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ORTHOFIX iPhone X OFIX MIS App Workflow

# ORTHOFIX iPhone X OFIX MIS App Workflow User Guide

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**ORTHOFIX**

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## Specifications

- **Compatible Devices:** iPhone X and newer with camera and screen resolution higher than 2532×1170 pixels, screen size larger than 14 x 9.1 cm, and iOS version 15.0 and above.
- **Tested iOS versions:** 15.6.1, 16.1, 16.2

## Product Usage Instructions

OFIX MIS App is available only for iPhones. Ensure your device meets the following requirements:

- Perform a trial run with examples from the Appendix on first use to verify expected results.
- Capture images with the phone as close as possible for optimal image size and quality.
- Zoom the image to maximum size during calibration for precise capture of the calibration circle over implant edges.
- Pay attention to measured rod length versus suggested rod size; confirm rod selection before insertion.
- Use the Lateral view if screws are not at the same level compared to the AP view.
- Differentiate left and right implant heads by adjusting Phoenix towers before taking lateral X-rays.
- Archive saved reports periodically to free phone memory storage.
- Refer to example images in the Appendix for known results; use these images on a fresh install for verification.
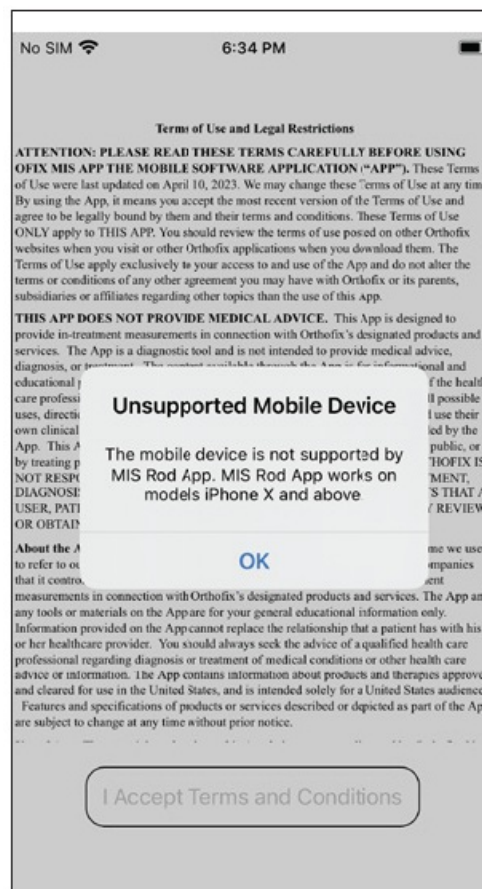
## FAQ

- **Q:** What should I do if the app shows an alert for incompatible devices?
- **A:** If your device is incompatible, ensure it meets the specified requirements or consider using a compatible device.
- **Q:** How can I differentiate between left and right implant heads in a lateral X-ray?
- **A:** Adjust Phoenix towers on one side towards the head and on the other side towards the feet of the patient to distinguish left and right implants.

## INSTALL

**Compatible Devices**
OFIX MIS App is available only for iPhones. The models supported are iPhone X and newer with camera and screen resolution higher than 2532×1170 pixels and screen size larger than 14 x 9.1 cm, and iOS version 15.0 and above. The App was tested with iOS versions 15.6.1, 16.1, and 16.2. In case of incompatible devices, the App will show an alert right after accepting the Terms and Conditions.



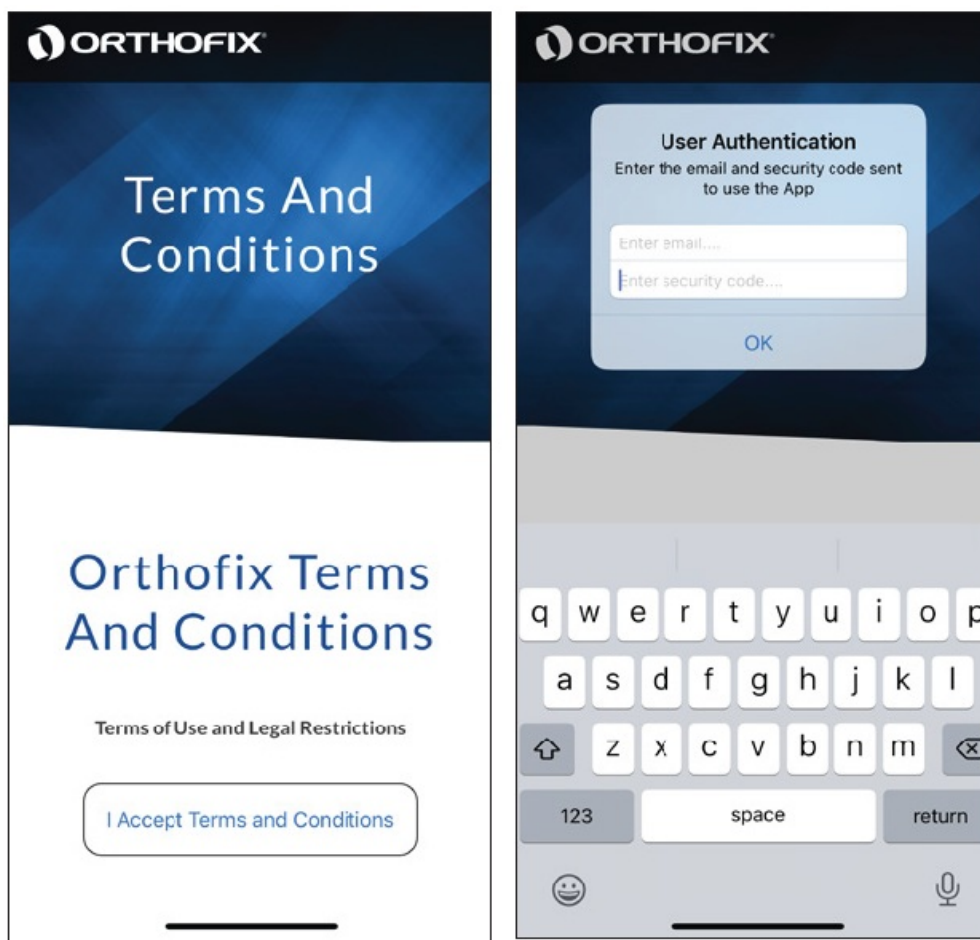**Instructions on How to Download the App**

1. Open the URL to download the app from your email.
2. Tap Download to download the app.
3. Go to the 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 your email address and the passcode provided in an email sent to you confirming your download.

**Terms and Conditions**
The user must accept the Terms and Conditions before proceeding.
**Security Code**
For first-time use only, the user must enter his or her specific email and assigned passcode before proceeding.



## BEST PRACTICES

1. On first use with a mobile phone, it is suggested to perform a trial run using the example(s) in the Appendix to confirm the results are as expected.

2. When capturing the image, place the phone as close as is practical to maximize the size of the image. Ensure best practices were followed and the image is of good quality before moving to start calibration.

3. When calibrating, it is best to zoom the image to its maximum allowable size to allow a more precise capture of the calibration circle over the edges of the implant.

4. The app rounds up to provide the suggested rod size. It is advisable to pay close attention to the measured rod length versus the suggested rod size. Confirm and verify rod selection before insertion. The suggested rod length is for informational purposes only and is not a substitute for the professional judgment of the health care professional.

5. If the screws are not at the same level, using a Lateral view rather than an AP view is recommended.

6. 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, the appropriate healthcare provider should push the Phoenix towers on one side toward 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.

7. To preserve the phone's memory storage, it is recommended to archive the saved reports from time to time and remove them from the phone's file system.
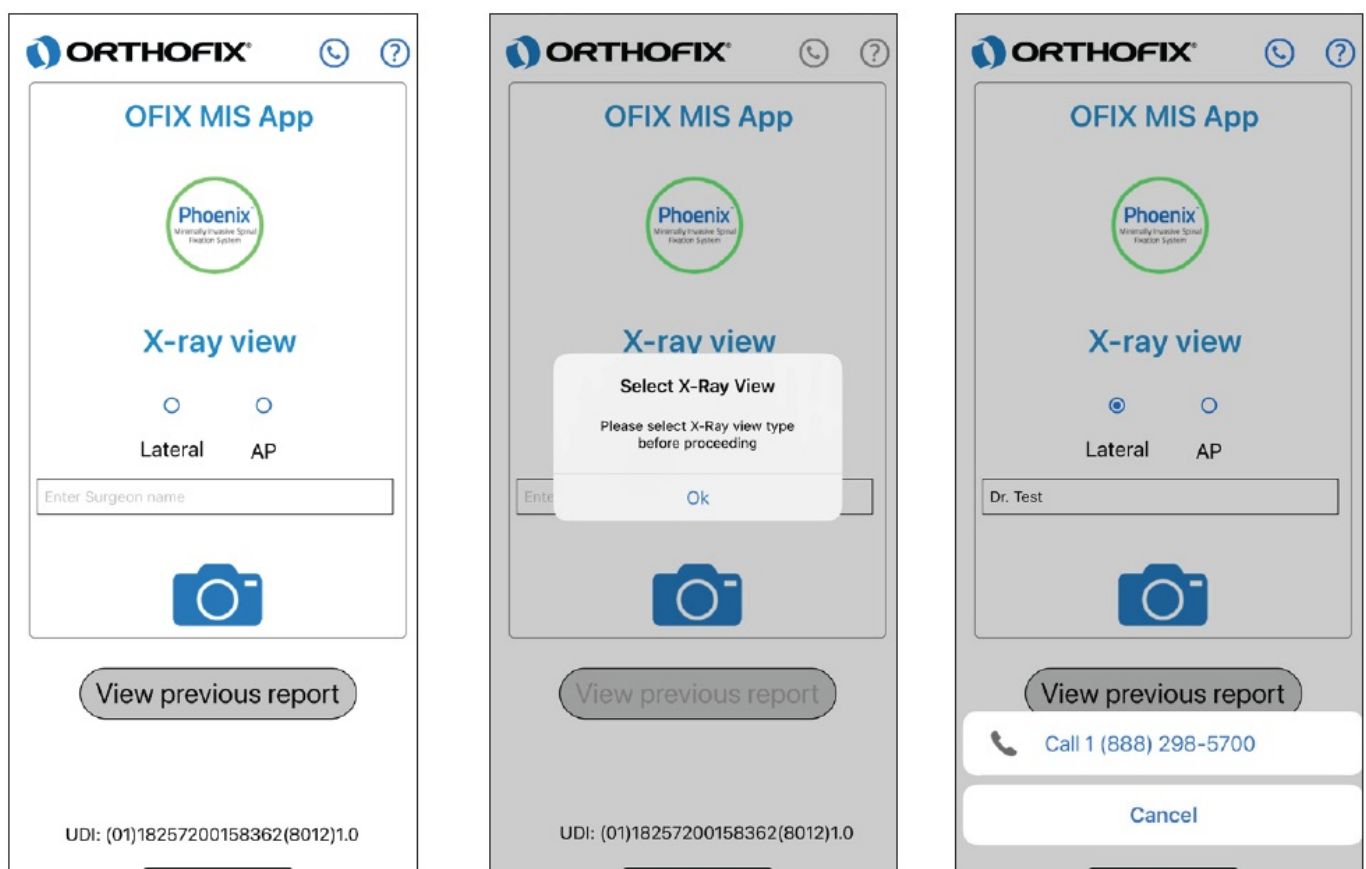
8. Refer to the Appendix, for example, images with known results for both AP and Lateral views. It is suggested to use these images on a fresh install to verify the app is providing the user with the expected results. To initiate a fresh install remove the App from the phone. Then refer back to the URL to download the app from your email.
9. For proper functioning of the app, accept the permissions requested by the app.
10. The OFIXMISAPP is intended to be used in the Operating Room with no custom lighting, screen settings, or other adjustments required. ONLY use the OFIXMISAPP in the non-sterile zone of the Operating Room. Follow all recommended procedures as provided by the Operating facility.

Surgeon should confirm rod size before implantation.
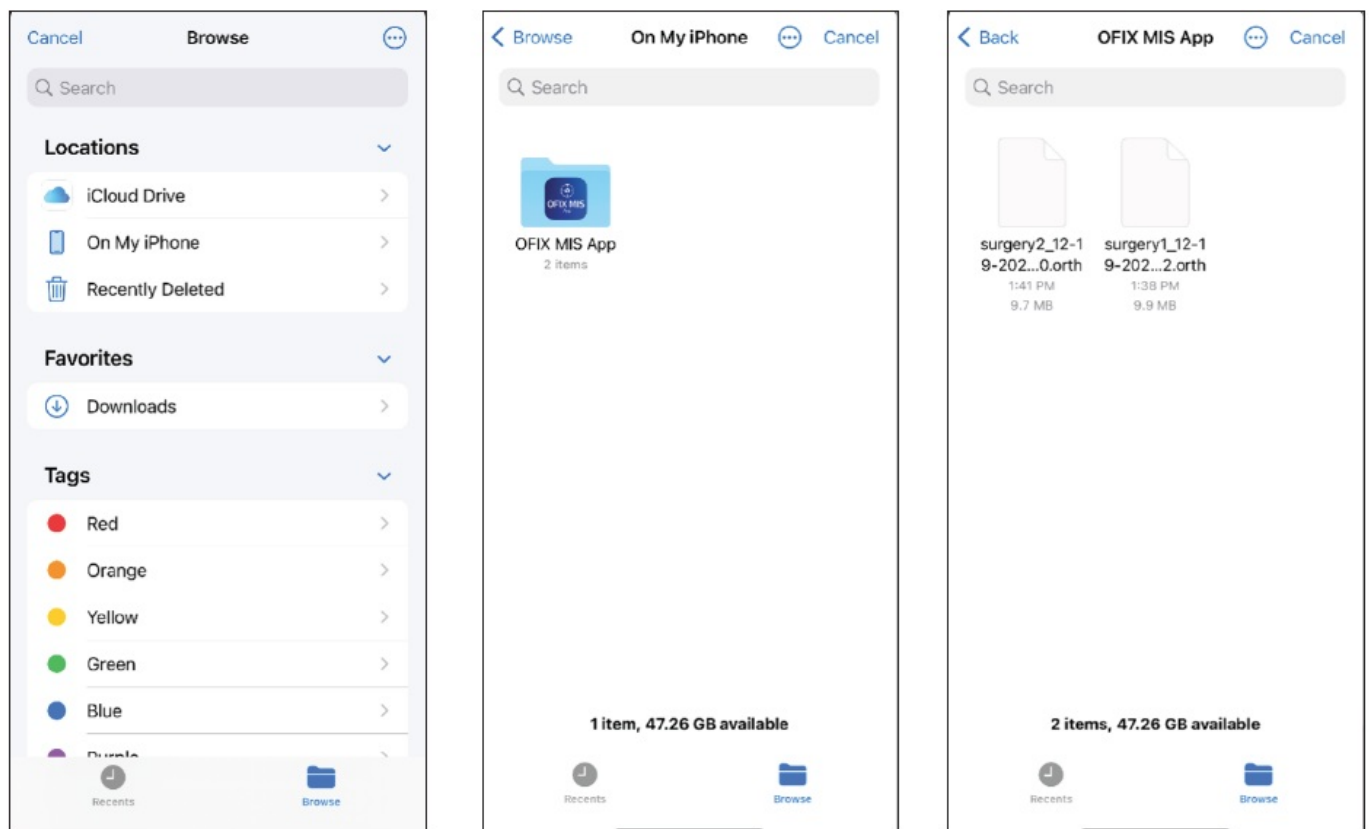
## APP WORKFLOW

### Surgery Information

- The user must select an X-ray view and enter a surgeon's name before the camera icon is enabled.
- If the user taps the camera icon before selecting an X-ray view AND entering a surgeon name, a pop-up will come telling the user to enter a surgeon name or select an X-ray view.
- The phone icon brings up a standard phone pop-up 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.
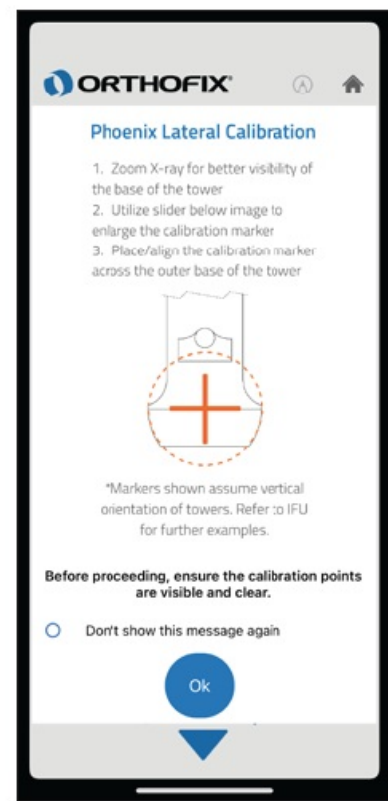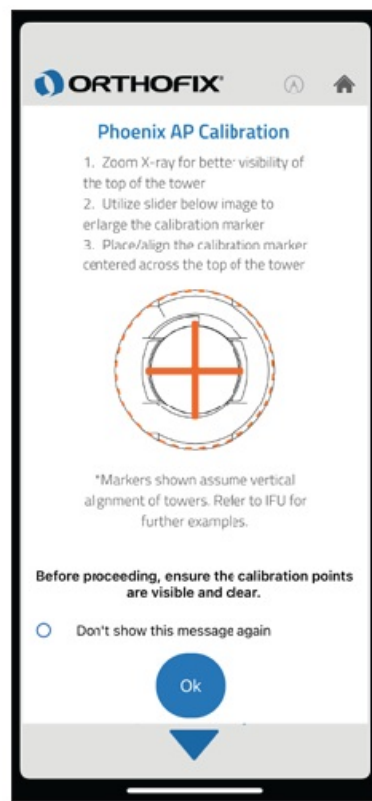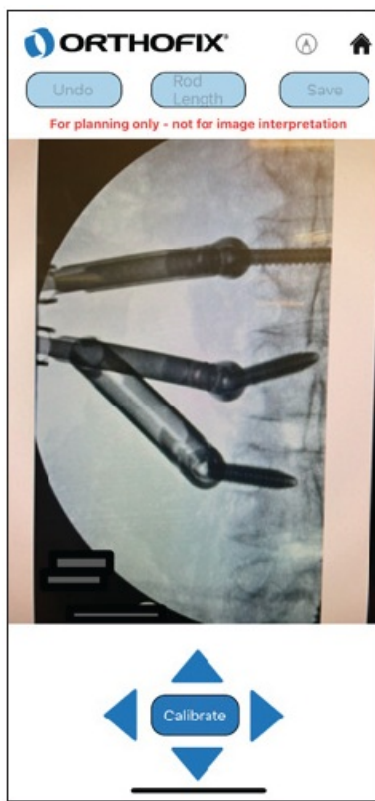
**Image Capture**

- Upon pressing the camera icon the image capture screen will appear.
- For the user's convenience, a reference green bar is on the screen during image capture to aid in image alignment. The user should align the green bar to the top of the image as an initial reference for orientation purposes.
- On first-time use of the app, there will be a pop-up asking the user for permission to use the camera. The permissions can be changed by going to phone Settings and selecting the 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 best practices were followed, the image is of good quality, and the calibration marker points are visible and clear. No custom lighting or display settings are required for the App use, however these may affect the quality of the image.
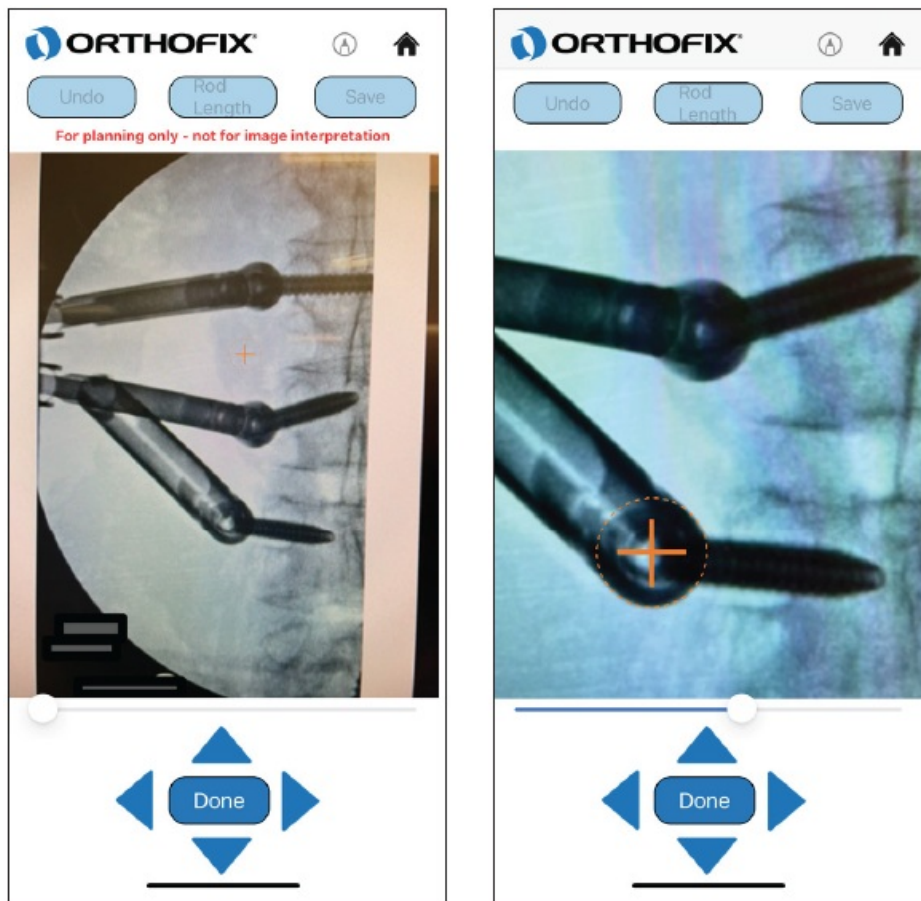
**Start Calibration**

- If the user taps on the Home icon on the top-right corner, the app will discard the current session and return to the Surgery Info screen, and all unsaved work will be lost.
- When the user taps on "Calibrate," an instructional guide is presented showing the proper positioning for the calibration marker for either the Lateral or AP view, depending on which view was selected.

- The user is given the option never to see the calibration position screen again. If the user selects this option, the screens will not come up again unless the user re-installs the app.

**Calibration**

- The user is given a light orange dotted marker for Calibration. Place the marker at the calibration points as defined in the Calibration Instruction pop-up.
- The user can 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.
- The user can resize the calibration marker using the slider.

Before proceeding, ensure best practices were followed in completing the calibration step. Improper calibration will negatively impact the results of the OFIX MIS App.
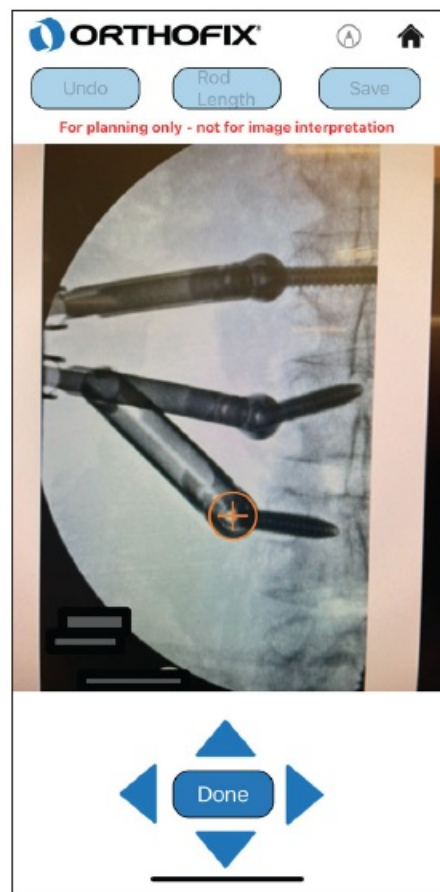
**Start Marker 1**

- 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.
- If the user taps on "Marker 1," an instructional guide is presented to show the proper positioning for Marker 1 and Marker 2 for either the Lateral or AP view, depending on what the user selected on the Surgery Info screen.
- Refer to the 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.
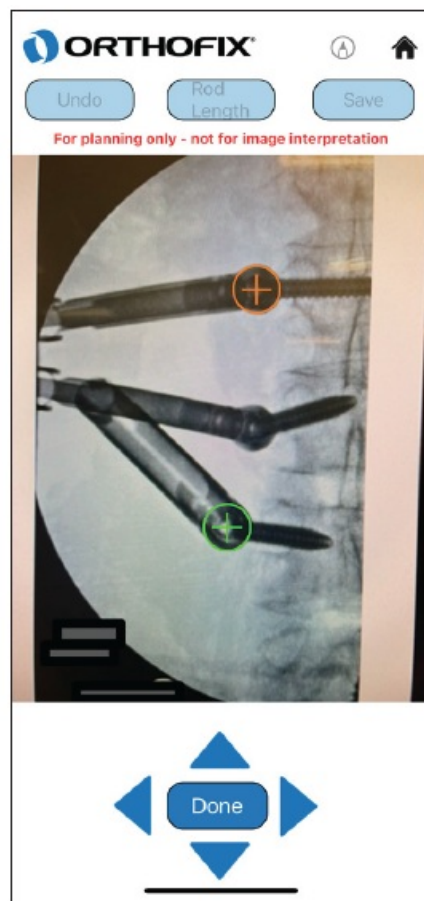
**Marker 1**

- If the user taps on the Home icon, he or she will be taken back to the Surgery Info screen and all work will be lost.
- If 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. Once the user clicks Done, the marker color changes to green showing the final positioning of the marker and the marker cannot be moved.
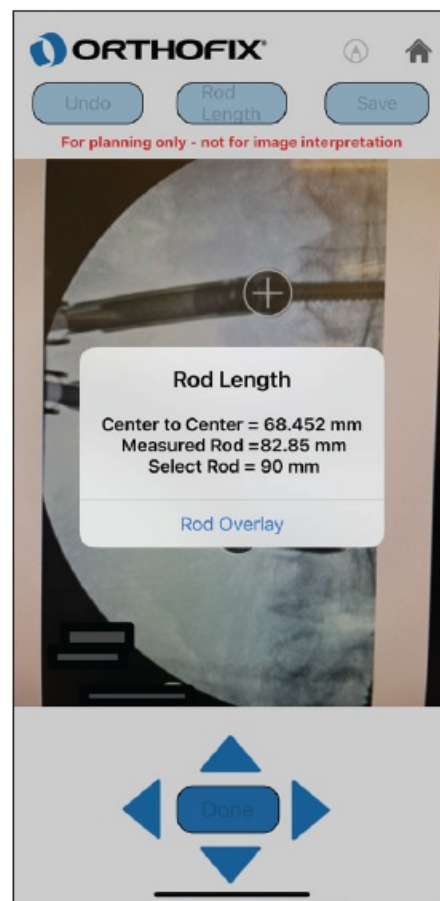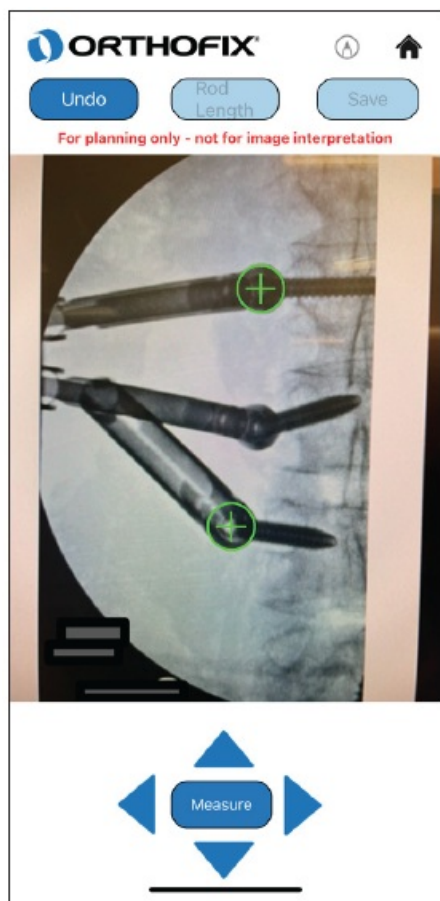
**Marker 2**

- If the user taps on the Home icon, the user will be taken back to the Surgery Info screen and all work will be lost.
- If 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. When the user clicks 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.
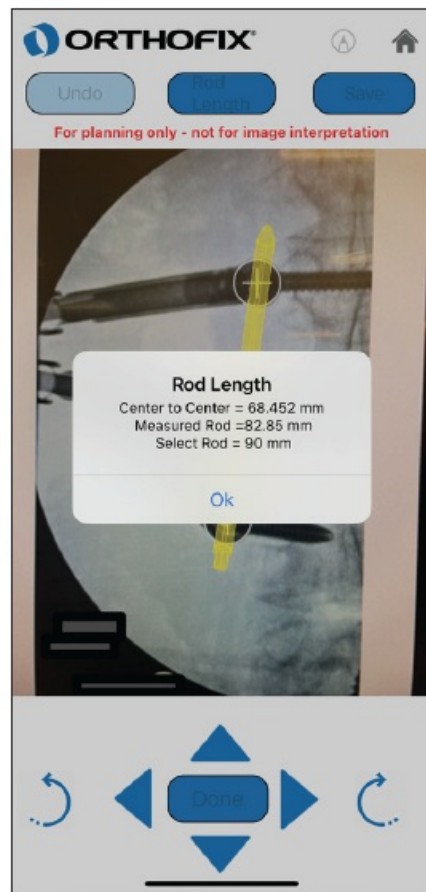
**Measure**

- If the user taps on the Home icon, the user will be taken back to the Surgery Info screen and all work will be lost.
- If 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 pop-up displaying the suggested rod size.
- The user taps on "Rod Overlay" to see the Rod overlay on the image.

- Upon completing the rod length measurement, the app will provide a suggested rod size. It is advisable to pay close attention to the measured rod length versus the suggested rod size. The suggested rod size is for informational purposes only and is not a substitute for the professional judgment of the health care professional.
- If deemed necessary return to the Image Capture stage and repeat the steps to confirm the Rod Length results. The OFIX MIS App achieves accurate results as defined by the Phoenix system rod sizes (within ±7%) when placed within 20cm and at ±15° from the display.

**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 can use one finger to drag the overlay around the screen.
- The user can use two fingers to rotate the overlay on the screen. The user can double-tap the rod image to flip the orientation.
- If fine motions are needed, the user can tap the four pointers around the Done button to move the overlay or can use the left and right buttons to rotate the overlay counterclockwise and clockwise.
- The Rod Length button will raise a pop-up displaying the Rod Measurement estimates.
- The Save button will raise the Save Rod Calculations pop-up.
- Once the user clicks Done, the suggested rod cannot be moved for more adjustments.
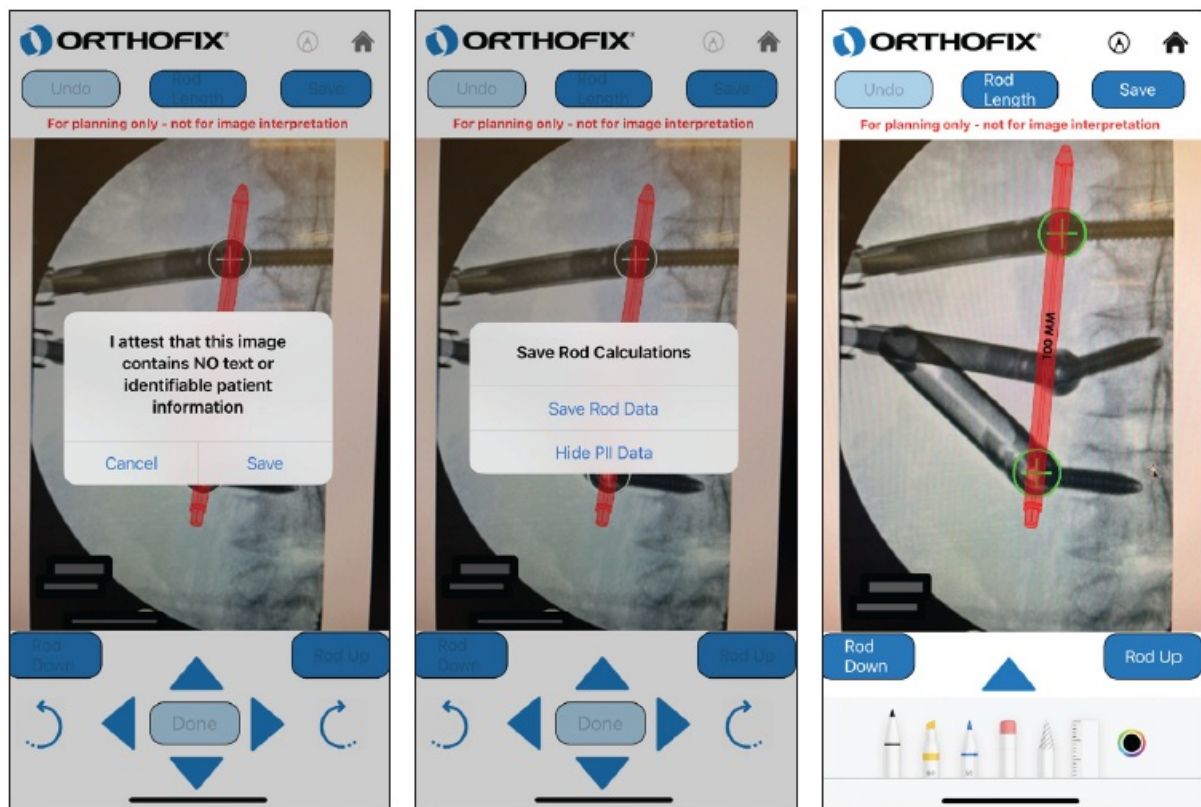
**Rod Size**

- If the user taps on the Home icon, the user will be taken back to the Surgery Info screen and all work will be lost.
- The user may tap on Rod Up or Rod Down to display rods of various sizes. New rods of various sizes will be red.
- The user can use one finger to drag the overlay around the screen.
- The user can use 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 buttons to rotate the overlay left and right.
- The Rod Length button will raise a pop-up displaying the Rod Measurement estimates.
- The Save button will save the screen to an encrypted file.

**Save Rod Calculations**

- When the user taps the Save button, the Save Rod Calculations pop-up appears.
- When the user selects "Save Rod Data," a second dialog will appear asking the user to attest that all patient identifying information and other personally identifiable information (collectively, PII) is not visible on the screen. If the user cancels from the attest pop-up, the user will be returned to the original screen. If the user taps "Save" on the pop-up, the screen will be saved and the user will be returned to the original screen.
- If the user taps on "Hide PII Data," the 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. The user can tap the pen icon on the top-left corner to close.
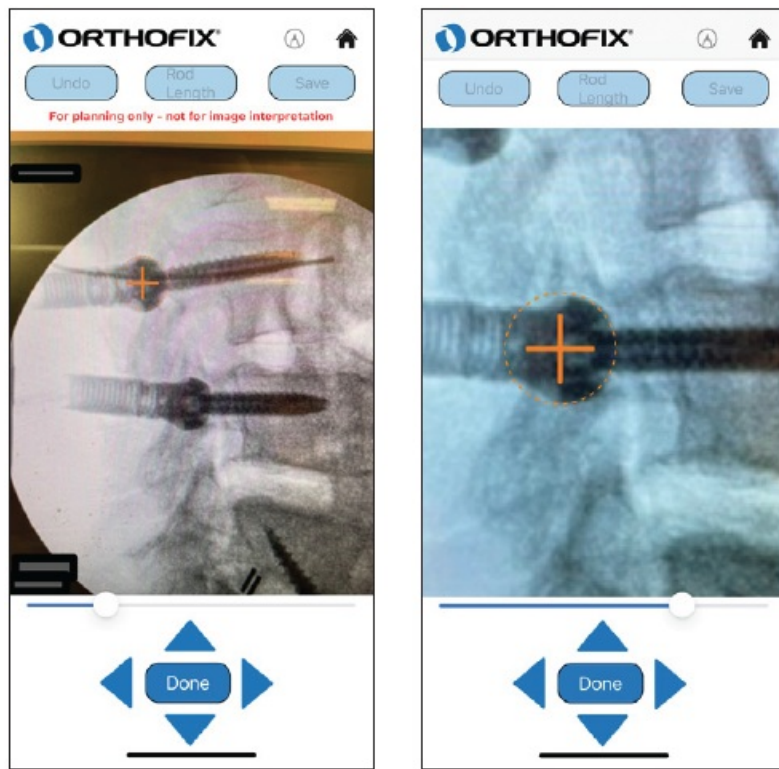
## Appendix

- Images for Appendix A (Reference Construct for Calibration):
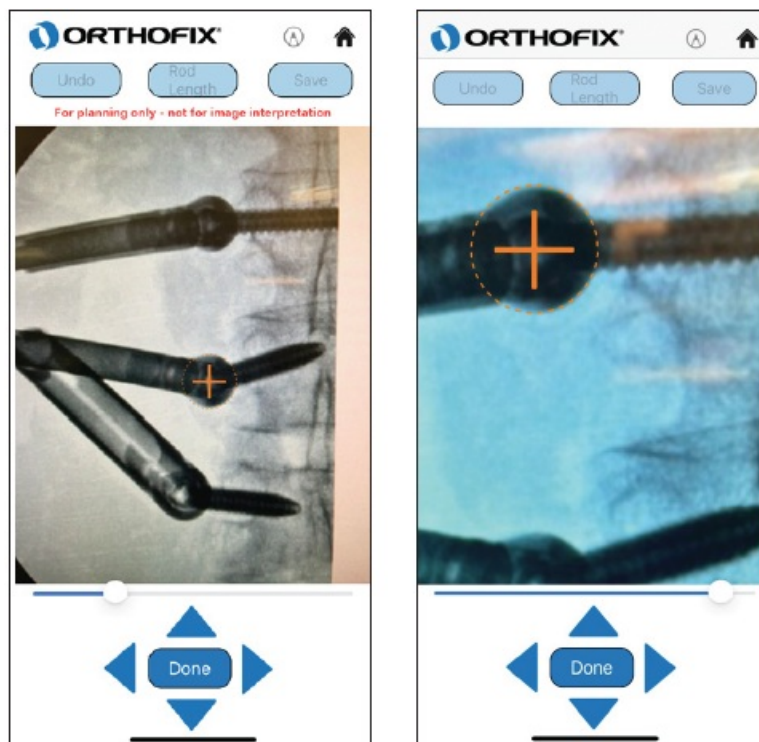
**Calibration on a Lateral View**

- Take a picture of the Fluoro with clear visibility of the tower system and eliminate any unwanted parts.
- Find the tower with the best-defined 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 with the outer base of the implant.
- The expected rod size for a provided image is 50mm.

**Calibration with AP View:**

- Take a picture of the Fluoro with clear visibility of the tower system and eliminate any unwanted parts.
- Find the tower with the best-defined 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 of the implant.
- The expected rod size is 90mm.



**Description**

The OFIX MIS App is a device mobile software application that supplements the use of callipers when selecting rods used in the immobilization and stabilization of pedicle screw-type spinal systems. The OFIX MIS App will rely on capturing 2D images used in spinal implant procedures through the use of a mobile device camera. The OFIX MIS App measures the difference between known Orthofix pedicle screw diameters and provides feedback useful in determining the appropriate rod length to use with the corresponding Orthofix product number.

**Indications for Use**

The OFIX MIS App software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The app allows service providers to plan surgical procedures by making measurements for the placement of surgical implants.

Clinical judgement and experience are required to properly use the software.

**Contraindications**

The OFIX MIS App has no contraindications

**Warnings and Precautions**

OFIX MIS App is currently only compatible with Orthofix's Phoenix System.

Images captured and reports saved are for planning only, not for image interpretation.

**Precautions**

Clinical judgment and experience are required to properly use the OFIX MIS App.

You are responsible for ensuring that all patient identifying information and any other personally identifiable information (collectively, PII) is removed before saving the final result.

Any healthcare professional or other user of this mobile device application who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix US LLC, 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-**214-937-3199** or 1-**888-298-5700** or by e-mail at **complaints@orthofix.com**.

**Caution**

Federal law (USA) restricts these devices to sale by or on the order of a physician.

**Glossary**

- **Rx Only** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- ⚠ See Instructions for Use

- 📖 **Orthofix.com/IFU**

- 🏭 Manufacturer

**CONTACT**

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## Documents / Resources

**ORTHOFIX iPhone X OFIX MIS App Workflow** [pdf] User Guide
iPhone X OFIX MIS App Workflow, iPhone X OFIX, MIS App Workflow, App Workflow, Workflow

## References

- **Orthofix - Medical Devices & Solutions**
- **Instructions for Use - Orthofix**
- **Orthofix - Medical Devices & Solutions**
- **User Manual**