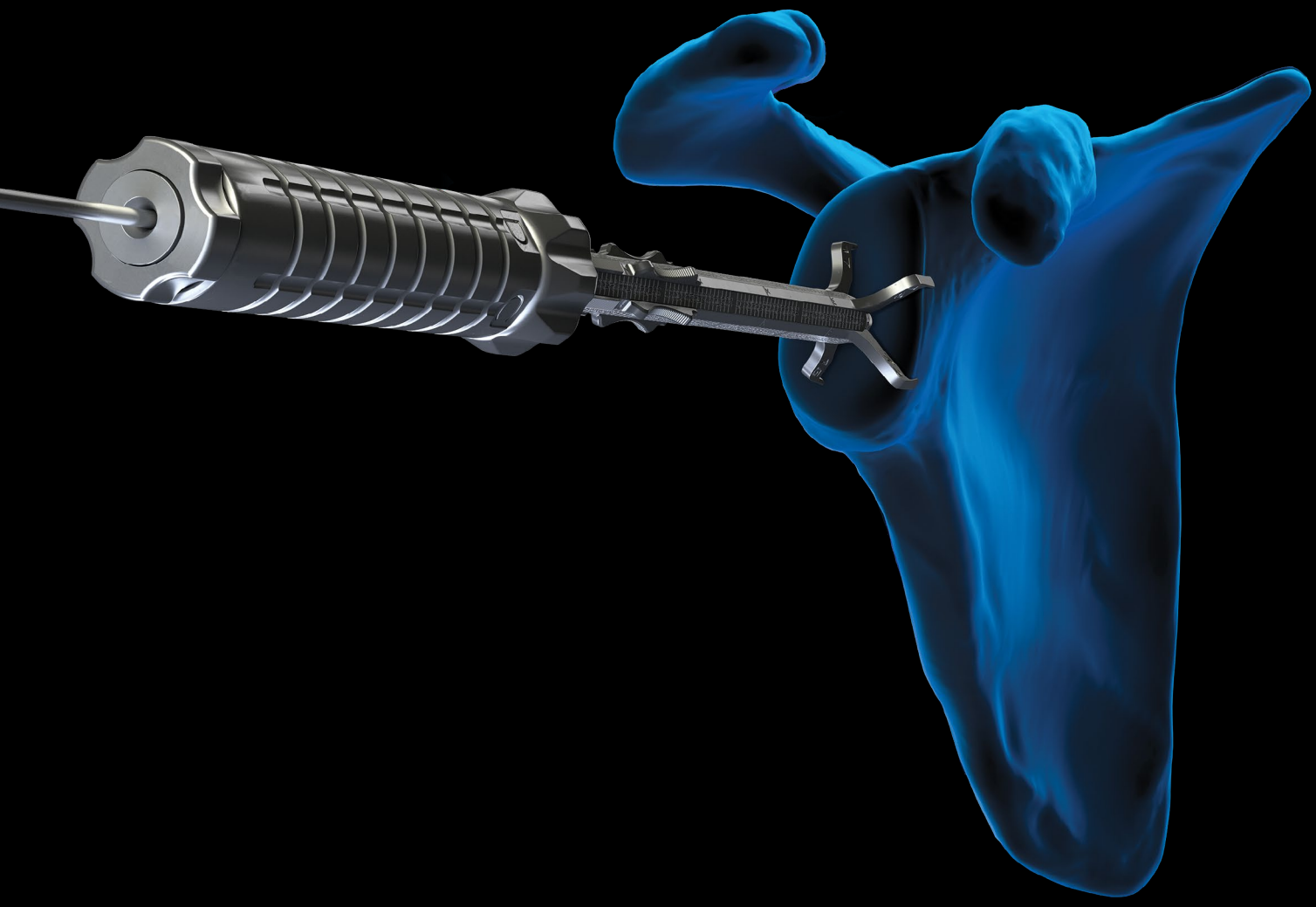
Virtual Implant Positioning™ (VIP™) Web Portal

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

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 ±30°
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 ±20°
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 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 "Viewer" 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 views.
- Approve preoperative plans by typing username and password into the web portal (surgeons only).
- 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.

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 (LI1-00022-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 username and password. If a username 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.

Lastly, a reCAPTCHA is required for user verification. If reCAPTCHA is unsure that a click is performed by a human, additional verification questions will be displayed. Press "Register" to submit the form and complete registration. Press "Cancel" to return to the main screen.

Figure 1

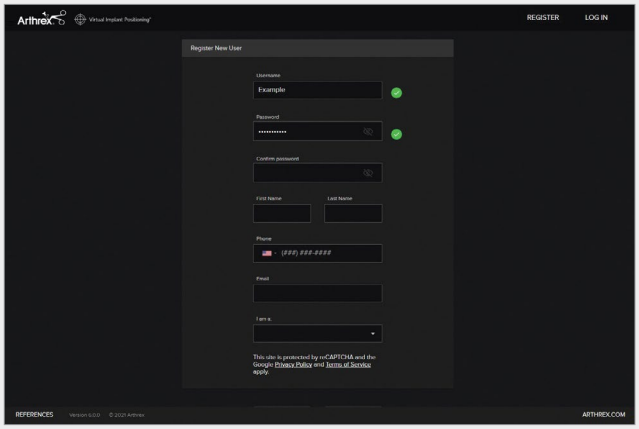


Figure 2

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		

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

[b]When 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]).

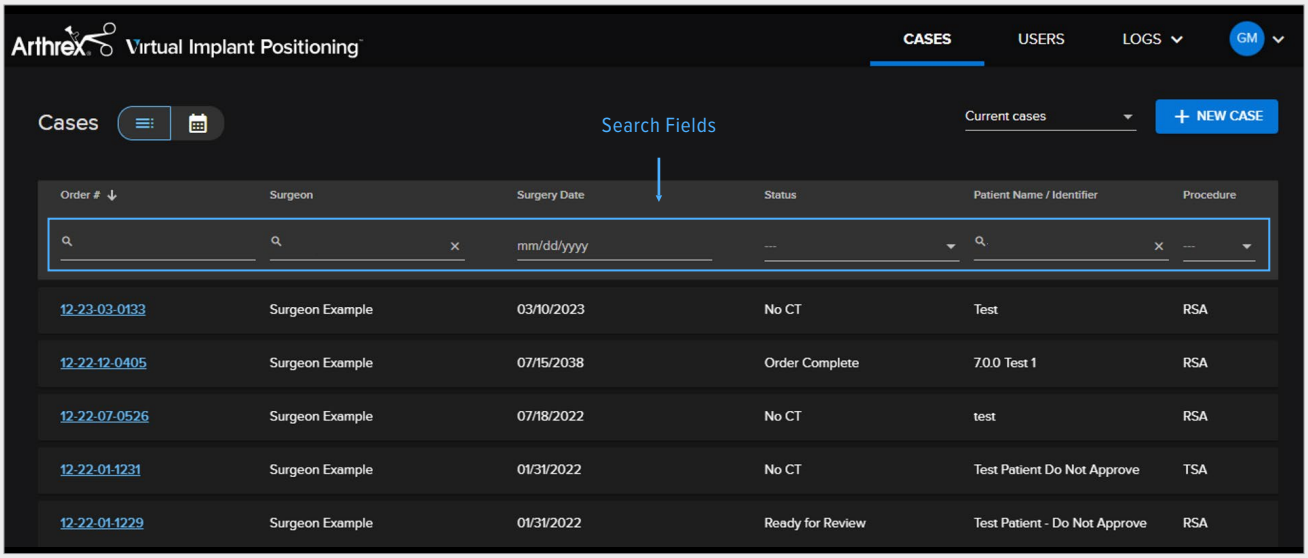


Figure 3

- **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).

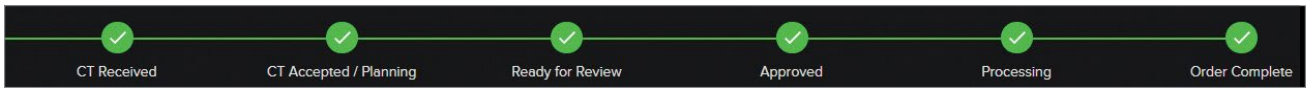


Figure 4. Case status flowchart

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.

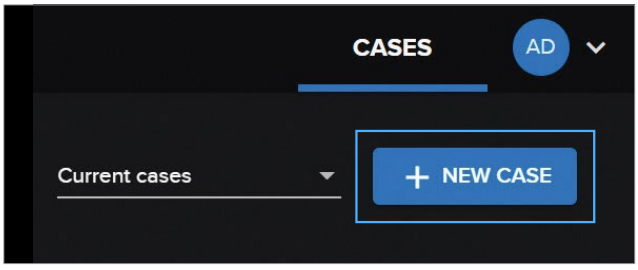


Figure 5. New Case button
(upper right corner of the Cases page)

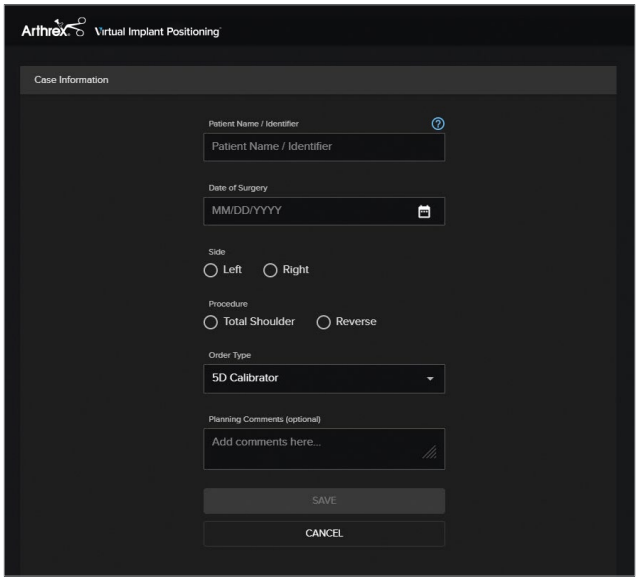


Figure 6. New Case page

Cases 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).

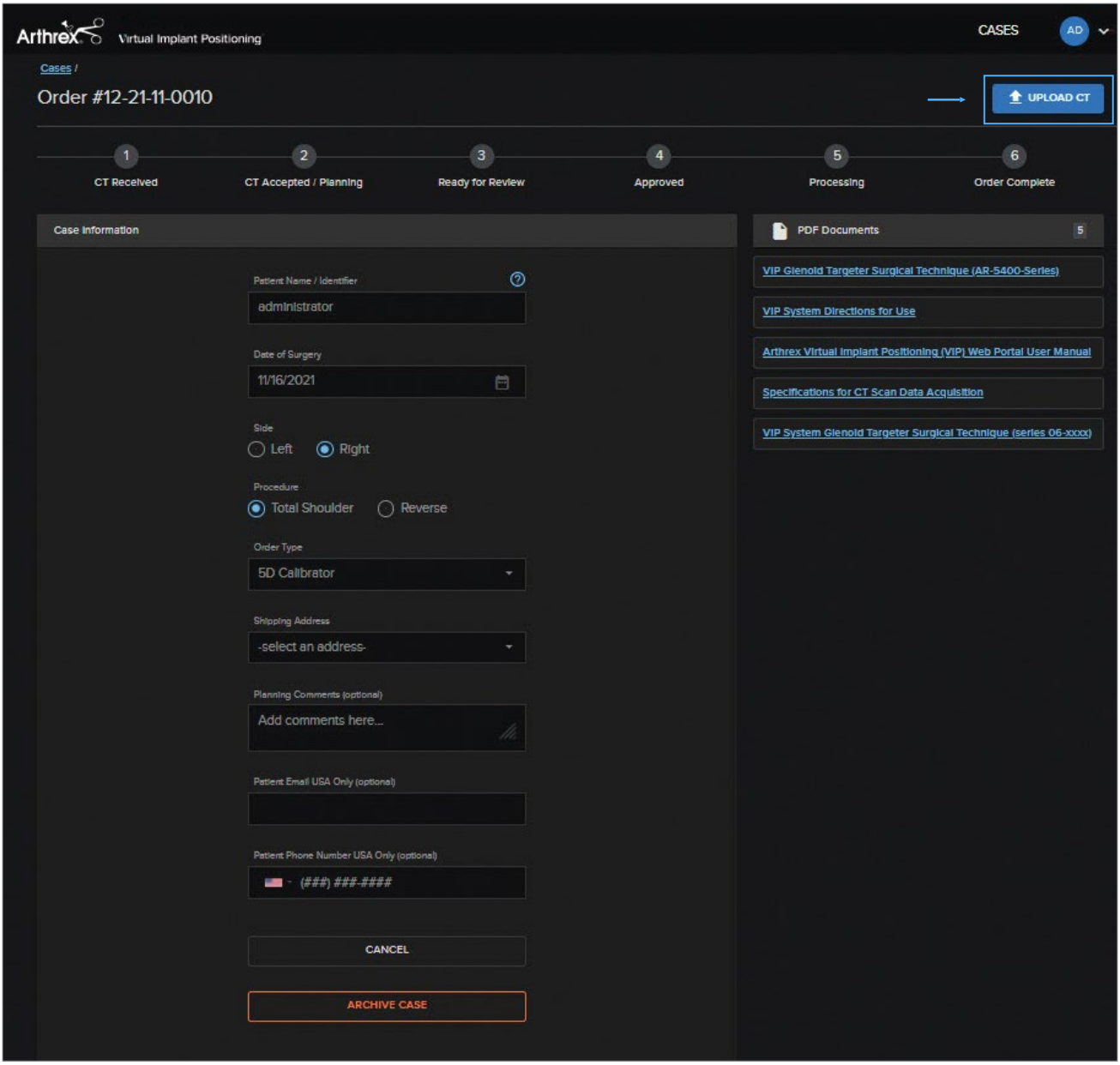


Figure 7. Case and CT upload forms

Uploading CT Images

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

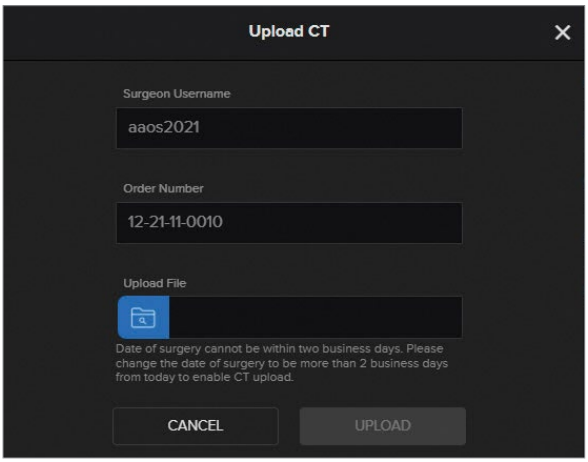


Figure 8. Upload CT page

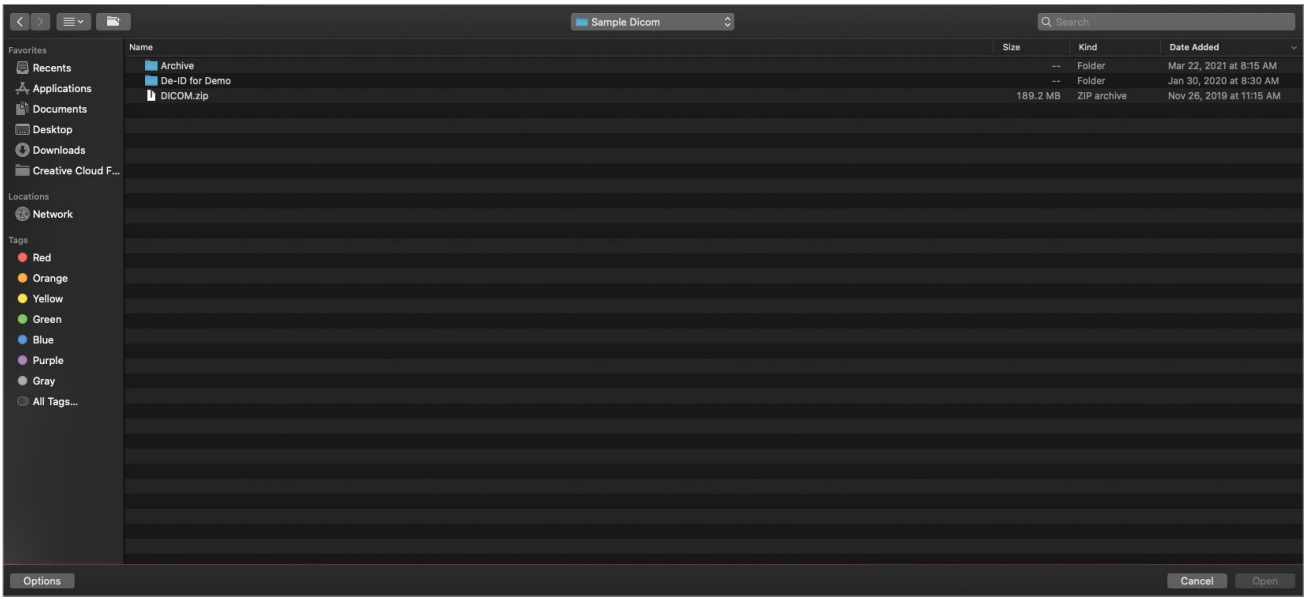


Figure 9. Locating compressed folder

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.

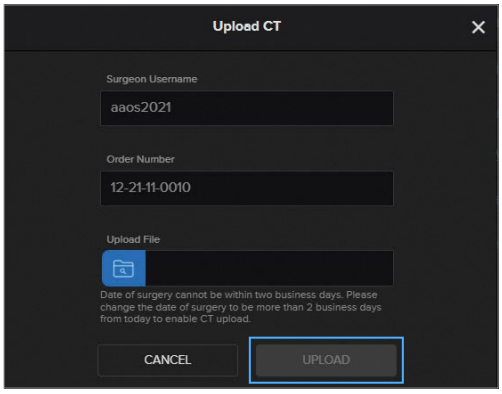


Figure 10. “Upload” button that initiates CT upload

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 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.

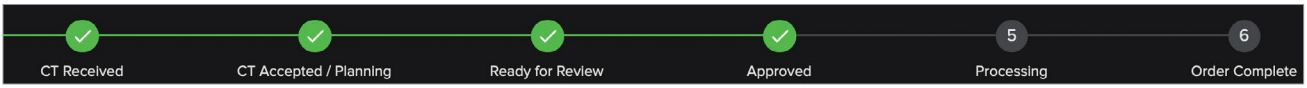


Figure 13. Case status flowchart

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.

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.

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.

Cases Page

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.

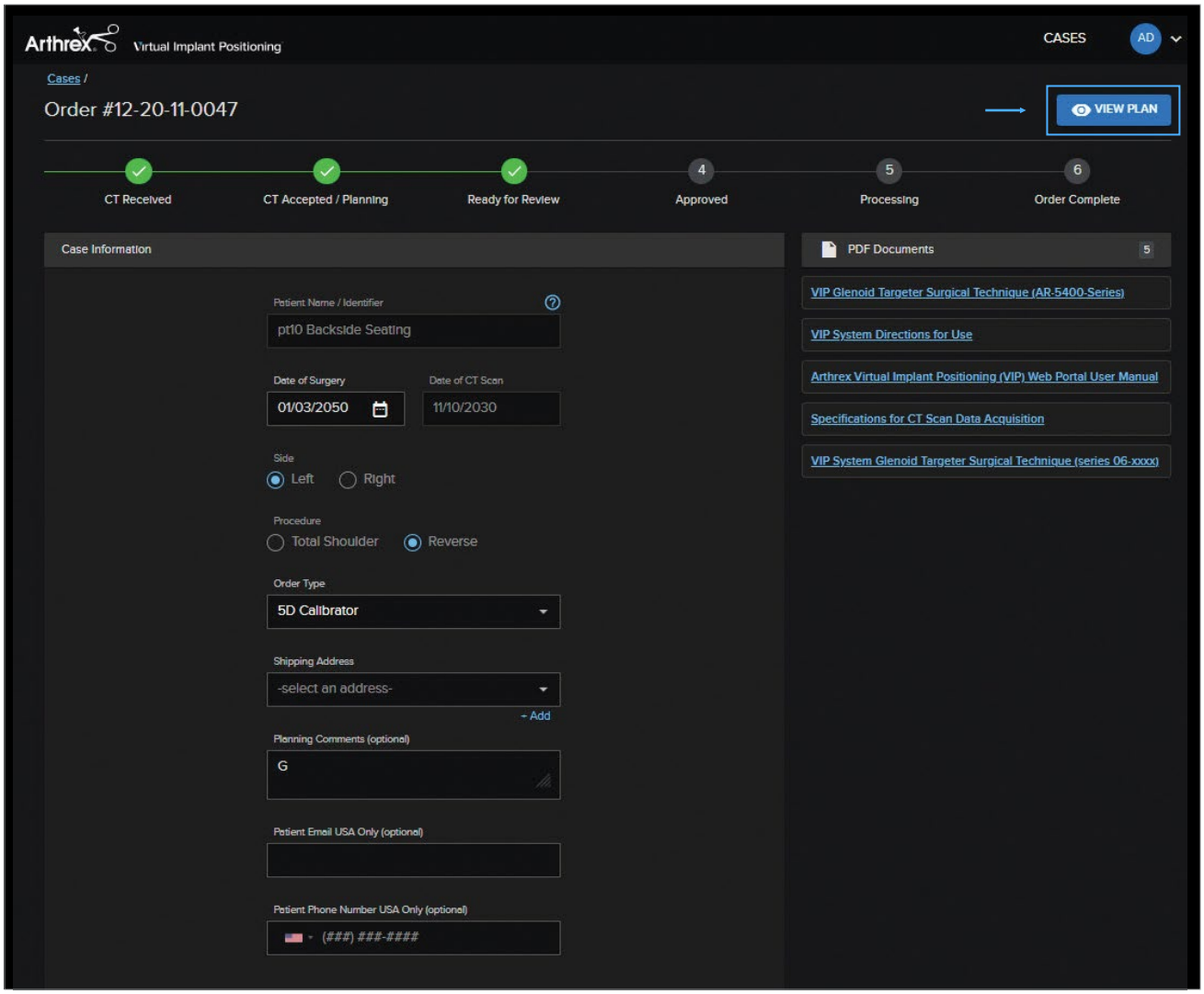


Figure 14. The Case Details page showing the View Plan button that links to the Viewer page

Glenoid Viewer Page

Clicking on “View Plan” 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 can be modified, 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 15. When selected, the 2D images will enlarge as shown in Figure 15a.

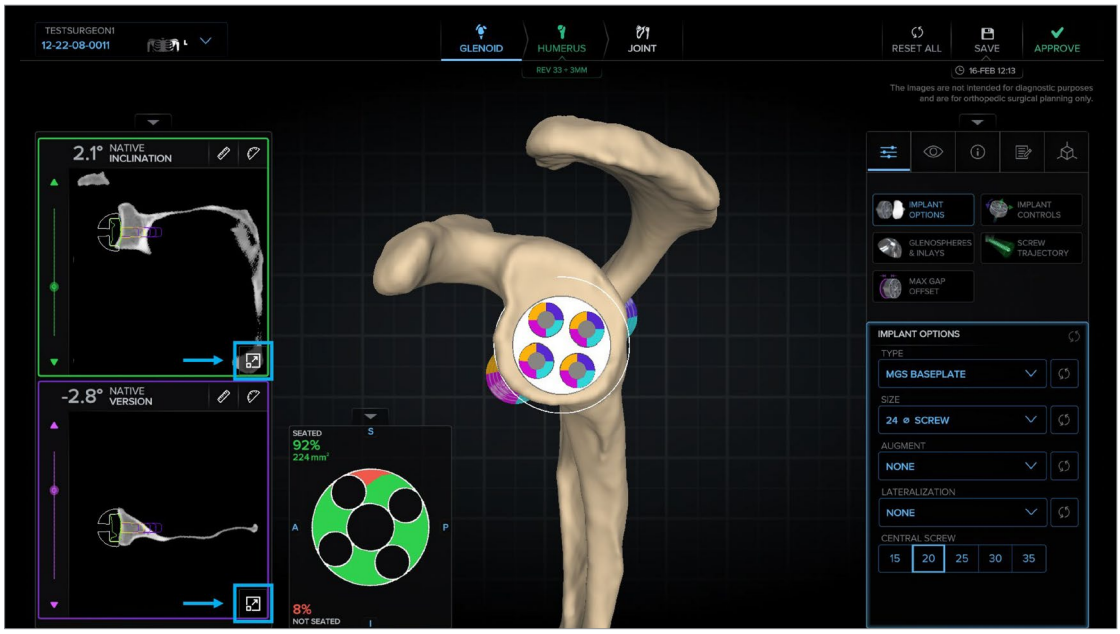


Figure 15. Glenoid Viewer page displaying proposed preoperative plan

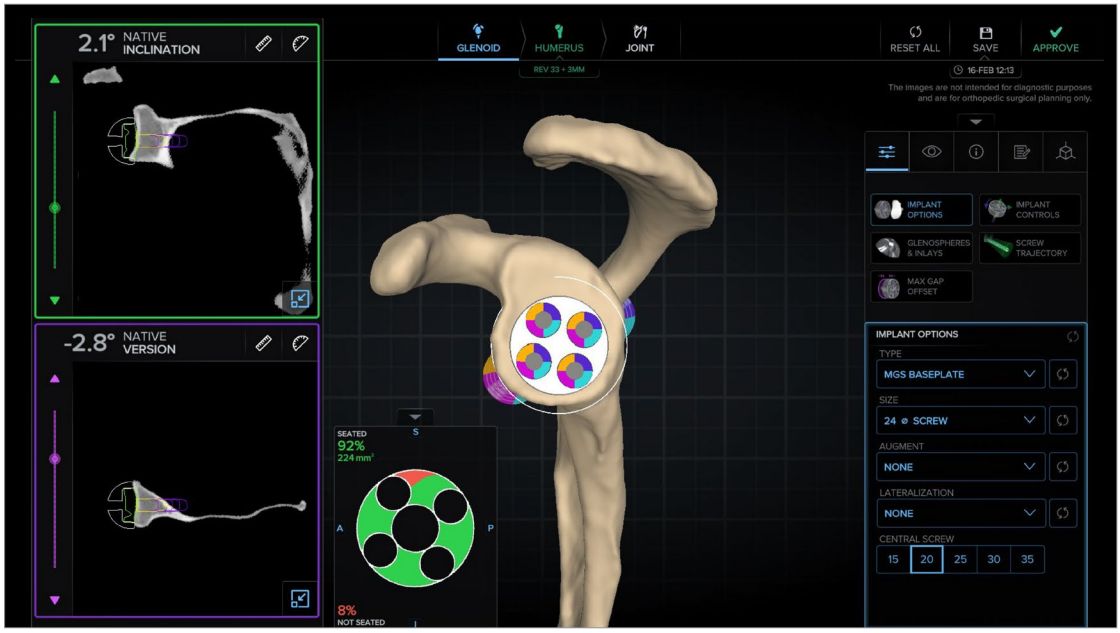


Figure 15a. Glenoid Viewer page with enlarged 2D views.

Measurement Tools

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

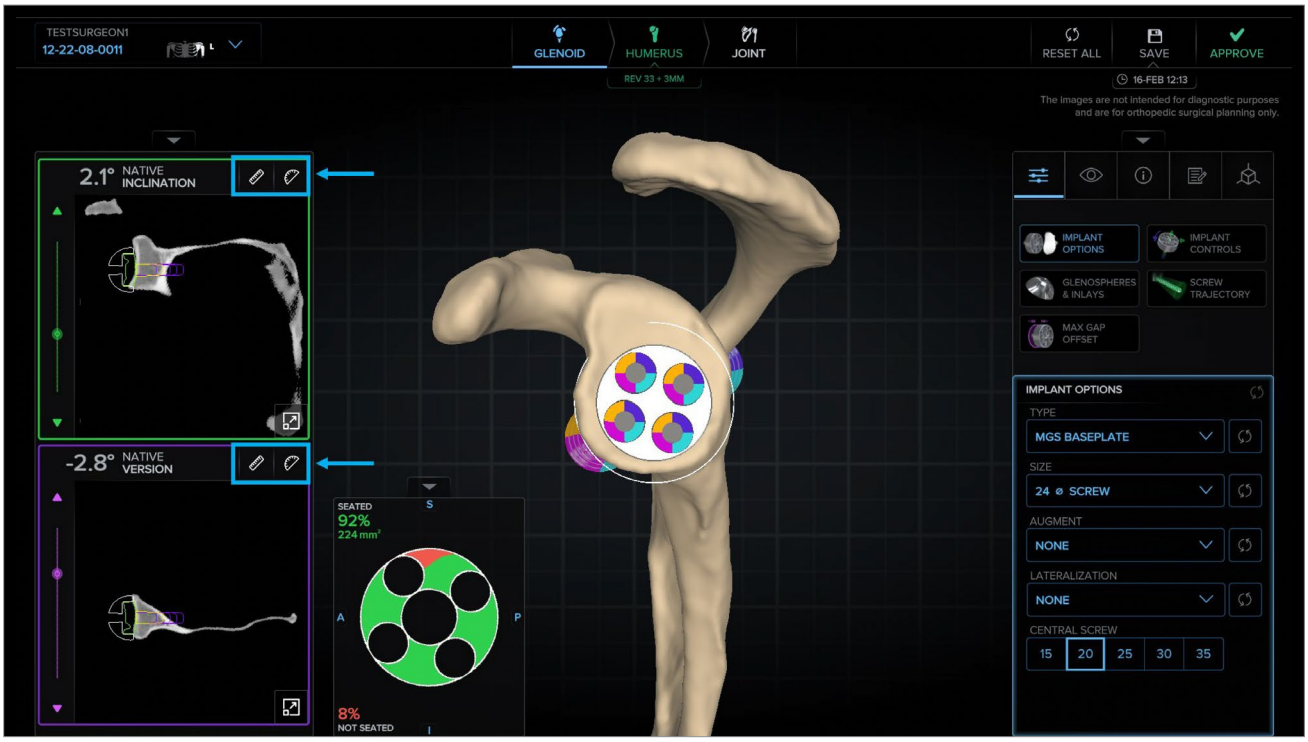


Figure 16. Glenoid Viewer page displaying the proposed preoperative plan

Measure Length

- Click on the ruler 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 hold to drag the remaining blue circle to the second reference point.

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

Control Panels
Available controls on the “Glenoid Viewer” page are divided into five control panels: Controls, Visibility, Info, Planning Comments, and Camera (Figure 17).

Implant Options (Figure 18)

- Located under the Controls tab.
- 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.

Implant Controls (Figure 19)

- Located under the Controls tab.
- 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 in 1° increments. 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 (0.5 mm increments) 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 (0.5 mm increments) 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 (0.5 mm increments) 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.
- Reset one of the individual controls by clicking on the ↺ to the right of the desired control to be reset. Click on the ↺ in the top right of the “Implant Controls” panel to reset all controls to their last saved settings.

Figure 17. Glenoid viewer page control panels

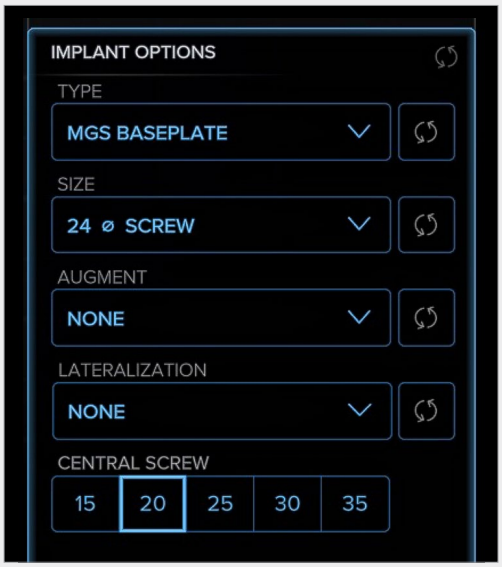


Figure 18. Implant Options control panel

Figure 19. Implant Controls panel

Interface Functionality

Glenospheres & Inlays (Figure 20)

- Located under the Controls tab.
- 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.

Note: Once a glenosphere diameter is selected, the "Joint" tab will appear at the top center to the right of the "Humerus" tab.

Figure 20. Glenospheres & Inlays function

Screw Trajectory (Figure 21)

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

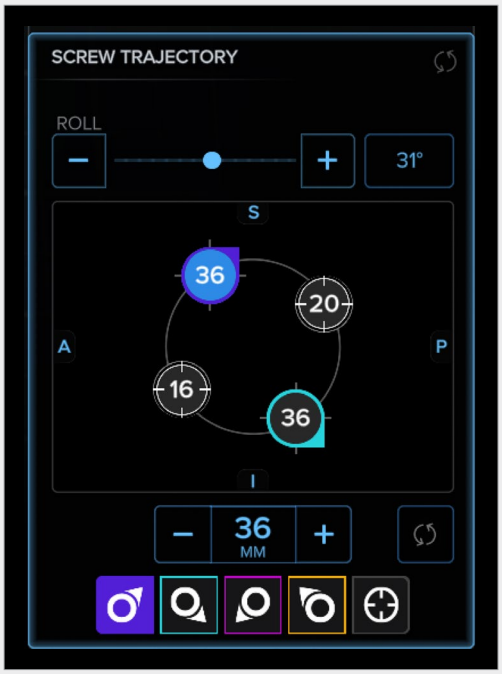


Figure 21. Screw Trajectory function

Implant Compatibility Warnings

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 as seen in Figure 22. 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 as seen in Figure 22a. Once the Humeral tab is selected, the system will default to the suture cup/insert combination that matches the selected glenosphere diameter.

Figure 22. Anatomic implant compatibility warning

Figure 22a. Reverse implant compatibility warning

Max Gap Offset (Figure 23)

- 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—and location of largest depth—that the backside of the implant is into the bone, excluding the buildup of the augment.

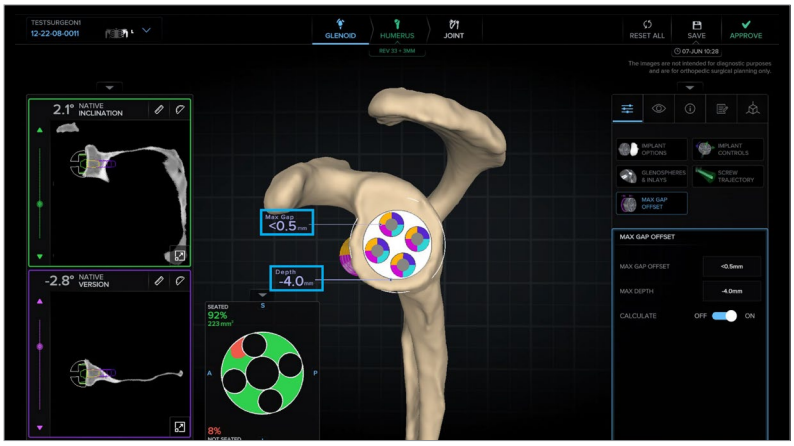


Figure 23. Max Gap Offset output

Backside Seating (Figure 24)

- This measurement can be maximized or minimized using the arrow above the Backside Seating Heat Map (shown in blue box in Figure 24).
- This feature shows areas where the backside of the implant is not contacting bone in red (see red arrows in Figure 24) and areas where the backside of the implant is contacting bone in green (see green arrows in Figure 24) in both 2D and 3D views.

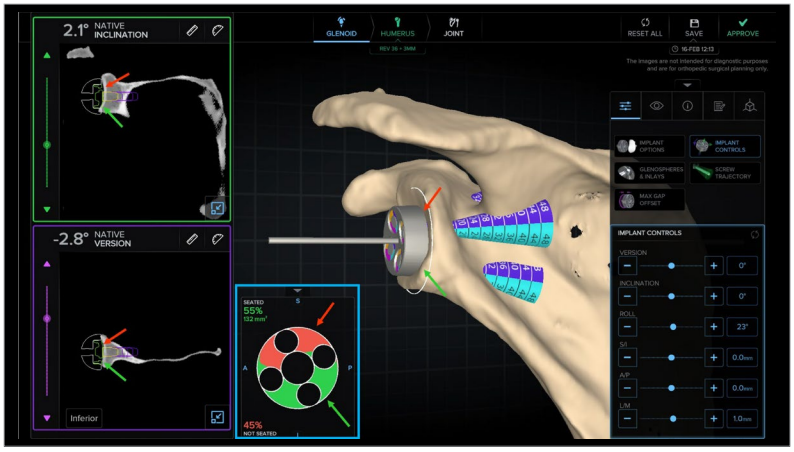


Figure 24. Backside Seating feature

Implant Perforation (Figure 25)

- This feature within the backside seating heat map will show areas where the implant perforates the glenoid medially as shown in Figure 25.
- 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.

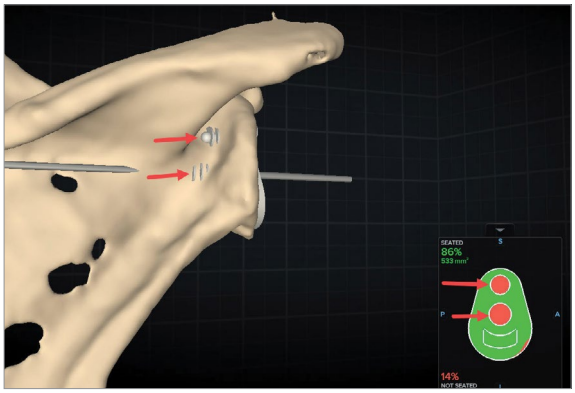


Figure 25. Implant perforation in Backside Seating feature

Interface Functionality

Visibility Controls (Figure 26)

- 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 26)

- 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 26)

- 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.

Info Tab

Clicking the icon displays detailed information about the plan, including the type, size and orientation of the implants currently saved to the plan.

Planning Comments Tab

The icon allows users to submit comments. 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.

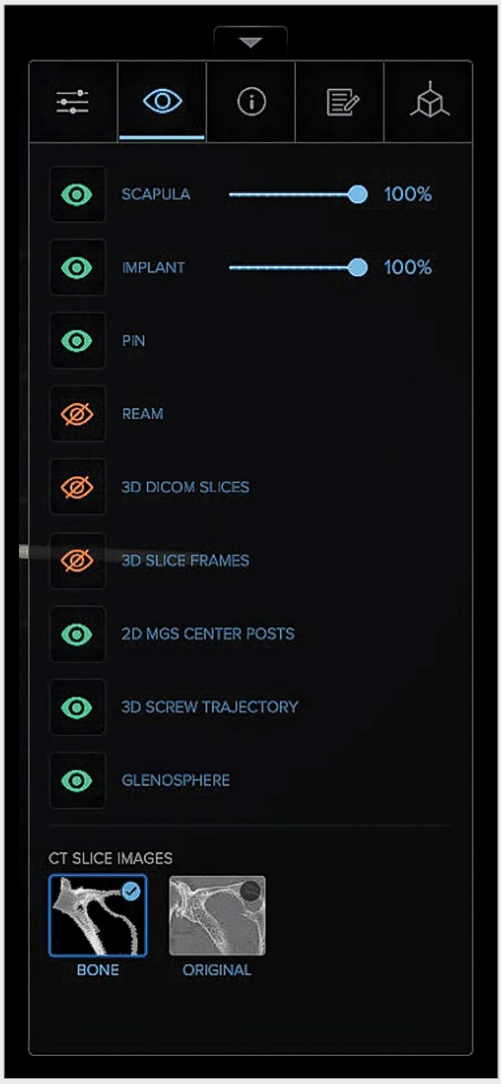


Figure 26. Glenoid Viewer Visibility controls panel

Snap-to Views and Reset View

Click on the icon at the top right of the control panel to open the snap to and reset view options. Click the desired 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.

To reset the image view, click on the icon at the top right of the control panel.

Figure 27. Glenoid Viewer page displaying the proposed preoperative plan

Save

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. Once the plan has been saved, it will be time-stamped as shown in Figure 28. The “Reset All” function will set all parameters to the last saved configuration.

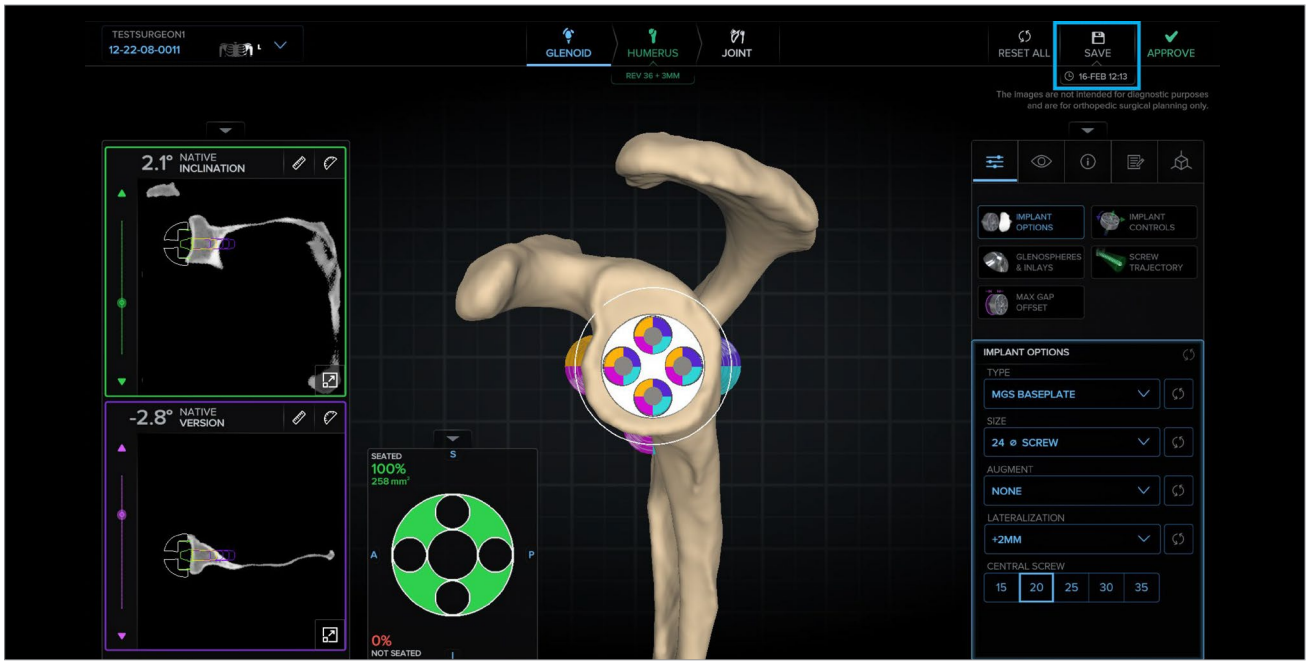


Figure 28. Glenoid Viewer page displaying the proposed preoperative plan

Figure 29. Center of rotation (coronal view)

Center of Rotation (Figures 29 and 30)

The “Joint” 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 viewer defaults to the coronal view. To access the axial view, select the icon as shown in Figure 29. Joint subluxation can be viewed by clicking the corresponding toggle as shown in Figure 30.

Figure 30. Center of rotation and joint subluxation (axial view)

Humeral Viewer Page

Clicking on the “Humerus” tab 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 can be modified, saved, and approved. The coronal view is shown in the left pane in 2D, the cut surface with the implant placement is shown in the center pane, and the 3D-rendered humerus with the proposed implant is shown in the right pane.

Figure 31. Humeral Viewer page: Anatomic

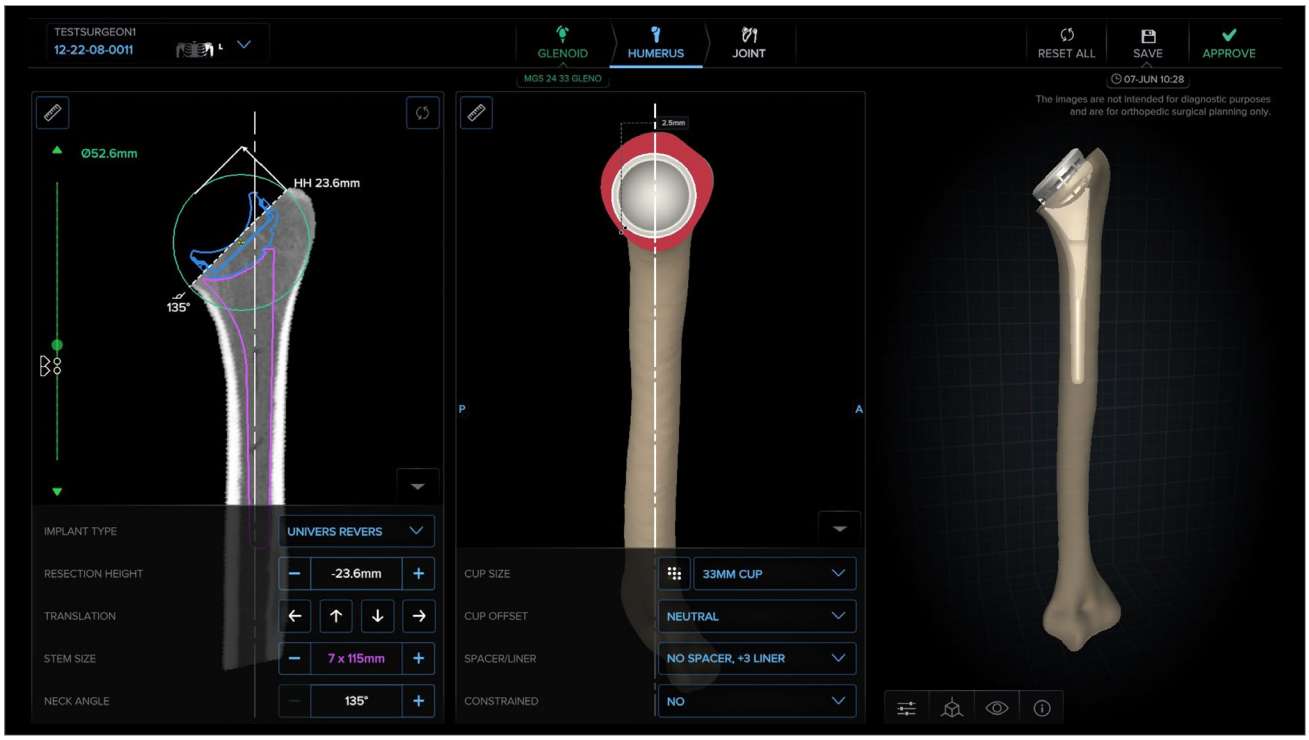


Figure 31a. Humeral Viewer page: Reverse

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. In this pane, users can see the type and modify the size of the proposed implants, and adjust the height of the humeral resection as well as the neck angle. Zoom in and out of the 2D image by using the mouse’s center scroll wheel and pan by right-clicking and dragging.

Anatomic (Figure 32)

- Adjust the height of the humeral resection in 1 mm increments.
- Select the appropriate Eclipse™ cage screw size.
- Adjust the neck angle in 2.5° increments.

Reverse (Figure 32a)

- Adjust the height of the humeral resection in 1 mm increments.
- Adjust the position of the Revers™ or Revers Apex stem in the humerus.
- Select the appropriate Revers or Revers Apex stem size.
- Adjust the neck angle between 135° and 155°.

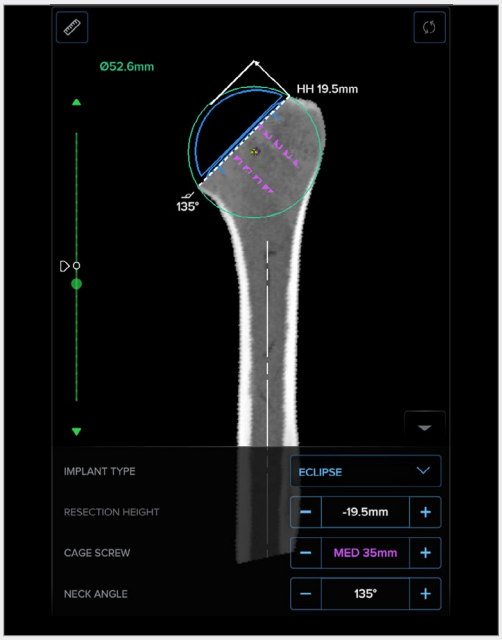


Figure 32. Humeral Viewer left pane: Anatomic

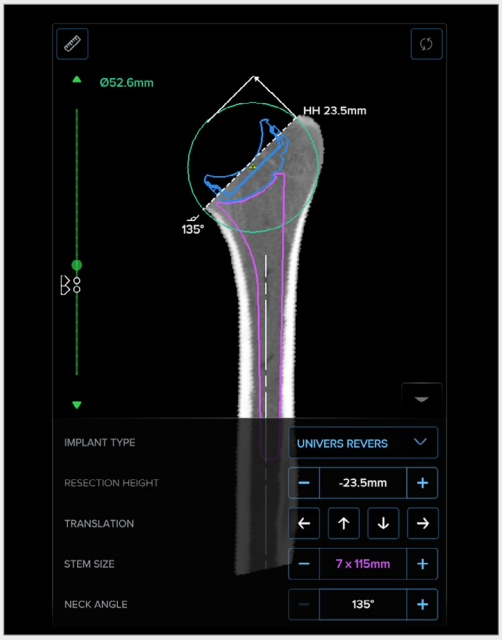


Figure 32a. Humeral Viewer left pane: Reverse

Interface Functionality

Measurement Tool and Reset Function

- Click on the at the top left of the 2D view. 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.
- Click on the 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.
- 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 as seen in Figure 33.

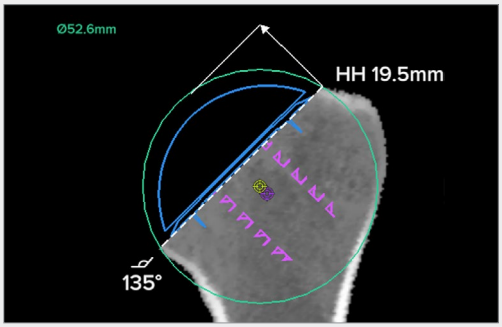


Figure 33. Anatomic and Prosthetic COR

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 34 and 34a).
- 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 central pane of the “Humeral Viewer” page.
- 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 central pane.
- All perforation warnings can be visualized and verified on the 3D bone model shown in the right pane of the “Humeral Viewer” page.

Figure 34. Perforation Warnings: Anatomic

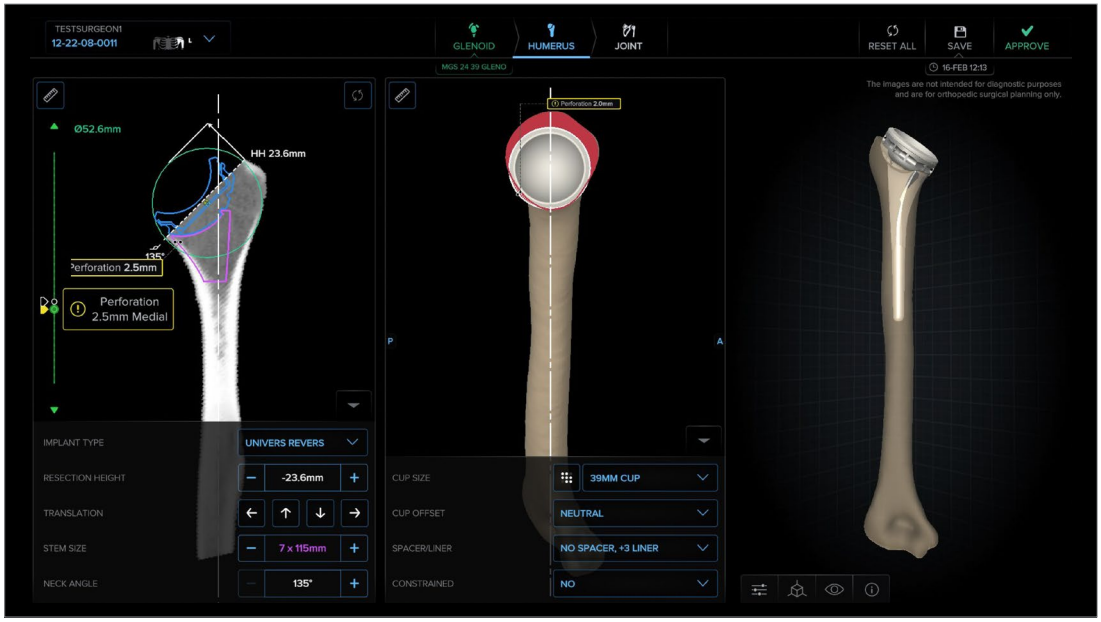


Figure 34a. Perforation Warnings: Reverse

Interface Functionality

The central pane of the “Humeral Viewer” page displays the cut surface of the humerus and the proposed position of the humeral implants. In this pane, users can modify the size and position of the implants as well as access the compatibility matrices for glenoid and humeral implants (Figures 38 and 38a) as shown in Figures 35 and 35a.

Anatomic (Figure 35)

- Select the Eclipse™ humeral head component diameter and height.
- Adjust the position of the Eclipse implant on the humeral cut surface.

Note: The Eclipse trunnion diameter matches the selected humeral head diameter in VIP™.

Reverse (Figure 35a)

- Select the diameter of the suture cup and polyethylene insert.
- Select the offset of the suture cup as shown in Figure 36.
- Select the thickness of the insert/spacer construct as shown in Figure 37.
- Select the constrained or standard polyethelene insert implant geometry.

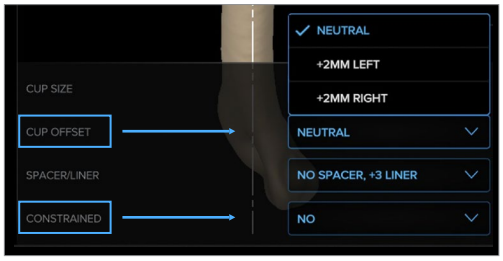


Figure 36. Suture cup offset selection

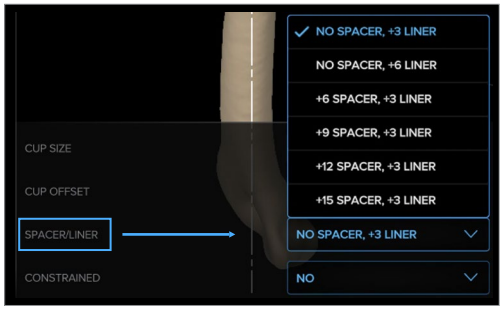


Figure 37. Polyethelene insert and spacer selection

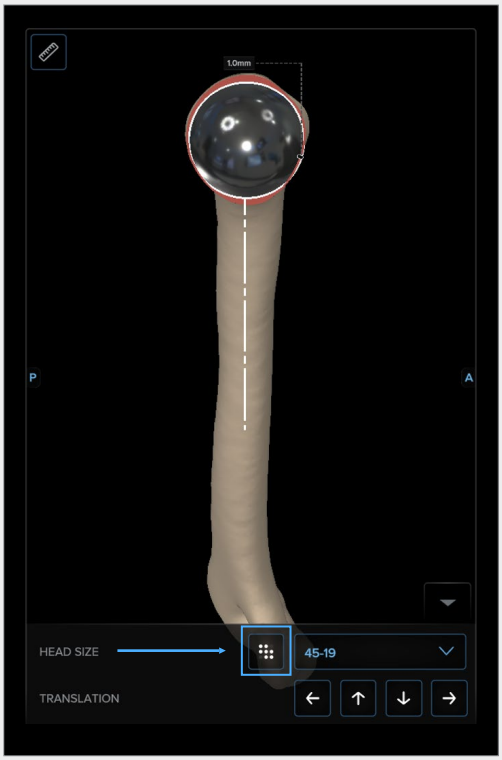


Figure 35. Humeral Viewer center pane: Anatomic

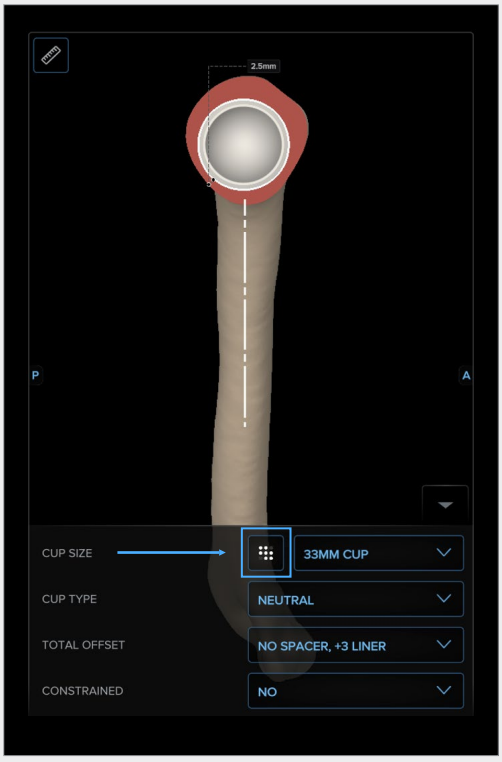


Figure 35a. Humeral Viewer center pane: Reverse

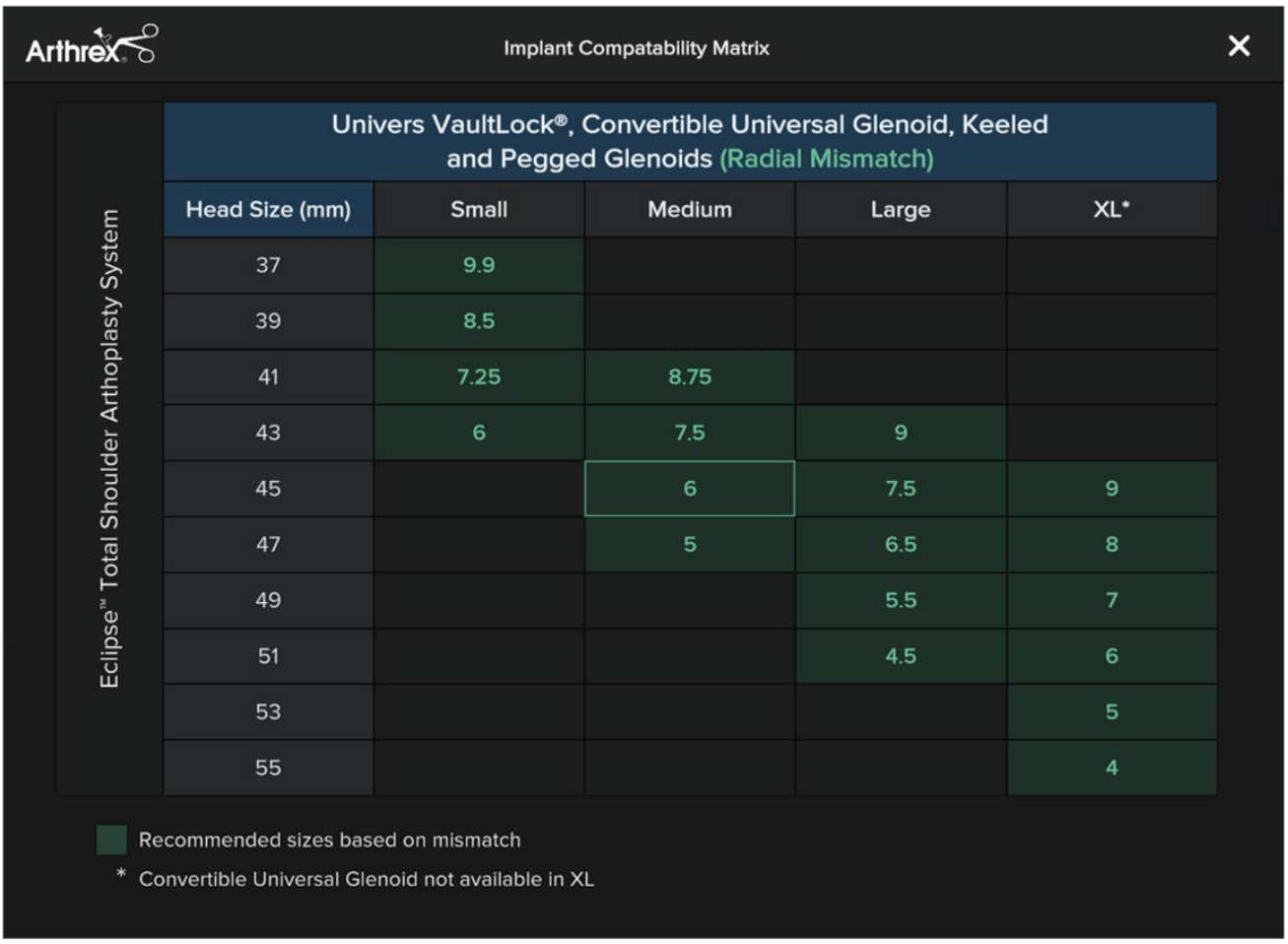


Figure 38. Anatomic Implant Compatibility Matrix: Eclipse total shoulder arthroplasty system

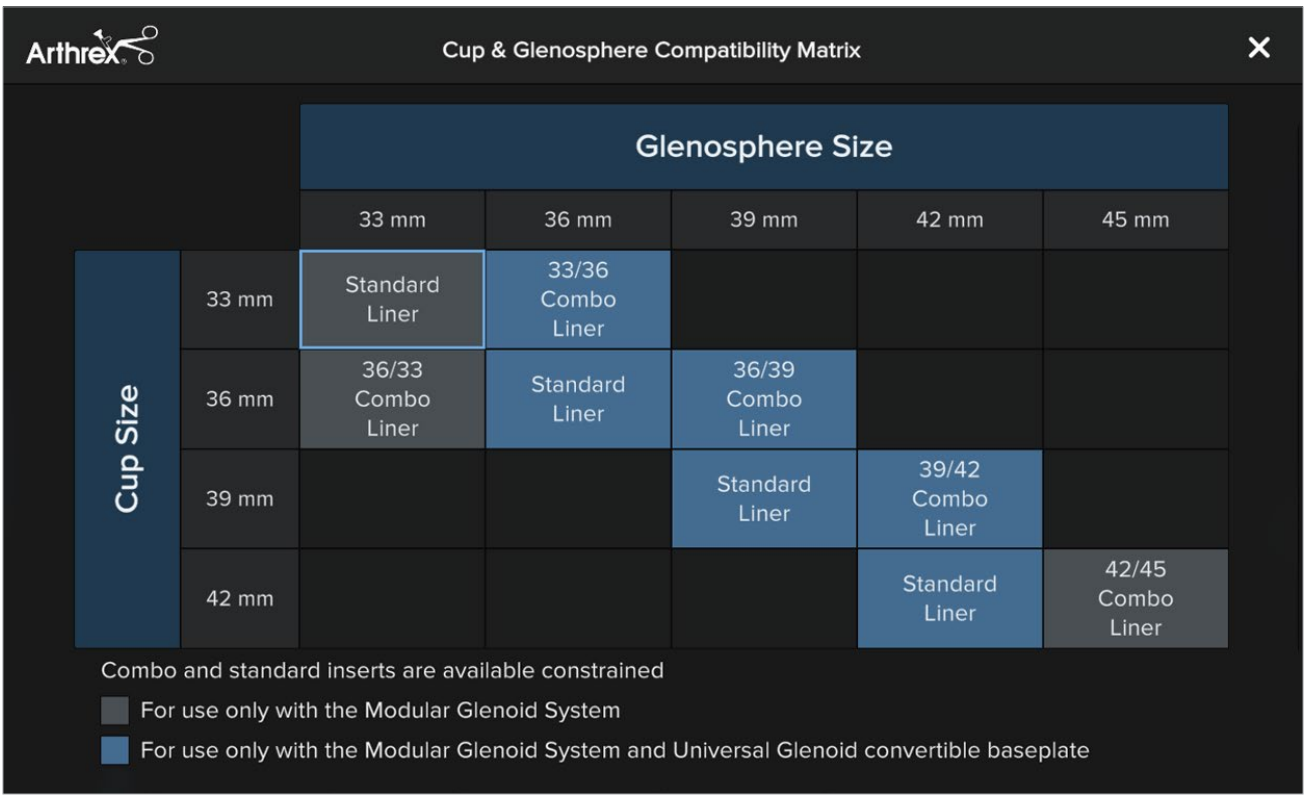


Figure 38a. Reverse Implant Compatibility Matrix

Interface Functionality

The right pane of the “Humeral Viewer” page displays the 3D rendering of the humerus and the humeral implant in its proposed location. Similar to the function of the 3D view of the scapula on the “Glenoid Viewer” page, the user can 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.

Version, Varus/Valgus, and A/P Translation Controls (Figures 39 and 39a)

- Version (or torsion) can be adjusted for all humeral implants using the control at the bottom of the right pane. Click the “+” or “-” buttons to adjust the selection in 1° increments from the patient’s native version.
- In reverse humeral planning, the varus/valgus position of the Revers™ or Revers Apex stem may be adjusted from its default position in line with the humeral shaft axis. Click the “+” or “-” buttons to adjust the selection in 1° increments.
- A/P translation is available for all stemmed humeral components. Select the ← → controls to shift the stem in the desired direction in 1 mm increments.

Snap-to Views and Reset View (Figure 40)

Click on the icon at the bottom left of the right pane to open the snap to and reset view options. Click the desired 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. To reset the image view, click on the icon at the bottom right of the control panel.

Figure 39. Humeral Viewer right pane: Anatomic

Figure 39a. Humeral Viewer right pane: Reverse

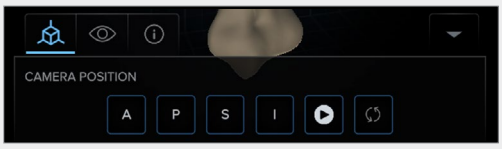


Figure 40. Snap-to views controls

Interface Functionality

Visibility Controls (Figures 41 and 41a)

- 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.

Info Tab

Clicking the icon displays detailed information about the plan, including the type, size and orientation of the implants currently saved to the plan.

Figure 41. Visibility controls: Anatomic Eclipse humeral head

Figure 41a. Visibility controls: Reverse

Interface Functionality

Approve Button (Figure 42)
Clicking the “Approve” button opens a dialogue box (Figure 43) in which surgeons must enter their password to finalize the plan’s approval. Users must also confirm the “Order Type” and the “Shipping Address.”

Note: Entering the surgeon’s password and clicking “Approve Plan” constitutes a legally binding electronic signature of approval.

Once “Approve Plan” is selected, the plan is approved. Any changes that were made to the plan are saved, and the user is returned to the “Case Details” page. The case status will now be displayed as “Approved.”

Note: Once approved, a plan cannot be changed or unapproved. Also, “Not Used” plans cannot be changed or approved.

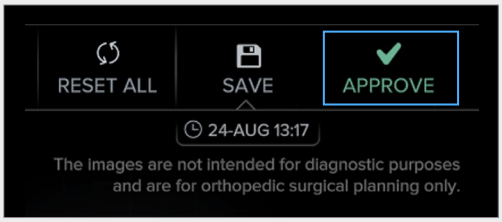


Figure 42. Approve button

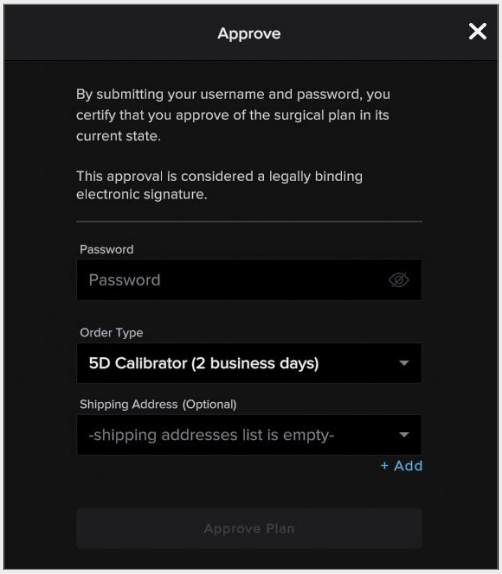


Figure 43. Approve tab

User Profile Options Page

Profile Tab

Within the web portal, users can view their user profile (Figure 44), which displays:

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

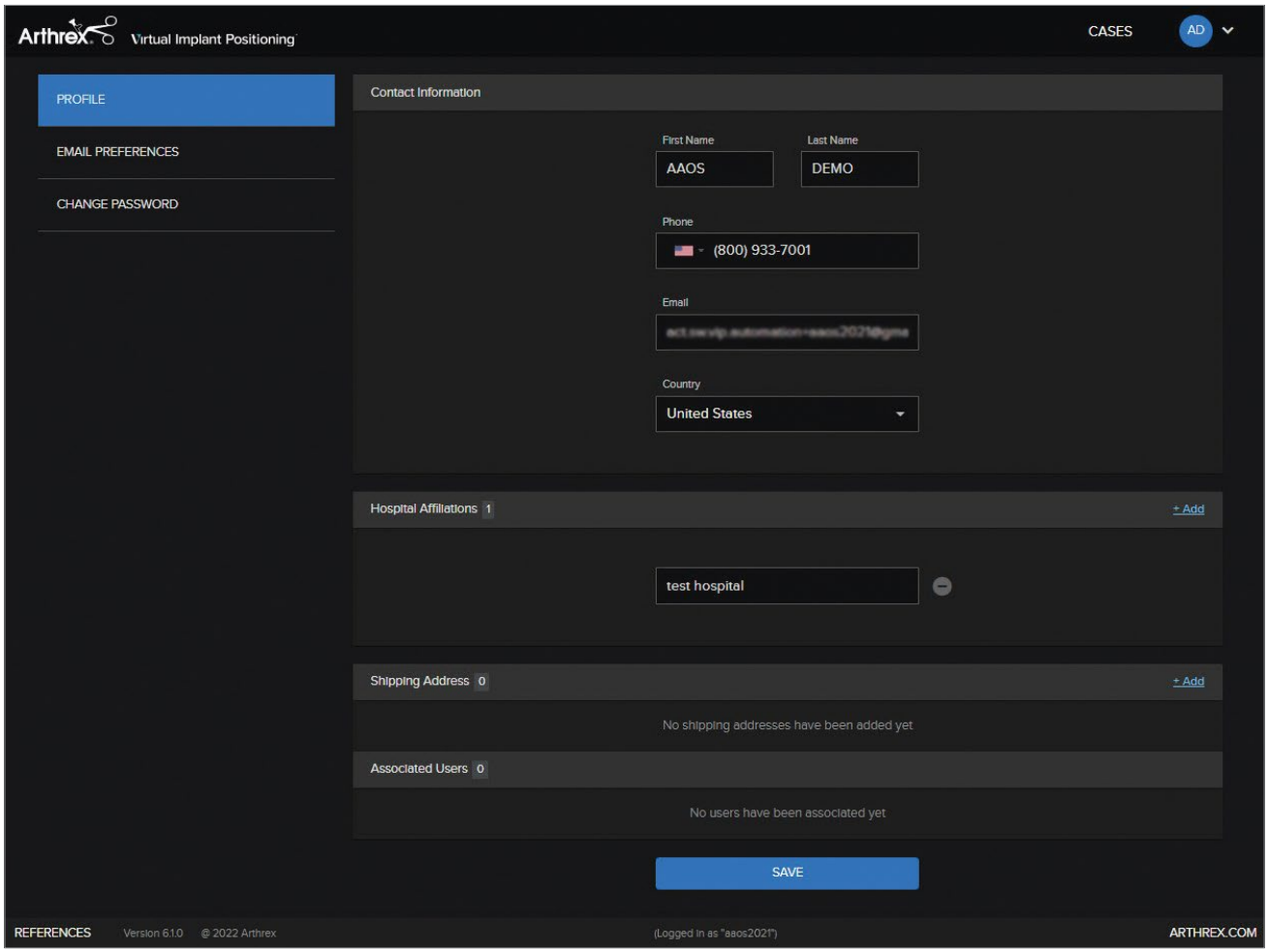


Figure 44. Profile page

User Profile Options 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 45).

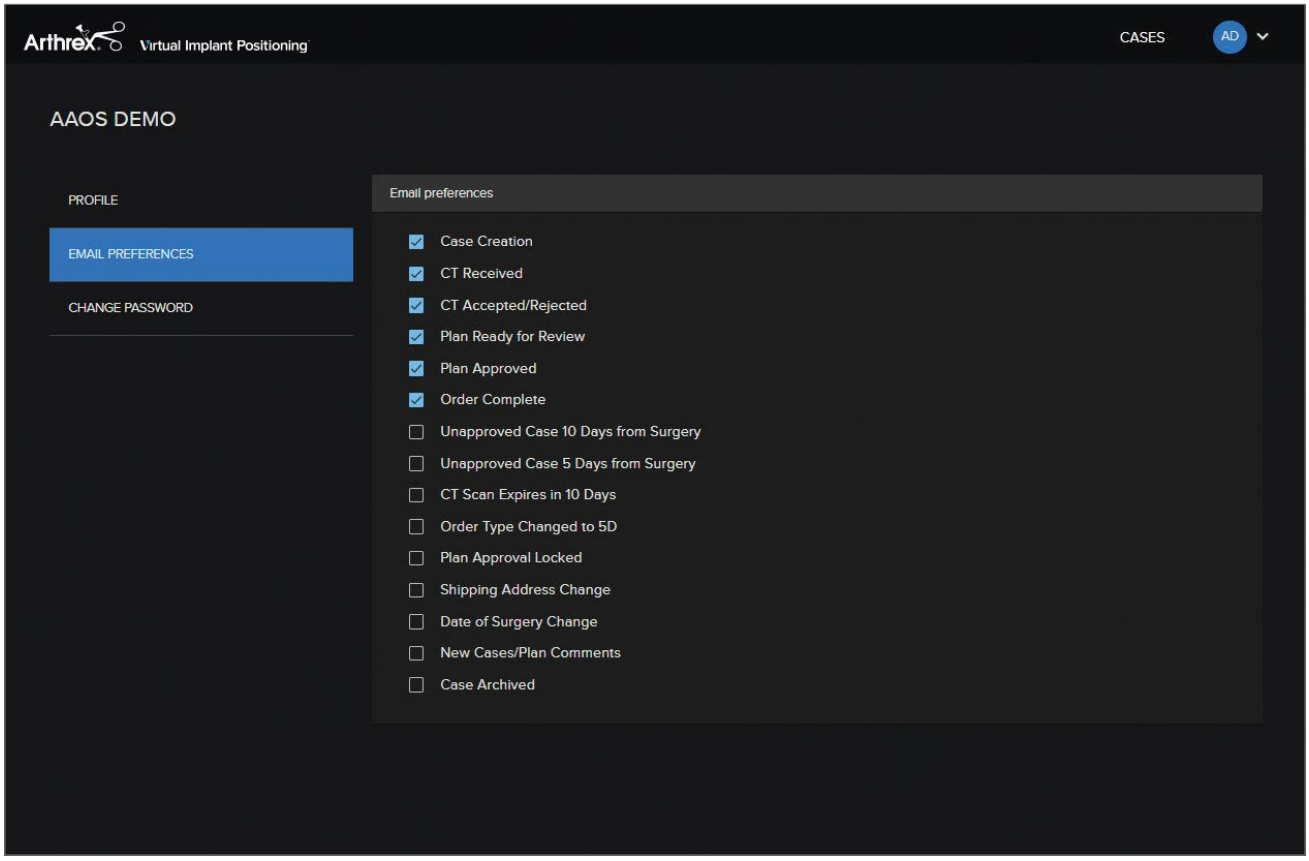


Figure 45. User Email Preferences page

Change Password Tab

Users also have the ability to change their password using the “Current password” and “New password” fields (Figure 46).

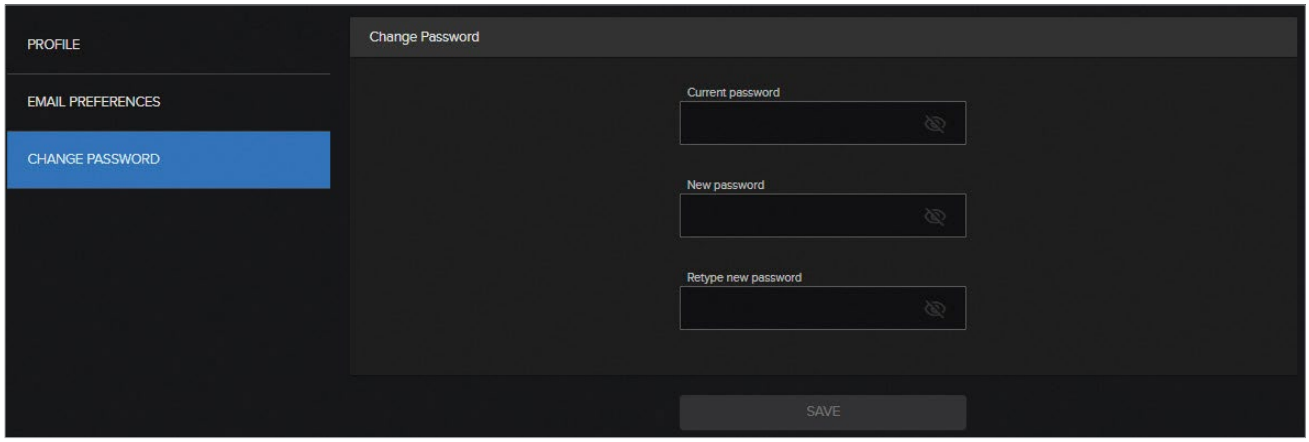


Figure 46. Change Password page

Log Out

The “Log Out” button appears at the top right of 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

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

CE 2797

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

Arthrex®

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.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

arthrex.com