

Virtual Implant Positioning™ (VIP™) Web Portal

User Manual



Arthrex® 

All surgeon and patient details appearing in the demo screen shots are fictitious. Any resemblance to real persons is coincidental.

Important Contact Information

Email: VIP_Support@arthrex.com

Table of Contents

Definitions	04
Use Environments.....	06
Training	06
Introduction	07
Intended Use.....	07
Instructions	08
System Requirements.....	08
Features.....	09
Navigating the Web Portal.....	10
Cases Page.....	12
Joint Viewer Page.....	21
Interface Functionality	22
Glenoid Viewer Page	26
Interface Functionality: Glenoid Planning	27
Humeral Viewer Page.....	32
Interface Functionality: Humeral Planning.....	33
Interface Functionality: Range of Motion	41
Interface Functionality: Research	44
User Profile Options Page	46

Definitions

3D model—A 3D-printed, surrogate model of a patient's glenoid that interfaces with the glenoid targeter device, enabling the transfer of the planned pin trajectory from the model to the patient.

3D order—This order type includes a plan viewable within the VIP™ preoperative planning system, as well as a 3-dimensional bone model. This order involves the use of the glenoid targeter device.

3D and 5D order—This order type includes everything from the 3D and 5D order types.

5D calibrator—The instrument that is used in conjunction with the glenoid targeter device (06-xxxx series). Arthrex provides the 5D calibrator settings for patients based on their surgical plan. When set up properly, the 5D calibrator establishes the correct leg height settings on the glenoid targeter device.

5D order—This order type includes a plan viewable within the VIP system and specific instructions for setting the 5D calibrator (06-xxxx series) or targeter leg heights (AR-5400 series). This order involves the use of the glenoid targeter device.

Administrator—This user has access to all other users' profiles and cases. The number of users at Arthrex with administrator privileges will be very limited.

Approved preoperative plan—The final, surgeon-approved preoperative plan that is referenced at the time of surgery. It exists in digital (web session) form. Once a preoperative plan is approved, it cannot be modified.

Archive—Case action that hides a case from the “Cases” page to keep it from becoming overpopulated and cluttered.

Arthrex technician or technician—A trained Arthrex employee who is tasked with creating preoperative plans and interacting with web portal users to fulfill their requests.

Assistant—Any colleague, such as a nurse or resident, of a surgeon user who can upload a CT scan to the web portal on behalf of the surgeon. Assistants must register in the web portal under a surgeon.

“Case Details” page—The page where the individual case details can be viewed and edited.

Case ID—A unique alphanumeric ID that is assigned to each case.

Case status—The status of preoperative plan creation. A list of statuses within the Arthrex workflow can be found under the “Cases” page section of this document (see page 13).

Case status flowchart—A flowchart at the top of the “Case Details” page that allows users to track a case status throughout the planning process.

“Cases” page—The page where cases can be managed and accessed. Administrators and technicians can view all the cases on the web portal. Other users' access is limited to their specific cases.

Expiration date—The expiration date of an approved preoperative plan. This occurs 6 months from the date that the CT scan was taken.

Glenoid targeter device—This instrument, which is a part of the VIP system, transfers the preoperatively planned pin trajectory to a patient's glenoid.

Main screen—The home page that is visible when entering the VIP web portal.

“New Case” page—The page where new case information is entered by a web portal user.

“New User Registration” page—The page where new users can register for the VIP web portal.

Order number—The unique number (based on the date and number order for a certain month) Arthrex uses to trace the status of an order and complete it. The form of this number is: [2-Digit Project Number]-YY-MM-[4-Digit Sequential for Month]. For example, the 50th order of the Arthrex glenoid targeter device for September 2015 is: 12-15-09-0050.

OrthoVis—This desktop software, which is used by Arthrex technicians, has more advanced functions than the web portal, including thresholding and separation of the bony joint.

Plan—A web session, OrthoVis session, approved preoperative plan, etc. It is the preoperative plan that exists in any state throughout the planning process.

Definitions

Plan ID—The identification number for an approved or unapproved plan on the web portal. When a web session is created, it is given a plan ID that it holds through approval. The plan ID is typically “plan 1.”

Plan-only order (1D)—This order type includes only a plan viewable in the VIP™ web portal.

Plan status—Listed as “Approved” or “Ready for Review,” this refers to the status of the planned implant placement with regard to surgeon approval.

“Register New User” page—The location on the VIP web portal where a new user enters their information.

Surgery date—The date on which the preoperatively planned surgery will take place. This date is entered by the operating surgeon or assistant when a new case is created.

Username—The unique name that a user selects for logging into ArthrexVIP.com. Users can be given one of five designations based on their function: surgeon, assistant, sales, technician, or administrator.

“Viewer” page—The online web portal viewer that allows surgeons and Arthrex technicians to communicate and adjust/approve a plan (web session). Approval creates an approved preoperative plan.

Virtual Implant Positioning™ (VIP) system—A shoulder arthroplasty surgical planning system that can include the following: glenoid targeter, 3D model, 5D calibrator, and surgical tray. The VIP web portal is indicated for use with the VIP system.

VIP web portal or web portal—The Arthrex website for which this document was written. It facilitates communication between surgeons and Arthrex technicians during preoperative surgical planning.

Web session—An unapproved plan on the web portal that a surgeon and Arthrex technician can adjust. Once approved by a surgeon, it becomes an approved preoperative plan.

Use Environments

The VIP™ web portal—viewed on a desktop display—is primarily used in a typical office environment or a remote office. Table 1 outlines the general, visibility, and physical characteristics of viewing the desktop display in an office environment. Alternatively, users may also view and plan on an iPad with the VIP app or use another mobile device for view-only functions since the planning and save/approve functions cannot be used on other mobile devices. Table 2 outlines the general, visibility, and physical characteristics of viewing the tablet or mobile display in a remote setting.

Training

Technology consultants can provide in-service training for one or more users at the customer's location. Training videos are also available on Arthrex.com.

Table 1. Characteristics of Desktop Display in Office Environment

General
Indoor
Viewable on single or multiple monitors
Visibility
Ambient luminance range: 100 lux to 1500 lux
Viewing distance: 40 cm to 70 cm
Viewing angle: Normal to the desktop display $\pm 30^\circ$
Physical
Temperature range: 20° C to 26° C
Relative humidity range: 20% to 60%
Background sound pressure level: <70 dBA in the range of 100 Hz to 8 Hz

Table 2. Characteristics of Tablet or Mobile Phone Display in Office, Home, Hospital, or Operating Room Environment

General
Indoor
Visibility
Ambient luminance range: 100 lux to 1500 lux
Viewing distance: 20 cm to 40 cm
Viewing angle: Normal to the mobile or tablet display $\pm 20^\circ$
Physical
Temperature range: 10° C to 26° C
Relative humidity range: 20% to 75% noncondensing
Background sound pressure level: <70 dBA in the range of 100 Hz to 8 Hz
Orthopedic operating room peak level up to 110 dBA ^{1,2}

References

1. Nott MR, West PD. Orthopaedic theatre noise: a potential hazard to patients. *Anaesthesia*. 2003;58(8):784-787. doi:10.1046/j.1365-2044.2003.03257
2. Love H. Noise exposure in the orthopaedic operating theatre: a significant health hazard. *ANZ J Surg*. 2003;73(10):836-838. doi:10.1046/j.1445-2197.2003.02776

Introduction

The VIP™ preoperative planning system web portal is a medical device designed to facilitate the transfer of information between surgeons and Arthrex technicians. With purposeful functionality, the portal allows surgeons to make adjustments to protocol-based plans created by Arthrex technicians. Once the initial plan is created, it is uploaded into a web session within the portal, in which surgeons can adjust an implant's type,

position, and orientation on the isolated scapula or humerus in both 2D and 3D. The web portal also acts as a communication channel between surgeons and technicians throughout the approval process. Once a plan is approved in the portal, further changes are prohibited. Approved 2D and 3D plans can be accessed as locked PDF files via the “Case Details” page.

Intended Use

Indications for Use

The VIP web portal is intended for use as a software interface and for the transfer of imaging information from a medical scanner such as a CT scanner. It is also intended as software for displaying/editing implant placement and surgical treatment options that were generated in the OrthoVis desktop software by trained Arthrex technicians. The VIP web portal is intended for use with the VIP glenoid instrumentation and with the OrthoVis preoperative plan. It is indicated for use with the following implant lines: Univers™ II and Univers Apex total shoulder systems, keeled or pegged glenoid components, the Univers VaultLock® glenoid component, as well as the Univers Revers™ baseplate component (Universal Glenoid), Univers Revers™ Modular Glenoid System (MGS) baseplates, and Arthrex humeral implants compatible with these implant lines.

Contraindications

- The VIP web portal is not to be used with any shoulder replacement system, or component, other than the total shoulder systems and components identified in the Indications for Use.
- The VIP web portal and/or VIP system is indicated for use with certain total shoulder systems, listed in the Indications for Use. The contraindications associated with those systems remain the same, unaltered, as described in each implant system's labeling (with or without the use of the VIP web portal).
- The VIP web portal is not indicated for use in shoulder hemiarthroplasty.
- An unapproved preoperative plan is not to be used for clinical purposes.

Warnings

- Do not use the approved preoperative plan on anyone other than the patient indicated on the approved preoperative plan or in the web portal.
- The surgeon who will be performing the surgery must be the user responsible for approving the preoperative plan.
- Do not use the approved preoperative plan after its expiration date (6 months after the CT scan).
- The VIP preoperative planning system web portal is indicated for use with specific total shoulder systems. The warnings associated with those systems remain the same, unaltered, as described in each implant system's labeling (with or without the use of VIP web portal).
- Use of the web portal or OrthoVis is not a guarantee of improved accuracy or results as the approved preoperative plan is for visual reference only.
- Do not use an unapproved preoperative plan (web session or OrthoVis session) for clinical purposes.
- Due to resolution variation across devices, the images displayed on the web portal are not intended for diagnostic purposes and are for orthopedic surgical planning only. A persistent on-screen message displays this information on the web portal viewer.
- CAUTION: US federal law restricts this device to sale on or by the order of a physician.

Patient Counseling and Patient Information

Physicians should consider the following in counseling patients about this product:

- Discuss the risks of using the web portal in conjunction with OrthoVis or with the VIP system as a visual reference/planning tool for total shoulder arthroplasty.

Instructions

Inspection Prior to Use

- Inspect the approved preoperative plan to confirm that it corresponds with the patient who will be undergoing surgery. Also inspect the side of the patient that the surgery will take place on (left or right).
- If you are referring to a hard copy of the plan, ensure that all pages are available.
- Make sure that the approved preoperative plan is not expired (6 months after CT scan).

Review the Preoperative Plan

- Surgeons can review and approve the web session any time prior to the operation.
- Surgeons should be thoroughly familiar with the approved preoperative plan before using it in the OR.

Intraoperative References

- When using the approved preoperative plan by itself as a planning tool (without any other tools/devices, such as the glenoid targeter device), the images within the plan are used for visual reference only. The images help to facilitate the accurate placement of the glenoid guide pin and glenoid implant.
- Be sure to maintain sterility by keeping the nonsterile preoperative plan document out of the sterile field and away from contact with the patient.
- Surgeons can use the locked digital plan on the web portal or the plan PDF as an intraoperative reference. The digital plan on the web portal can be viewed as a 2D and 3D model in real time (web session), but the implant and guide pin location cannot be changed after surgeon approval.

System Requirements

Graphics Card/Chipset

- Graphics memory: At least 256 MB recommended.
- All graphics cards and chipsets that support OpenGL 2.1 or higher should be supported. This typically includes all contemporary graphics cards from NVIDIA, AMD, or Intel, and the latest integrated graphics chipsets.
- On Windows systems: Install the latest drivers for the graphics card/chipset.
- For detailed information, see WebGL specifications at www.khronos.org/webgl/wiki/BlacklistsAndWhitelists.

Web Browser

- Google Chrome, Microsoft Edge, Safari, and Firefox are the browsers that support the web portal software. In general, it is recommended for security and stability that the latest versions of these browsers be used.

iPhone/iPad Compatibility

- Arthrex VIP™ software is compatible with all iPad hardware running iOS 15 or later.
- Preoperative planning is done on the Arthrex VIP app, available in the iOS App Store.
- Preoperative planning is not available on the iPhone; however, order status, targeter settings, and case information are available.

Minimum Recommended End-User Cybersecurity Practices

- It is recommended the Arthrex VIP software only be accessed via a device running antimalware software.
- It is recommended the Arthrex VIP software only be used after the end-user has completed employer-provided training regarding phishing for reasons of security and stability.
- It is recommended the Arthrex VIP software only be accessed via a password-protected device with multifactor authentication (aka, MFA or 2FA).

The VIP web portal is located at ArthrexVIP.com. It is meant to facilitate communications between surgeons and technicians, while working toward a final approved preoperative plan that can be used in the OR.

Features

- Securely upload patient-specific CT data.
- View bones and implants in 3D as well as orthographic 2D cross sections.
- Display/adjust plans created by Arthrex technicians in OrthoVis.
- Display the case and plan status.
- Use the comments function to communicate between surgeons and technicians.
- Perform angle and length measurements in 2D and 3D (length only) views.
- Organize cases and plans into an easy-to-read table.
- Archive cases that have passed their surgical date.
- Allow surgeon assistants and technology consultants to upload CTs on a surgeon's behalf.
- Snap the view of the 3D model to anatomic reference planes (ie, anterior, posterior, inferior, and superior).
- Adjust type and size of implant that was chosen by Arthrex technician.
- Reset implant placement to what was originally planned by Arthrex technician.
- Show/hide 3D model components (ie, guide pin, implant, and bone).
- Show the original CT slices in the coronal and axial views.
- Adjust the transparency of the bone in the 3D view from 0% to 100% transparency.
- View articulating surfaces for both anatomic and reverse total shoulder replacements.
- View screw trajectory for baseplates with screw options.
- View backside seating and the maximum gap/depth of implant to patient anatomy.
- Remove and mark osteophytes on the glenoid and humerus.
- Create up to 3 VIP™ plans within the same case.
- View range of motion simulations in RSA constructs and compare values across up to 3 different VIP plans.
- Approve up to 2 VIP plans per case.

Navigating the Web Portal

Main Screen

Access the VIP™ preoperative planning system web portal by navigating the supported web browser to ArthrexVIP.com. After the program initializes, you will be presented with the main screen (Figure 1). From here you can register as a new user (Figure 2) or log in as a current user (upper right corner of main screen).

Additionally, the bottom right of the main screen includes a link to Arthrex's corporate website (Arthrex.com). The "References" link at the bottom left of the screen links to a page that contains reference documents for the VIP web portal device.

This "References" link includes:

- Arthrex Virtual Implant Positioning (VIP) Web Portal User Manual (L11-00022-en-US).
- VIP Glenoid Targeter Surgical Technique (AR-5400 Series) (LT1-000040-en-US).
- Specifications for CT Scan Data Acquisition (LR1-000018-en-US).
- VIP System Directions for Use (DFU-0289-4).
- VIP System Glenoid Targeter Surgical Technique (series 06-xxxx) (DFU-0289-4).
- VIP System Glenoid Reamer Surgical Technique (LT1-000246-en-US).

Register New User

At the top right of the main screen, click the "Register" link to access the Terms & Conditions, which must be agreed to and accepted prior to registration. Once the Terms & Conditions have been accepted, the registration form will appear. Users must enter a unique email address and password. If an email address is not available, the user will be alerted to choose another. Passwords must be at least 7 characters long with at least 1 alpha, 1 nonalpha, and 1 special character required. The password will need to be entered twice for confirmation.

Users must then enter their full name (first and last), phone number, and email address. A drop-down field allows users to define the capacity in which they will use the system. Selections include surgeon, assistant, and sales representative. If "surgeon" is selected, additional fields will populate for hospital affiliations, city, state/province, and sales rep email. If "assistant" is selected, no additional fields will populate. If "sales representative" is selected, additional drop-down fields will populate for agency and region.

NOTE: Upon logging in for the first time, the user will be redirected to an Okta login screen to verify their identity. Users should always use their email address to log in to VIP.



Figure 1

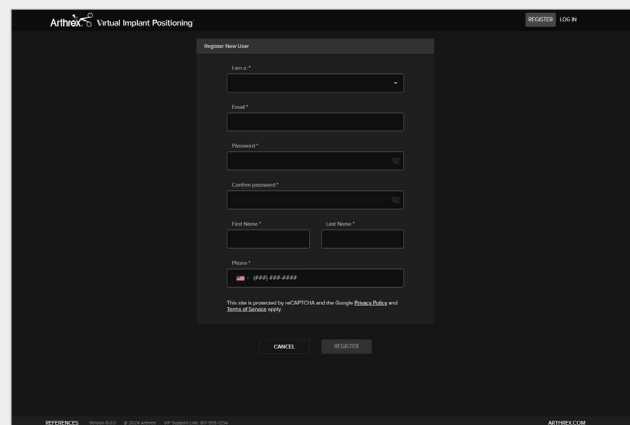


Figure 2

User Permissions

Surgeon	Assistant	Technology Consultant
Register as user ^a	Register as user ^b	Register as user ^b
Change own profile info	Change own profile info	Change own profile info
Add assistants and technology consultants to profile	Change own password	Change own password
Change own password	View cases/plans of associated surgeons	View cases/plans of associated surgeons
View own cases and plans	Create cases for associated surgeons	Download PDFs for associated surgeons
Create cases	Upload CTs for cases of associated surgeons	Comment on associated cases and plans
Upload CT scans for cases	Edit associated cases	Edit associated cases
Edit own cases	Archive/unarchive cases of associated surgeons	Create cases for associated surgeons
Archive/unarchive cases	Edit plans of associated surgeons	Upload CT scans for associated surgeons
Edit plans	Download PDFs for associated surgeons	
Approve plans	Comment on associated cases and plans	
Download PDFs		
Comment on own plans and cases		

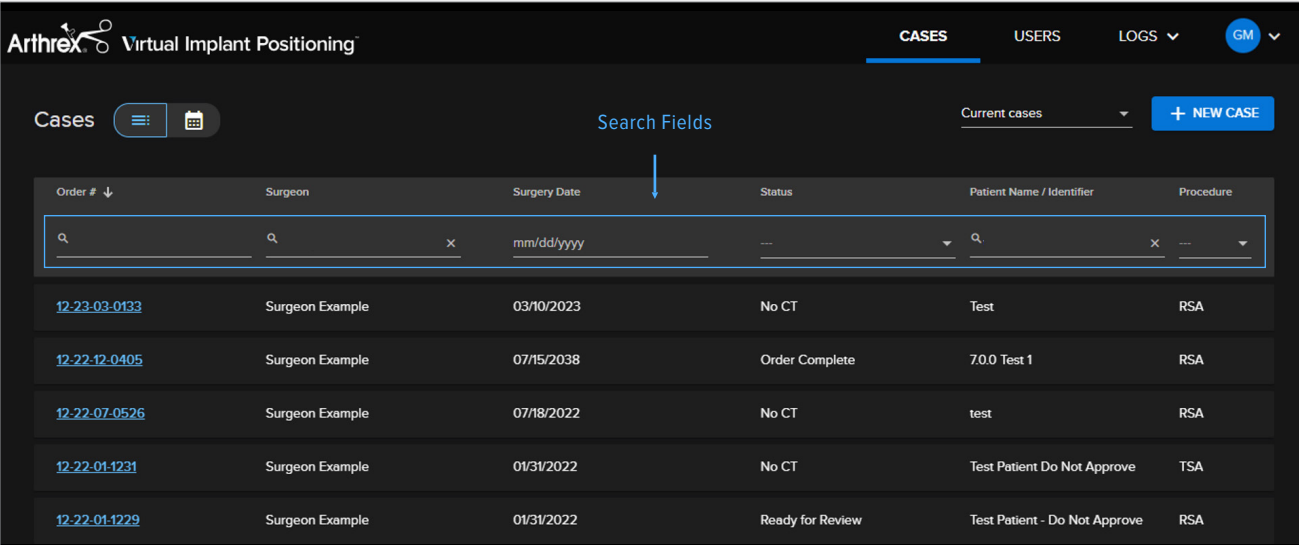
^aWhen a surgeon registers on the web portal, their identity must be verified by a system administrator before they can log into the web portal.

^bWhen a technology consultant registers on the web portal, they must be linked to a surgeon account in order to use manage cases and view plans. A surgeon or system administrator must link a technology consultant to a surgeon account before they can view or edit any cases.

Cases Page

Upon successfully logging in, the user is brought to the “Cases” page (whether they are a surgeon, assistant, or technology consultant).

- This page (Figure 3), which provides surgeons with an organized view of their cases, provides quick navigation, sorting options, and searchable columns.
- Each search bar queries within its respective column (category) and can be used to filter results. Multiple search bars can be used simultaneously.
- Each case is characterized by six categories (columns):
 - **Order #**—A unique identification number assigned to each case that ensures no two cases can be characterized in exactly the same way.
 - **Surgeon**—The name of the surgeon corresponding to a particular case.
 - **Patient Name**—The name of the patient corresponding to a particular case.
 - **Surgery Date**—The date on which the procedure is scheduled to be performed. As a registered web portal user, the surgery date listed in the VIP™ system can be changed by a surgeon, surgeon assistant, or Arthrex technician.
 - **Procedure**—The elected shoulder arthroplasty procedure (total shoulder arthroplasty [TSA] or reverse shoulder arthroplasty [RSA]).



The screenshot displays the 'Cases' page in the Arthrex Virtual Implant Positioning web portal. The page features a dark theme with a top navigation bar containing 'CASES', 'USERS', 'LOGS', and a user profile icon 'GM'. Below the navigation, there are 'Cases' and 'Search Fields' sections. The 'Cases' section includes a menu icon, a calendar icon, and a '+ NEW CASE' button. The 'Search Fields' section contains a search bar with a magnifying glass icon and a clear 'x' button. Below the search fields is a table with the following columns: Order # (with a dropdown arrow), Surgeon, Surgery Date (with a date format 'mm/dd/yyyy' and a dropdown arrow), Status, Patient Name / Identifier (with a search icon and a clear 'x' button), and Procedure. The table contains five rows of example data:

Order #	Surgeon	Surgery Date	Status	Patient Name / Identifier	Procedure
12-23-03-0133	Surgeon Example	03/10/2023	No CT	Test	RSA
12-22-12-0405	Surgeon Example	07/15/2038	Order Complete	7.0.0 Test 1	RSA
12-22-07-0526	Surgeon Example	07/18/2022	No CT	test	RSA
12-22-01-1231	Surgeon Example	01/31/2022	No CT	Test Patient Do Not Approve	TSA
12-22-01-1229	Surgeon Example	01/31/2022	Ready for Review	Test Patient - Do Not Approve	RSA

Figure 3

- **Status**—This indicates a case’s current status along the preoperative planning process (Figure 4). The case progresses through the following statuses during the preoperative planning workflow:
 - **No CT:** A new case has been created, but the CT has not been uploaded.
 - **CT Received:** A new case has been created, and the user has successfully uploaded CT images.
 - **CT Unacceptable:** The uploaded CT images do not pass the acceptance criteria for CT scans and must be reuploaded to continue processing the case.
 - **CT Accepted/Planning:** The CT images for a new case have been uploaded and have passed the preliminary CT scan acceptance criteria. An Arthrex technician begins planning the case according to the protocol. Though unlikely, it is possible an issue may be encountered during the planning process that prevents the technician from separating the bones accurately, prompting a rejection of the CT scan.
 - **Ready for Review:** A technician has uploaded a proposed preoperative plan for the case, and it is ready for surgeon review and approval.
 - **Approved:** A surgeon has accepted and endorsed a plan, including the implant types and sizes as well as their locations and orientations. Once the surgeon has approved the plan, no further changes can be made to the plan. The approved preoperative plan includes order type, which varies from case to case, and is based on surgeon needs for that particular case.

Note: The case cannot be processed without surgeon approval of the case plan.
 - **Processing:** Technicians are processing the case’s specific order requests.
 - **Order Complete:** Technicians have filled an order request (ie, 3D model has been shipped, an approved preoperative plan has been uploaded, or both).

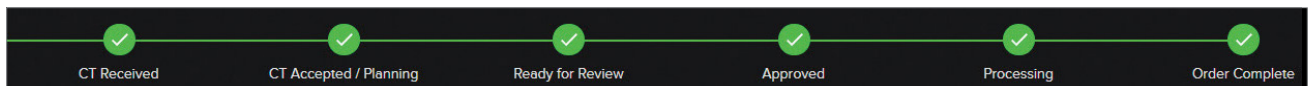


Figure 4. Case status flowchart

New Case

From the “Cases” page, click the “New Case” button (Figure 5) to reach the “New Case” page (Figure 6). The surgeon username (in this case: “arthrexdemocase”) will be autopopulated depending on which user is logged in. Using this form, users can enter and save descriptive information about the case.

When creating a new case, the following information is REQUIRED unless otherwise noted:

- **Side:** The shoulder that the surgeon will operate on (left or right).
- **Patient Name:** Patient’s name exactly as it appears in the associated DICOM file.
- **Date of Surgery:** Must be a date in the future.
- **Type of Procedure:** Total shoulder arthroplasty or reverse shoulder arthroplasty.
- **Status:** No action needed (prefilled and uneditable).
- **Order Type:** Defines the surgeon’s desired deliverable (eg, plan only, 3D model, 5D calibrator, or 3D model and 5D calibrator).
 - *Plan only*—The preoperative plan that is accessible and approved via ArthrexVIP.com.

- *3D model (3D)*—The physical, tangible 3D-printed bone model that is created with a pin trajectory derived from the surgeon’s approved plan. The 3D model is used to establish the targeter’s leg settings, which are required to intraoperatively achieve the approved plan’s trajectory of the guide pin.
- *5D Calibrator*—Includes the preoperative plan accessible via ArthrexVIP.com and a PDF with glenoid targeter heights (AR-5400-xx series).
- *3D and 5D*—Order type includes everything from the 3D and 5D calibrator.
- **Planning Comments:** Any further information regarding the case that Arthrex should be aware of (optional).

Clicking “Save” will create the new case, moving it to the “Cases” page.

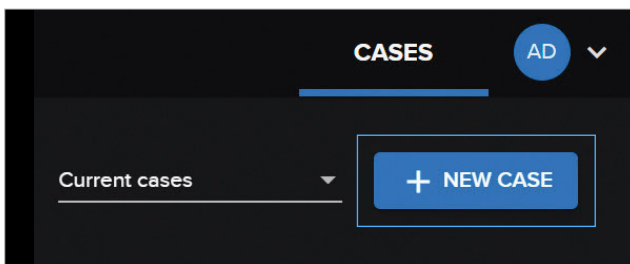


Figure 5. New Case button (upper right corner of the Cases page)

A screenshot of the 'New Case' page in the Arthrex Virtual Implant Positioning (VIP) web portal. The page title is 'Arthrex Virtual Implant Positioning' and the breadcrumb is 'Cases / New Case'. The form is titled 'Case Information' and contains several sections: 'Patient Details' with a field for 'Patient Name / Identifier *'; 'Case Information' with fields for 'Date of Surgery *' (with a calendar icon), 'Side *' (radio buttons for 'Left' and 'Right'), and 'Procedure *' (radio buttons for 'Total Shoulder' and 'Reverse'); 'Order Type *' with a dropdown menu currently set to '5D Calibrator'; and 'Planning Comments (optional)' with a text area for 'Add comments here...'. At the bottom of the form are 'SAVE' and 'CANCEL' buttons.

Figure 6. New Case page

MyVIP™ Automated Preoperative Texting Experience

If the patient wishes to be enrolled in the MyVIP experience, enter the patient’s phone number in the appropriate field at the bottom of the page. We developed an automated, presurgical texting experience that directly links to your surgical plan in our VIP™ software. Inspired by the Amazon delivery service, the MyVIP texting platform engages patients with meaningful information at specific checkpoints in their presurgical journey. The experience is carefully designed to always place the surgeon one step ahead, instill a sense of personalized medicine and strengthens the patient-surgeon connection. Please connect with your Arthrex Technology Consultant for more information.

Uploading CT Images

- Once a new case is created, click the “Upload CT” button to upload the CT images for this case (Figure 7).
- Please ensure that the CT being uploaded is in adherence to the protocol on the following page.

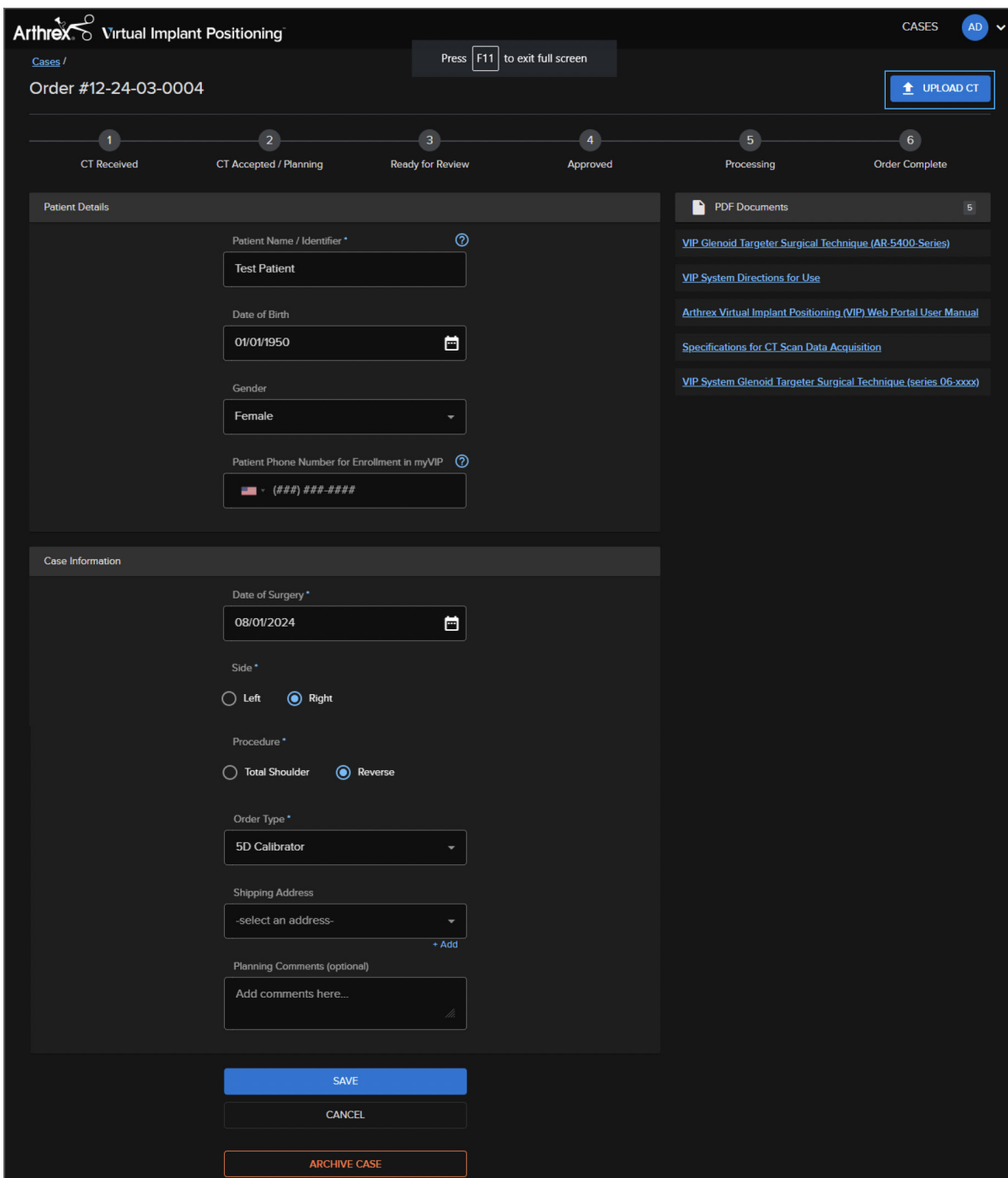


Figure 7. Case and CT upload forms

Preferred CT Data Specifications: Shoulder

Scan Protocol: CT shoulder without contrast.

Please transfer DICOM to CD or upload directly to the facility's admin account.

- The Virtual Implant Positioning™ (VIP™) system uses only the thin axial images
- Reformatted images will not be accepted
- Start the CT scan several slices above the AC joint and include the entire scapula and proximal third of the humerus
- The medial and inferior borders of the scapula must be included in the scan
- If the patient has any metal implants on the contralateral side, position the arm above the patient's head to minimize metal artifacts in the scan
- If the patient has metal on the affected side, use the appropriate Metal Artifact Reduction Algorithm per the manufacturer

To minimize the number of rejections due to incompatible or inadequate imaging, Arthrex reserves the right to reject CT scans that have one or more parameters outside the recommendations below.

CT scans will be accepted for VIP preoperative planning for up to 6 months from the date of the scan

Patient Position	Shoulder: Supine, arms at sides with shoulders in neutral rotation, shoulder centered in gantry
Slice Thickness	≤1 mm; minimum 0.2 mm; preferable 0.6 mm
Reconstruction Interval (collimation, scan spacing)	≤1 mm; preferably less
Acquisition	Spiral or helical mode
Field of View (FOV)	Start the CT scan several slices above the AC joint and include the entire scapula and proximal third of the humerus as small of a FOV as possible
Span Spacing	Contiguous slices
Pitch	<1
Gantry Angle	0° (no tilt)
Reconstruction filter/algorithm	Standard or Soft Tissue (not smooth, not sharp, not bone, not detail) No contrast (arthrograms NOT acceptable) Raw DICOM (grayscale only; no formatting)
Scan Strength (kVp)	140 kVp if available; otherwise, 120 kVp
Dose Modulation (mA)	300 mA with dose modulation; if modulation is not available, then 200 mA or higher depending on patient size

Page 1 of 1

This document is confidential and proprietary and it may not be reproduced, used, or disclosed to others without written consent of Arthrex, Inc.

Arthrex, Inc.
Specifications for CT Scan Data Acquisition
Revision Level: 1

arthrex.com

© 2022-12 Arthrex, Inc. All rights reserved. LR1-000018-en-US_B



Uploading CT Images

Within the upload form, the username and order number are autopopulated (Figure 8).

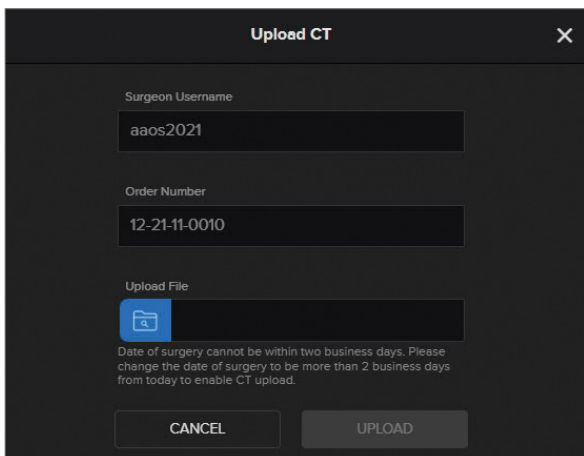


Figure 8. Upload CT page

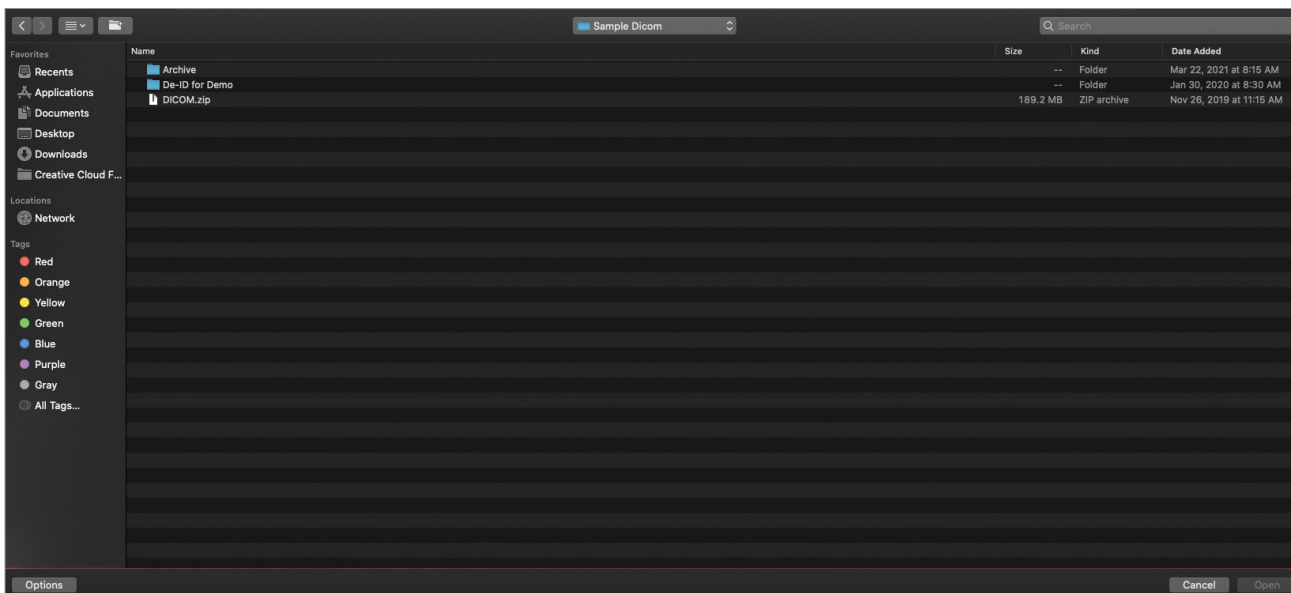


Figure 9. Locating compressed folder

From the upload form, click the “Choose File...” button to open a standard file browsing window (Figure 9). The user must navigate to a compressed folder (.zip file) containing the DICOM CT images. Select the compressed folder (.zip file).

Uploading CT Images

Once a file has been selected, click “Upload” to begin uploading the CT images (Figure 10). A spinning wheel indicates that the images are being uploaded and that the web portal has not frozen or crashed during the upload process. Upload progress can be viewed in the bottom left of the browser window.

Compressed .ZIP File Creation (Windows PC)—To create a compressed .zip file out of a folder of DICOM images, navigate to the folder containing the CT images. Right click the folder and in the pop-up menu that appears, select and choose “Compressed (zipped) folder” to create a single .zip file that can be selected using the “Choose File...” button. Select “Upload” to add the file to the newly created case within the web portal.

Compressed .ZIP File Creation (Mac)—To create a compressed .zip file out of a folder of DICOM images, navigate to the folder containing the CT images. Hold CTRL and click that folder. On the menu that appears, select “Compress Items” to create a single .zip file that can be selected with the “Choose File...” button. Select “Upload” to add the file to the newly created case within the web portal.

Once CT images are uploaded, the case status will automatically change from “No CT” to “CT Received.” At this point in the process, a technician will evaluate the CT scan to determine whether the resolution, quality, and field of view are in accordance with the CT scan parameters. If the CT scan is acceptable, a technician will accept the scan and mark the case status as “CT Accepted/Planning” (Figure 11).

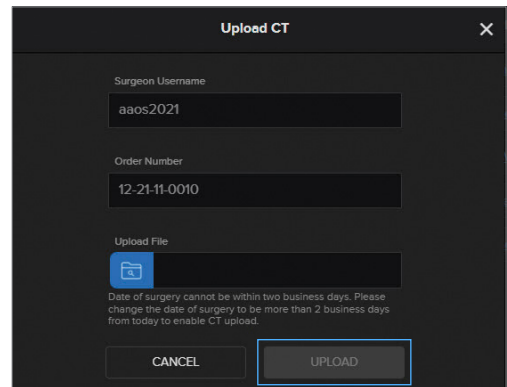


Figure 10. “Upload” button that initiates CT upload



Figure 11. Case status flowchart after CT has been accepted for planning

Uploading CT Images

If the CT scan is unacceptable, the technician will mark the case status as “CT Unacceptable.” They will note why the scan was unacceptable, so that it may be corrected. A case will remain in the “CT Accepted/ Planning” status until a technician uploads a proposed preoperative plan (web session) for that case. At this point, the case status immediately becomes “Ready for Review” (Figure 12).

When a case is ready for review, an email notification is sent to the surgeon and the surgeon’s assistants/ technology consultants that a case is ready for review on the web portal. This email reminder will be sent once per week until 1 week prior to the surgery date entered by the surgeon. At this point, if the plan is still not approved, daily reminders are sent until 3 days prior to surgery. Once the plan is approved, a confirmation email is sent and the case status is changed to “Approved.”



Figure 12. Case status flowchart once plan is ready for review

Case Status Flowchart

There is a status flowchart at the top of the “Case Details” page (Figure 13). This status flowchart will update itself throughout the planning process and is a convenient tool for case tracking. Note that no user can change a case status to approved/unapproved except the surgeon who placed the order for the case.



Figure 13. Case status flowchart

Archiving a Case

At the bottom of the “Case Details” page, there is an orange button labeled “Archive Case.” Clicking the “Archive Case” button stores the case away and removes it from the “Cases” page.

The user can view all archived cases while on the “Cases” page. In the top right corner of the page, click on the down arrow next to “Current Cases.” Click on “Archived Cases.” When the archived case is opened, an orange “Unarchive Case” button is available at the bottom of the “Case Details” page. Clicking “Unarchive Case” moves the case back to the “Current Cases” page.

Archiving a case does not delete it. Archived cases can be retrieved at any time by an administrator/technician, or by the surgeon who originally placed the order for the case.

Accessing the Viewer Page

To access a web session or an approved preoperative plan for a case, click on “View Plan” in the upper right of the “Case Details” page (Figure 14). This will direct you the viewer page of the VIP™ preoperative planning system web portal or the VIP app on an iPad.

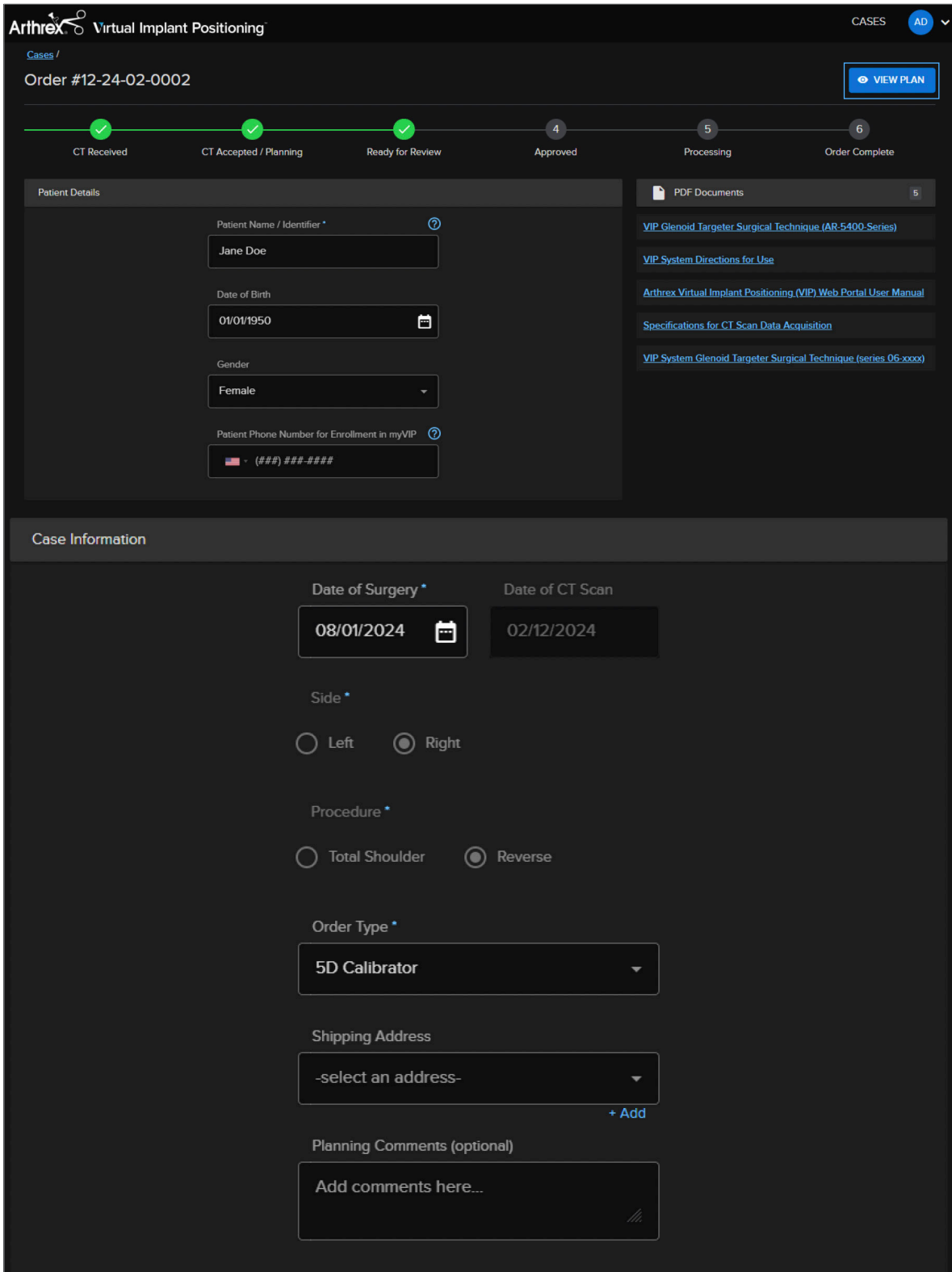


Figure 14. The Case Details page showing the View Plan button that links to the Viewer page

Joint Viewer Page

Clicking on “ViewPlan” opens the “Joint Viewer” page (Figure 16), which displays the rendered 3D image of the CT scan and the Arthrex-selected glenoid and humeral implants in their proposed locations and orientations per the planning protocol. Manipulate the 3D bone model by left-clicking on the model and moving the mouse to adjust its orientation. Zoom in and out of the 3D image by using the mouse’s center scroll wheel and pan by right-clicking and dragging the image.

From this page, the plan(s) can be duplicated, saved, and approved. Range of motion information for reverse plans is accessible from a drop-down menu, as is the research information on the ▲ of center of rotation in 3 dimensions for both anatomic and reverse plans.

The menu on the right side of the interface (Figure 15) will default to the “Case Details” section, displaying the patient name, sex, and age as entered in the VIP™ software, the native joint subluxation, and a summary of the implant selections displayed in the proposed preoperative plan. Additionally, a set of universal tools is anchored to the left side of the menu (highlighted in Figure 15) that are accessible throughout the interface for:

- Osteophyte removal
- Camera location
- Measurement in 2D and 3D views
- Visibility settings
- Case comments

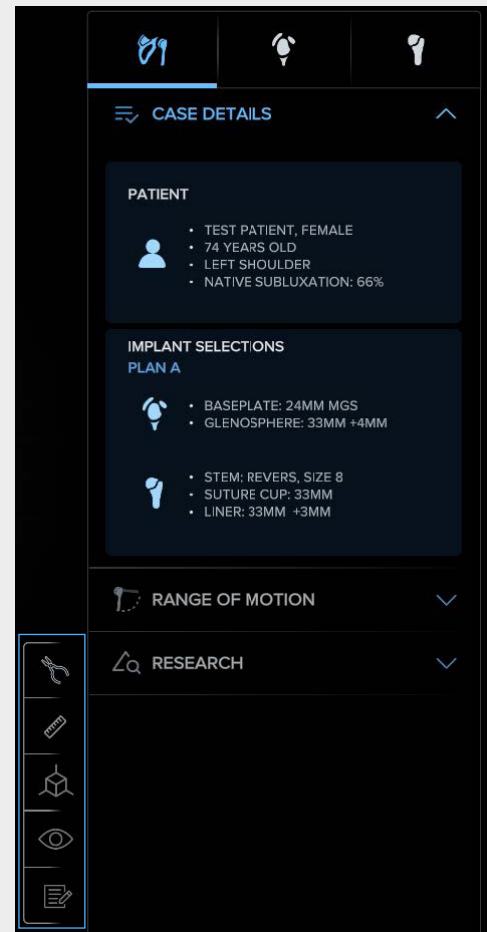


Figure 15. Case Details menu

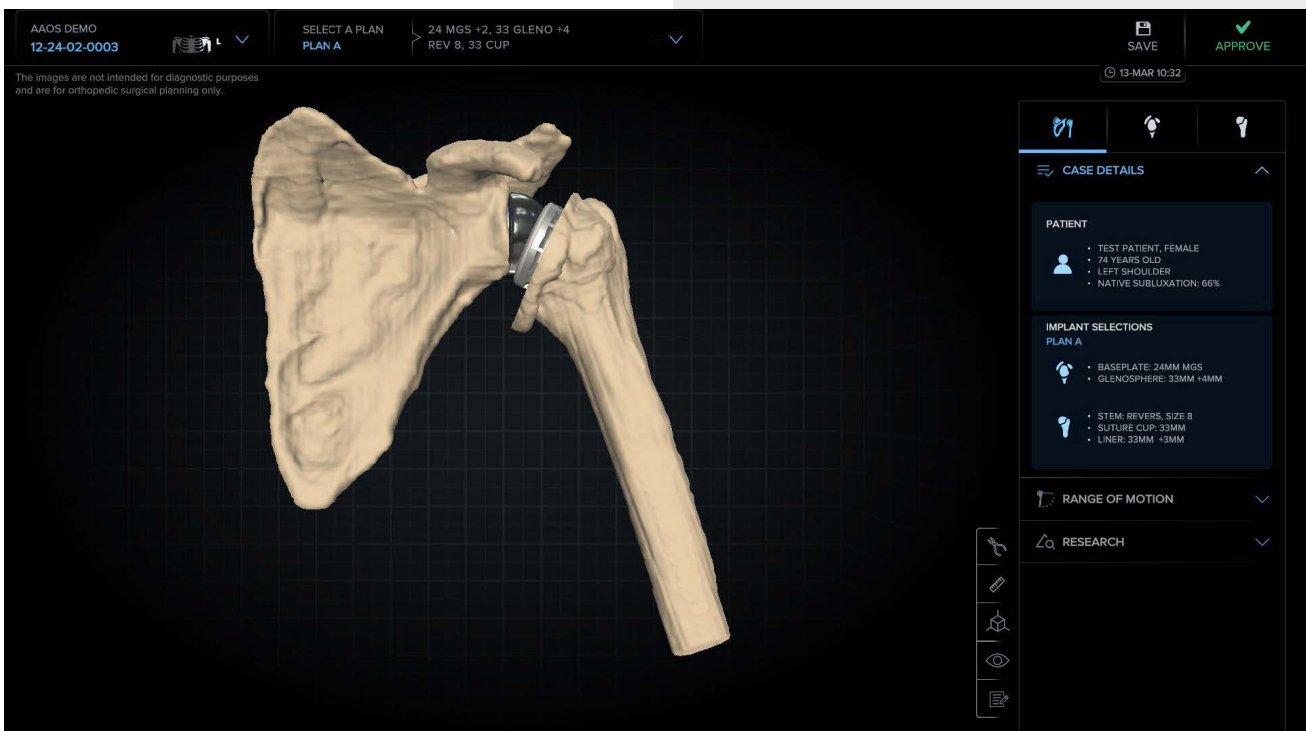


Figure 16. Joint Viewer page

Interface Functionality

Multiple Plan Creation

Users may create up to 3 plans within the same case to compare throughout the planning process and approve up to 2 plans for completion as Plan Only or 5D order types. If a 3D or 3D/5D order type is selected, a user may only approve one plan.

To create multiple plans, open the “Select a Plan” drop-down menu from the top of the screen and click the “Duplicate” button as shown in Figure 17 on the plan to be duplicated. Once duplicated, the new plan can be modified as desired.




- The active plan will have a blue outline as shown in Figure 18.
- To rename a plan, click on the  in the desired plan’s tile and input the desired name.
- To delete a plan, click on the  in the desired plan’s tile.
- To reset a plan back to its last saved configuration, click on the  in the desired plan’s tile.



Figure 17. Select a plan drop-down



Figure 18. Plan duplication

Osteophyte Removal Tool (Figure 19)

- Open the tool by selecting the rongeur icon on the universal tools menu.
- Select the desired radius of the resection sphere.
- Move the sphere over the osteophyte(s) to be removed and click to remove bone within the diameter of the resection sphere.

NOTE: The center of the resection sphere (denoted by the tip of the cursor) must be over bone for the sphere to appear.

- Use the “Undo/Redo” tool to iteratively restore or remove previously removed bone.

NOTE: Once a user navigates to new tab (Joint, Glenoid, or Humerus), all changes made to the anatomy are saved for that planning session and the “Undo/Redo” function will no longer be available. Changes are permanently applied to the plan when the user clicks the “Save” icon in the top-right corner of the interface.

- Use the “Revert to Original Anatomy” function to undo all changes made since the last save.
- Changes made to the anatomy with the osteophyte removal tool will transfer across all plans within the same case.
- Bone removed using the osteophyte removal tool can be visualized by selecting the “Osteophytes” toggle within the visibility tool (Figure 20) and are represented on the 3D model as shown in Figure 21. If the tool has not been used, the “Osteophytes” toggle will be hidden.

NOTE: Any osteophytes removed during the planning process will not affect the targeter settings or given version and inclination measurements



Figure 19. Osteophyte removal tool

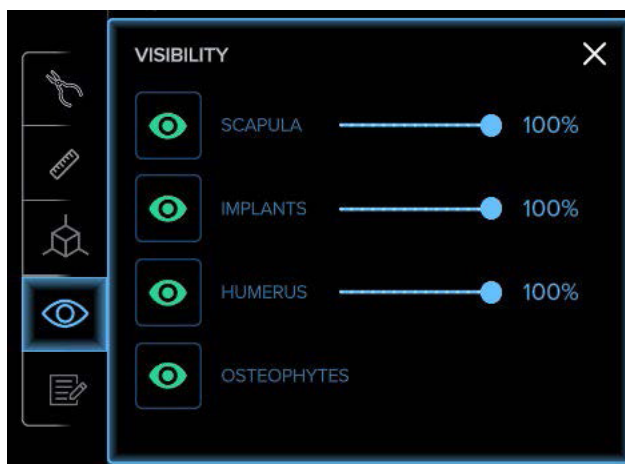


Figure 20. Osteophyte visualization toggle

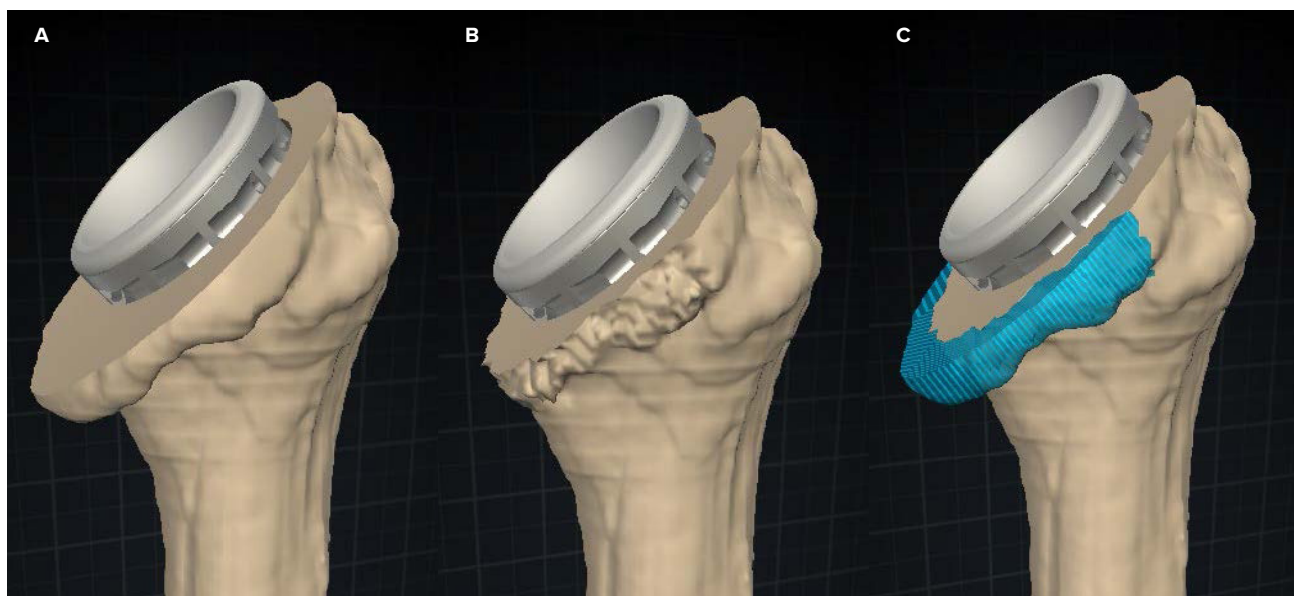


Figure 21. Native anatomy (A), osteophytes removed (B), and visualized (C)



Interface Functionality

Measurement Tool (Figure 22)

- Open the tool by selecting the ruler icon on the universal tools menu.
- While holding a mouse click, move a blue circle to establish the first reference point.
- Repeat the mouse click and hold to drag the remaining blue circle to the second reference point.

NOTE: When measuring in the 3D view, be sure to verify the placement of the blue circles to ensure an accurate measurement.

Camera Tool (Figure 23)

- Open the tool by selecting the cube icon on the universal tools menu.
- Click the desired arrow (left or right) or label (anterior, posterior, etc) to snap the camera to different anatomical references. The camera view aligns perpendicularly to the datum planes established in the OrthoVis desktop software for the 3D bone model.
- Play a looped video of the 3D anatomy rotating in space by clicking the  in the upper left corner.
- Reset the camera view to the default orientation, location and zoom by clicking the  in the top right corner.

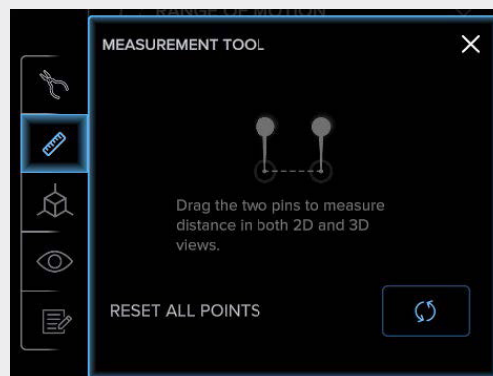


Figure 22. Measurement tool

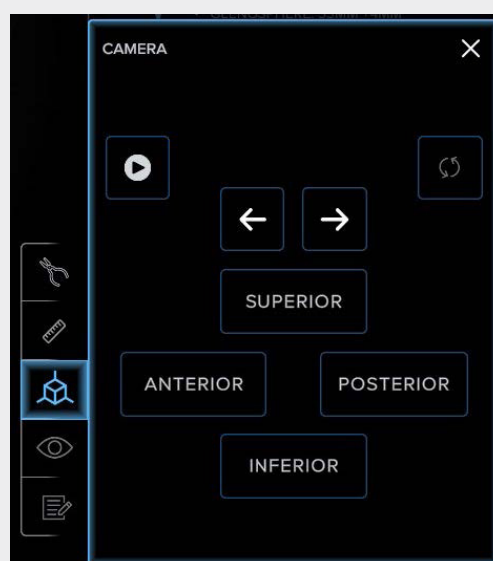


Figure 23. Camera tool

Interface Functionality

Visibility Tool (Figure 24)

- Open the tool by selecting the eye icon on the universal tools menu.
- Show/hide the scapula, humerus, or implants in the 3D view.
- Change scapula, humerus, and implant transparency from 0% to 100% in the 3D view.

Case Comments Tool (Figure 25)

- Open the tool by selecting the pen and paper icon on the universal tools menu.
- Enter the desired comments (additional posterior overhanging targeter leg, eg) and select “Save.”
- Comments are viewable by all who have access to the case (surgeon, assistant, technology consultant, technicians), and these individuals can respond with their own comments.

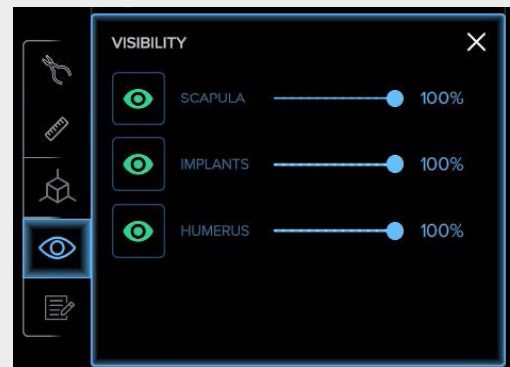


Figure 24. Visibility tool

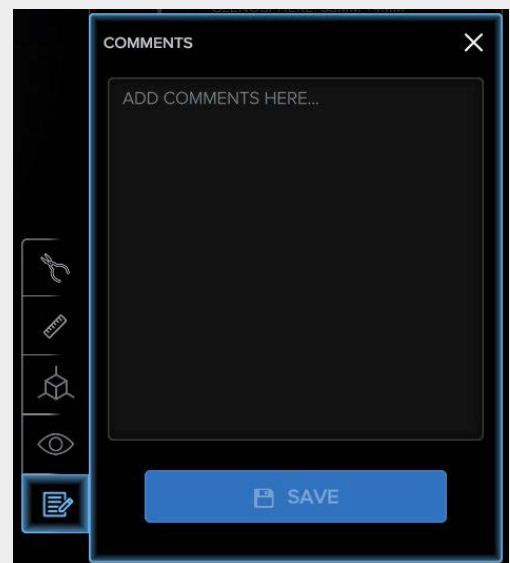




Figure 25. Case Comments tool

Glenoid Viewer Page

Clicking on the  opens the “Glenoid Viewer” page, which displays the rendered 3D image of the CT scan and the Arthrex-selected glenoid implant in its proposed location and orientation per the planning protocol. Manipulate the 3D bone model by left-clicking on the model and moving the mouse to adjust its orientation. Zoom in and out of the 3D image by using the mouse’s center scroll wheel and pan by right-clicking and dragging the image. From this page, the plan(s) can be modified, duplicated, saved, and approved. The coronal and axial views are shown to the left of the 3D view. Its two planes (green and

purple) correspond to the colored outline of each view (ie, the coronal plane slices are shown in the view outlined in green). Zoom in and out of a 2D image by using the mouse’s center scroll wheel and pan by right-clicking and dragging the image.

The coronal and axial views can be enlarged by clicking on the  in the lower right corner of each 2D viewer window, shown in blue boxes in Figure 26. When selected, the 2D images will enlarge as shown in Figure 26a.

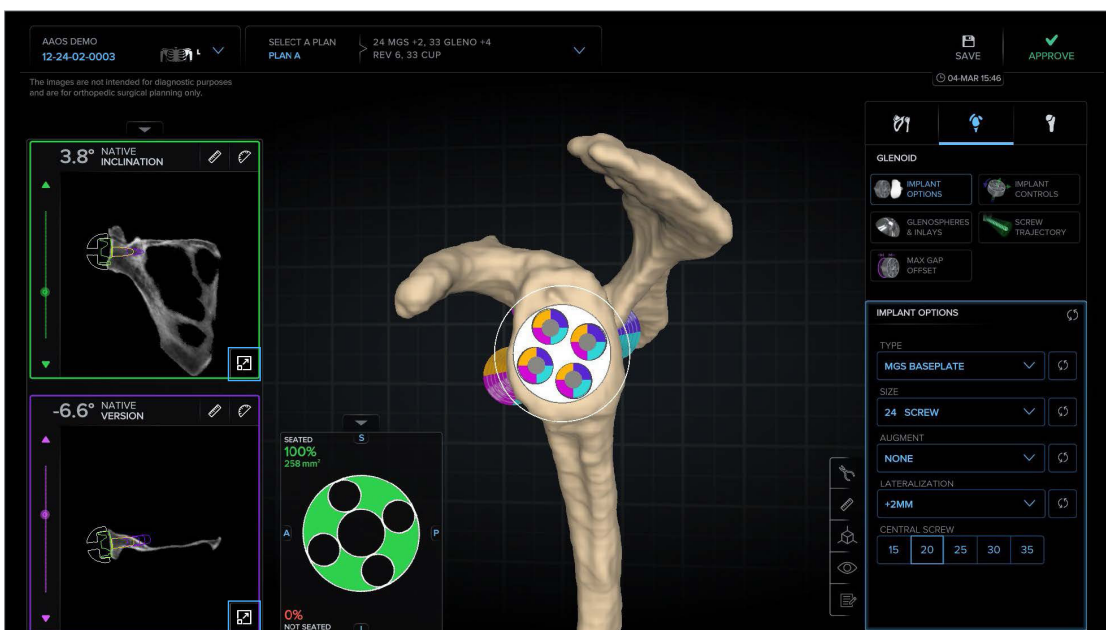


Figure 26. Glenoid Viewer page displaying proposed preoperative plan

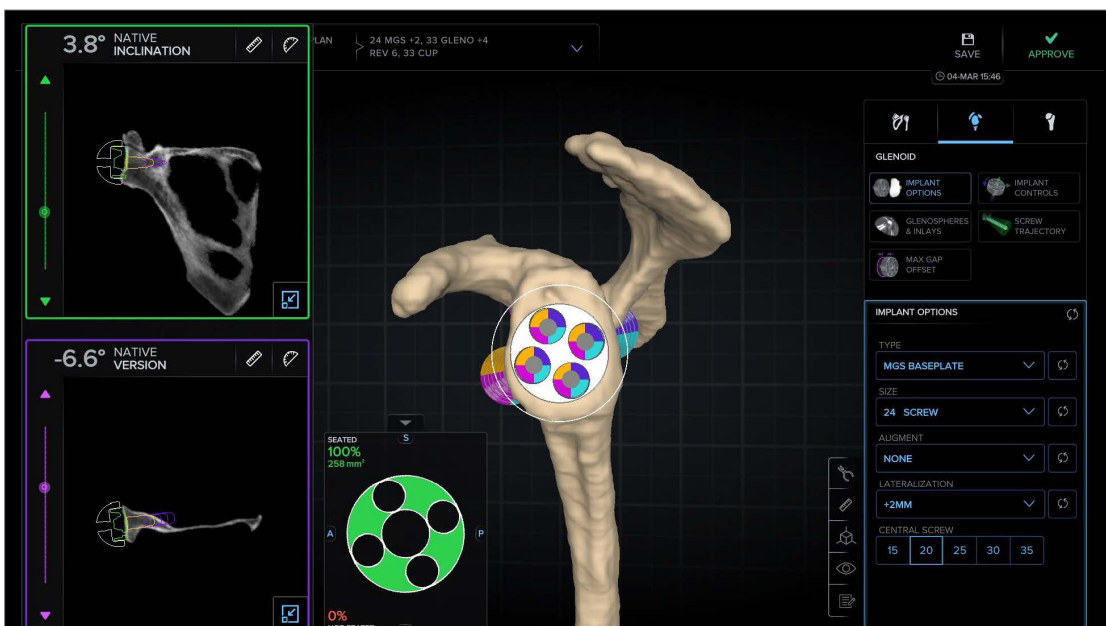


Figure 26a. Glenoid Viewer page with enlarged 2D views

Measurement Tools (Figure 27)

Measurement tools are located at the top right corner of each 2D viewer window (coronal [green box] and axial [purple box]) and on the universal tools menu. Use the ruler button to measure length and the protractor button to measure angle. Measurements for angulation can only be acquired in the 2D view.

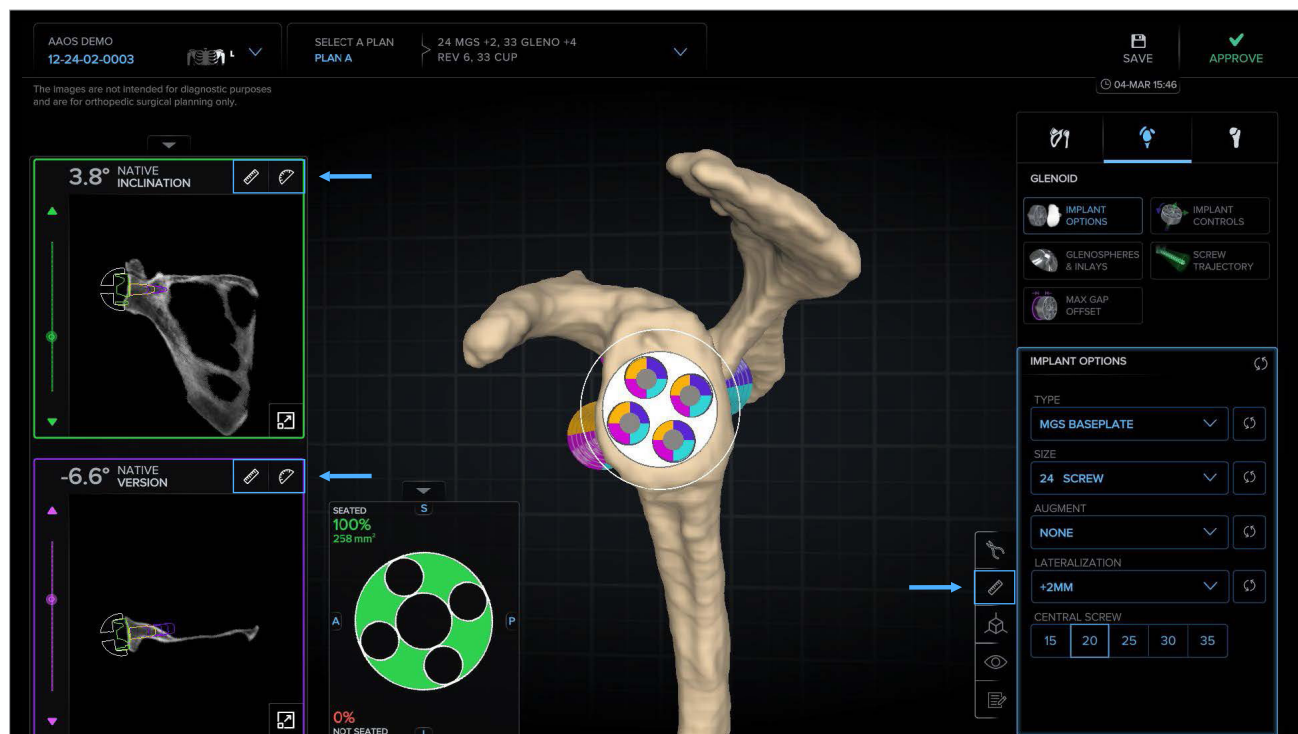


Figure 27. Glenoid Viewer page displaying the proposed preoperative plan

Measure Length

- Click on the ruler icon at the top right of the 2D view or on the universal tools menu.
- While holding a mouse click, move a blue circle to establish the first reference point.
- Repeat the mouse click and hold to drag the remaining blue circle to the second reference point.

Note: When measuring in the 3D view, be sure to verify the placement of the blue circles to ensure an accurate measurement.

Measure Angle

- Click on the protractor icon at the top right of the 2D view.
- While holding a mouse click, move a blue circle to establish the first reference point.
- Repeat the mouse click and drag the second blue circle to establish the vertex of the angle desired.
- Move the third surface point to generate the angle measurement, which will be displayed to the right of the 2D view.

Interface Functionality

Glenoid Implant Selection and Controls (Figure 28)

Available implants may be selected and positioned by selecting the corresponding function on the Glenoid Viewer Page implant control panel.

Implant Options (Figure 29)

- Change the implant type to Pegged, Keeled, VaultLock® Glenoid, Universal Glenoid, or MGS Baseplate.
- Change the implant size.
- Select a standard or augmented VaultLock Glenoid.
- Change the MGS Baseplate type and lateralization.
- Select the central screw or post length

Implant Controls (Figure 30)



- Adjust version, inclination, and roll of the implant.
- Adjust S/I, A/P, and L/M location of the implant.
- The orientation controls include version, inclination, and roll. Use the slider bars for gross adjustments of the implant orientation. Click the “+” or “-” buttons to adjust the selection in 1° increments. Users can also enter a whole number value into the orientation indicator boxes and press enter, or click elsewhere. Decimal values entered into the orientation controls are truncated and ignored.
- The S/I slider bar moves the implant position in the superior or inferior direction based on whether the bar slides to the left or right. Click the “+” or “-” buttons to adjust the selection in 0.5 mm increments.
- The A/P slider bar moves the implant position in the anterior or posterior direction based on whether the bar slides to the left or right. Click the “+” or “-” buttons to adjust the selection in 0.5 mm increments.
- The L/M slider bar moves the implant position in the lateral or medial direction based on whether the bar slides to the left or right. Click the “+” or “-” buttons to adjust the selection in 0.5 mm increments.
- Click on the  in the top right of the “Implant Controls” panel to open the reset controls menu. Users may reset one of the individual controls by clicking on the  to the right of the desired control to be reset or reset all controls to their last saved settings.



Figure 28. Glenoid viewer implant selection and control panel

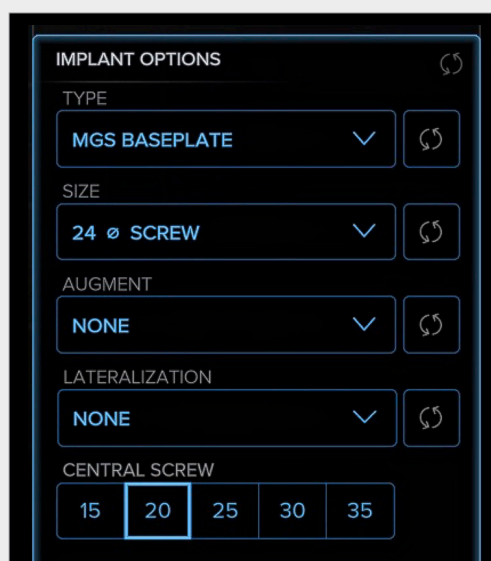


Figure 29. Implant Options control panel



Figure 30. Implant Controls panel

Interface Functionality

Glenospheres & Inlays (Figure 31)

- Visualize and select the diameter and lateralization of the glenosphere when using the Modular Glenoid System in both 2D and 3D views.
- Visualize and select the diameter and lateralization of the glenosphere or lateralization of the inlay when using the Universal Glenoid™ in both 2D and 3D views.

Screw Trajectory (Figure 32)

- Visualize and select peripheral screw types and trajectories that are possible when using the Universal Glenoid or Modular Glenoid System baseplates.

Implant Compatibility Warnings (Figure 33)

When planning an anatomic shoulder, the selection of a glenoid component that changes the glenohumeral mismatch to one outside of the recommended range will prompt a warning. Once the Humeral tab is selected, the system will default to the smallest humeral head size compatible with the selected glenoid component.

Similarly, when planning a reverse shoulder, the selection of a glenosphere that is not compatible with the planned suture cup/insert combination will prompt a warning. Once the Humeral tab is selected, the system will default to the suture cup/insert combination that matches the selected glenosphere diameter.

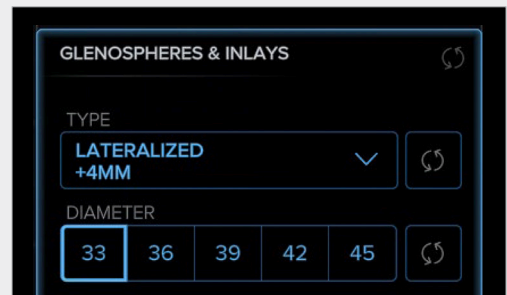


Figure 31. Glenospheres & Inlays function

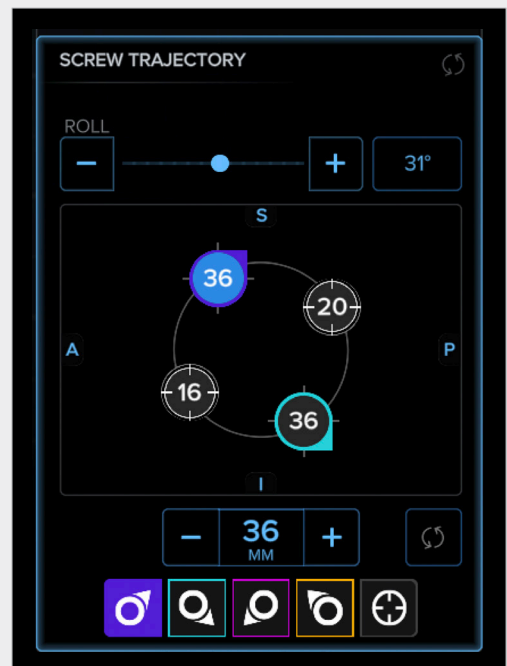


Figure 32. Screw Trajectory function

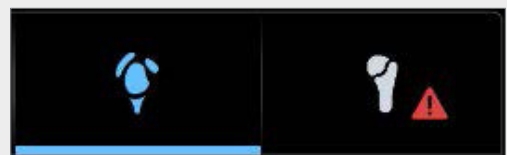


Figure 33. Implant Compatibility Warning

Max Gap Offset (Figure 34)

- Located under the Controls tab.
- This function can be turned on and off using the “Calculate” button.

The Max Gap output shows the largest distance—and location of max distance—between the backside of the implant and the bone, excluding the buildup of the augment.

The Depth output displays the largest depth—that the backside of the implant is into the bone, excluding the buildup of the augment.

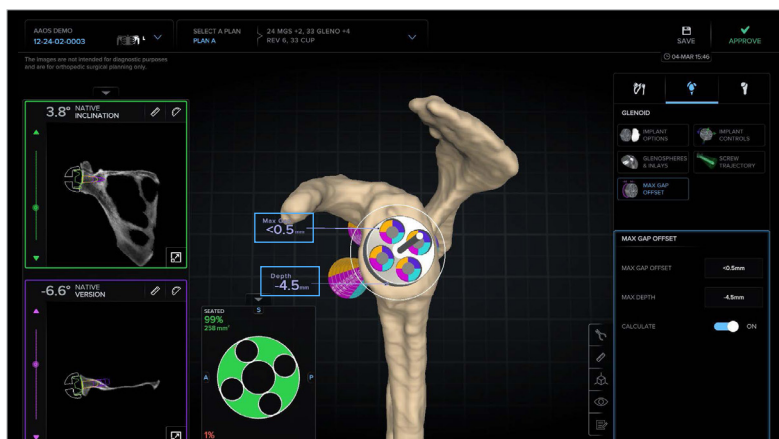


Figure 34. Max Gap Offset output

Backside Seating (Figure 35)

- This measurement can be maximized or minimized using the arrow above the Backside Seating Heat Map (shown in blue box in Figure 35).
- This feature shows areas where the backside of the implant is not contacting bone in red (see red arrows in Figure 35) and areas where the backside of the implant is contacting bone in green (see green arrows in Figure 35) in both 2D and 3D views.

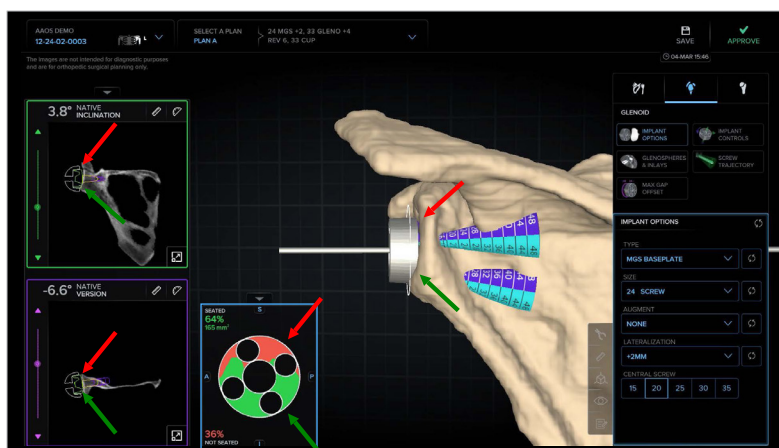


Figure 35. Backside Seating feature

Implant Perforation (Figure 36)

- This feature within the backside seating heat map will show areas where the implant perforates the glenoid medially as indicated by the red arrows shown in Figure 36.
- Occasionally, bone cysts in the glenoid contacting the implant will be represented as perforated areas on the heat map and should be confirmed as such on the 2D and 3D views.

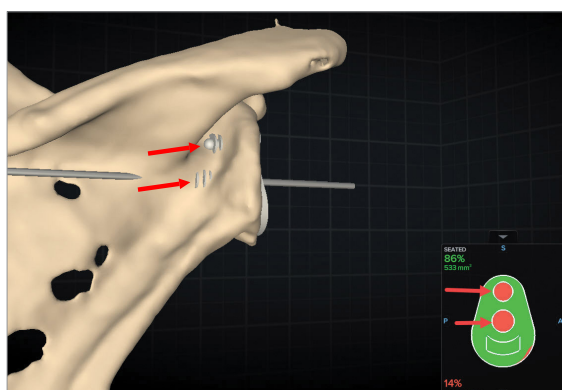


Figure 36. Implant perforation in Backside Seating feature

Visibility Controls (Figure 37)

- Show/hide elements in the 2D and 3D views (eg, implant, pin, bone, frames, CT slices, and reamed geometry).
- Change scapula and implant transparency from 0% to 100% in the 3D view.
- View the original coronal and axial DICOM slices in the 3D view.

Show/Hide Elements (Figure 37)

- Implant: Click the toggle to display or hide the implant in the 2D and 3D views.
- Pin: Click the toggle to display or hide the pin in the 3D view.
- Bone: Click the toggle to display or hide the bone in the 3D view.
- Frames: Click the toggle to display or hide the frames in the 3D view.
- Slices: Click the toggle to display or hide the 2D slice data projected onto the planes in the 3D-rendered model.
- Ream: Click the toggle to display or hide the instrumented ream/drill preparation for the implant in the 2D and 3D views.

Reamed Geometry (Figure 37)

- From the Visibility tab, the Reamed Geometry function is turned on (green icon), with corresponding 2D and 3D images appearing in the viewer.
- This feature gives users visibility to the instrumented ream/drill preparations for the selected implant.

Osteophytes (Figure 37)

- Show/hide any bony anatomy in the 3D model previously modified with the osteophyte removal tool.

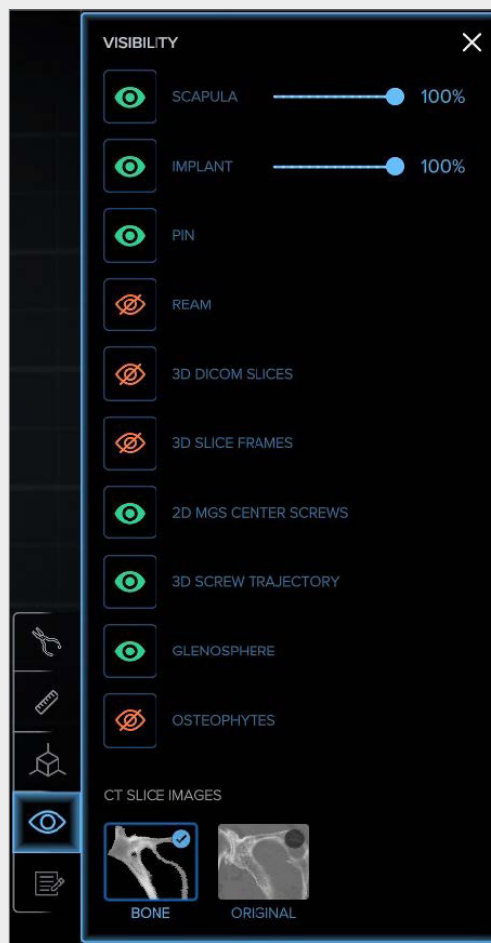



Figure 37. Glenoid Viewer Visibility controls

Humeral Viewer Page

Clicking on the  opens the “Humeral Viewer” page, which displays the rendered 3D Image of the CT scan and the Arthrex-selected implant in its proposed location and orientation per the planning protocol. From this page, the plan(s) can be modified, duplicated, saved, and approved. The coronal view is shown in the left pane in 2D, the cut surface with the implant placement centrally in an inset collapsible central panel, and the 3D-rendered humerus with the proposed implant is shown in the right pane.

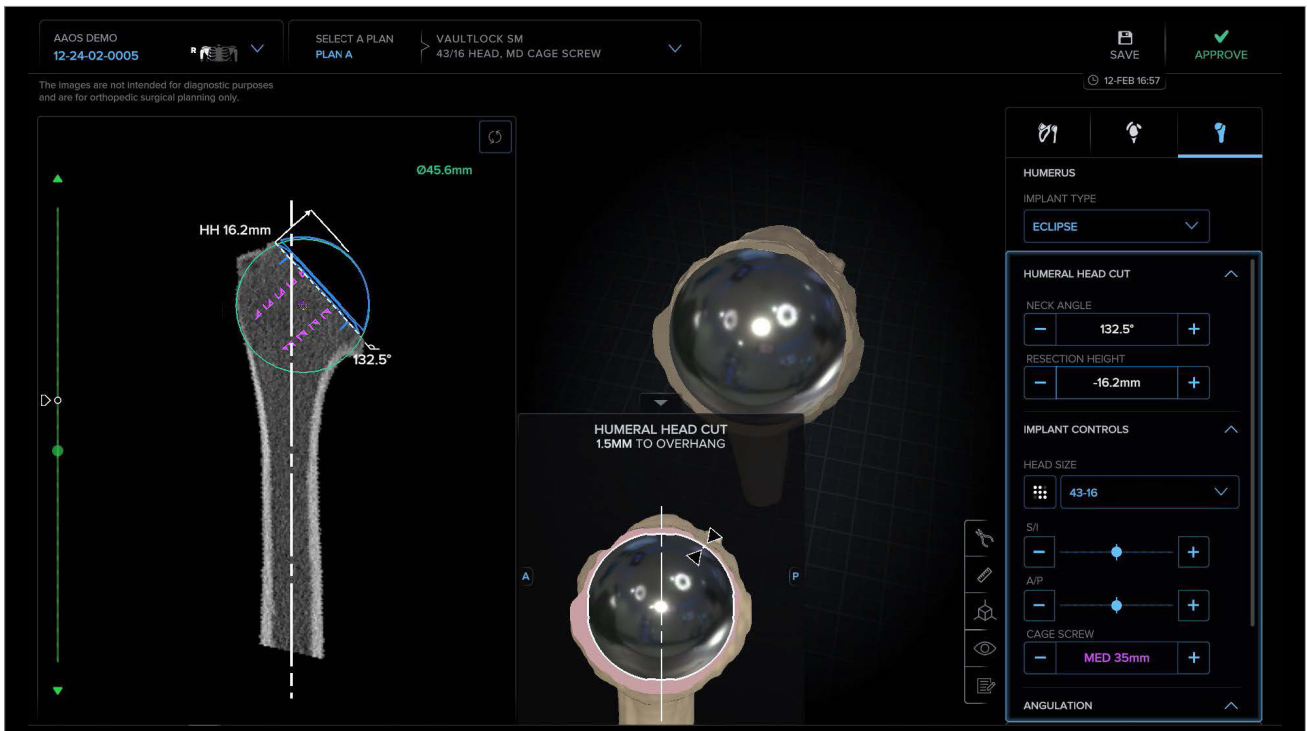


Figure 38. Humeral Viewer page: Anatomic

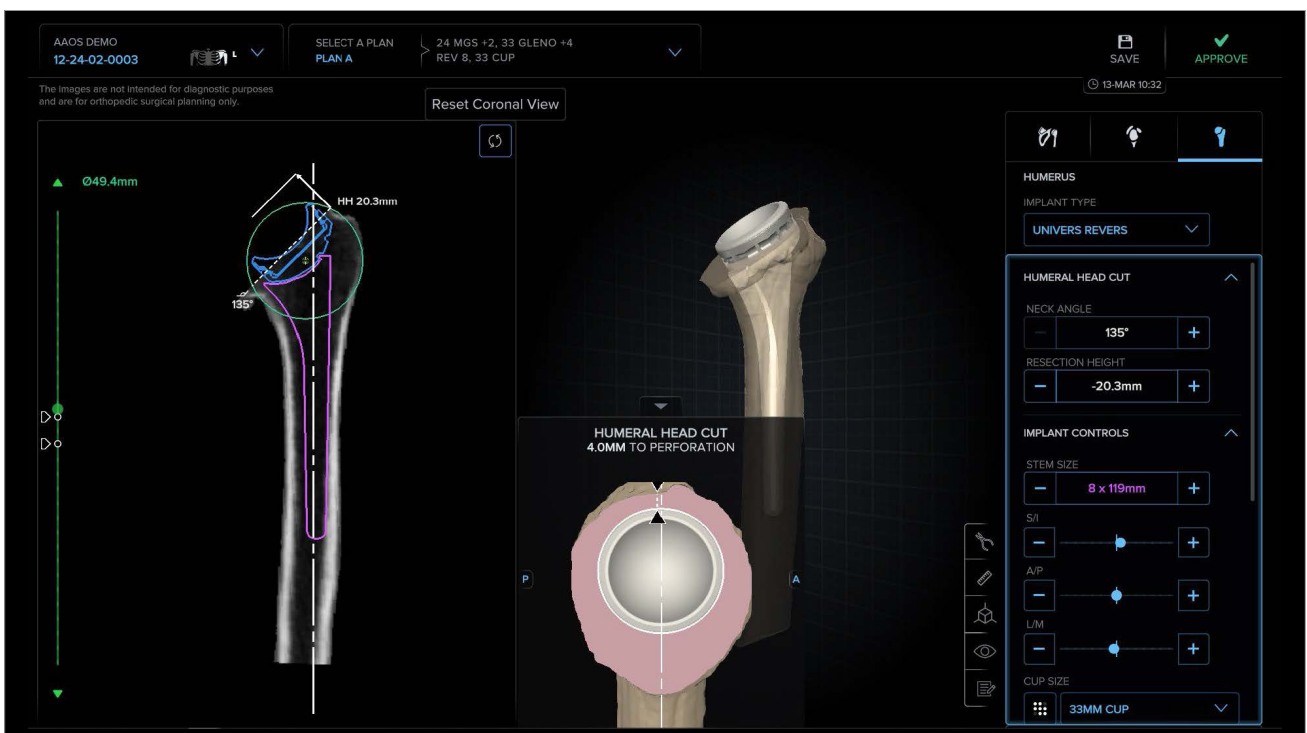



Figure 38a. Humeral Viewer page: Reverse

Interface Functionality: Humeral Planning


The left pane of the “Humeral Viewer” page displays the 2D views of the implant and humeral anatomy in the coronal view. Zoom in and out of the 2D image by using the mouse’s center scroll wheel and pan by right-clicking and dragging.

Interface Functionality

Measurement Tool and Reset Function

- Click the  on the universal tools menu. While holding a mouse click, move a blue circle to establish the first reference point. Repeat the mouse click and hold to drag the remaining blue circle to the second reference point. Measurement values are displayed in the center of the screen.

Note: When measuring in the 3D view, be sure to verify the placement of the blue circles to ensure an accurate measurement.

- Click on  at the top right of the 2D view. This will reset the view to the coronal slice that is closest to the center of the implant and place the image in the center of the pane at its original level of zoom.
- Use the green slider bar to the left of the 2D view to scroll through the CT slices. The flags along the bar denote the slices where the implant is closest to the cortex.

Center of Rotation Feature (Figure 40)

- The humeral head diameter is displayed in the top left of the 2D view and the anatomic circle is dynamically overlaid on the proximal humerus with the anatomic COR denoted by the yellow crosshair and the prosthetic COR denoted by the purple crosshair.
- The measurement tool can be used as described above using the center of each crosshair to find the Δ in the COR as described by Ianotti.

Note: The humeral prosthetic COR feature is only available when planning an anatomic

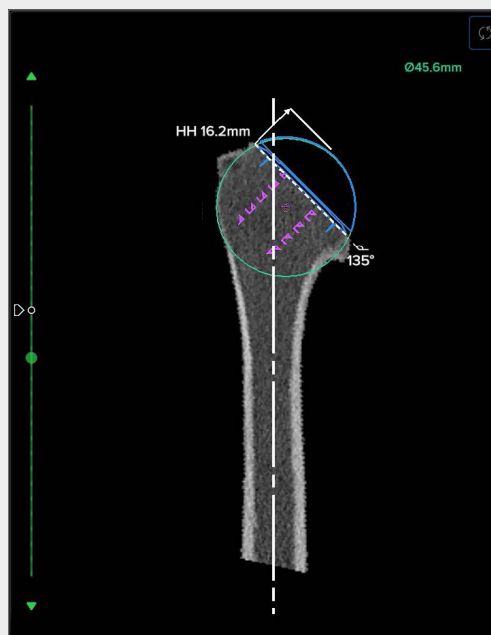


Figure 39. Humeral Viewer left pane: Anatomic

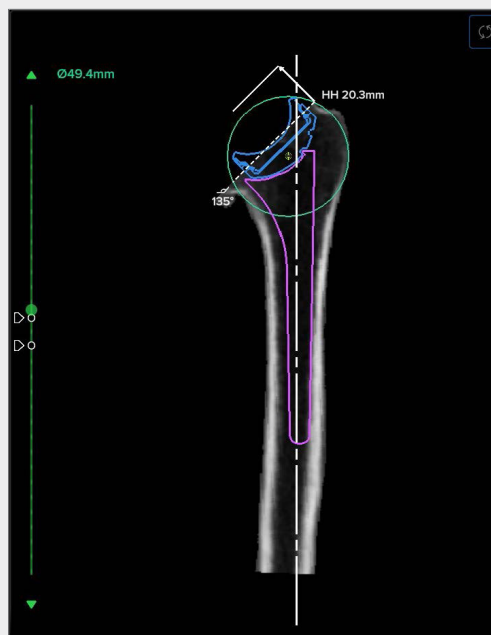


Figure 39a. Humeral Viewer left pane: Reverse



Figure 40. Anatomic and Prosthetic COR

Interface Functionality: Humeral Planning

The humeral control panel (Figure 41) on the right side of the interface allows users to:

- Select a humeral implant type compatible with the selected glenoid implant.
- Adjust the thickness and angulation of the humeral head resection.
- Select an implant size and position the selected implant in the humeral canal or on the cut surface.
- Adjust the angulation of the selected implant relative to the long humeral axis.

Implant Type Selection: Anatomic (Figure 42)

- Select an Eclipse™ or Apex OptiFit™ component.

Humeral Head Cut: Anatomic (Figure 43)

- Adjust the thickness of the humeral head resection in 1 mm increments.
- Adjust the angle of the humeral head resection in 2.5° increments from 120 –140°.
- Visualize the selections in the 2D view (Figure 46).

Implant Controls: Eclipse (Figure 44)

- Select the head size, the cage screw length and translate the selected head in 0.5 mm increments in S/I or A/P dimensions using the slider bars or by clicking the “+” or “-” buttons.
- Access the implant compatibility matrices (Figures 51 and 52) as shown in Figure 44.
- Verify placement of the Eclipse head on the collapsible humeral head cut panel. The location and distance from the edge of the implant to the cortical rim is indicated as pictured in Figure 45.
- Verify the restoration of humeral head height and the center of rotation as shown in the 2D view (Figure 46).

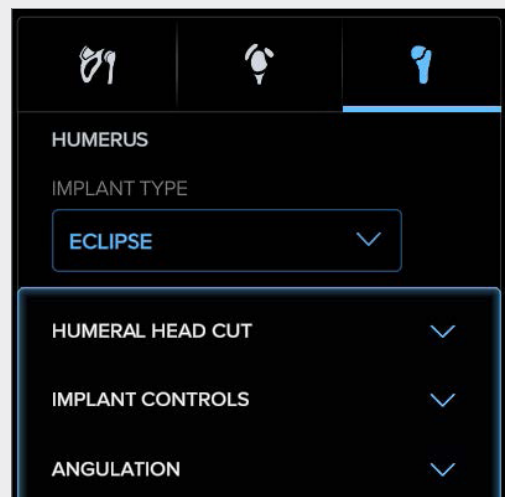


Figure 41. Humeral control panel

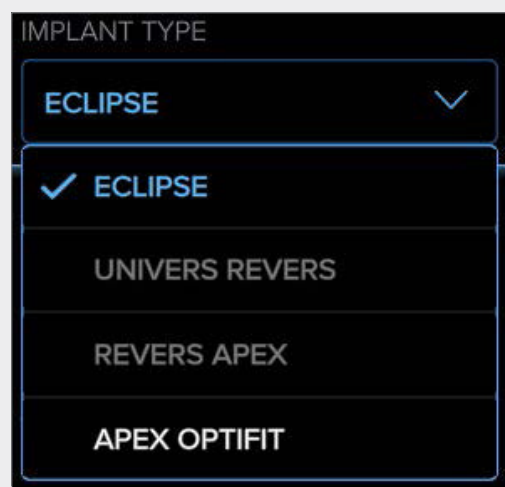


Figure 42. Anatomic implant selection



Figure 43. Humeral head resection

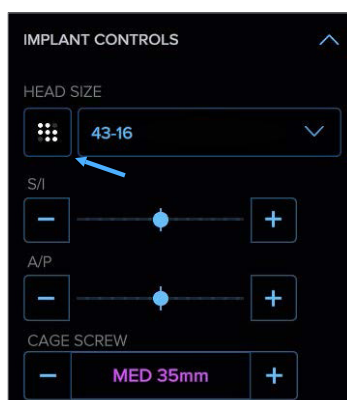


Figure 44. Eclipse implant controls

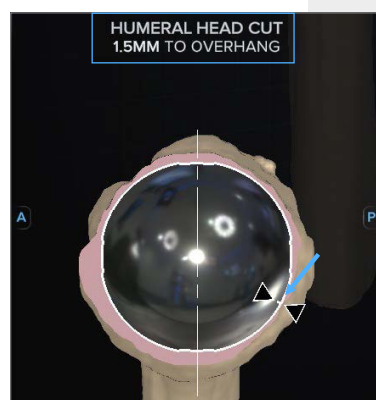


Figure 45. Humeral head cut panel

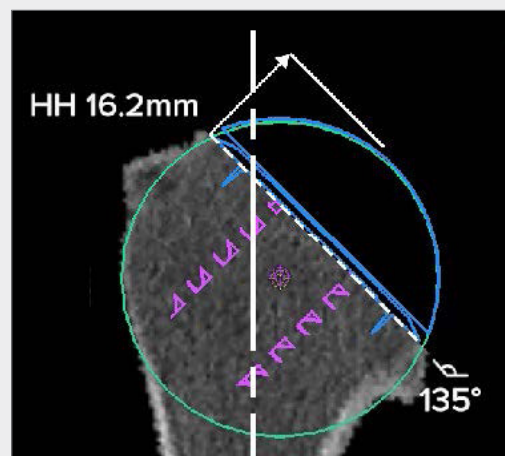


Figure 46. Coronal CT view

Implant Controls: Apex OptiFit (Figure 47)

- Select the stem size, the head size and translate the selected stem in 0.5mm increments in S/I, M/L or A/P directions using the slider bars or by clicking the “+” or “-” buttons.
- Access the implant compatibility matrices (Figures 51 and 52) as shown to the right (Figure 47).
- Adjust the clocking of the Univers II humeral head eccentricity with the “Head Offset” control as shown in Figure 47 by using the slider bar, clicking the “+” or “-” buttons or by entering a whole number between 1 and 12 in the text box.
- Verify the eccentricity of the Univers II head on the collapsible humeral head cut panel as shown in Figure 49, where the white line represents the maximum eccentricity of the implant. The location and distance from the edge of the implant to the cortical rim is indicated as pictured in Figure 49.
- Verify the restoration of humeral head height and the center of rotation as shown in the 2D view (Figure 50).

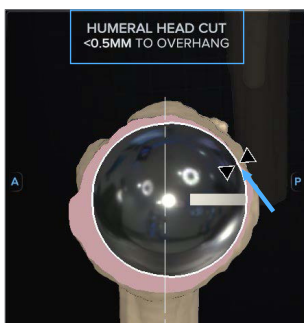


Figure 49. Humeral head cut panel

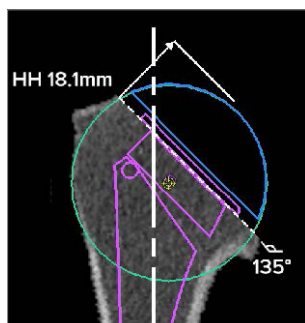



Figure 50. Coronal CT view

Angulation: Anatomic (Figure 48)

- Adjust the torsion of the selected component by clicking the “+” or “-” buttons in 1° increments up to $\pm 45^\circ$ from the patient’s native torsion.
- The  shown in Figure 48 displays the definition of torsion, which some literature uses interchangeably with version.
- Should the desired torsion exceed $\pm 20^\circ$ from the patient’s native torsion a warning will appear as shown in Figure 48a where the 2D view no longer provides the most accurate rendering of the implant’s position in the anatomy.

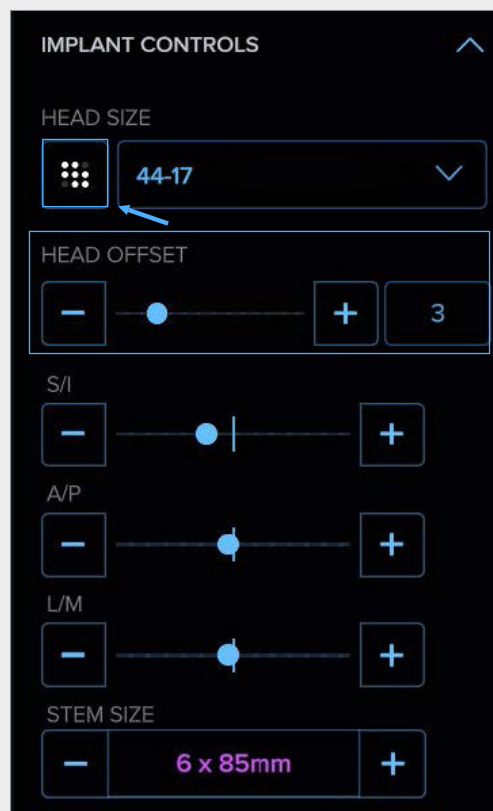


Figure 47. Apex OptiFit implant controls



Figure 48. Angulation control

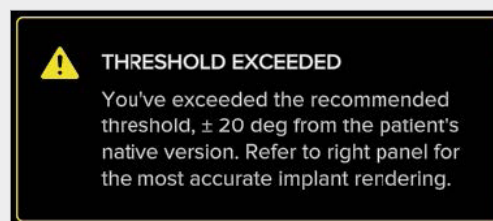


Figure 48a. Angulation control warning

Univers VaultLock®, Convertible Universal Glenoid, Keeled and Pegged Glenoids (Radial Mismatch in mm)				
Head Size (mm)	Small	Medium	Large	XL*
37	9.9			
39	8.5			
41	7.25	8.75		
43	6	7.5	9	
45		6	7.5	9
47		5	6.5	8
49			5.5	7
51			4.5	6
53				5
55				4

■ Recommended sizes based on mismatch
 * Convertible Universal Glenoid not available in XL

Figure 51. Eclipse implant compatibility matrix

Univers VaultLock®, Convertible Universal Glenoid, Keeled and Pegged Glenoids (Radial Mismatch in mm)				
Head Size (mm)	Small	Medium	Large	XL*
40	8.5			
42	7.5			
44	6.4	7.9		
46		6.8		
48		5.7	7.2	
50		4.6	6.1	
52			5.3	6.8
54			4	5.5
56				4.7

■ Recommended sizes based on mismatch
 * Convertible Universal Glenoid not available in XL

Figure 52. Apex OptiFit Implant compatibility matrix

Interface Functionality: Humeral Planning

Implant Type Selection: Reverse (Figure 53)

- Select a Univers Revers or Revers Apex component.

Humeral Head Cut: Reverse (Figure 54)

- Adjust the thickness of the humeral head resection in 1 mm increments.
- Adjust the angle of the humeral head resection between 135° or 155°.
- Visualize the selections in the 2D view (Figure 57).

Implant Controls: Univers Revers and Revers Apex (Figures 55 and 56)

- Select the stem size and translate the selected stem in 0.5 mm increments in S/I, M/L or A/P directions using the slider bars or by clicking the “+” or “-” buttons.
- Select the suture cup size and offset.
- Select the desired spacer and liner combination (the interface will default to the thinnest liner option).
- Select a standard or constrained liner.
- Access the implant compatibility matrix (Figure 59) as shown below in Figure 56.

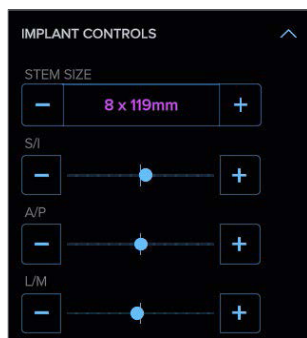


Figure 55. Reverse implant controls

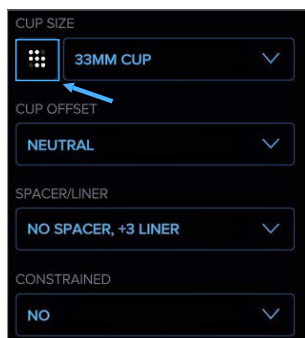


Figure 56. Cup/Liner selection

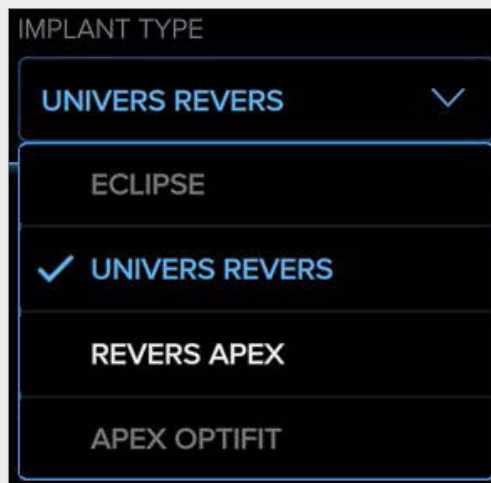


Figure 53. Reverse implant selection



Figure 54. Humeral head resection

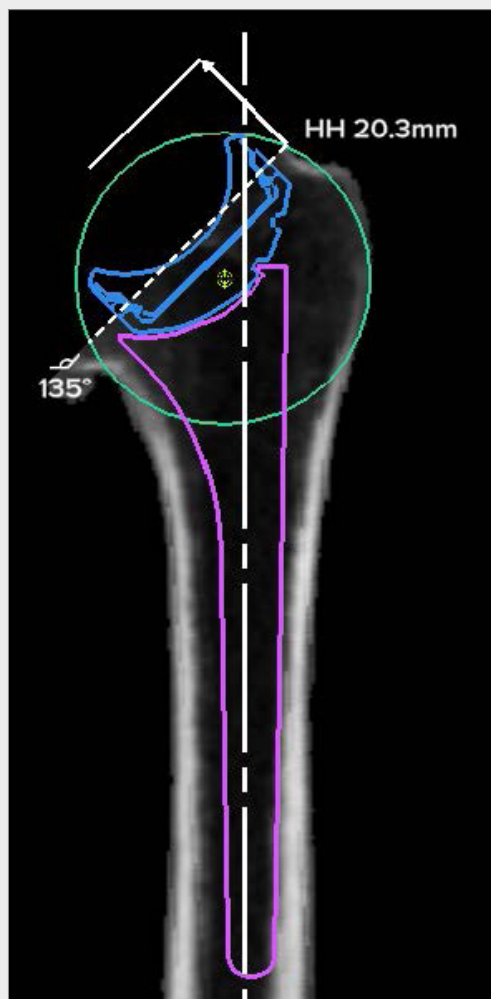


Figure 57. Coronal CT view

Interface Functionality: Humeral Planning

Angulation: Reverse (Figure 58)


- Adjust the torsion of the selected component by clicking the “+” or “-” buttons in 1° increments up to ±45° from the patient’s native torsion.
- Should the desired torsion exceed 20° from the patient’s native torsion a warning will appear as shown in Figure 58a where the 2D view no longer provides the most accurate rendering.
- The  shown in Figure 58 displays the definition of torsion, which some literature uses interchangeably with version.
- Adjust the varus/valgus tilt of the implant in 1° increments by clicking the “+” or “-” buttons.



Figure 58. Angulation control

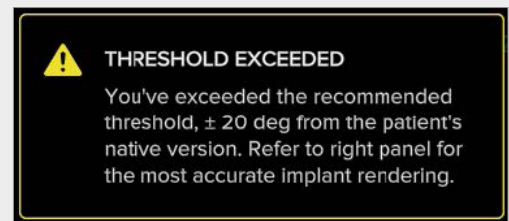


Figure 58a. Angulation control warning

		Glenosphere Size				
		33 mm	36 mm	39 mm	42 mm	45 mm
Cup Size	33 mm	Standard Liner	33/36 Combo Liner			
	36 mm	36/33 Combo Liner	Standard Liner	36/39 Combo Liner		
	39 mm			Standard Liner	39/42 Combo Liner	
	42 mm				Standard Liner	42/45 Combo Liner

Combo and standard inserts are available constrained



-  For use only with the Modular Glenoid System
-  For use only with the Modular Glenoid System and Universal Glenoid convertible baseplate

Figure 59. Unvers Revers and Revers Apex implant compatibility matrix

Perforation Warnings

- In the event that the user selects an implant or positions the implant so that it that violates the humeral cortex a perforation warning will appear in the left pane of the “Humeral Viewer” page. A yellow flag will appear along the green slider bar to the left of the 2D image referencing the CT slice that shows the perforation (Figures 60 and 62).
- If the user selects or positions a humeral head/trunnion construct when planning an anatomic so that the implant overhangs the humeral cortex, a warning

will appear in the collapsible central panel of the “Humeral Viewer” page (Figure 61).

- If the user selects a suture cup size or type when planning a reverse that violates the humeral cortex, a warning will appear in the collapsible central panel (Figure 63).
- All perforation warnings can be visualized and verified on the 3D bone model shown in the right pane of the “Humeral Viewer” page.

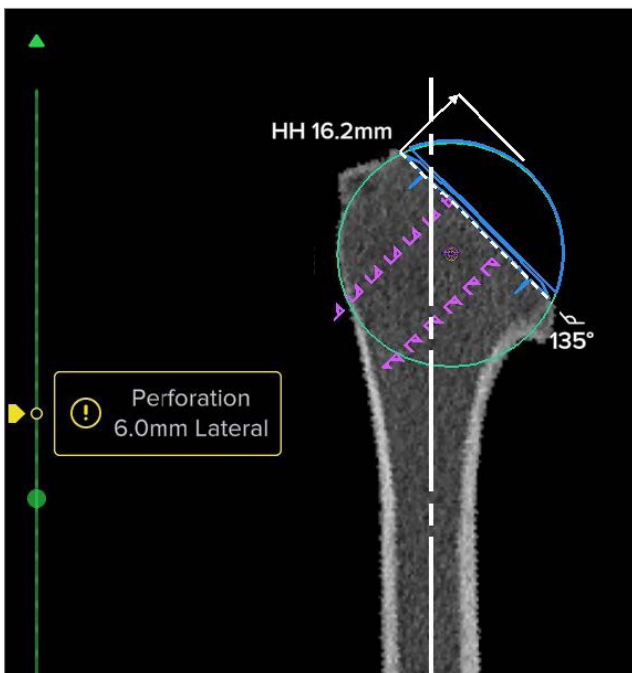


Figure 60. Eclipse cage screw perforation warning

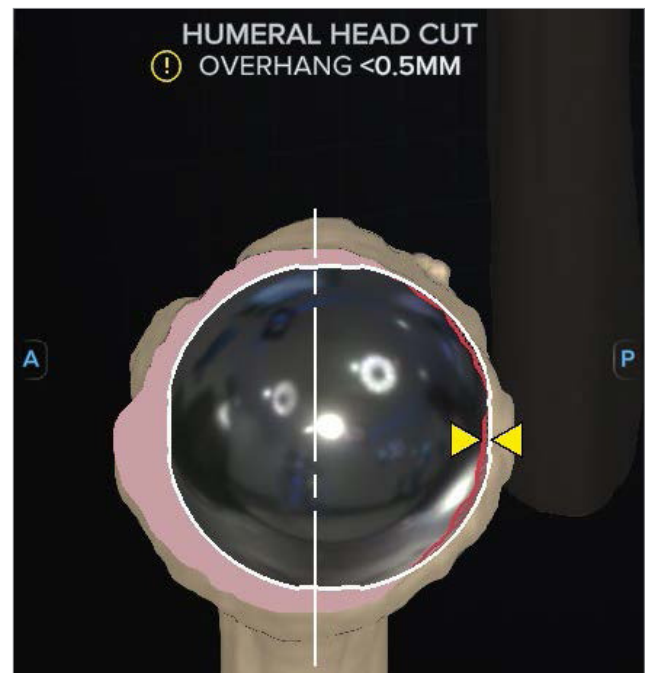


Figure 61. Anatomic head overhang warning

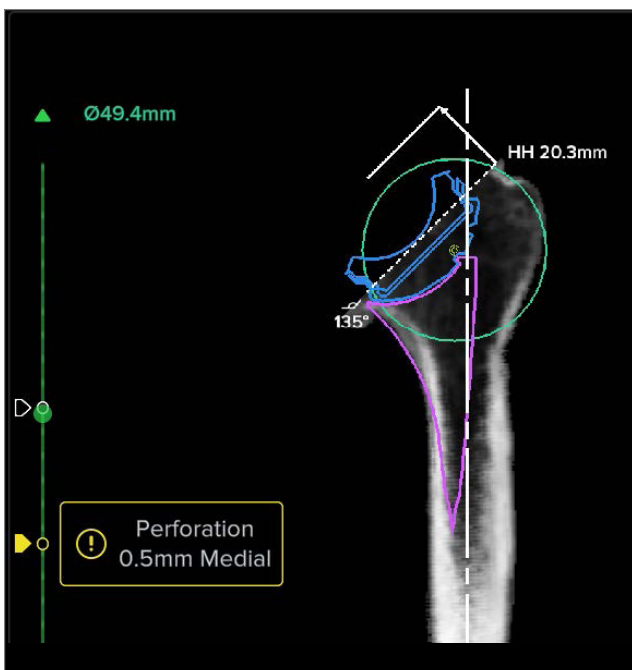


Figure 62. Stemmed implant perforation warning

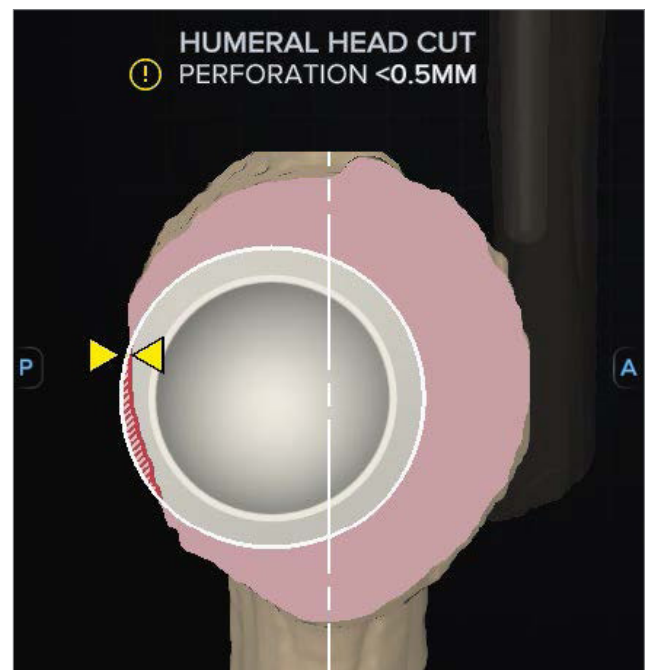


Figure 63. Suture cup perforation warning

Interface Functionality

Visibility Controls (Figures 64 and 64a)

- Show/hide elements in all 3 panes (implants, native head, and humerus).
- Show/hide the estimated premorbid humeral head in the 2D CT view.
- Change the humerus and implant transparency from 0% to 100% in the 3D view.
- View the original coronal DICOM slices in the 3D view.
- Show/hide the humeral axis in the 3D view.
- Show/hide any bony anatomy in the 3D model previously modified with the osteophyte removal tool.



Figure 64a. Visibility controls: Eclipse

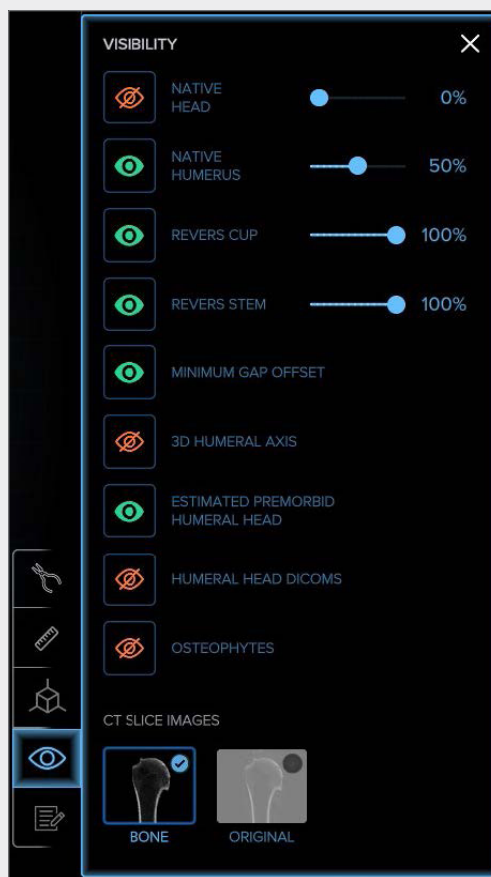



Figure 64a. Visibility controls: Revers and Revers Apex

Interface Functionality: Range of Motion

Once glenoid and humeral implants have been selected when planning a reverse, click  to open the “Joint Viewer” page and select the “Range of Motion” drop-down menu as seen in Figure 65 to open the “Range of Motion Viewer” page (Figure 66).

This page displays the rendered 3D Image of the CT scan and the selected implants in their locations and orientations per the preoperative plan along with the impingement points at the terminal ranges of motion displayed on the right side of the page.

The impingement points for each range of motion are denoted by red markings on the 3D model. These may be toggled on and off by clicking the show/hide icon highlighted in Figure 66.

Manipulate the 3D bone model by left-clicking on the model and moving the mouse to adjust its orientation. Zoom in and out of the 3D image by using the mouse’s center scroll wheel and pan by right-clicking and dragging the image.

From this page, the plan(s) can be duplicated, saved, and approved.

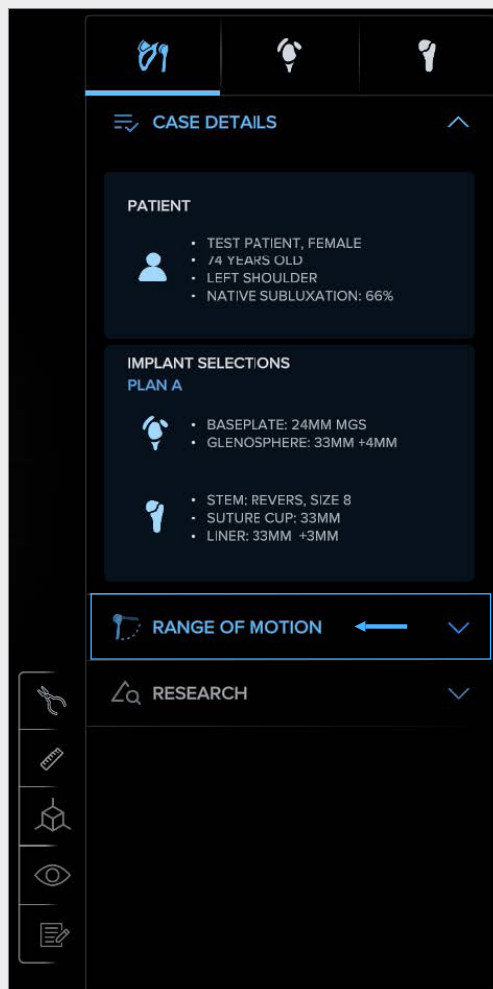


Figure 65. Range of motion selection

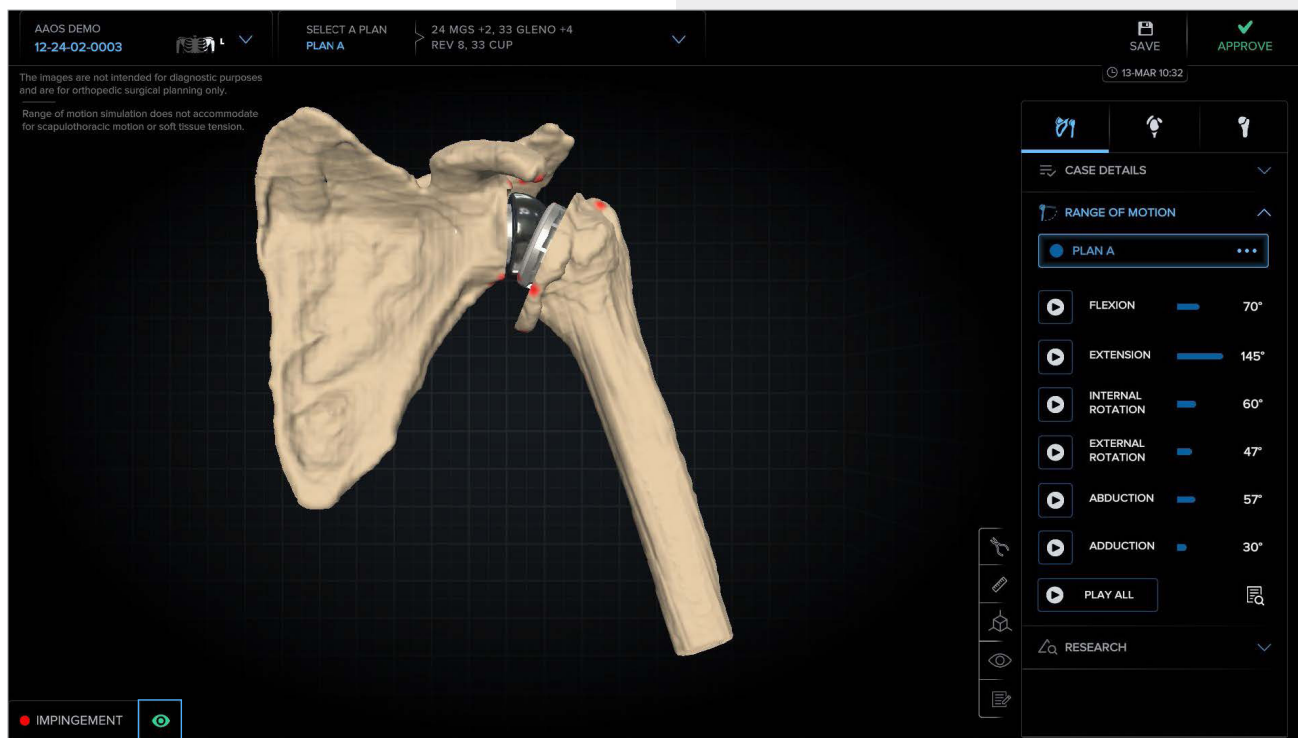





Figure 66. Range of motion viewer page

Interface Functionality

Upon opening the Range of Motion drop-down menu, the user is presented with the calculated ranges of motion for the given motions as displayed in Figure 67.

- Users may play each motion individually or select “Play All” to play each motion in sequence by clicking the  to the left of the desired motion.
- To reset the anatomy to a neutral position, click the  to the left of the motion most recently played.
- Clicking the  will display a summary table of the ranges of motion for the selected plan.
- When playing a motion, the humerus will move along the defined arc as shown for flexion in Figure 68 until impingement occurs, as denoted by the red mark circled in Figure 68.
- Users may use the osteophyte removal tool to remove areas of bony impingement. Once the osteophyte removal tool is closed, the ranges of motion for all plans will be recalculated.
- Users may left-click and drag the white sphere to move the humerus through the defined motion arc.
- The break in the arc is a neutral arm position and denotes the separation between the two motions making up the complete arc, as shown with flexion and extension in Figure 68.

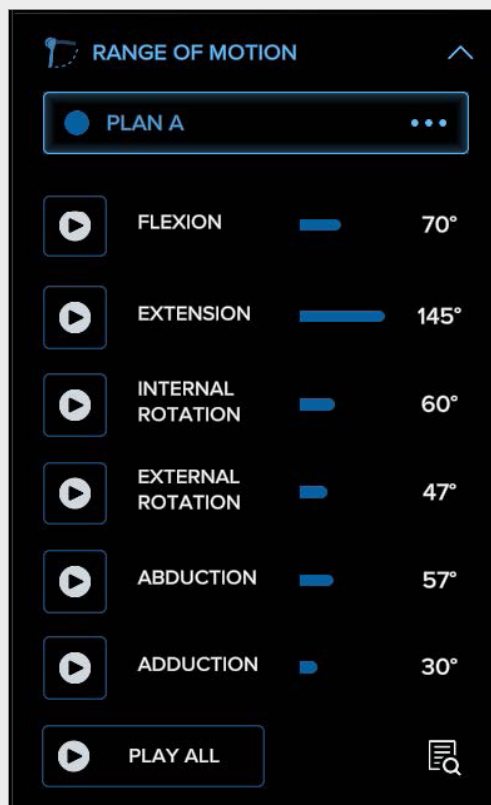


Figure 67. Range of motion summary

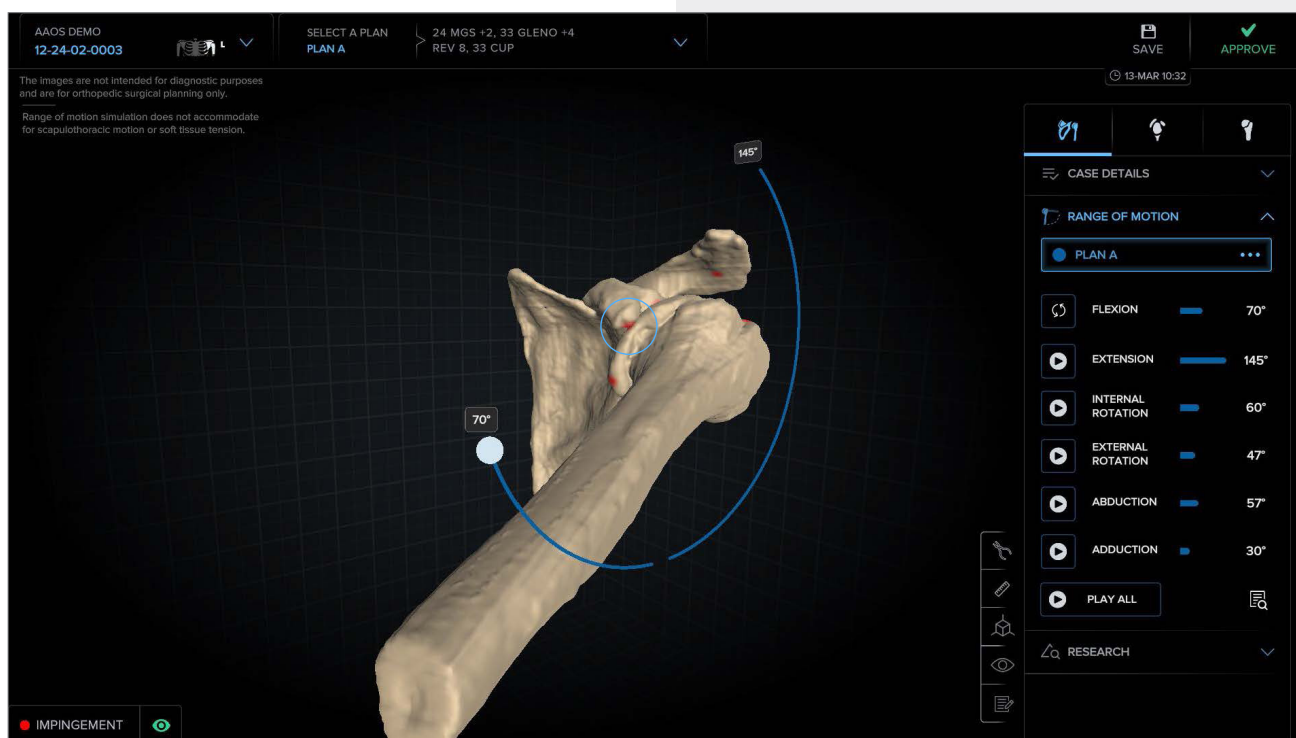


Figure 68. Flexion/extension arc

Interface Functionality

Range of Motion Comparisons

If a user would like to see how changes to implant selection, angulation or position affect simulated range of motion, they may do so using the plan duplication workflow and navigate to the range of motion drop-down once up to 3 plans have both glenoid and humeral components selected as shown in Figure 70.

- Users may rename each plan as desired by clicking on the pencil icon next to the plan name as shown below in Figure 70 and entering the desired name in the text field that appears.
- The ranges of motion for each plan are displayed as shown in Figure 69.
- The active plan is highlighted by a blue outline as shown in Figures 69 and 70 and the number values for the ranges of motion for the selected plan are displayed in white text while the non-active plan number values are dimmed.
- Using this tool, users may compare different implant selections, angulations and positions to determine which construct will give the greatest simulated range of motion for the rendered 3D anatomy.

Note: Anatomic plans will not be displayed in the range of motion viewer as range of motion functionality is only available for reverse planning.



Figure 69. Range of motion chart

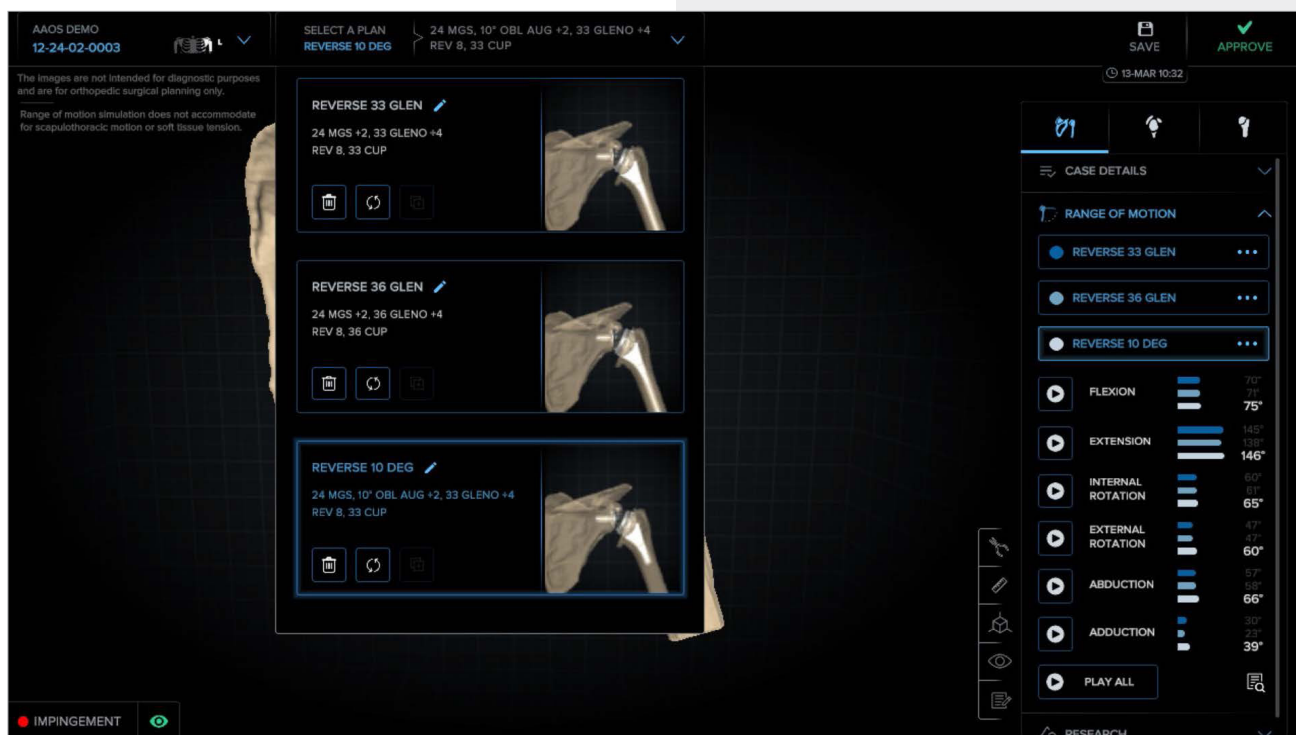



Figure 70. Range of motion comparisons

Interface Functionality: Research

The “Research Viewer” page is accessible by selecting the “Research” drop-down menu from the “Joint Viewer” page as shown in Figure 71. From this page, the plan(s) can be duplicated, saved, and approved

The Research Viewer tab will allow visualization of:

- The center of rotation in each of the 3 planes (M/L, A/P, S/I) and the delta distance of the overall center of rotation.
- The native and prosthetic humeral head subluxation.
- The viewer defaults to the axial view. To access the coronal view, select the  as shown in Figure 73.
- The measurement tool may be used to compare native and prosthetic positions of the anatomy.

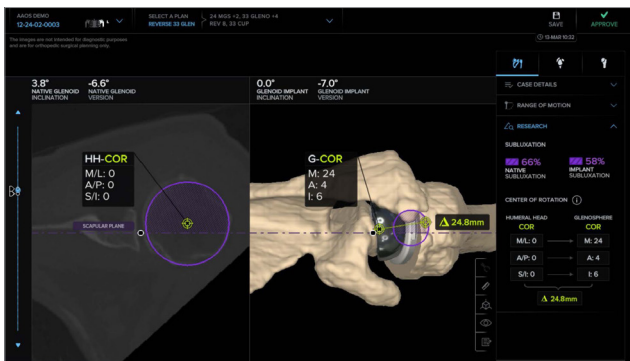


Figure 72. Research Viewer page

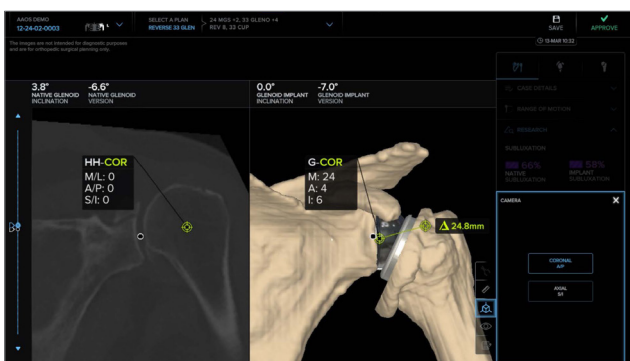


Figure 73. Research Viewer page camera toggle

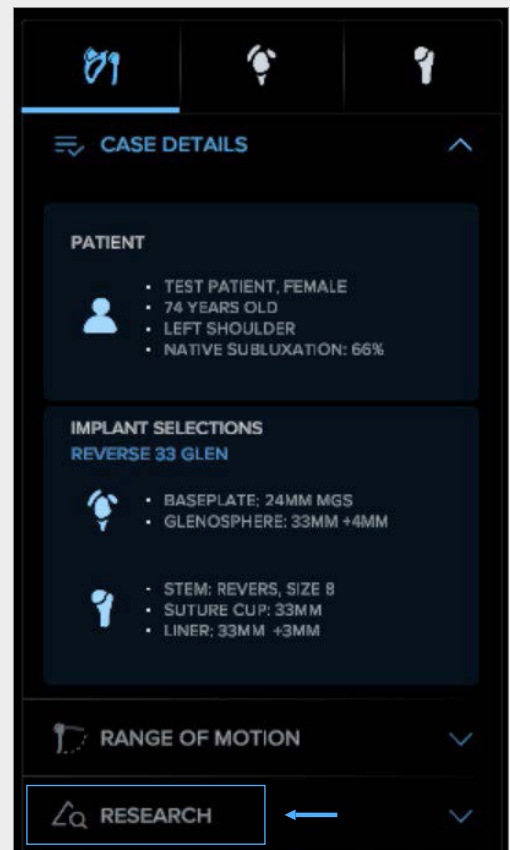


Figure 71. Research drop-down selection

Interface Functionality

Save Button (Figure 74)

- Click on the “Save” button in the upper right corner to save changes to the type, location, and orientation of implants without approving the plan(s). Once the plan has been saved, it will be time-stamped as shown in Figure 74.

Approve Button (Figure 74)

- Clicking the “Approve” button opens a tab (Figure 75) in which surgeons may select to approve both the glenoid and humeral plan(s) or just the glenoid plan(s).
- Selecting either option will open the plan approval page (Figures 76 and 77), where a comprehensive plan summary is listed for each plan and surgeon users may select up to 2 plans for approval.
- Once “Approve” is selected, the plan(s) is(are) approved. Any changes that were made to the plan(s) are saved, and the user is returned to the “Case Details” page. The case status will now be displayed as “Approved.”
- The user may re-open the case at any time after approval and manipulate the existing plan(s).

Note: Range of motion summaries are only provided for reverse plans

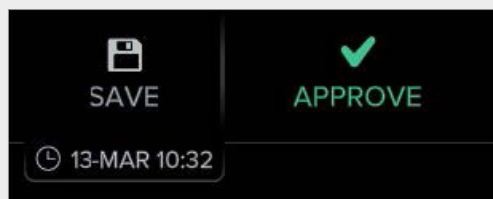


Figure 74. Save and approve buttons

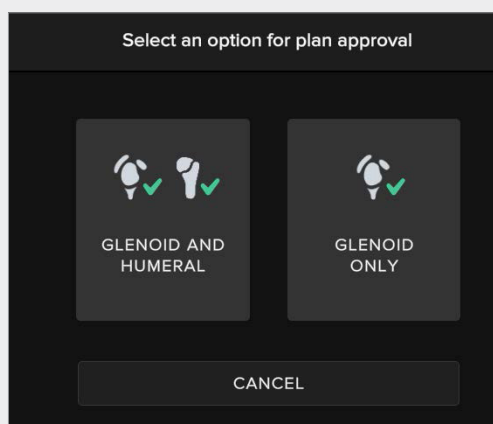


Figure 75. Plan Approval tab

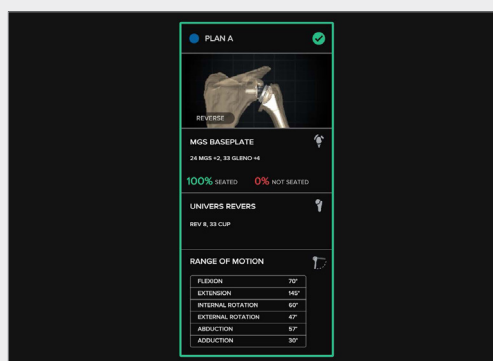


Figure 76. Single Plan Approval page

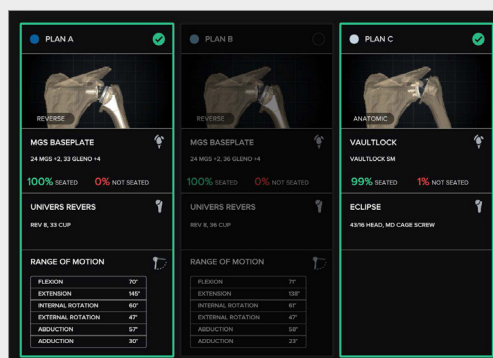


Figure 77. Multiple Plan Approval page

Profile Tab

Within the web portal, users can view their user profile (Figure 78), which displays:

- Full Name
- Phone
- Email
- Hospital Affiliations
- Shipping Addresses
- Sales Reps
- Assistants

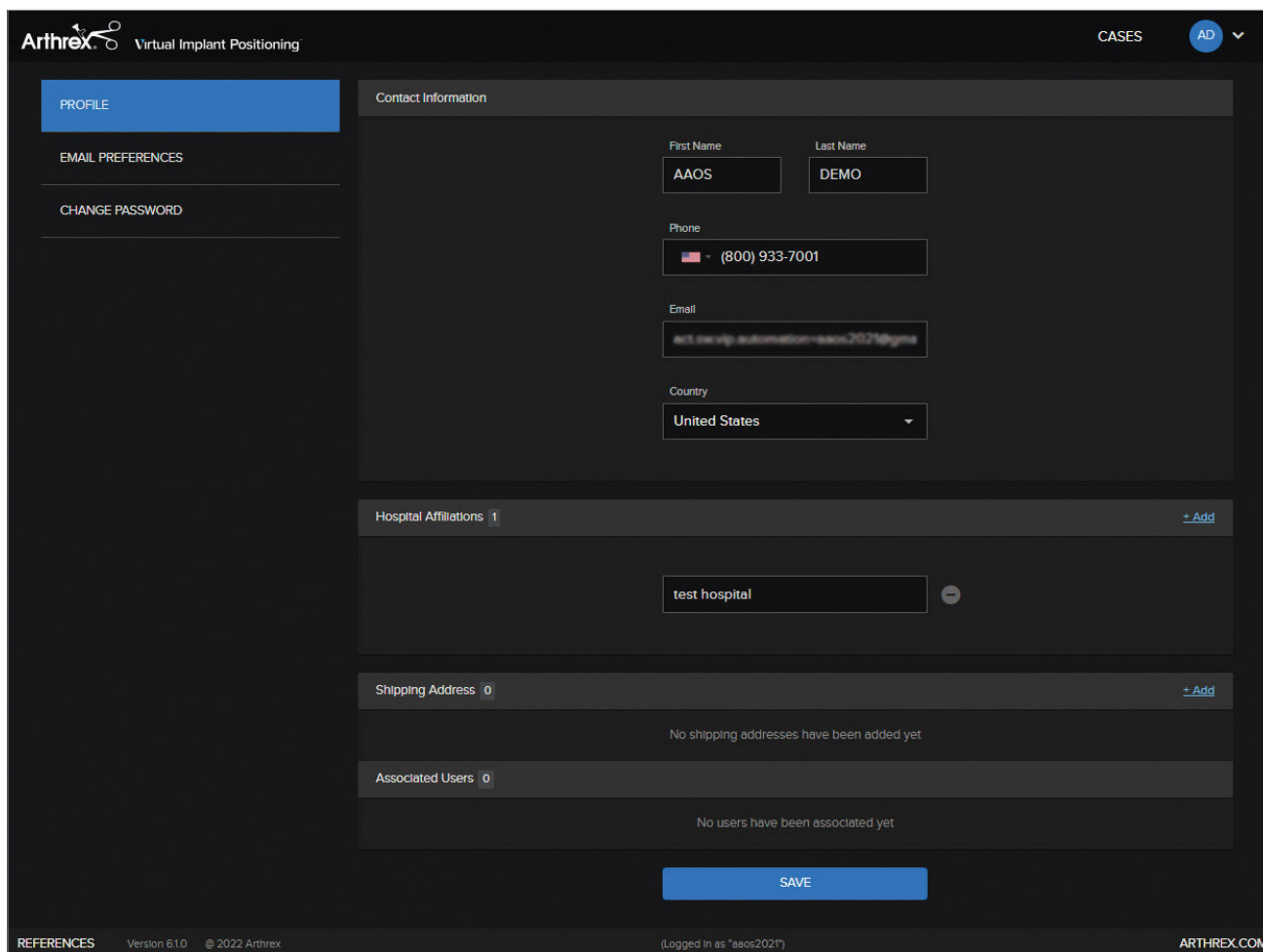


Figure 78. Profile page

Email Preferences Tab

As cases are processed, notification emails will be sent to users regarding various status changes. Users can modify email notification settings by toggling the buttons for each specific notification (Figure 79).

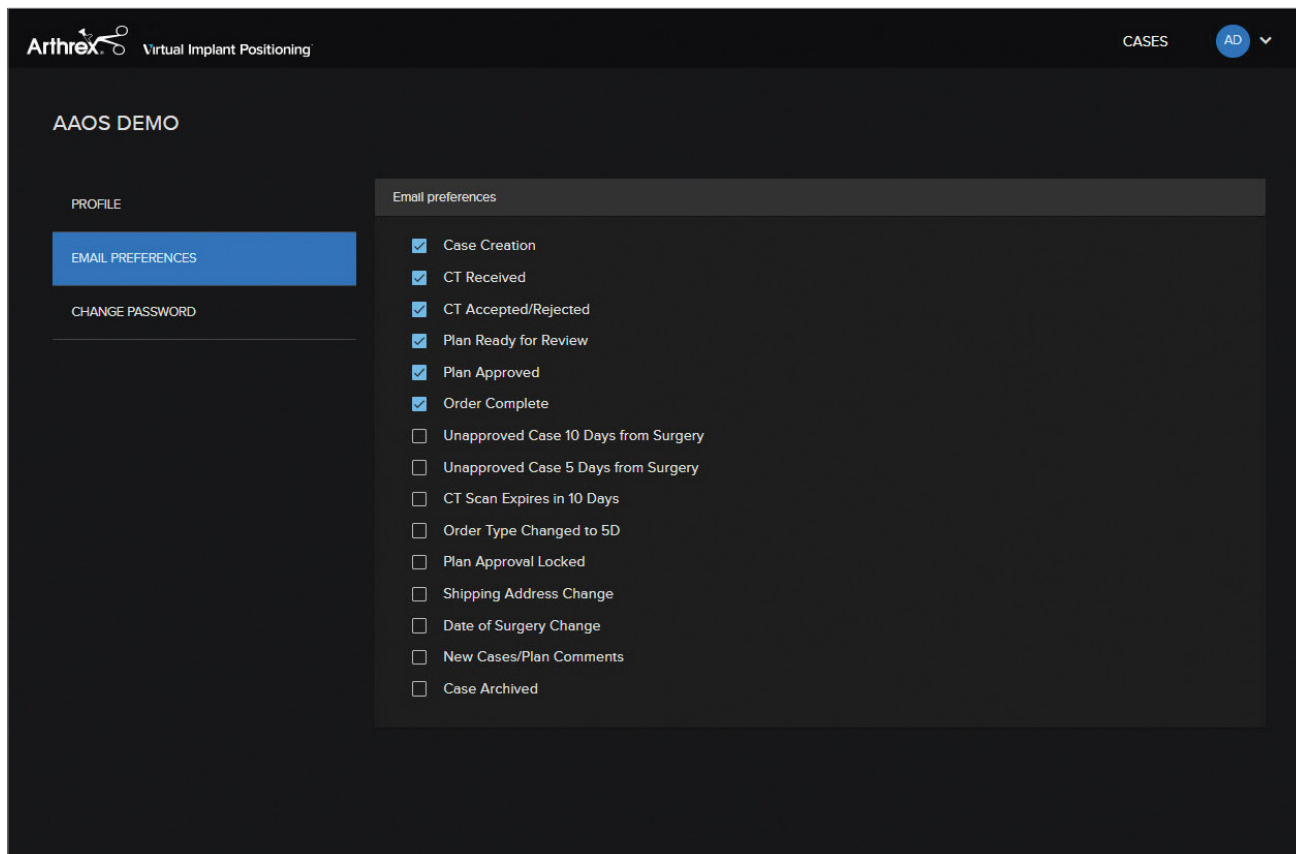


Figure 79. User Email Preferences page

Change Password Tab

Users also have the ability to change their password using the “Current password” and “New password” fields (Figure 80).

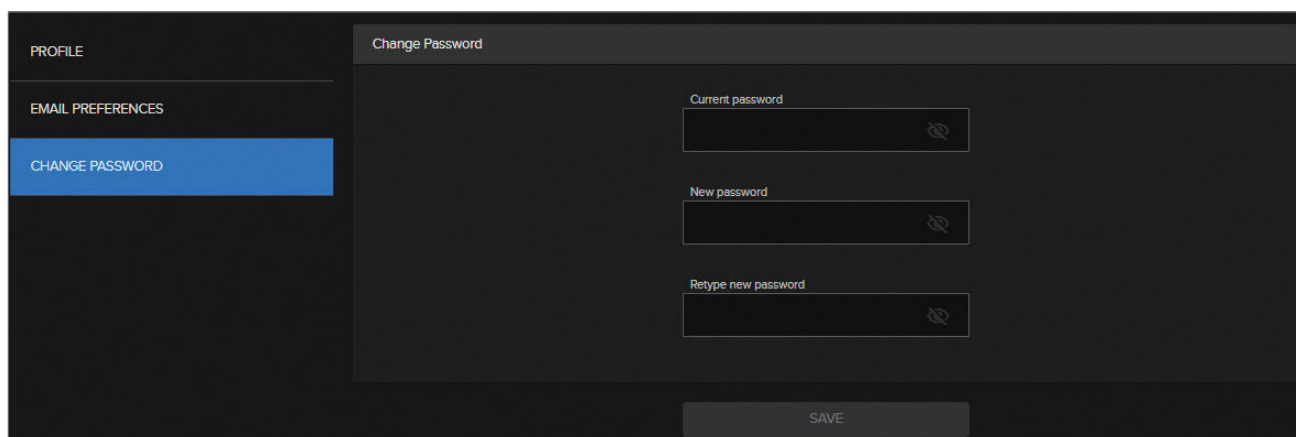


Figure 80. Change Password page

Log Out

The “Log Out” button appears at the top right of [ArthrexVIP.com](https://arthrexvip.com) and immediately logs users out, returning them to the main screen.



Arthrex, Inc.
 1370 Creekside Blvd.
 Naples, FL 34108, USA
 +1 800 934-4404
 arthrex.com
 arthrex.com/eDFU



Arthrex GmbH
 Erwin-Hielscher-Strasse 9
 81249 Munich, Germany
 +49 89 90 90 05-0
 arthrex.de
 info@arthrex.de



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



This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.



Arthrex manufacturer,
 authorized representative,
 and importer information
 (Arthrex eFUs)



US patent information

arthrex.com