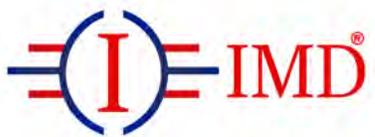


Surgical Technique



| Wrist External Fixation System



YDFIX[®] Wrist External Fixation System

IMD offers the YDFIX Wrist External Fixation System for treatment of complex distal radius fractures. The YDFIX External Fixator is designed to hold pins in place for fracture reduction or distraction to align the wrist and to provide ligamentotaxis to the wrist on a temporary basis while the distal radius heals.

Indications of Use

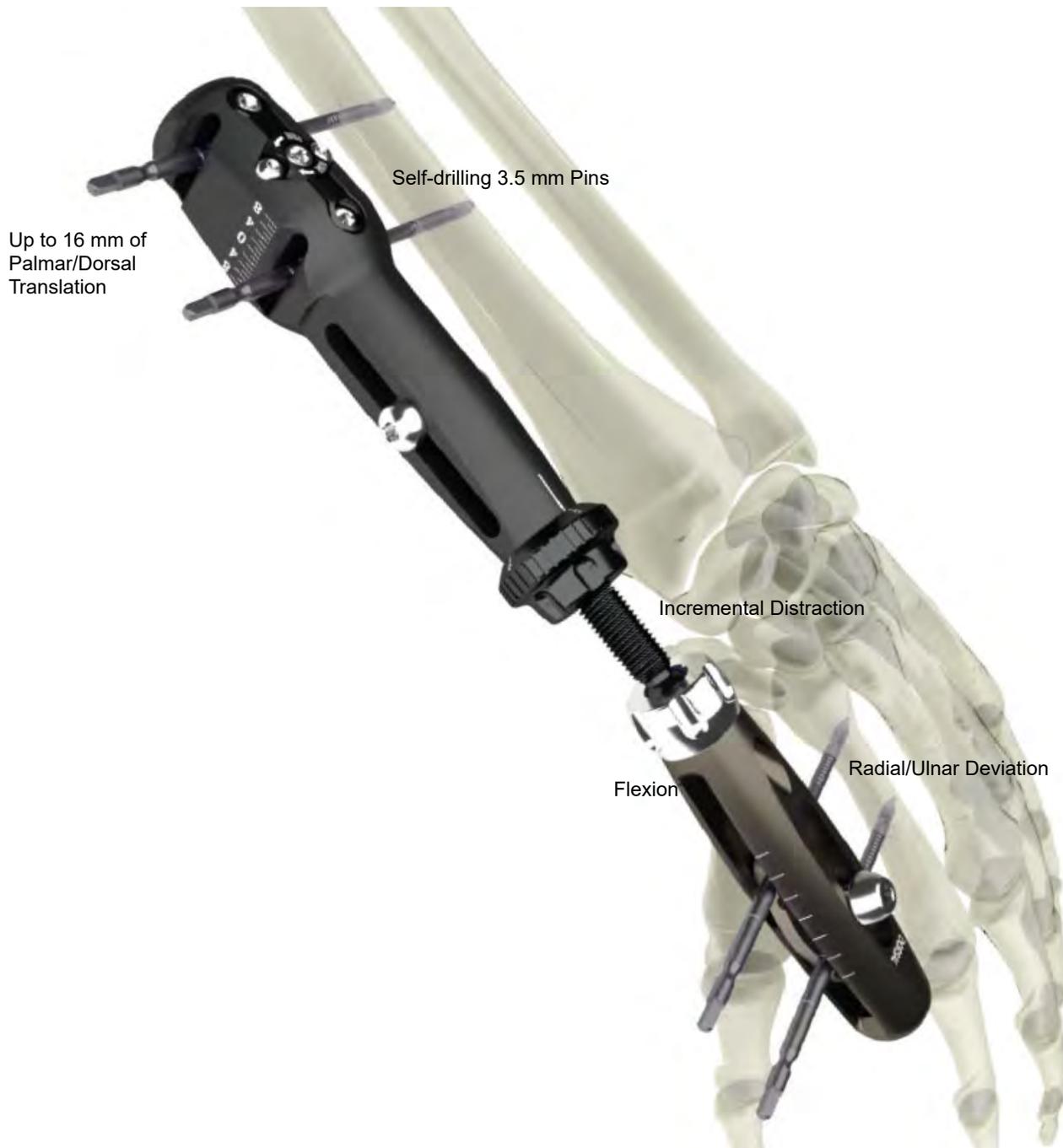
The YDFIX External Fixation System is indicated for fixation of Colles' fractures and osteotomies of the distal radius. It is not intended for use in the spine. The YDFIX External Fixator is a radiolucent device designed to aid in repairing unstable distal radius fractures. The YDFIX External Fixator allows for two proximal and two distal pins to be inserted through the fixator body and into the metacarpal and radius bones. The construct is designed for the surgeon to gain initial reduction with the fixator in place and then independently adjust only those planes needing correction. This system is packaged sterile with all instruments and pins needed to complete a case.

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System Features

- Versatility allows the surgeon to gain initial reduction with the fixator in place and then independently adjust only those planes needing correction. Adjustments may be made independently for distraction, radial/ulnar deviation, flexion/extension and dorsal/palmar translation.
- Self-drilling 3.5 mm pins are designed as self drilling and come standard in the YDFIX kit.
- Radiolucent body aids in surgeon visualization during fracture reduction and distraction. The YDFIX External Fixator is designed to be lightweight.

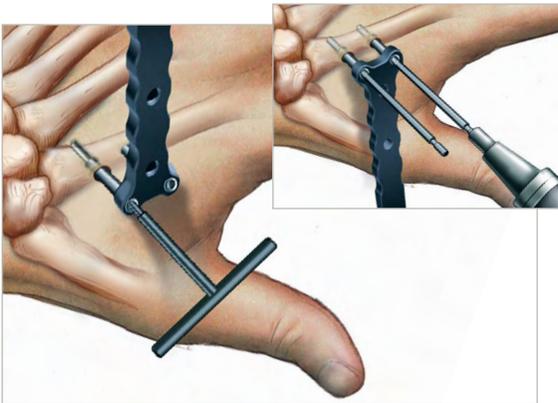




1 PRE-SURGICAL PLANNING

To determine the proper position of the YDFIX External Fixator in relation to the radius, center of the wrist and second metacarpal, you must first loosen the ball joint set screw (1) and ball shaft locking screw (2) on the YDFIX External Fixator with the provided T-handle Hex Driver. Align the YDFIX External Fixator Assembly with the extended extremity, lining up the approximate center of wrist rotation with the ball joint. Locate and mark the position of the proximal and distal pins. The YDFIX Fixator should not be fully distracted or fully compressed when determining pin positions.

Placing the YDFIX Fixator in the transverse plane or rotated dorsally up to 20 degrees will increase the accuracy of subsequent adjustments.

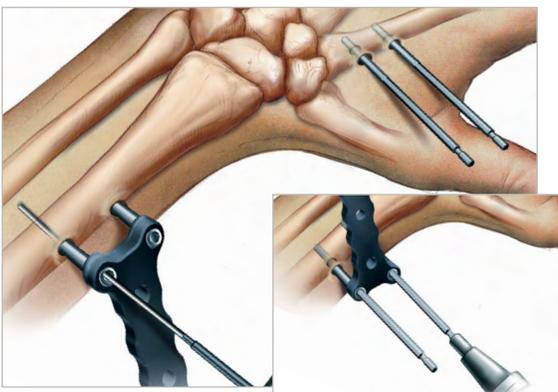


2 INSERT DISTAL FIXATOR PINS

The appropriate incision and dissection steps are carried out. Centering the longer cannula of 25 mm Drill Guide on the bone, the first Fixator Pin is inserted with the T-handle YDFIX Pin Driver through the base of the second metacarpal and can be extended into the first cortex of the third metacarpal, if desired. Although the Fixator Pins have a self-drilling feature, a 3.2 mm Pilot Drill is provided if predrilling is needed due to dense bone.

Rotate the 25 mm Fixator Drill Guide 180 degrees so the short cannula is placed over the previously inserted Fixator Pin. Making sure the longer cannula is centered on the bone, predrill and insert the second Fixator Pin. Advance the Fixator Pins until two to three threads have extended through the far cortex.

Note: The 25 mm Fixator Drill Guide assures the Fixator Pins are placed parallel.



3 INSERT PROXIMAL FIXATOR PINS

After incision and careful dissection to the distal radius has been completed, the convex center of the radius is identified. Using the long cannula on the 25 mm Fixator Drill Guide, drill bicortically through the radius and insert the first Fixator Pin. The Fixator Pins may also be used as self-drilling as described earlier. Remove the 25 mm Fixator Drill Guide and rotate 180 degrees placing the shorter cannula over the previously inserted Fixator Pin. Insert the second Fixator Pin in the same manner as the first radius Fixator Pin.

Note: Use care when drilling through the radius to avoid over drilling.

4 APPLY YDFIX FIXATOR

Making sure the distal clamp is loose (1) and the main body set screws are loose (2), slide the YDFIX Fixator Assembly onto the Fixator Pins. Align the YDFIX Fixator on the wrist so the ball joint (3) is positioned over the center of wrist rotation. This will aid in the accuracy of subsequent adjustments.

Lightly tighten the distal pin clamp, the ball shaft locking screw, the ball joint set screw and the main body set screws, provisionally locking the YDFIX Fixator into position.



5 DISTRACTION/LIGAMENTOTAXIS

To apply distraction to the wrist, turn the distraction nut towards the housing to apply the required amount of distraction. One complete revolution of the distraction nut equals 1 mm of distraction (1). Lock the ball shaft locking screw (2).

Note: The distraction nut is marked with "A,B,C,D" as a reference to indicate where distraction began.



6 DORSAL/PALMAR TRANSLATION

Place the YDFIX Hex Driver into the jack screw (1) on the dorsal side of the main body of the fixator. Turn the YDFIX Hex Driver clockwise for palmar translation and counterclockwise for dorsal translation.

The surgeon is able to determine the amount of translation by the scale on the side of the YDFIX Fixator. There are 8 mm of translation available in either direction.



7 RADIAL/ULNAR DEVIATION

Gain proper anatomic alignment of the fracture on the radial/ulnar plane by loosening the distal pin clamp (1). This allows free movement in both the medial/lateral (M/L) and radial/ulnar direction.

Note: Traction may be lost when the distal pin clamp locking screw is loosened.





8 FLEXION/EXTENSION

To achieve the desired angle of wrist flexion: Loosen the ball joint (1), adjust to the flexion desired, then lock the ball joint.

9 POST-OPERATIVE PROTOCOL

After completion of all adjustments, the YDFIX External Fixator is locked into its final position.

Wounds are dressed based on surgeon preference and dry sterile gauze is recommended to be wrapped around the Fixator Pins to prevent pistoning of Fixator Pins and soft tissue.

Note: The Hex Driver may be used for in-office adjustments, and the Pin Driver may be used for pin removal at the appropriate time. Please save these parts from your sterile procedure pack and utilize the appropriate Instructions for Use for sterilization parameters.

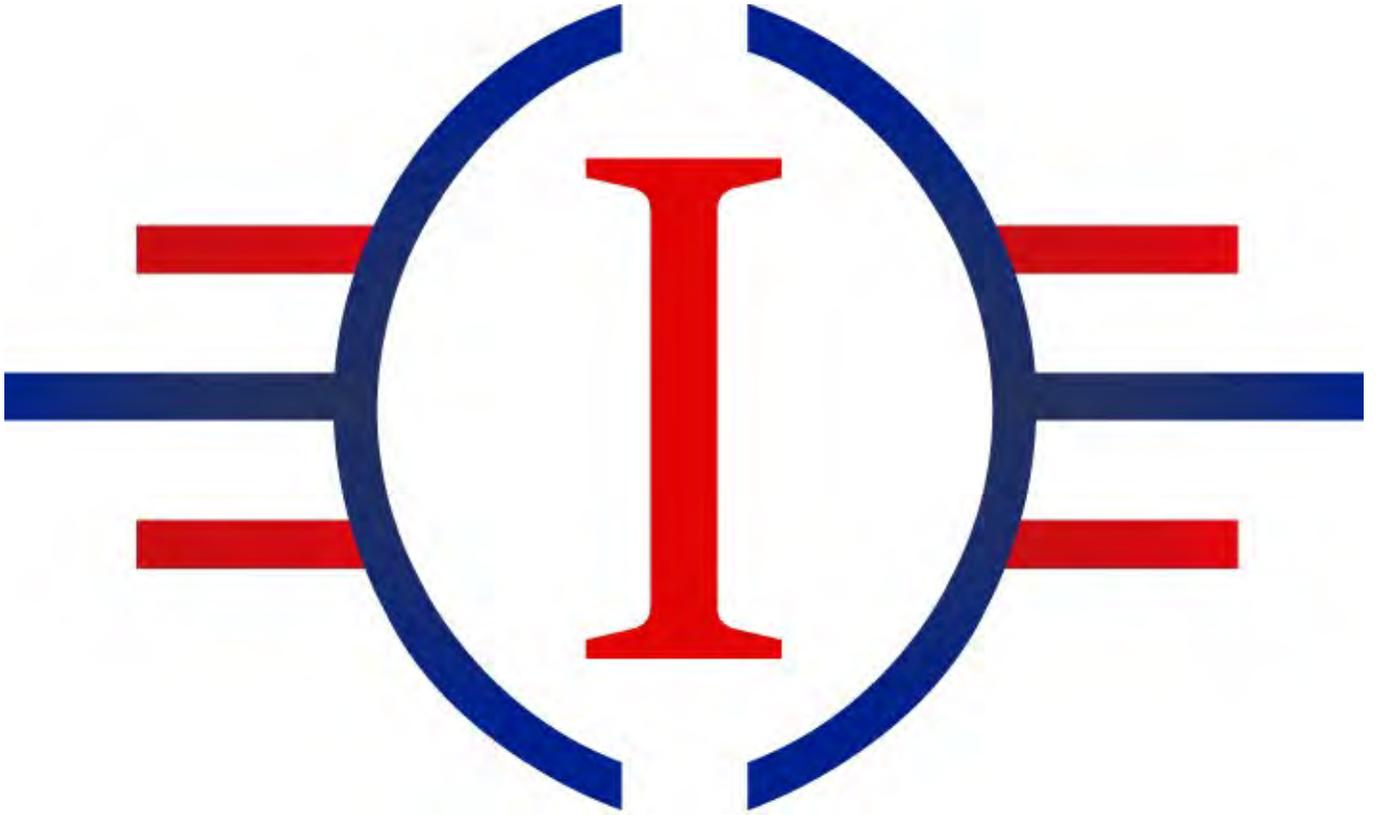
Ordering Information

YDFIX External Fixation System

YDFIX External Fixator Kit	YDFIX 200
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External Fixator Pins

3.5 mm x 60 Self-Drilling Pin	2001103060 (1 each)
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