

OFIX MIS App Workflow



Instructions on How to Download App

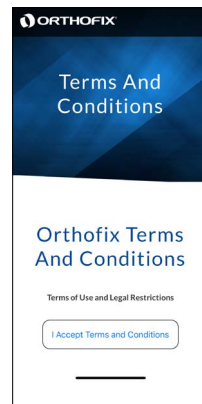
1. Open url to download the app from your email.
2. Tap Get to download the App.
3. Go to iPhone home screen to verify the App has been downloaded.
4. On the phone settings navigate to General -> Device Management -> Click Trust Orthofix Inc for OFIX MIS App.
5. Confirm the installation by launching the App and click Accept for Terms and Conditions. Enter the email and the passcode provided in the email.

Compatible Devices

OFIX MIS App is available only for iPhone. The models supported are iPhone X and newer and iOS version 15.0 and above.

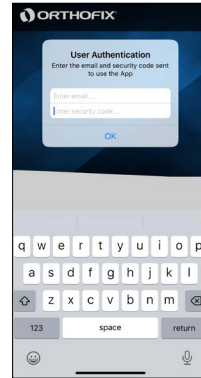
Terms and Conditions

The User must accept the Terms and Conditions before proceeding.



Security Code

The User must enter a valid email and passcode before proceeding. This is only done on first time usage of the App.



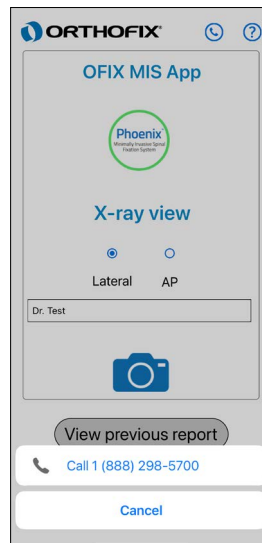
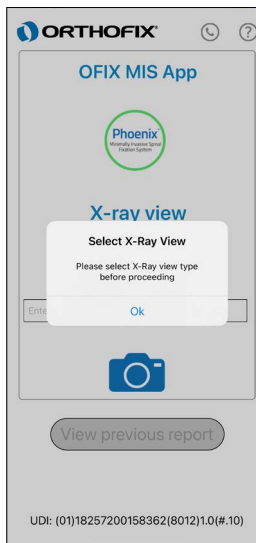
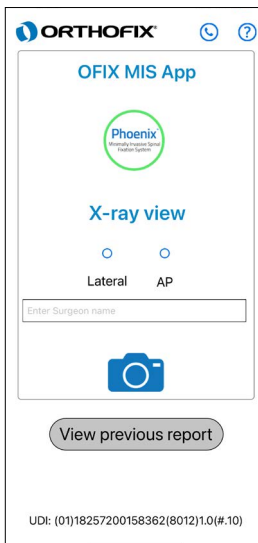
Surgery Info

The User must select a x-ray view and enter a surgeon's name before the camera icon is enabled.

If the user taps the camera icon before selecting a x-ray view AND entering a surgeon name, a popup will come telling the user to enter a surgeon name or select a x-ray view.

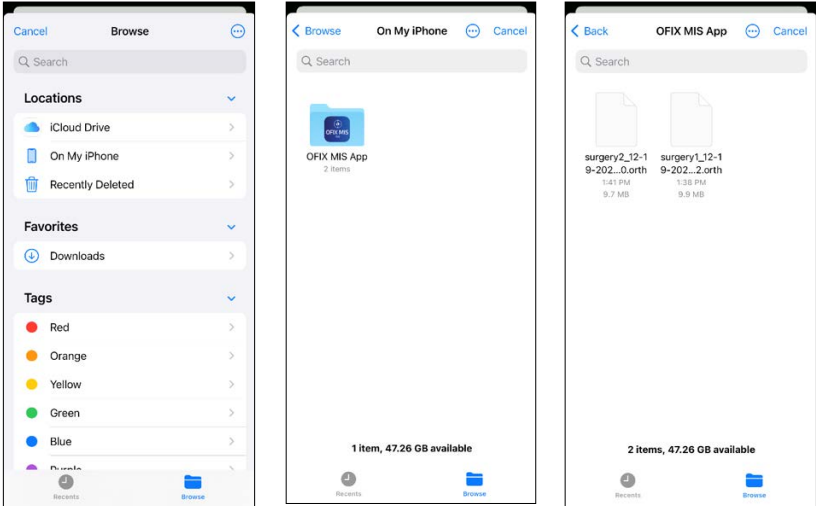
The phone icon brings up a standard phone popup so the user can call the OrthoFix Help Desk.

The Help icon takes the user to a help screen/page.



View Previous Report

The user can navigate to select the file of interest. To navigate to the correct file click on Browse at the bottom right of the screen -> Click On My iPhone -> Select OFIX MIS App and select the file to view.



The user is presented with a list of reports from previous uses of the App.

Each report is encrypted and can only be opened from within the App.

The files are named with the Surgeon's name entered on the Surgery Info screen plus the date and time the image was saved. Date and time are used since multiple images may be saved during one surgery.

Help

This is under development

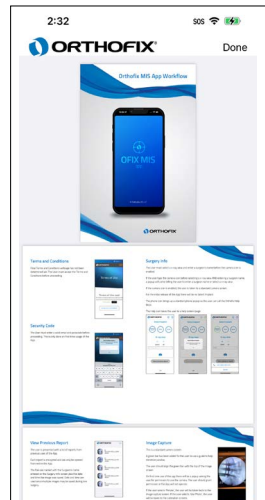


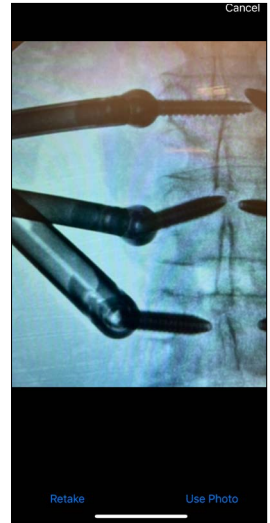
Image Capture

This is a standard camera screen.

A green bar has been added for the user to use a guide to help minimize parallax. The user should align the green bar with the top of the image screen.

On first time use of the app there will be a popup asking the user for permission to use the camera. **The permissions can be changed by going to Phone settings and selecting OFIX MIS App from the list.** The user should grant permission or the App will not operate.

If the user selects 'Retake', the user will be taken back to the image capture screen. If the user selects 'Use Photo', the user will be taken to the calibration screens.



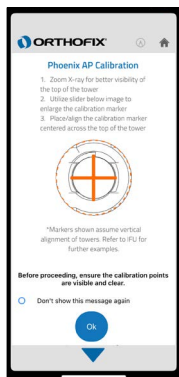
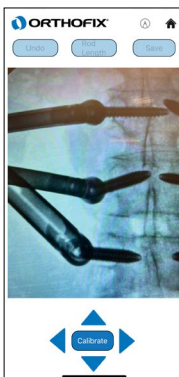
Before proceeding, ensure the calibration points are visible and clear.

Start Calibration

If the user taps on the Home icon on the top-left corner, the app will discard the current session and return back to Surgery Info screen, and all unsaved work will be lost.

When the user taps on 'Calibrate', a screen showing the proper positioning for the calibration marker for either the lateral or AP view (depending on what the user selected on the surgery info screen).

The user is given the option to never see the calibration **position** screen again. If the selects this option, the screens will never come up again unless the user re-installs the App.



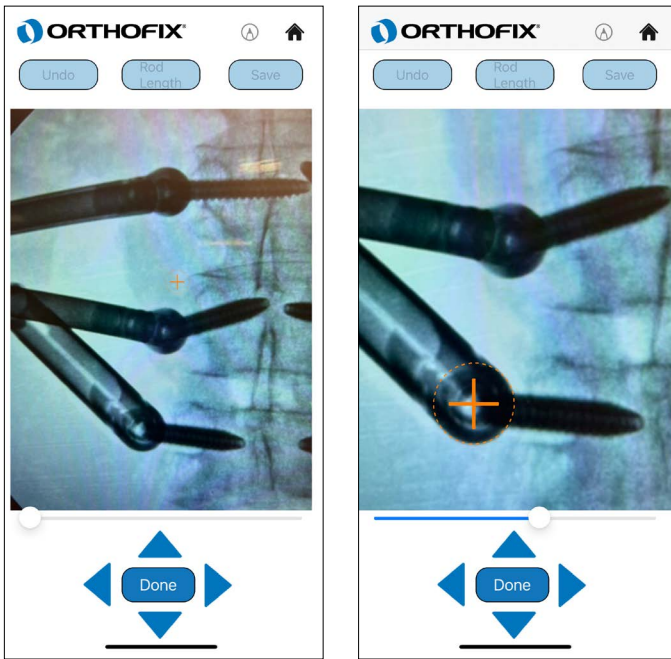
Calibration

The user is given a light orange marker to position and resize.

The user zoom in or out on the image using finger pinching motions.

The user can move the marker by dragging it with a finger, or if fine motions are needed, use the four pointers around the 'Done' button.

Using the slider, user can resize the calibration marker to to the right size.



The App rounds up to provide the suggested rod. It is advisable to pay close attention to the measured rod length versus the suggested rod.

Start Marker 1

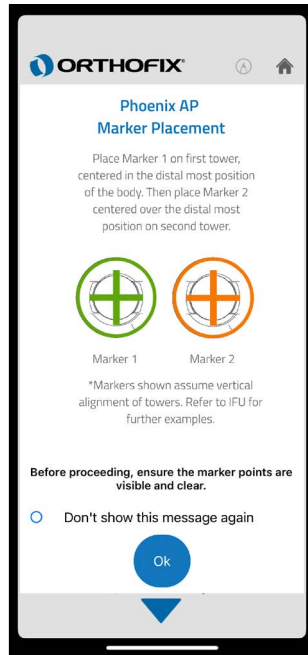
If the User taps on the Home icon , he will be taken back to the Surgery Info screen and all work will be lost.

When the User taps on the Undo button, the User will be taken back to the Start Calibration screen.

When the user taps on "Marker 1", an instructional guide is presented to show the proper positioning for marker1 and marker 2 for either the lateral or AP view (depending on what the user selected on the surgery info screen)

Refer to Appendix for additional reference images.

The user is given an option to never see the marker placement instructional guide again. If the user selects this option, the screens will never come up again unless the user re-installs the App.



Marker 1

If the User taps on the Home icon , he will be taken back to the Surgery Info screen and all work will be lost.

When the User taps on the Undo button, the User will be taken back to the Start Marker 1 screen.

The user taps on the 'Marker 1' button to start positioning Marker 1.

The user can drag Marker 1 using finger gestures to the appropriate location on the screen. If fine motions are needed, the user can tap the four pointers around the 'Done' button to move Marker 1. On click Done, the marker color changes to green showing the final positioning of the marker and the marker cannot be moved.



Marker 2

If the User taps on the Home icon , he will be taken back to the Surgery Info screen and all work will be lost.

When the User taps on the Undo button, the User will be taken back to the Start Marker 1 screen.

The user taps on 'Marker 2' to start positioning Marker 2.

The user can drag Marker 2 using finger gestures to the appropriate location on the screen. If fine motions are needed, the user can tap the four pointers around the 'Done' button to move Marker 2. On click Done, the marker color changes to green showing the final positioning of the marker and the marker cannot be moved using the finger drag gesture.



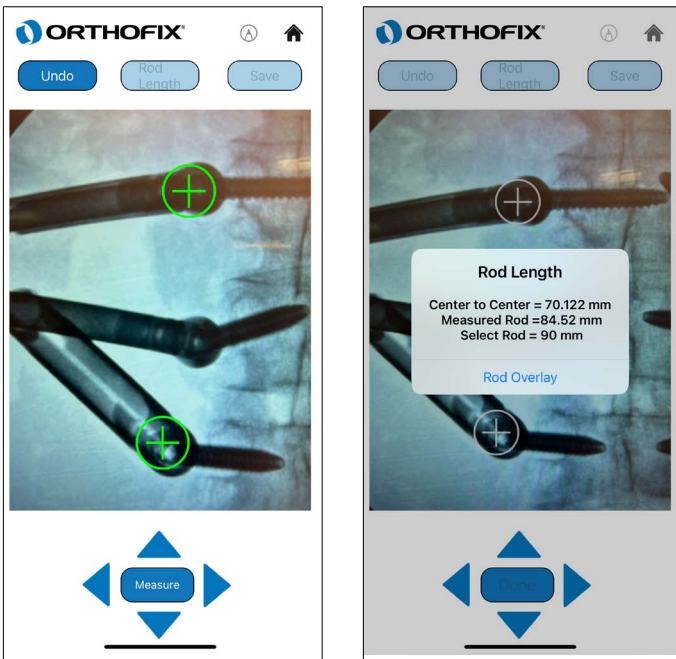
Measure

If the User taps on the Home icon , he will be taken back to the Surgery Info screen and all work will be lost.

When the User taps on the Undo button, the User will be taken back to the Start Marker 2 screen.

The user taps on the 'Measure' button to **raise** the measurement popup.

The user taps on '**Rod Overlay**' to see the Rod overlay on the image.



The App rounds up to provide the suggested rod. It is advisable to pay close attention to the measured rod length versus the suggested rod length.

Rod Overlay

If the User taps on the Home icon , he will be taken back to the Surgery Info screen and all work will be lost.

A yellow rod calibrated to the estimated size of the size will be displayed on the screen. The user uses one finger to drag the overlay around the screen.

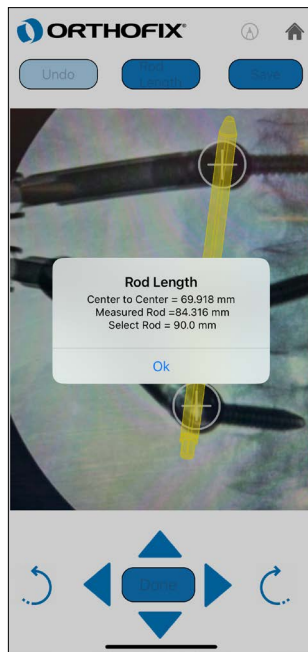
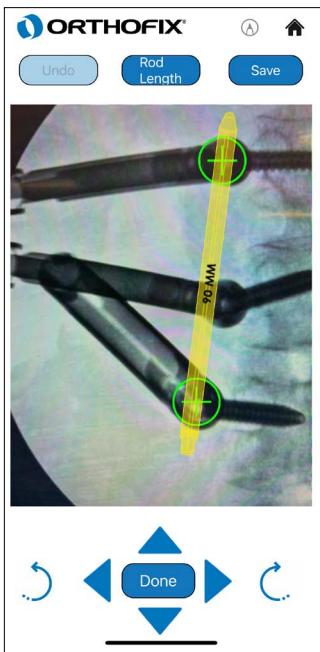
The user uses two fingers to rotate the overlay on the screen.

If fine motions are needed, the user can tap the four pointers around the 'Done' button to move the overlay or can use the rotate left and right buttons to rotate the **overlay counterclockwise and clockwise**. The rod images in lateral view can be flipped by double tapping on the rod image.

The Rod length button will raise a popup displaying the Rod Measurement estimates.

The Save button will raise the Save Rod Calculations popup.

Click the done button once the rod overlay has been positioned at the desired position. On click Done the suggested rod cannot be moved for more adjustments.



Rod Size

If the User taps on the Home icon , he will be taken back to the Surgery Info screen and all work will be lost.

The User taps on Rod Up or Rod Down to display rods of various sizes. New rods of various sizes will be red in color.

The user uses one finger to drag the overlay around the screen.

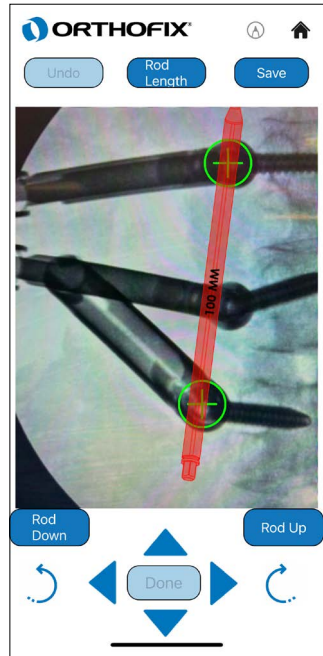
The user uses two fingers to rotate the overlay on the screen.

If fine motions are needed, the user can tap the four pointers around the 'Done' button to move the overlay or can use the rotate left and right buttons to rotate the overlay.

The Rod length button will raise a popup displaying the Rod Measurement estimates.

The Save button will save the screen to an encrypted file.

The Done button will take the user to the Rod Overlay resize screen.

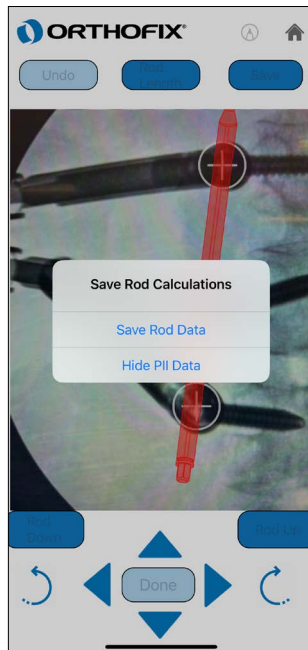
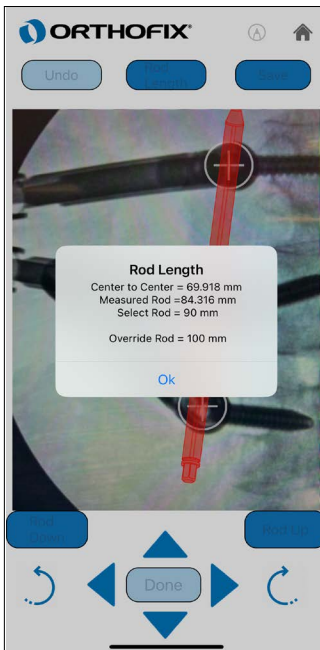


Save Rod Calculations

When User taps the Save button, the Save Rod Calculations popup appears.

When the User selects 'Save Rod Data' a second dialog appears asking the user to attest that PII is not visible on the screen. If the user cancels from the attest popup, the user will be returned to the original screen. If the user taps 'Save' on the popup, the screen will be saved and the user is returned to the original screen.

If the user taps on 'Hide PII Data', screen shall enable the pens button and a selection of pens will appear on the bottom of the screen. The user can then use the pens to cover any PII data. **Tap the pen icon on top-left corner to close.**



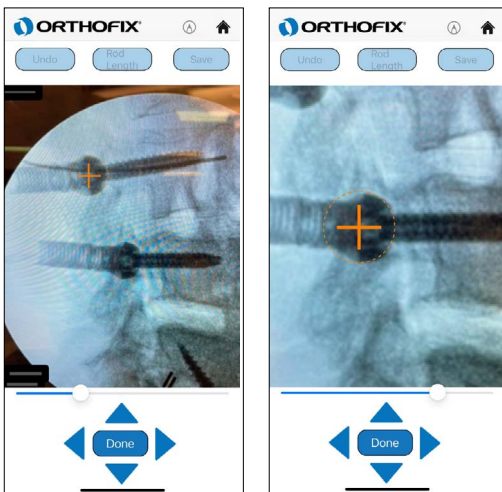
Best Practices

1. When capturing the image, place the phone as close as is practical to maximize the size of the image.
2. When calibrating it is best to zoom the image to its maximum allowable to allow more precise capture of the calibration circle over the edges of the implant.
2. The App rounds up to provide the suggested rod. It is advisable to pay close attention to the measured rod length versus the suggested rod.
3. If the screws are not at the same level using Lateral view is recommended rather than an AP view.
4. If an image contains implant heads bilaterally it may be difficult to discern which side the implants are on in a lateral x-ray. To help differentiate between left and right have the surgeon push the Phoenix towers on one side towards the head of the patient and on the other side towards the feet of the patient before taking the lateral x-ray. This way it is easier to discern which implants are on each side.
5. To preserve the phone memory storage it is recommended to archive the saved reports from time to time and remove them from the phone's files system.

Appendix

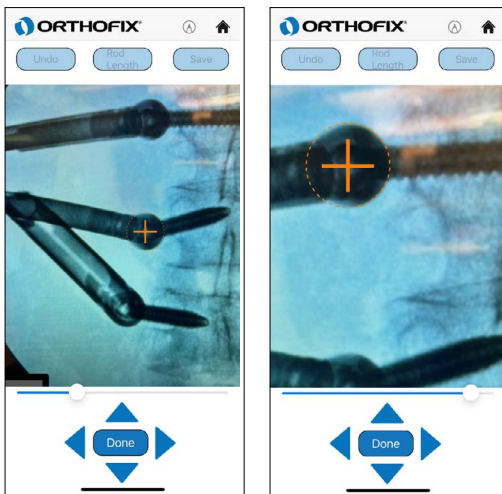
Images for Appendix A (Reference Construct for Calibration):

Calibration on a Lateral View:



- Take a picture of the Fluoro with clear visibility of the tower system and eliminating any unwanted part.
- Find the tower with the sharp edges for calibration.
- Zoom the image to the maximum allowable limit.
- Use the slider to enlarge the calibration marker.
- Adjust the image zoom and the slider so the calibration marker aligns over the outer base of the implant.

Calibration with AP View:



- Take a picture of the Fluoro with clear visibility of the tower system and eliminating any unwanted part.
- Find the tower with the sharp edges for calibration.
- Zoom the image to the maximum allowable limit.
- Use the slider to enlarge the calibration marker.
- Adjust the image zoom and the slider so the calibration marker aligns over the edges for the implant.

