Wristore™ Distal Radius Fracture Fixator Surgical Technique

Visualize, stabilize, mobilize
Surgical Technique
For Wristore™ Distal Radius Fracture Fixator
Instruments and surgical technique developed in conjunction with

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Introduction

Fracture of the distal radius (DRF) is one of the most common types of wrist fracture. A DRF may be comminuted, and is accompanied by a fracture of the ulnar styloid process in about 50%-60% of cases.¹ If untreated, or inadequately treated, a DRF may result in shortening of the radius and dorsal inclination of its articular surface. Other potential complications of a DRF include unstable reduction, incongruity of joints, subluxation of the distal radioulnar joint, compression of the median nerve, ulnar nerve injury, entrapment of the flexor tendons, reflex sympathetic dystrophy, carpal malalignment, and nonunion.

The goal in the treatment of a DRF is to restore function while avoiding the potential complications. Understanding the mechanics of the fracture and the treatment options available is important when presented with a DRF. Accurate reduction and adequate immobilization are imperative in obtaining an optimal outcome.

Reduction can often be accomplished with traction and manual manipulation. Treatment generally includes immobilization with a splint or cast for simple fractures, while comminuted or severely displaced fractures may be treated with open reduction and internal fixation. An alternative surgical intervention is to use an external fixator, such as the Wristore Distal Radius Fracture Fixator, which provides a less invasive option for most distal radius fractures with or without comminution.

Distal Radius Fracture Classifications

The classifications of a DRF are based on the location of the fracture (intra-articular vs. extra-articular), and the presence or absence of ulnar fracture.

The \textit{Wristore} Fixator is applicable for use in unstable and comminuted distal radial fractures (A2, A3, B2, C1, C2, and C3) which can be anatomically reduced with closed reduction methods. Refer to the AO Classification of Fractures of Long Bones for more specific information.

The \textit{Wristore} Fixator should not be used where anatomic reduction cannot be achieved in a closed fashion or where volar instability exists.

Design Rationale

The \textit{Wristore} Fixator is indicated for external fixation of the upper extremity. In addition to providing stable fixation across the joint, the system is designed to capture and stabilize distal radial fragments. The design is intended to improve healing by providing better stability of the fracture fragments near the joint. This allows the option to begin early motion of the wrist to avoid “freezing” of the joint, and subsequent loss of range of motion due to soft tissue fibrosis or contracture.
**Wristore Components**

The *Wristore* Fixator is a modular system which facilitates spanning and non-spanning external fixation. The device consists of a Fixator Body and a Dorsal Outrigger with two Universal Wire Arms. The Fixator Body consists of four parts: the Radial Body Segment, a Threaded Bar, a Universal Joint, and the Metacarpal Body Segment.

The Dorsal Outrigger is a triangular extension that attaches to the Radial Body Segment by the Dovetail Slide. It contains slots that accept the Universal Wire Arms. These articulated arms are designed to secure K-wires to the Fixator.
Fixator Design

One of the key design goals was to combine the benefits of a multiplanar device with the ease of application of a unilateral device. More specific design goals included:

- Universal adjustability - The Fixator Body has multiplanar adjustability, allowing the surgeon to manipulate and reduce the fracture. Adjustments can be made to achieve:
  1. Compression/distraction - Slide the threaded bar proximally or distally within the Radial Body Segment or advance the thumb wheel on the Fixator Body. The main adjusting screw should be loosened while compressing/distracting.
  2. Flexion/extension - Adjust the Universal Joint between the Radial and Metacarpal Body Segments.
  3. Radial/ulnar deviation - Adjusted via the Universal Joint.
  4. Pronation/supination - Rotate the distal segment at its articulation with the Universal Joint.

- Secure K-wires to Fixator Body – Dovetail Slide, Dorsal Outrigger and Universal Wire Arms work together to link fragments to the Fixator.

- Conversion from spanning to nonspanning fixation - when applied with both the Radial and Metacarpal Body Segments, the Fixator provides spanning fixation to immobilize the wrist joint. The modularity allows the Fixator to be applied as a spanning device, and then converted to a nonspanning device by removing the Metacarpal Body Segment. This allows for early, rehabilitative motion of the wrist while maintaining stable fixation.

  NOTE: To use in a non-spanning configuration, the Dorsal Outrigger with K-wire fixation is required.

- Fixator Body components are numerically marked as follows:
  1 = Radial Body Segment
  2 = Metacarpal Body Segment

- Screws are color-coded as follows:
  Blue = Pin locking screws
  Black = Wrist position adjustment screws
  Grey = Connection screws
Fixator Materials
The Fixator Body, Dorsal Outrigger, and Universal Wire Arms are made from molded Ultem material, a high strength polymer. This results in a completely radiolucent frame, and allows for an unobstructed radiographic image of the joint, the fracture, and the location of the pins and K-wires. The Ultem material was also chosen for its light weight, providing more comfort for the patient.

Pins and K-wires
The stainless steel pins are self-drilling and self-tapping so pre-drilling and tapping are not required for pin insertion. The system includes:
- Threaded 3.0mm Radial Pins
- Threaded 2.5mm Metacarpal Pins
- 1.6mm stainless steel K-wires
  - The system includes pin caps that will fit either size pins, and K-wire caps for the 1.6mm K-wires.

Instrumentation
The system includes three instruments, specifically designed for use with Wristore components, which are intended for single-patient use.
- Pin Inserter/Remover - This stainless steel T-handled device with a hex tip is used to drive and remove the threaded pins.
- Pin Guide - This guide is used for pin insertion and to protect soft tissue. The head has two sleeves that are spaced to match the spacing of the pin holes on the Fixator Body. One sleeve is fixed, while the other is adjustable so it will fit the specific patient anatomy. This sleeve can be moved up and down, and then locked into the appropriate position.
- Wrench/Driver - This instrument, has a blade tip that is used to tighten the locking screws on the Wristore construct, and an open hex end that is used to tighten and loosen the hex nut that secures the Universal Wire Arm to the Dorsal Outrigger.

Packaging
The Wristore Fixator is packaged in a sterile-pack kit that includes all Fixator components and instruments in one tray. The kit includes:
- Fixator Body
- Pin Inserter/Remover
- Five pin caps
- Pin Guide
- Two 3.0mm Radial Pins
- Two 2.5mm Metacarpal Pins
- Dorsal Outrigger
- Dovetail Slide
- Five K-wire caps
- Four 1.6mm K-wires
- Two Universal Wire Arms
- Wrench/Driver

The surgical technique steps are illustrated on the underside of the lid.
Preoperative Planning

Determine the appropriate K-wire positions, depending on fracture comminution and the location of major fragments. In general, biplanar pin placements which transfix the intact cortex opposite the fracture fragment result in the most stable configuration.2

Surgical Procedure

Patient Positioning

Place the patient in the supine position with the injured extremity on a hand table. If desired, use finger traps. Fracture reduction can be performed using the Fixator. Alternatively, reduction can be accomplished using finger traps, traction devices or manual reduction.

Step One: Pin Placement

Proximal (Radial Shaft)

You will need the following components:

- Power Driver (not provided)
- B) Pin Inserter/Remover
- D) Pin Guide
- E) 3.0mm Self-Drilling/ Self-Tapping Radial Pins

A direct (open) incision is used for inserting the Radial Pins. Identify and mark a skin location on the lateral aspect of the radial shaft approximately 8cm proximal to the radial styloid tip. An appropriate incision should be made centered on this point (Fig. 1). The distal end of the Radial Body Segment should line up with the fracture site.

The superficial radial nerve will be encountered with this approach. Identify and protect the nerve before dividing the deep tissue to expose the bone.

NOTE: When making the incision, take into account the width of the Pin Guide.
NOTE: Care should be taken to ensure pin placement in the Mid-Lateral plane. Dorsal or volar angulation will cause the Dorsal Outrigger to be positioned in a non-anatomical orientation.

Place the Pin Guide against the surface of the radius in the mid-lateral plane and centered within the incision. The V-surface of the Pin Guide will aid in the stabilization of the guide upon the surface of the bone. Insert the first 3.0mm Self-Drilling/Self-Tapping Radial Pin thru the Pin Guide until the tip penetrates the opposite cortex (Fig. 2).

NOTE: The pins may be inserted initially under power. Final adjustment of the pin depth should be performed manually with the Pin Inserter/Remover provided in the Wristore Sterile Kit.

Slide the fixed sleeve of the Pin Guide over the first radial pin until it contacts the bone. Then position the adjustable sleeve so it contacts the exposed radial shaft.

NOTE: The Pin Guide should be in a stable position with both sleeves firmly against the bone surface. Use of the Pin Guide will help ensure that the second Radial Pin position is parallel to the first with the appropriate span for application of the Wristore Fixator.
Insert the second 3.0mm Self-Drilling/Self-Tapping Radial Pin in the same manner as the first pin (Fig. 3). Confirm final pin depth using fluoroscopy and remove the Pin Guide.

Prior to inserting the Metacarpal Pins, confirm the correct orientation of the Radial Pins in the Mid-Lateral Plane by trialing the Fixator Body with the Dorsal Outrigger assembly.

Positioning of the Fixator with the Outrigger assembled onto the Radial Pins should result in an Outrigger position which coapts with the distal radial anatomy with approximately 1 cm of clearance above the skin (Fig. 4).
Distal (Metacarpal)

You will need the following components:
   A) Power Driver (not provided)
   B) Pin Inserter/Remover
   D) Pin Guide
   F) 2.5mm Self-Drilling/Self-Tapping Metacarpal Pins

A direct (open) or percutaneous insertion can be utilized for the Metacarpal Pins depending upon the surgeon’s preference. For direct insertion, make a mark on the skin at the second metacarpal, approximately 5mm distal to the metacarpal/carpal joint. Then, beginning at the mark, make an appropriate incision and dissect soft tissues to bone (Fig. 5). Place the Pin Guide against the surface of the second Metacarpal.

Fig. 5

Incision For Pin Placement

Superficial Radial Nerve
The V-surface of the Pin Guide will aid in the stabilization of the guide upon the surface of the bone. Insert the first 2.5mm Self-Drilling/Self-Tapping Metacarpal Pin thru the Pin Guide until the tip penetrates the opposite cortex and enters the third metacarpal (Fig. 6). The pins may be inserted initially under power. Final adjustment of the pin depth should be performed manually with the Pin Inserter/Remover provided in the Wristore Sterile Kit.

Slide the fixed sleeve of the Pin Guide over the first metacarpal pin until it contacts the bone. Then position the adjustable sleeve so it contacts the exposed metacarpal shaft next to the first pin.

NOTE: The Pin Guide should be in a stable position with both sleeves firmly against the bone surface. Use of the Pin Guide will help ensure that the second Metacarpal Pin position is parallel to the first with the appropriate span for application of the Wristore Fixator.

Insert the second 2.5mm Self-Drilling/Self-Tapping Metacarpal Pin in the same manner as the first pin, stopping when the pin penetrates the opposite cortex (Fig. 7). Confirm final pin depth using fluoroscopy and remove the Pin Guide.
Step Two: Fixator Application
You will need the following components:
   A) Fixator Body
   L) Wrench/Driver

Once the Radial and Metacarpal Pins are placed, the Fixator can be applied.

Loosen (but do not remove) all the screws on the Fixator assembly.

**NOTE:** The Radial and Metacarpal Segments can be separated before installation by removing the black Universal Connector Screw. After installation, the screw is replaced to reattach the segments.

Place the Fixator Body on the Radial Pins using the dorsal holes.

Leaving approximately 1.5cm of clearance between the fixator and the skin, tighten the blue locking screws to secure the Fixator Body to the Radial Pins.

**NOTE:** If the fixator is too close to the skin, it may not be possible to capture a radial styloid K-wire.
Place the Metacarpal Segment onto the Metacarpal Pins, again leaving approximately 1.5cm of clearance between the Fixator and the skin. Tighten the blue locking screws to secure the Metacarpal Segment to the Metacarpal Pins (Fig. 8).

**NOTE:** Ultem screws and fixator components have different strength characteristics than metallic components. Care should be taken to secure, but not overtighten screws.
Fracture Reduction
Reduce fracture manually or by using the Fixator as a traction device. While holding the hand in the desired position, tighten the rotational locking screw, and the Universal Joint locking screws to maintain the position. In this manner, the Fixator may be utilized to hold the wrist in the desired orientation, thus maintaining anatomic reduction for placement of percutaneous K-wires.

To achieve minor adjustments, the Fixator allows selective positioning of:
(see figures 9 and 10)
- Compression/Distraction (CD)
- Radial/Ulnar Deviation (RU)
- Pronation/Supination (PS)
- Flexion/Extension (FE)

Confirm the fracture reduction with fluoroscopy.

NOTE: K-wires can be inserted to assist in fracture reduction.
Step Three: K-Wire Fixation
You will need the following components:
  - Power driver (not provided)
  - 1.6mm K-wires (4 ea.)

According to preoperative planning, place the first 1.6mm K-wire in the tip of the radial styloid (Fig. 11a), passing obliquely to the proximal radial cortex.

Insert the K-wire percutaneously, then attach a wire driver to achieve bicortical placement.
Place another K-wire, dorsal to volar, in the void between the second/third and fourth dorsal extensor compartments (Fig. 11).

**NOTE:** Intra-articular fractures may require variations in pin configurations to achieve fracture stability. Biplanar and bicortical pin fixation is optimal. If transfixion pins are not feasible, intra-fragment pins may be incorporated into the Fixator with the Dorsal Outrigger Assembly to achieve stability.

Check finger and thumb motion to ensure that all extensor tendons have motion and have not been captured by a K-wire. Replace any K-wires that prohibit tendon motion.

Confirm K-wire placement using fluoroscopy.
Step Four: Outrigger Application
You will need the following components:
G) Dorsal Outrigger
H) Dovetail Slide
L) Wrench/Driver

Attach the Dovetail Slide to the Fixator Body. (Fig. 12).

NOTE: The arrow on the Dovetail Slide should be oriented towards the Radial Pins for correct assembly (Fig. 13).

Attach Dorsal Outrigger to Dovetail Slide (Fig. 14).
Adjust the position of the Dorsal Outrigger within the Dovetail Slide (for dorsal/volar position), or by moving the Dovetail Slide (proximal/distal position). The Outrigger should be positioned within 1cm of the radiocarpal joint with 1 to 1.5cm of dorsal clearance (Fig. 15).

Do not tighten screws in the Dovetail Slide at this point.
Step Five: K-Wire Incorporation
You will need the following components:

K) Wire arm assemblies (2 ea.)
L) Wrench/Driver

The Universal Wire Arms connect the K-wires to the Outrigger.

To facilitate K-wire incorporation, disassemble the stem from the tower, and loosen all locking screws on the Universal Wire Arm (Fig. 16). Slide the wire holder over the K-wire(s) and align the stem over the Outrigger. Slide the attachment base into the appropriate slot on the Outrigger, and reintroduce the stem into the tower without placing tension on the K-wire(s) (Fig. 17).
After assembly, use the blade tip end of the Wrench/Driver to tighten the locking screws that secure the wire holder to the K-wires (Fig. 18).

**NOTE:** Be sure that the wire holder does not touch the skin before it is secured to the K-wire(s). If the wire holder cannot be positioned off the skin, bend the K-wire(s) to move the device away from the skin. A 20°-40° bend is usually adequate.

Tighten all the locking screws of the Universal Wire Arm. Then use the open hex end of the Wrench/Driver to tighten the hex nut on the attachment base, securing the Universal Wire Arm to the Outrigger (Fig. 19).

Repeat the above procedure using the other Universal Wire Arm for the dorsal K-wire(s). Tighten screws, securing Dovetail Slide to the Fixator and Outrigger at this point.

Additional K-wires can be placed using the vacant hole(s) in the Universal Wire Arms to guide them during insertion.

**Step Six: Final Adjustments**

When fixation is complete, relax the traction and return the hand to a more neutral position. Ensure that the Interphalangeal and Metacarpal Phalangeal joints can achieve 90° of passive flexion. Then use fluoroscopy to confirm fracture reduction and pin/wire placement.

Confirm all screws, including thumb wheel and main adjusting screw, are locked tight. Insert pin caps over the Radial and Metacarpal Pins. If desired, cut the K-wires off and insert wire caps.
Postoperative Protocol

For comminuted, unstable fractures, maintain fixation without distraction, using the metacarpal segment and Universal Wire Arms, for approximately 3-4 weeks. Encourage finger and thumb movement.

As healing progresses, the Metacarpal Segment of the Fixator Body and the Metacarpal Pins may be removed to mobilize the wrist (Fig. 20 & 21). To remove the Metacarpal Segment:

- Loosen the blue pin locking screws in the Metacarpal Segment
- Loosen the black Universal Joint Locking Screws
- Remove the grey main adjusting screw
- Remove the two Metacarpal Pins
- Remove the Metacarpal Segment, Universal Joints and Threaded Bar

Wrist range of motion exercises can be initiated in this non-spanning configuration.

A custom thermoplast splint can be worn for comfort and removed for wrist and finger therapy and showering. When the fracture is healed, the Fixator can be removed.
## Ordering Information

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<th>Description</th>
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