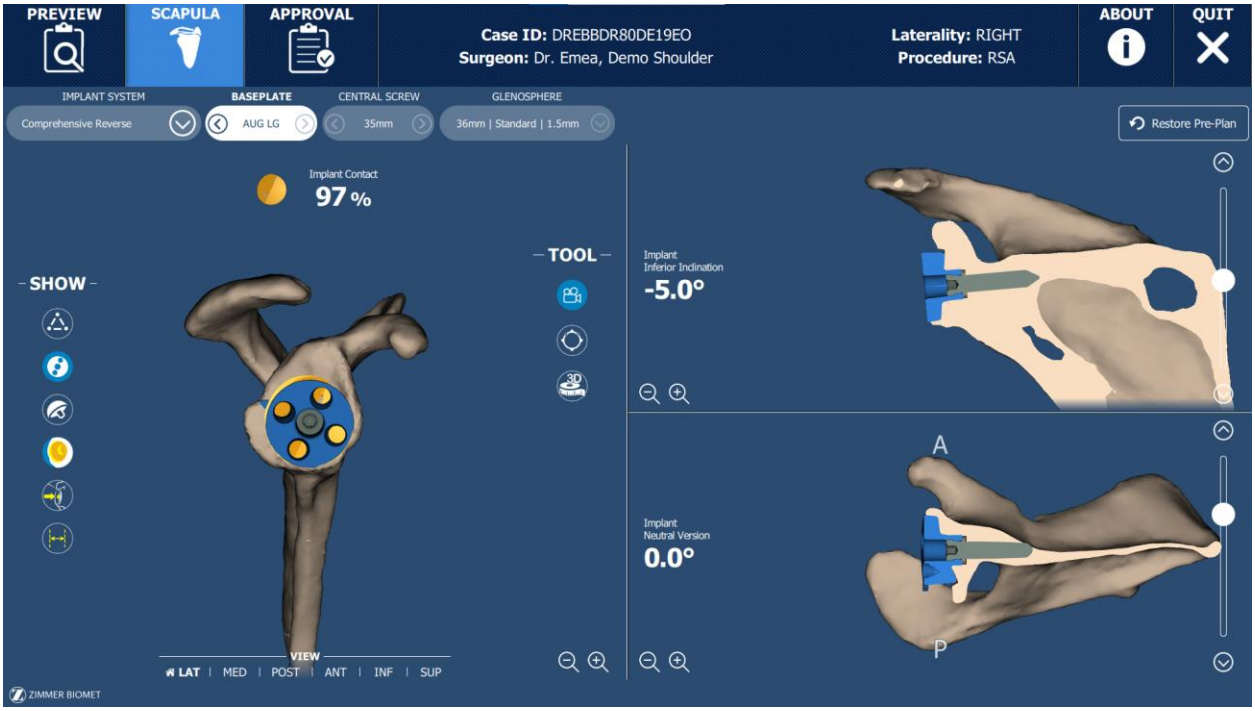


Figure 5 - Scapula tab in the Signature™ ONE Planner application. 3D model view (on the left side), a 2D coronal view (upper right) and a 2D transverse view (lower right) (Note: figure content may differ from version 1.0)

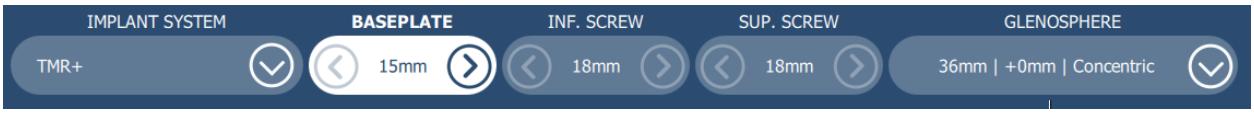


Figure 6 - Implant selection and sizing menus

Above the 3D model view are the implant component selection menus (Figure 6). The selected object (the applicable glenoid component or baseplate, screw or glenosphere) will appear in blue in the interface, as shown on Figure 5, where the baseplate is selected.
Note that a component has to be selected in order to change its size. All sizes and lengths can be adjusted by using the left and right arrows to respectively increase and decrease the component size to the next applicable size, except for the Alliance Glenoid component and the Glenospheres, where a drop down menu is used to select the appropriate size.

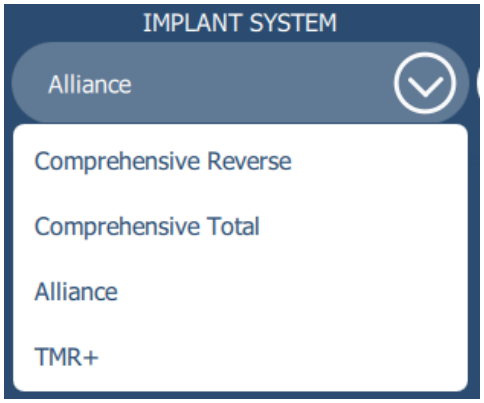


Figure 7 - Available implant brands (figure content differs from version 1.0)

In the implant system drop down menu, 4 implant brands are available (Figure 7).

The following parameters may be adjusted from the selection menus:

For Comprehensive Total:
- Glenoid Component size

For Comprehensive Reverse:
- Baseplate/Augment size
- Central Screw length
- Glenosphere

For TMR+:
- Baseplate size
- Superior Screw length
- Inferior Screw length
- Glenosphere

For Alliance (not available in version 1.0)*:*
- Glenoid Component size

The Alliance glenoid drop down menu allows selection of 4 glenoid component parameters (see Figure 8):
- Number of pegs
- Peg type

- Augment option
- Glenoid Component size

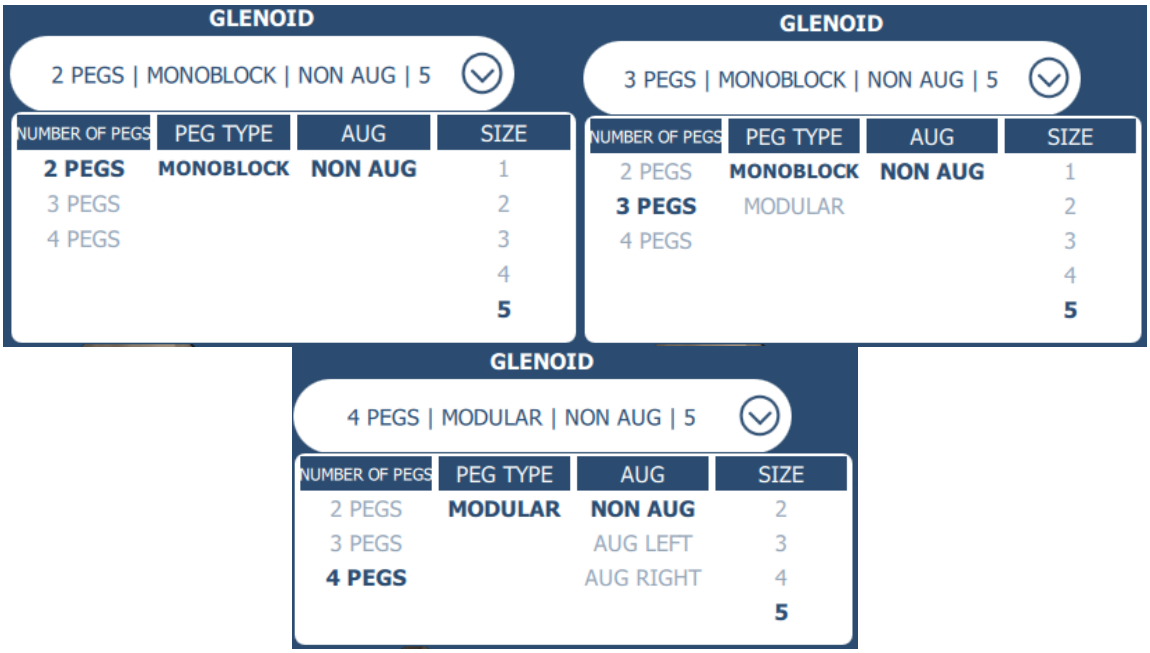


Figure 8 - Glenoid Component parameters for Alliance (not available in version 1.0)

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

The glenosphere drop down menu allows selection of 3 glenosphere parameters (see Figure 9):

- Glenosphere diameter
- Medio-lateral offset
- Inferior eccentricity

The planner allows display of the glenosphere eccentricity in the inferior direction (no controls for glenosphere rotation are provided).

Figure 9 - Glenosphere sizing options, TMR+ on the left and Comprehensive Reverse on the right (Note: figure content may differ; 40mm diameter glenosphere for Comprehensive is only available in version 1.2)

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

For TMR+, the peripheral screw sizes may also be selected on top of the 3D view (Figure 10).

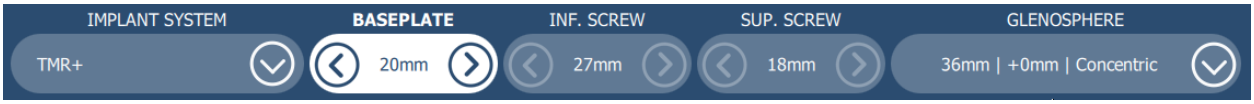
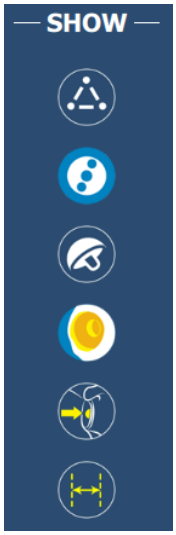


Figure 10 - Inferior and superior screw size adjustment

In the 3D model view, there are several controls to position the implant components and control the display options.

- **Display options**

The controls shown in Figure 11 allow showing or hiding different components. Note that depending on the implant system, the glenosphere display controls may be not available.



Landmarks and Friedman line

Glenoid component or baseplate and screws

Glenosphere

Reaming

Deepest point of the glenoid

Implant medial/lateral translation dimension

Figure 11 –Show/hide controls (Note: figure content differs from version 1.0)

- **Baseplate/Glenoid component manipulator in the 3D view**

The manipulator allows changing the position and orientation of the glenoid component. To activate it, click on the manipulator button in the tools menu (see Figure 12).

Note: The baseplate selector in the top of the 3D view (Figure 12) must be enabled in order to be able to select the corresponding manipulator. It will not be available if another component is selected.

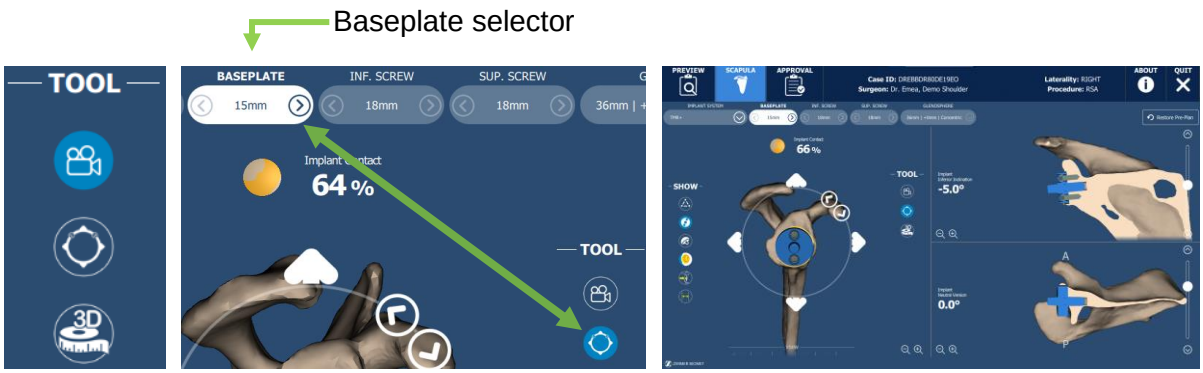


Figure 12 – Left: manipulator button (bottom button, highlighted) to move implant. Center: Baseplate must be selected to see manipulator button. Right: Manipulator showed on 3D model (Note: figure content may differ from version 1.0)

The 4 position arrows (Figure 12 and Figure 13) allow the user to move the implant along the following directions: superior, inferior, posterior and anterior. **Each click corresponds to a movement of 0.5mm.**

The 2 arrows contained in white circles (Figure 12 and Figure 13) allow rotation of the glenoid component about the implant axis, with **1 degree of rotation per click**.

To close the implant manipulation widget, either click outside of the widget's circle or click on the camera icon in the tools menu (Figure 14). The bone can then be moved around in 3D space.

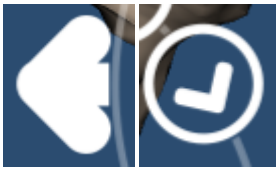


Figure 13 - Implant position arrow (left) and implant rotation arrow (right)

Figure 14 : Camera button to allow freehand manipulation of the 3D model (Note: figure content may differ from version 1.0)

- **3D measurement tool** (not available in version 1.0)

The 3D measuring tool allows taking 3D distance measurements on the model in the 3D view and/or in a cut plane in the 2D views. To activate it, click on the 3D measurement button in the tools menu (Figure 15 - Left).

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

The two selected points and the line between the two are displayed and the 3D distance dimension is displayed in the 3D view in mm (Figure 15 – Right).

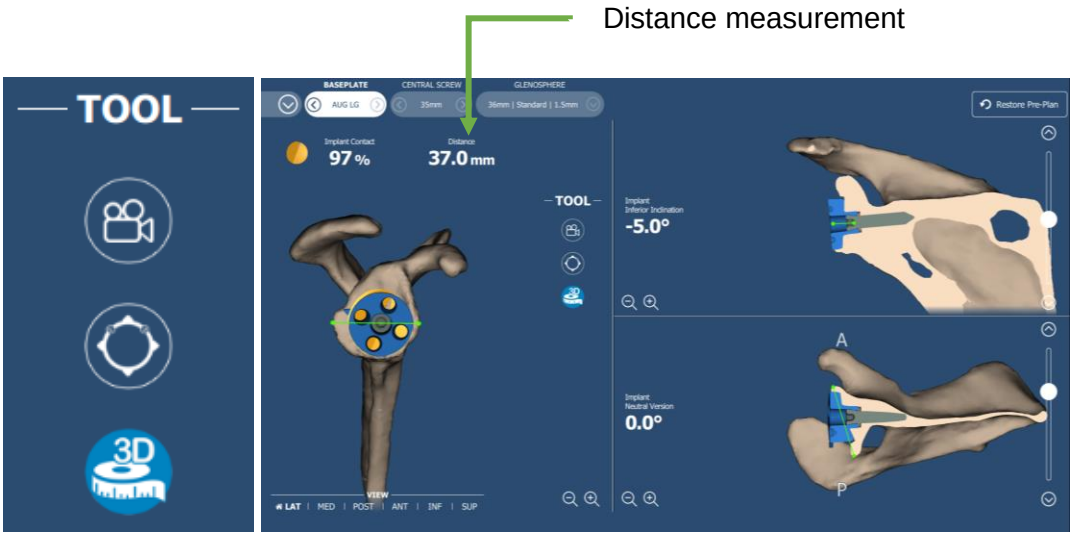


Figure 15 – Left: 3D measuring tool (bottom button, highlighted) to take 3D distance measurements. Right: 3D distance measurement shown on 3D model in the 3D view and in 2D views (Note: figure content may differ from version 1.0)

- **Baseplate/Glenoid component manipulator in the 2D views**

If the baseplate is selected it is highlighted in blue and, in the coronal view, the 4 arrows (Figure 16) allow the user to move the implant superiorly, inferiorly, medially and laterally. **Each click corresponds to a movement of 0.5mm.**

The 2 arrows contained in white circles (Figure 16) allow adjustment of the baseplate or glenoid component **inclination**, with 0.5 degree of rotation per click. The current implant inclination is displayed in the coronal 2D view. A negative number indicates inferior inclination and a positive one indicates superior inclination.

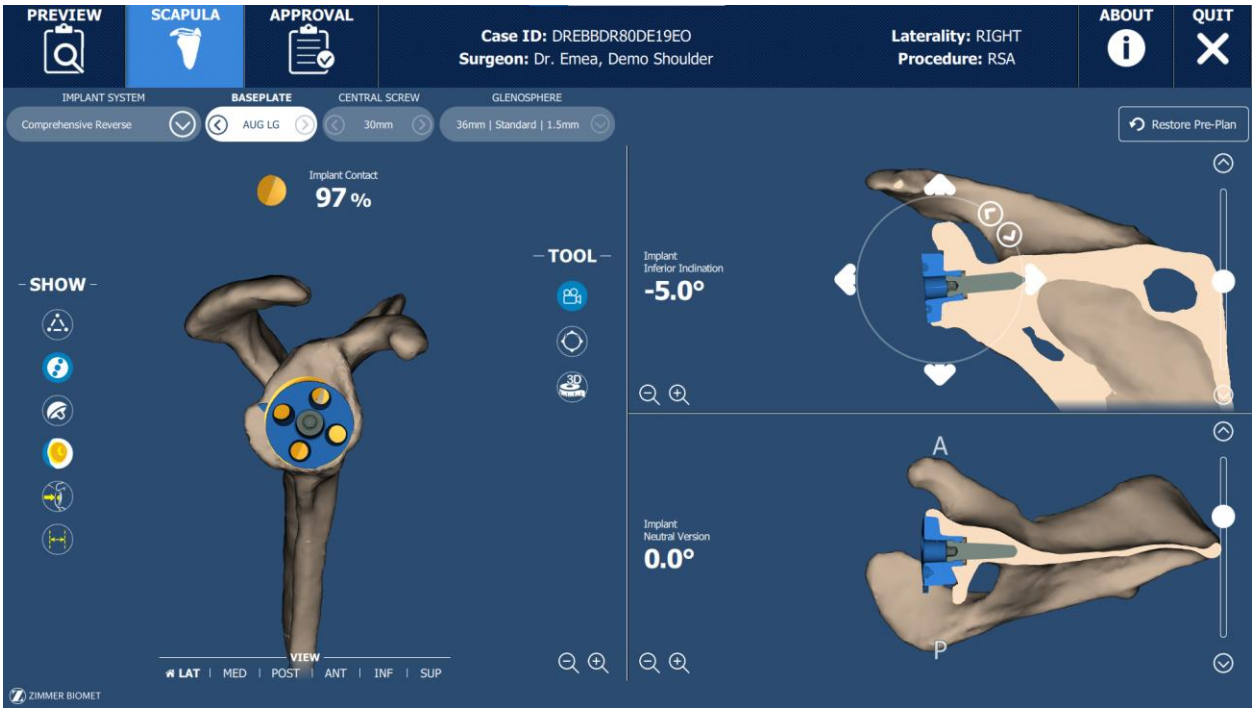


Figure 16 - Baseplate button is selected, allowing the user to show the manipulator in the 2D views to move the baseplate (Note: figure content may differ from version 1.0)

If the baseplate is selected, the same controls are provided to allow the user to move the implant posteriorly, anteriorly, medially and laterally in the transverse view. The baseplate or glenoid component **version** can also be adjusted with 0.5 degree of rotation per click. The current implant version is displayed in the transverse 2D view. A negative number indicates retroversion and a positive one indicates anteversion.

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.

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 17). This value is incremented in steps of 0.5 mm and is equal to the distance along the Friedman's line between the most lateral point of the glenoid and the implant's backside.

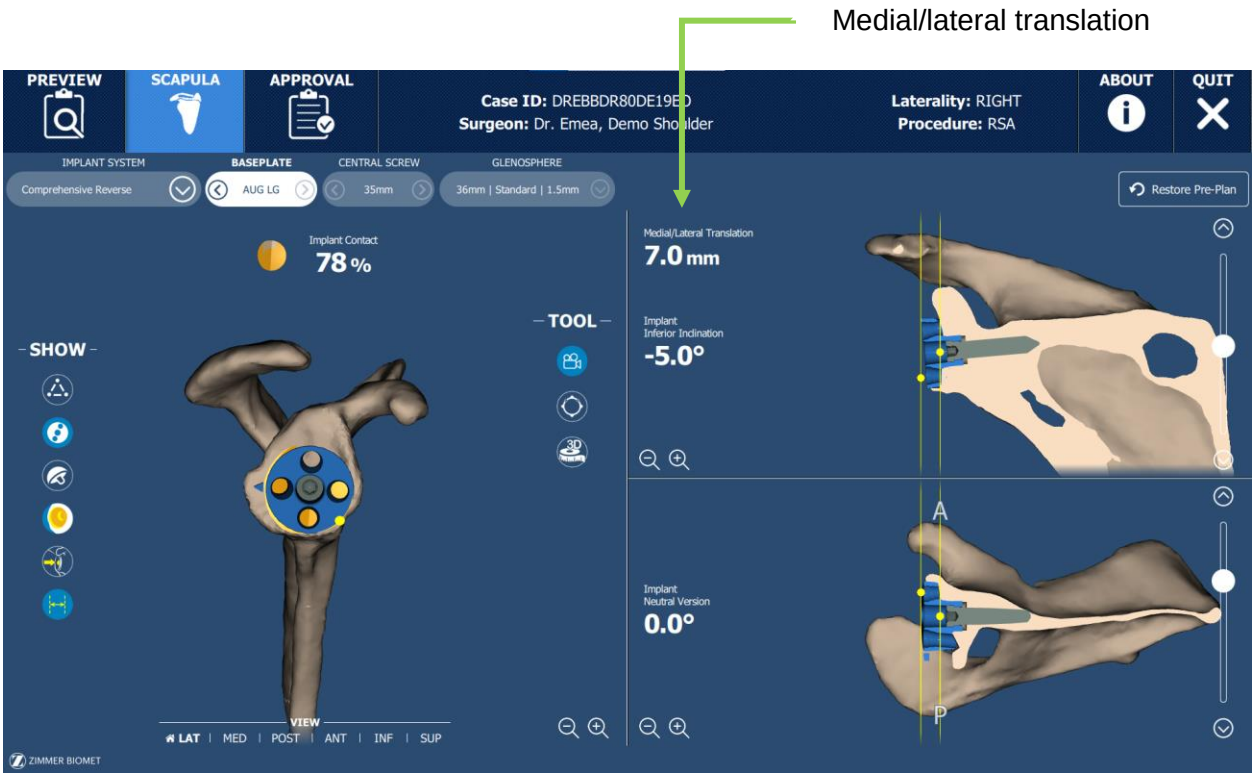


Figure 17 - Medial/Lateral Translation is shown (last button on the left is selected) and its value is displayed in the coronal view (Note: figure content may differ from version 1.0)

If an augmented Comprehensive Reverse implant is selected, an arrow is provided to indicate the direction of the augment on the baseplate. The deepest point of the glenoid can be displayed to assist in the positioning of the augmented Comprehensive Reverse implant. This point indicates the most medial point of the glenoid surface based on the plane normal to the Friedman line. At the surgeon's discretion, the arrow indicating the direction of the augment on the baseplate can be oriented to point towards the deepest point (Figure 18).

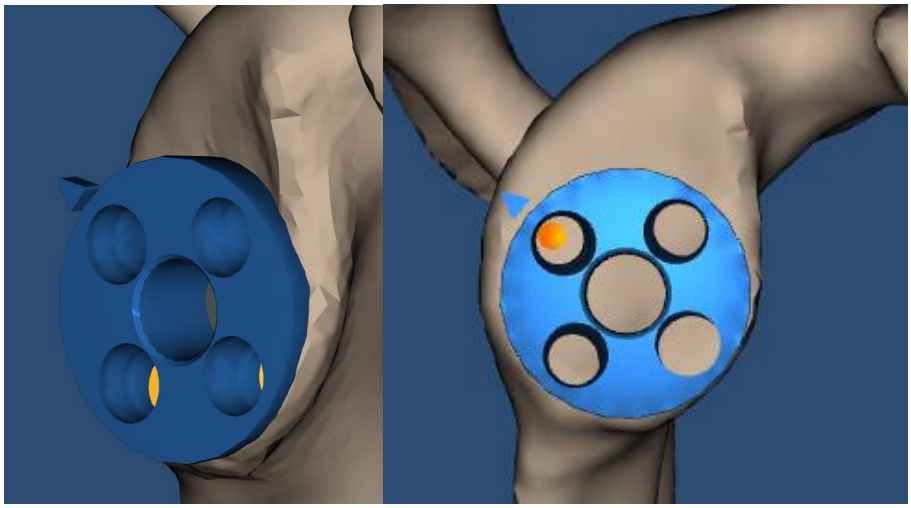


Figure 18 - Baseplate with the arrow indicating the augment direction and the deepest point

- **Peripheral screws manipulator in the 2D views (for TMR+ only)**

To change the size of one of the peripheral screws, click on the desired screw on the Implant selection and sizing menu and then click on the arrow (Figure 19).

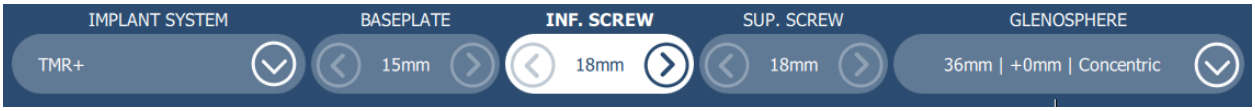


Figure 19 – Inferior screw is selected

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 20). The screw selected is highlighted in blue.

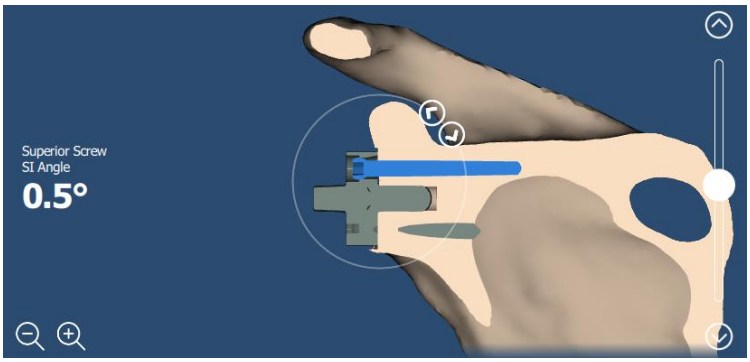


Figure 20 - Angular adjustment of the peripheral screws in the 2D views

The 2 arrows contained in white circles (Figure 20) 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 total angle of each screw (AP and SI combined) must be less or equal than 8° total (Figure 21). 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 22). 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.

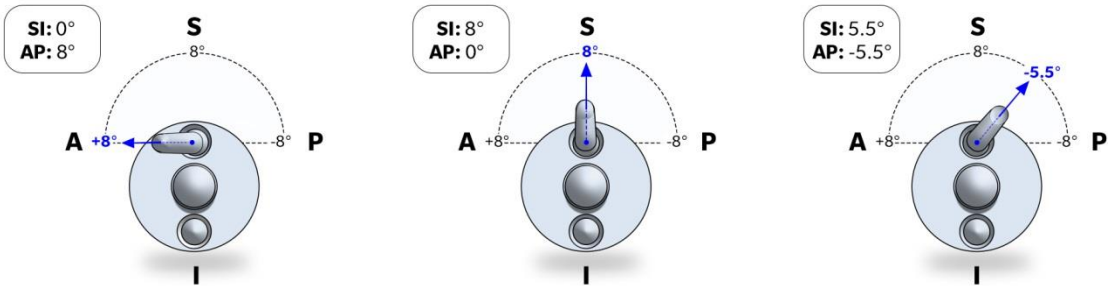
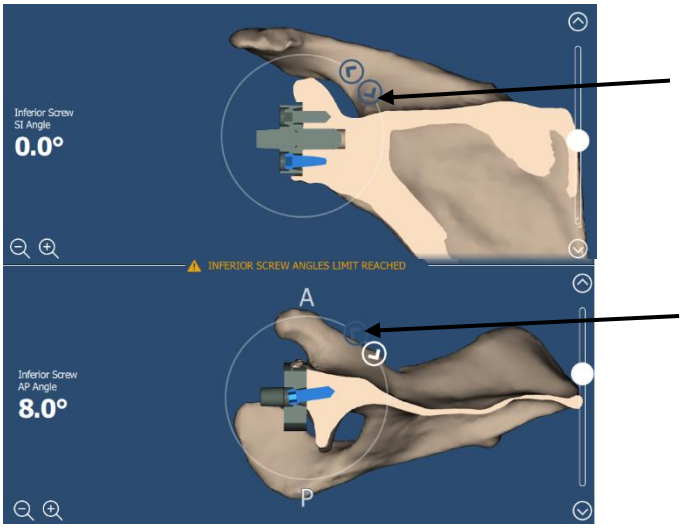


Figure 21 - Maximum angles of the peripheral screws in the implant



The inferior screw AP angle is at maximum value. The control to change 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 22- Inferior Screw AP angle at maximum value, blocks the control to change the angle to a more inferior angle and adjustment of the SI angle. A notification is displayed between the 2D views (Note: figure content may differ from version 1.0)

- **Scrolling in the 2D views**

In each 2D view, a scroll bar allows the user to navigate through the bone model. 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.

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 changes the view to a more superior one and scrolling down changes the view to a more inferior one.

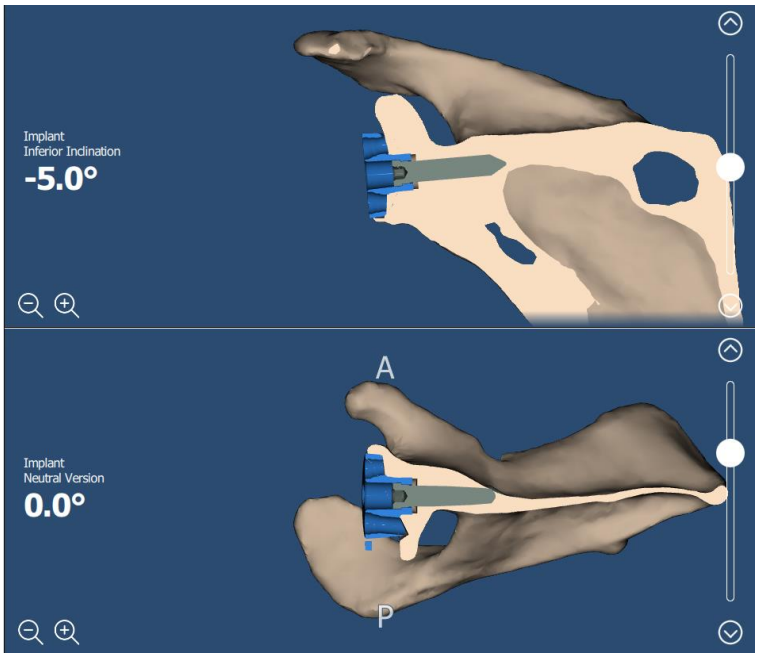


Figure 23 - Coronal and transverse views of the scapula and implant components (Note: figure content may differ from version 1.0)

- **Screws marked as incomplete**

If the baseplate is moved after completing the screw placement, the screws are marked as incomplete (Figure 24) in the application to ensure that their orientation and/or length is reviewed prior to approving the case.

In this case, the APPROVAL tab is 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 APPROVAL tab again.

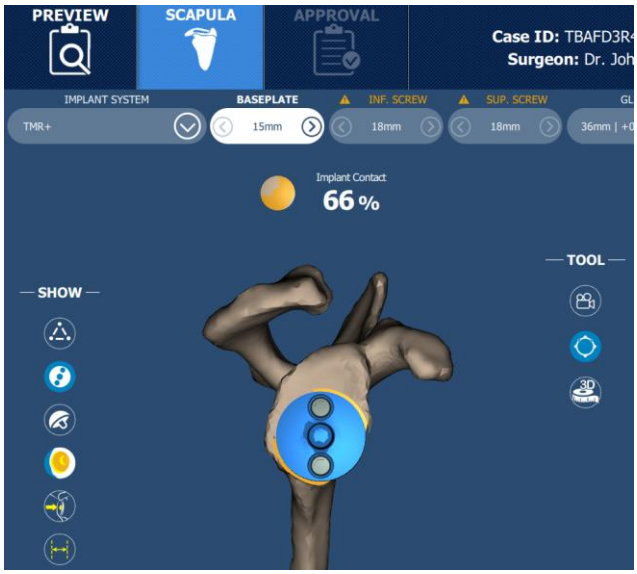
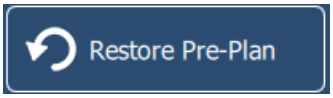


Figure 24 : Screws marked as incomplete; Approval tab is disabled (Note: figure content may differ from version 1.0)

- **Restore the Zimmer Biomet pre-plan**

If the user wishes to restore the planning to its initial state provided by Zimmer Biomet, the user may click on the “Restore Pre-Plan” button on the top right of the model views. This prompts the user to return to the Zimmer Biomet pre-planning.



PRE-OPERATIVE REVIEW AND APPROVAL

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

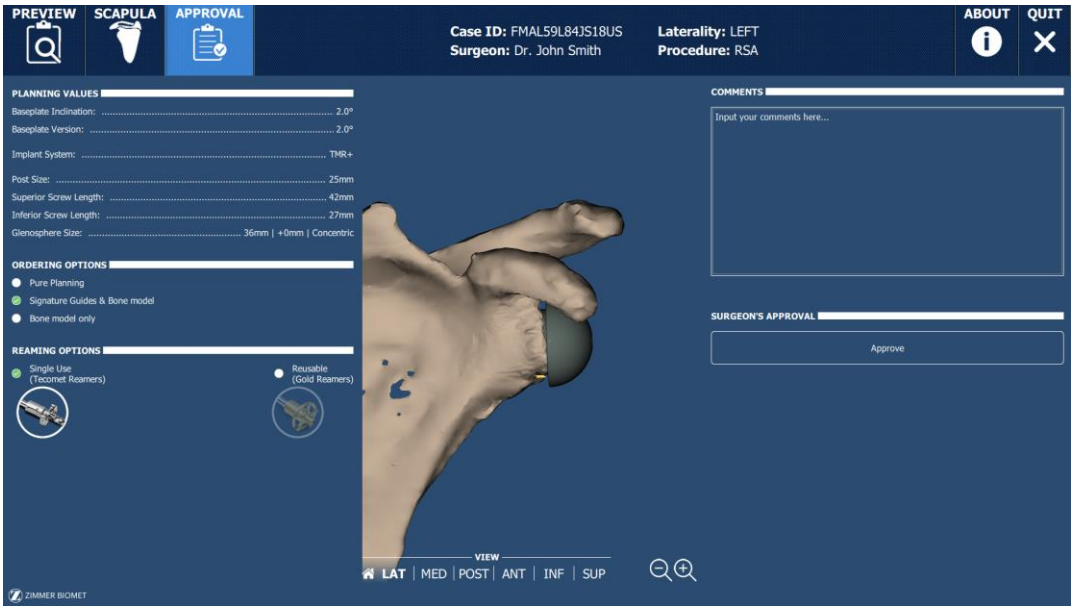


Figure 25- Approval tab

The Approval tab presents a summary of implant component angles, sizes and brand selected in the scapula tab.
In the middle of the screen is a 3D view of the scapula and all the implant components that can be manipulated in the 3D space (Figure 25).
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: Digital planning report is provided, without guides or bone model
- Guides and Bone Model: a pin guide, reaming guide, applicable impactor guide, applicable screw guide and a 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 bone.

For TMR+ cases, if the guides and model option is selected, the user must select a reaming option: either the Single Use or Reusable reamer (Figure 26).

Figure 26 - Reamer options for TMR+ cases

**Note that the selected reamer must be used in surgery. Otherwise, do not use the reamer guide in surgery.*

When ready to approve, the user may click on the Approve button, at which point they will be prompted with a window asking to confirm the ordering options (Figure 25).

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 27).

After clicking the *Confirm* button, a window asking for the surgeon credentials (Figure 28) is shown. Once the credentials are entered and the approve button is clicked, the plan is saved, is sent for manufacturing and the application will close. If the application is closed before approving the plan, the plan will not be saved.

Note that only one plan can be created per case. Therefore, upon saving the currently displayed plan, any other plans for other implant systems will be discarded.

No changes can be made to the pre-operative plan after the *Approval* button has been clicked. If the case is reopened in the Signature™ One planning application, the case will be in read-only mode and no changes will be saved.

The application will automatically close and generate the Surgical Planning Report in .pdf format (see Appendix A).

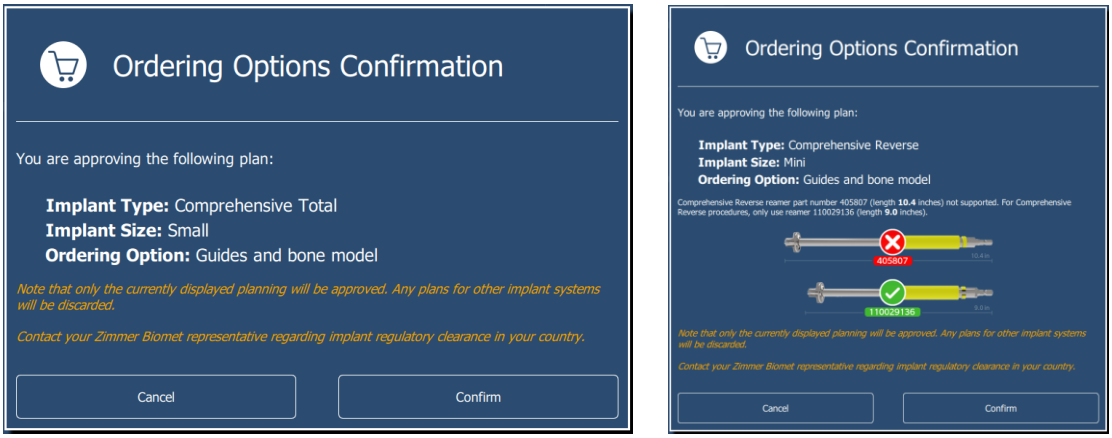


Figure 27– LEFT: Ordering Options Confirmation for Comprehensive Total. RIGHT: Ordering Options Confirmation for Comprehensive Reverse.

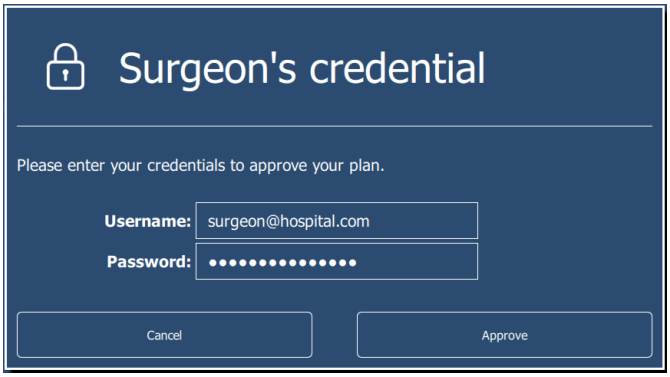


Figure 28- Plan approval with credentials

Surgical Planning Report

The Surgical Planning Report document includes information on the case and planned glenoid implant components' orientation and sizing. Surgeon name, PSI Case ID, Operated Side and native glenoid version and inclination are displayed in *General Information* table. The planned implant components sizing and orientation such as: implant type, baseplate or glenoid component size, version and inclination, superior/inferior screw length and applicable glenosphere are shown in the *Glenoid Component Planning* Table.

Screenshots are provided on the Surgical Planning Report so the surgeon can confirm that the plan was reproduced correctly intra-operatively, such as the depth of 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

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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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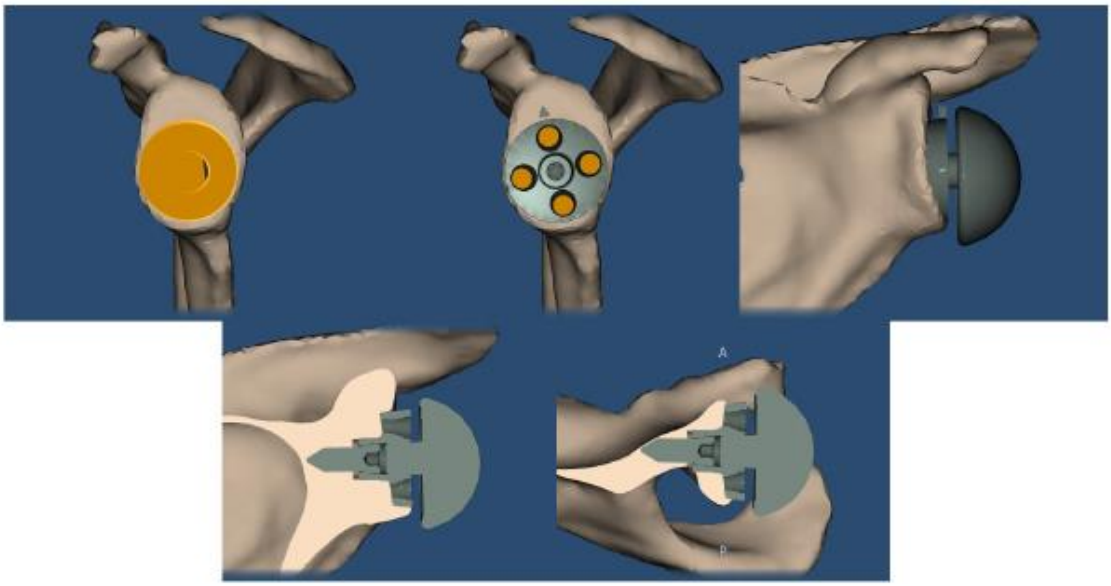
APPENDIX A

ZIMMER BIOMET

PATIENT SPECIFIC INSTRUMENTATION / SURGICAL PLANNING REPORT



GENERAL

Creation Date	2021-05-20 14:01:40
Surgeon	John Smith
Signature Case ID	AFO0589L
Patient Side	LEFT
Native Glenoid version	3.0°
Native Glenoid inclination	2.0°
Reamer Guide ID	AFO0589L
Guides ID	058
Ordering Option	Guides and bone model
Reamer Option	N/A

GLENOID COMPONENT

Implant System	Comprehensive Reverse
Baseplate Size	Augment Small
Baseplate Inclination	1.0°
Baseplate Version	-1.0°
Central Screw Length	20mm
Glenosphere Size	36mm | Standard | 1.5mm
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).

SURGEON COMMENTS

N/A

Approved by:

Date: 2021-05-20 14:01:40 Eastern Daylight Time (YYYY-MM-DD)

Disclaimer: This Patient Specific Instrumentation Surgical Planning Report ("Report") must be approved by a licensed surgeon via zimmersms.com or paper. By approving this Report through zimmersms.com 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.

iOne Planner Application - 1.2.0.5

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