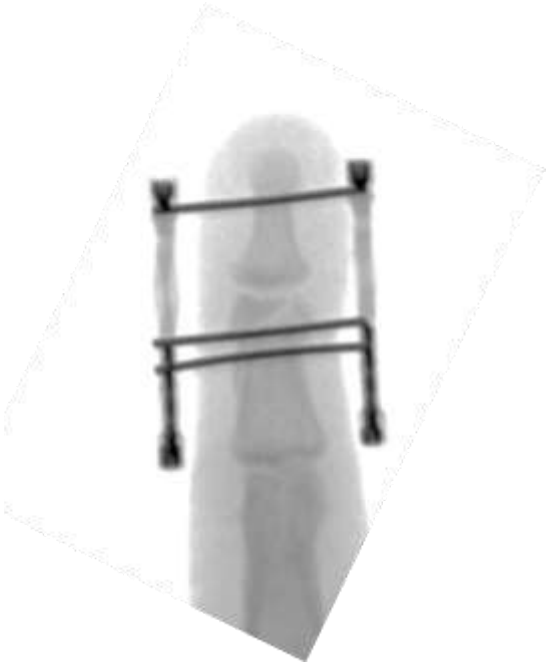
Virak Orthopedics LLC

DigiFix®

External Fixator System



SURGICAL TECHNIQUE FOR THE HAND

DigiFix®

United States Patents: 8,277,449
8,282,636

FDA 510(k) Approval: K132731

Surgical Technique Manual

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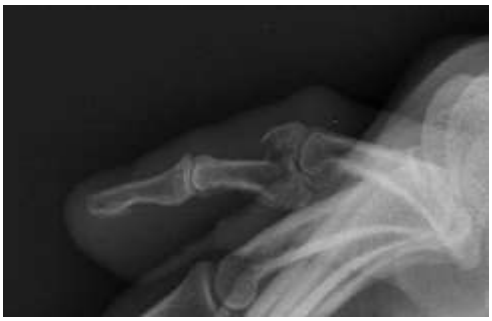
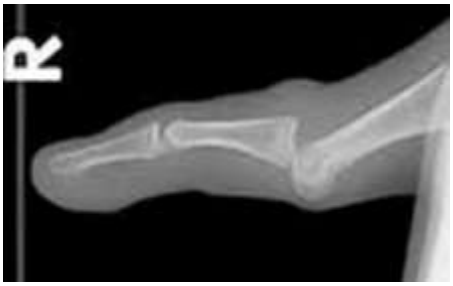
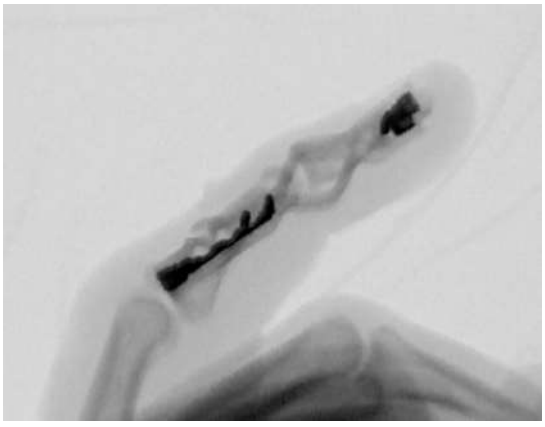
PRODUCT INFORMATION

Finger injury is common in sporting activities and falls. Although most of these injuries can adequately be treated with traditional means including closed reduction, splinting or internal fixation, there are some injuries that are difficult to effectively manage, due to the severity of bony comminution and/or joint involvement. Post-traumatic arthritis and contracture of the finger may develop if early mobilization and accurate reduction are not achieved. Finger stiffness and contracture may limit usefulness of the hand in grip and grasp, resulting in functional loss.





In an effort to improve the outcome of complex bone and joint injuries of the finger, we have developed an external fixator that attaches to the bony skeleton on the sides of the finger with smooth stainless steel K-wires. In the dynamic mode, the design permits joint movement, with or without distraction, to allow concentric proximal interphalangeal (PIP) motion. In the static mode, the DigiFix® provides rigid fixation across the bony segments, providing stability to allow healing.



INDICATIONS

The DIGIFIX® External Fixation System is intended to be used in skeletally mature patients in treatment of:

DYNAMIC MODE:

1) Complex fracture-dislocations or fracture-subluxation, unstable dislocations, and pilon fractures of the interphalangeal (IP) joint;
2) Post-traumatic joint contracture of the proximal interphalangeal (PIP) joint;

STATIC MODE:

1) Fractures of the phalanges and;
2) Interphalangeal (IP) joint arthrodesis.

CONTRAINDICATIONS

- Poor patient compliance.
- Active infection of the digit.
- Severe osteoporosis whereby there is poor purchase of K-wires into the phalanges.

WARNINGS AND PRECAUTIONS

1. Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.

2. K-wire security in bone and device integrity should be routinely checked by the surgeon or hand therapist. Pin track infections need prompt recognition and treatment and may require early device removal.

3. As with all percutaneous skeletal fixation, pin care is important in reducing the incidence and severity of pin track infections.

4. K-wire placement in bone requires accurate anatomic alignment to avoid damage to nerves, blood vessels and tendons. Use caution when handling the sharp tip of the K-wires.

5. Fracture reduction may be compromised and/or the device may be damaged if the patient accidentally hits the hand against an object or catches the device on clothing or bedding. Instruct the patient to use care to protect the hand.

6. For each case, the *Diamond* should be plastically deformed only one direction to avoid breakage.

7. The DigiFix® Brackets are designed to be single use. Do not reuse.

POTENTIAL ADVERSE EFFECTS

The following list includes potential complications typically associated with external fixation devices.

- Prolonged healing
- Distraction of the fracture site
- Pin insertion can result in damage to nerves and vessels
- Infection, painful, swollen or inflamed implant site
- Device fracture
- Loosening or dislocation of the implant requiring revision surgery
- Edema
- Loss of range of motion, joint contracture, joint subluxation, and joint dislocation
- Compartment syndrome
- Septic arthritis
- Delayed unions and intractable pain

- Initial condition may persist or recur requiring further treatment
- Replacement of apparatus or components resulting in reoperation
- Pin insertion leading to tissue necrosis
- External components leading to skin pressure
- Allergic reaction(s) to implant material(s)
- Muscle tendon impalement and excessive operative bleeding
- Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
- Loss of bone mass
- Abnormal growth plate development
- Bone fractures of regenerated bone after device removal
- Discrepancy in limb length
- Excessive motion at the fracture site due to improper device set-up
- Heat build-up and bone necrosis with bone sequestration due to rapid drilling of the bony cortex
- Bone deformity
- Thrombosis, late erosion or arteriovenuos fistulas
- Osteomyelitis and persistent drainage at wire site after wire removal
- Inability to compress the bone surface due to poorly secured pins seated in the bone

No other risks are known to be associated with the DigiFix® External Fixator.

Design Rationale

The unique design of the DigiFix® allows it to function in either the dynamic (ie distraction) or static (ie non-distracted or compression) mode. In the dynamic mode, the axis of rotation of the DigiFix® is aligned to the axis of rotation of the PIP joint, and the distal skeletal fixation is collinear to the mid-axis of the bone to maintain concentric joint reduction. Joint distraction is achieved by elongating the *Diamond* portion of the device with pliers **(CAUTION: DO NOT USE THE COMPRESSION SPREADER INSTRUMENT TO ELONGATE THE DIAMOND)**. The DigiFix® rotates about the axis pin without this pin moving in the bone.

The DigiFix® can be also be used in the static mode in cases of phalangeal shaft fractures or joint fusions. Compression, if desired, is generated by opening the *Diamond* with the Compression Spreader instrument.

All K-wires, except for one through the *Axis Pin Hole*, can be locked to the DigiFix® Bracket with set screws.

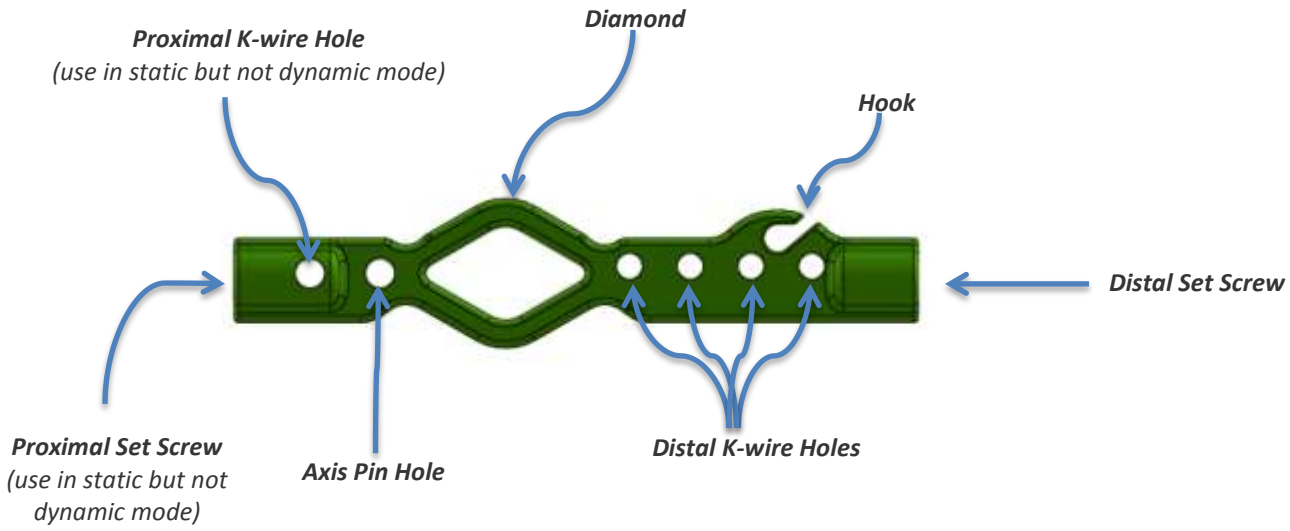
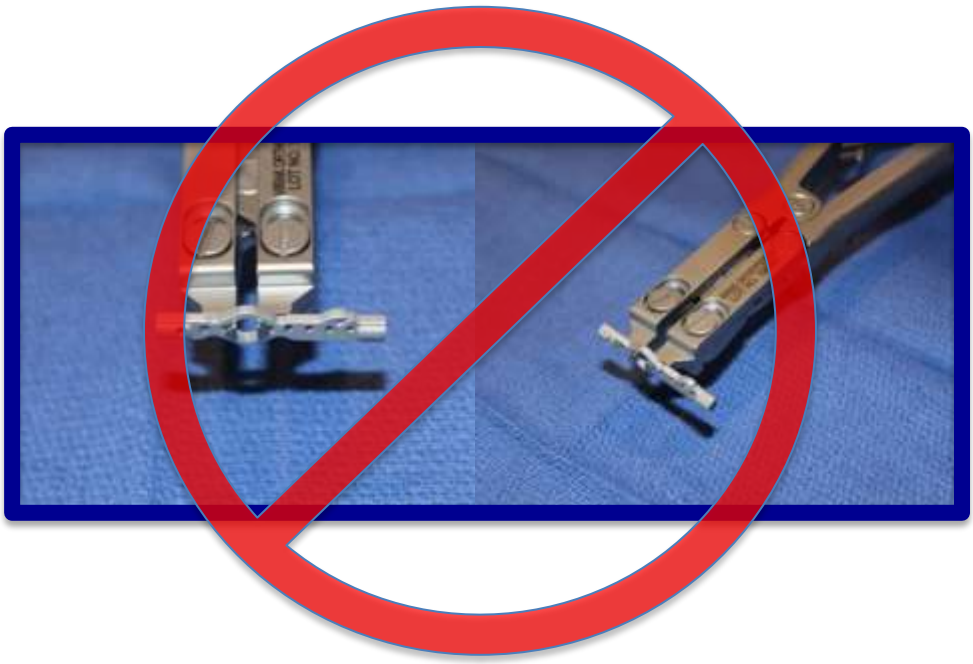


Figure: Diagram of the DigiFix® Bracket.



<u>CAUTION</u>: DO NOT USE THE COMPRESSION SPREADER INSTRUMENT TO ELONGATE THE DIAMOND!

MATERIALS

The DigiFix® is manufactured using 6061 T6 Aluminum, which allows radiographic visualization of the bone and joint during insertion and post-operative imaging. The K-wires are Stainless Steel (316 LVM implant grade).

PREOPERATIVE PLANNING

Before placing the DigiFix® on a patient, it is helpful to discuss the rationale and goal of the treatment. Even in the emergency situation, information about the duration of external fixation, potential problems, expected outcome, and complications should be discussed with the patient.

FRACTURES

For comminuted fractures of the middle or proximal phalanx, the surgeon should carefully plan fixation placement and determine optimal surgical exposure. Additional screw fixation, tension band wire, and K-wire fixation can be used in combination with the DigiFix®. Each fracture or dislocation must be managed individually. Some patients can tolerate early motion, while others may have more swelling and pain precluding early motion.

VOLAR PLATE ARTHROPLASTY

When using the DigiFix® with volar plate arthroplasty, the surgeons must still adhere to the Eaton principles. The collateral ligaments should be excised as part of the volar plate arthroplasty procedure. The anchoring suture through the volar plate should not be tied until the DigiFix® is properly placed and secured. Once the DigiFix® is maintaining joint reduction, the suture can be tied over the button on the dorsum of the finger. The PIP joint is held in nearly full extension for the first two weeks. Then, gentle flexion is initiated, incrementally increasing the range of flexion over the subsequent weeks. Try to increase the amount of flexion of the frame by appropriately 20° to 30° per week. When not moving the joint passively or actively, the joint is held in nearly full extension. It is also important to check lateral X-rays on a weekly basis to ensure reduction of the joint. Before frame removal, try to achieve as much flexion as possible.

CONTRACTURES

For patients with contractures of the joint, tenolysis may need to be considered as part of the treatment. If there is doubt as to the degree of tendon adherence, it may be advantageous to perform the capsular release first, regaining requisite passive motion, and delay the tenolysis or reconstruction till a later date. There are occasions where a small zone of flexor adherence is present and tenolysis could be performed as a part of the contracture release and external fixator placement.

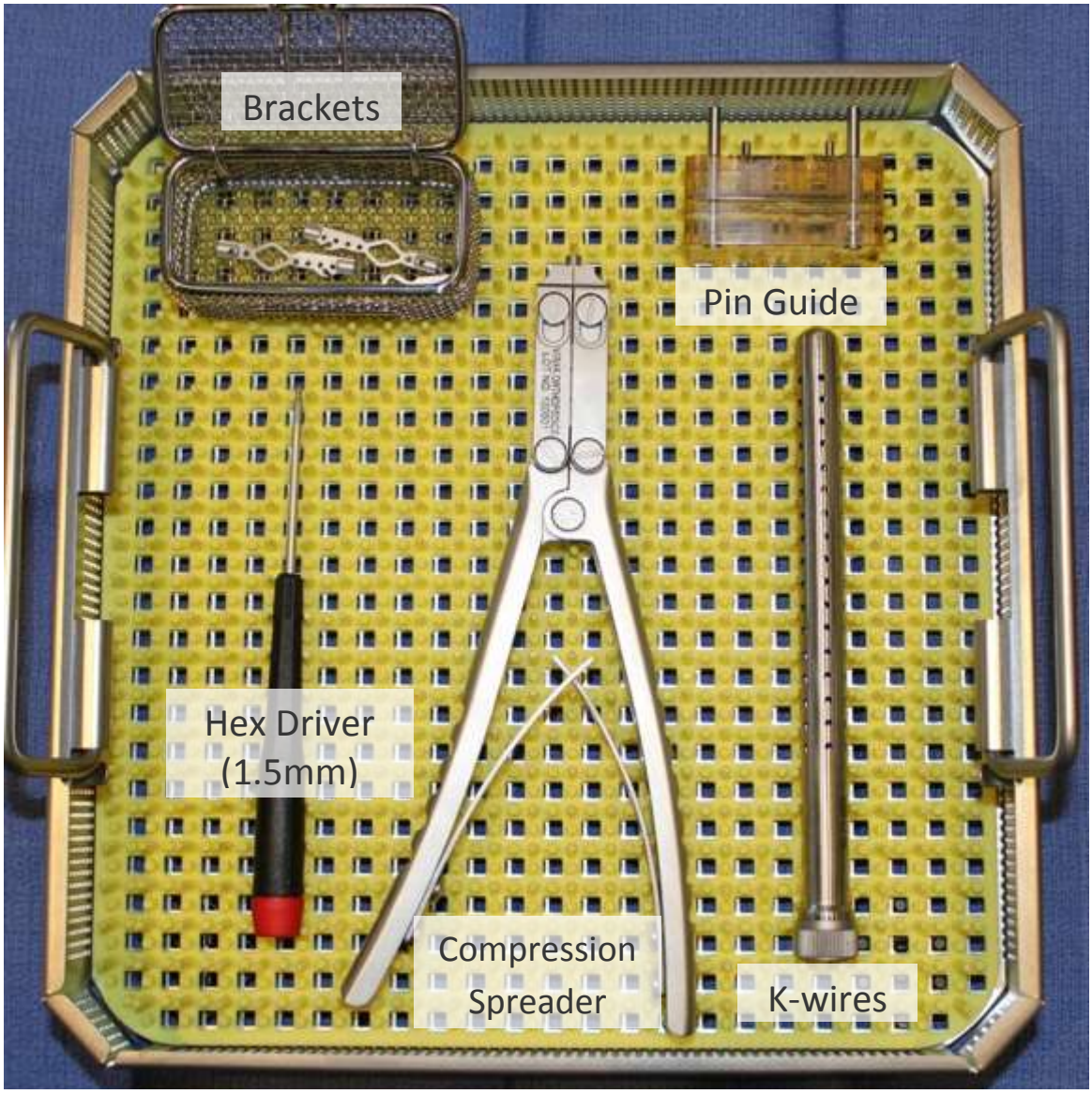
The extensor mechanism may be attenuated in patients with long-standing flexion contractures of greater than 50°. In this situation, a boutonniere reconstruction may be needed to provide an active extensor mechanism.

For active boutonniere reconstructions, the DigiFix® should be left in an extended position for at least three weeks. From then, a gradual and incremental program of passive flexion is started, preventing full flexion for six weeks. When not flexing the joint, the fixator should be left in full extension, especially overnight. Each week, 10-20° of flexion is added to the program. Active flexion and extension should be cautiously initiated to limit attenuation of the reconstructed extensor mechanism. Some permanent extensor lag should be expected in all of these patients.

Joint Arthrodesis

In arthrodesis cases, joint preparation is done in the standard fashion prior to placing K-wires for the DigiFix®. The joint is denuded of cartilage, and bone cuts are performed to achieve the desired amount of angulation. The DigiFix® will accommodate up to about 40° of flexion, depending on the individual anatomy.

DigiFix® TRAY



SURGICAL TECHNIQUE

REQUIRED IMPLANT AND EQUIPMENT

- DigiFix® Tray
- Wire driver
- Wire cutter
- Pliers (parallel closing)

OPTIONAL IMPLANT

- K-wire (0.062”)
- K-wire (0.045”)

AXIS PIN INSERTION

Using fluoroscopy, a true lateral of the PIP joint is obtained. A 0.054” (or 0.062”) K-wire (ie. axis pin) is inserted through the axis of rotation of the PIP joint. This axis pin should be placed transverse to the long axis of the finger in the coronal plane and parallel to the joint surface. The axis pin should exit the other side of the finger, and the position checked by fluoroscopy on both the lateral and AP views. If the axis pin is poorly placed or angulated, the DigiFix® may not function properly in the dynamic mode.

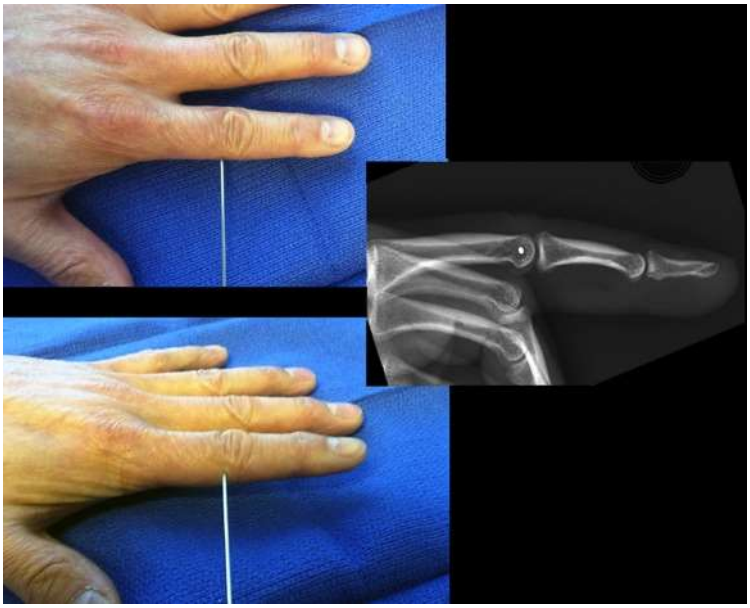


Figure: The axis pin should be placed transverse to the long axis of the finger and parallel to the joint surface at the center of rotation of the PIP joint. On a true lateral view, the axis pin should appear as a dot (white) in the head of P1.

DISTAL K-WIRES INSERTION

Once the axis pin is in place, slide the DigiFix® Bracket over the axis pin, through the *Axis Pin Hole*. Next, using the DigiFix® Bracket as a guide, percutaneously insert a 0.054" K-wire through the most proximal of the *Distal K-wire Holes* and drive it across the middle phalanx to exit on the other side of the finger. This K-wire should to be perpendicular to the long axis and in the mid-axial plane of the middle phalanx to ensure that the PIP joint will be concentrically reduced. The phalanges tend to be more dorsal than expected. It is important not to angulate the pin to engage bone, but instead obtain reduction of the PIP joint and adjust the DigiFix® Bracket to align with the middle phalanx.

Figure: Bracket is slid over the axis pin.

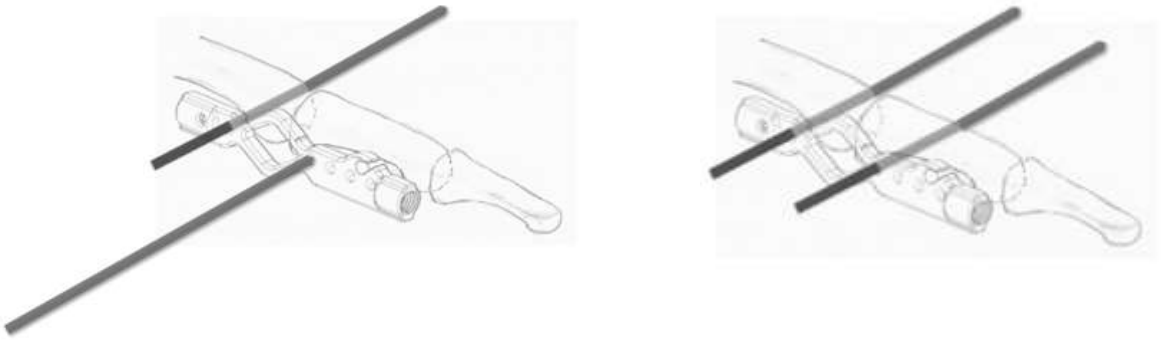


Figure: An 0.054" K-wire is inserted through the most proximal of the *Distal K-wire Holes* and driven across the middle phalanx to exit on the opposite side of the finger.

After placing the first K-wire distally, a second 0.054" K-wire is then inserted in a similar manner through one of the remaining *Distal K-wire Holes.* The hole is chosen such that the second K-wire is in the middle phalanx (not the DIP joint or distal phalanx). This K-wire should also be perpendicular to the long axis and in the mid-axial plane of the middle phalanx. The two distal K-wires can be cut flush with the outer portion of the DigiFix®. Before cutting the wires, check to see that the DigiFix® is not too close to the skin. Some swelling is bound to occur in the postoperative period. Use the Hex Driver to tighten the *Distal Set Screw* to lock the K-wires to the DigiFix® Bracket.

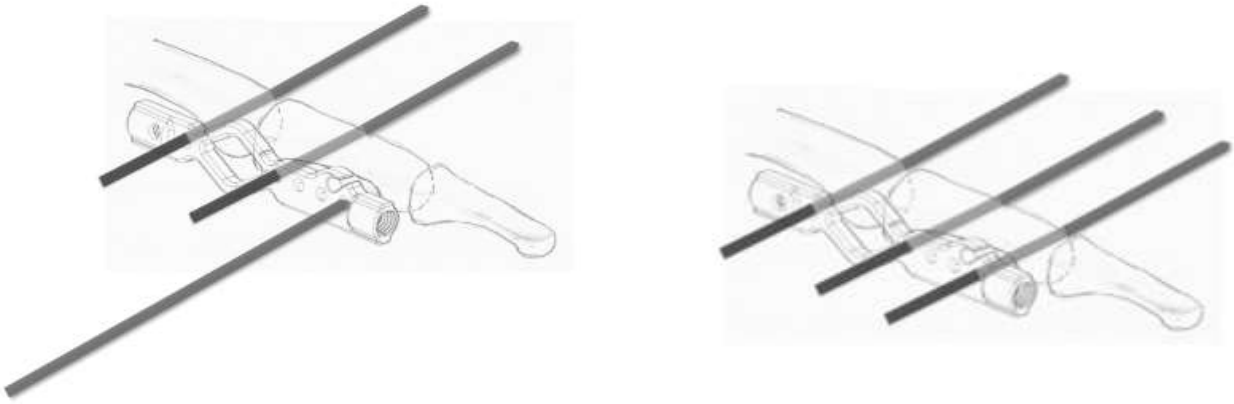


Figure: A second K-wire is placed in a similar manner through one of the remaining *Distal K-wire Holes*.

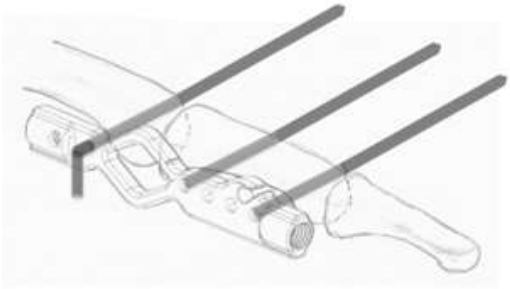


Figure: The distal K-wires are cut flush with the outer portion of the DigiFix® Bracket, and the axis pin is bent and cut short. The K-wires are locked to the Bracket by tightening the *Distal Set Screw.*

Alternative Pin Placement Using Pin Placement Guide

The surgeon may elect to use the radiolucent pin guide to place the K-wires. Place the pin guide around digit with the cluster of proximal holes in the guide near the axis of rotation of the PIP joint. The guide may be adjusted in the proximal-distal direction, as well as rotationally, such that one of the proximal holes in the guide lines up with the axis of rotation of the PIP joint. Once confirmed under fluoroscopy, the axis K-wire is then inserted through the guide into the bone and existing on the opposite side through the corresponding hole in the guide.

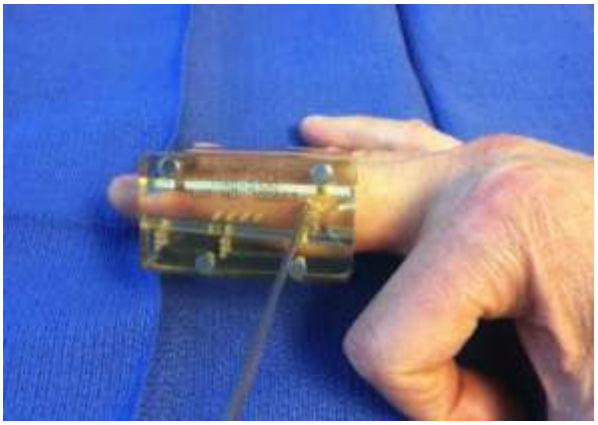


Figure: Using the pin guide to place the axis pin. The K-wire is inserted through one of the proximal holes in the guide that lines up with the axis of rotation of the PIP joint.

With the axis pin in place, if necessary, re-center the guide onto the Centering Hole for the axis pin. Re-centering is achieved by first removing the guide from the axis pin, then sliding the guide back on the axis pin through the Centering Hole on the guide. The distal holes on the guide will now line up to the holes in the DigiFix® Brackets.

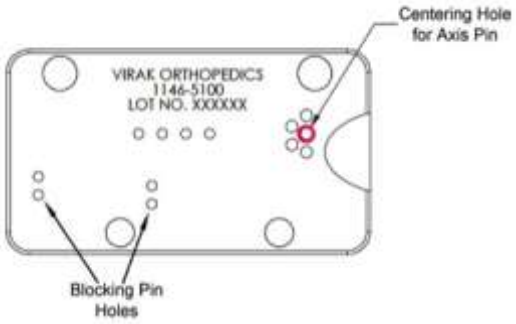
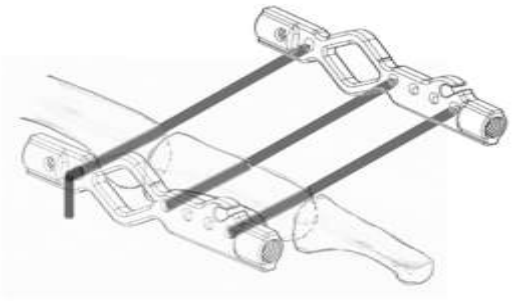


Figure: Diagram of the pin guide showing the Centering Hole and Block Pin Holes.

A K-wire may be inserted in through one of the Blocking Pin Holes to keep the finger in the extended position during the procedure.

Multiplanar Stabilization

A second DigiFix® Bracket is placed over the K-wires on the other side of the finger for multiplanar (quadrilateral) stabilization. The Bracket is slid over the axis pin and K-wires using the corresponding holes. In a similar manner, the Bracket is kept 2-3mm off the skin to allow for post-operative swelling. The K-wires are cut flush with the outer portion of the DigiFix®, and the *Distal Set Screw* tightened.



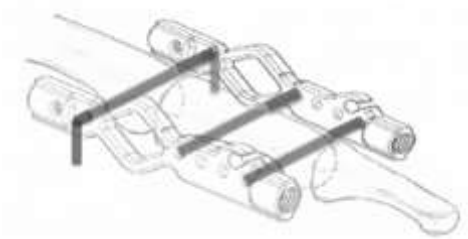


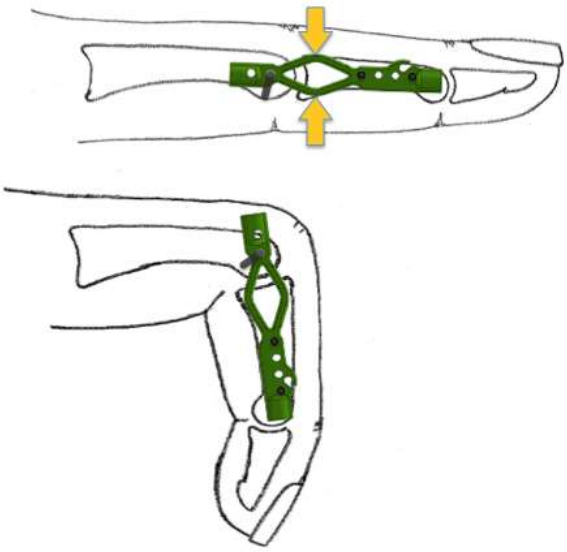
Figure: A second DigiFix® Bracket is placed on the opposite side of the finger using the corresponding holes. The distal K-wires are cut flush with the outer portion of the DigiFix® Bracket, and the axis pin is bent and cut short. The K-wires are locked to the Bracket by tightening the *Distal Set Screw.*

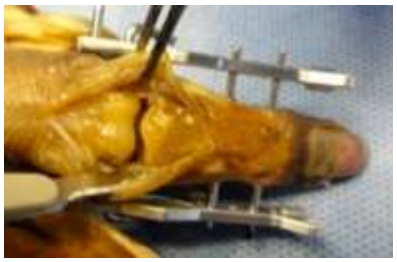
Dynamic Mode

If not already done, the axis pin is bent 90° over the outside portion of the DigiFix® on each side of the finger to prevent the Bracket from sliding off the pin. Each *Diamond* is squeezed down independently with pliers (in the dorsal-volar plane) to achieve the desired amount distraction. In most cases, 1 – 2 mm of distraction is sufficient.

Figure: The Diamond is elongated with pliers to gain distraction. **DO NOT USE THE COMPRESSION SPREADER INSTRUMENT TO ELONGATE THE DIAMOND!**

Fluoroscopy is used to confirm that the joint is symmetrically distracted on the AP view and concentrically reduced on the lateral view. The PIP joint is passively ranged to ensure that the joint is freely moving and remains reduced throughout the arc of motion.





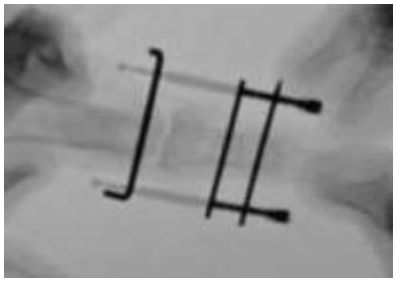
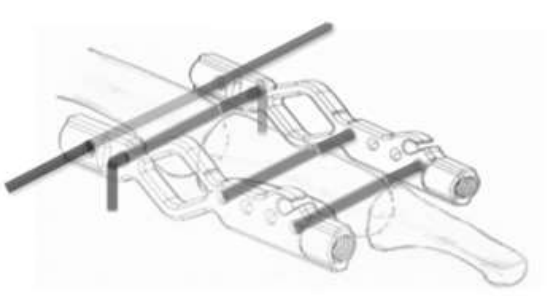


Figure: Dynamic Mode. Distraction of the joint is achieved by squeezing down on the *Diamond* portion of the Bracket with pliers. The joint and DigiFix® rotate about the axis pin. Photograph and radiograph showing the joint distraction.

Light gauze dressing is placed around the K-wires. The dressing may be removed in 3 – 5 days, and the hand washed with soap and water. If there is bleeding, daily light dressing changes are done until the bleeding ceases. Motion may be tailored to the particular needs of the patient and injury pattern.

STATIC MODE

In certain clinical scenarios, the surgeon may want to have static fixation of the finger. In such cases, with the DigiFix® Brackets already secured on each side of finger, an additional K-wire (can be size 0.045", 0.054" or 0.062") is inserted through the *Proximal K-wire Hole*s and bone. The joint or bone segment is held in the desired position during insertion of this K-wire. The K-wire is cut flush with the Bracket and the *Proximal Set Screw* is tightened to lock the K-wire to the Bracket.



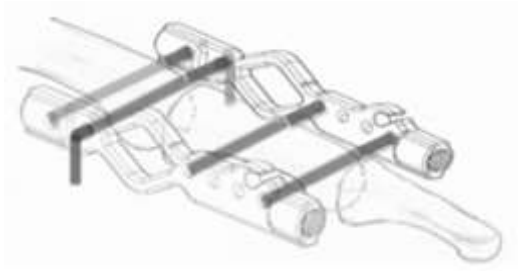
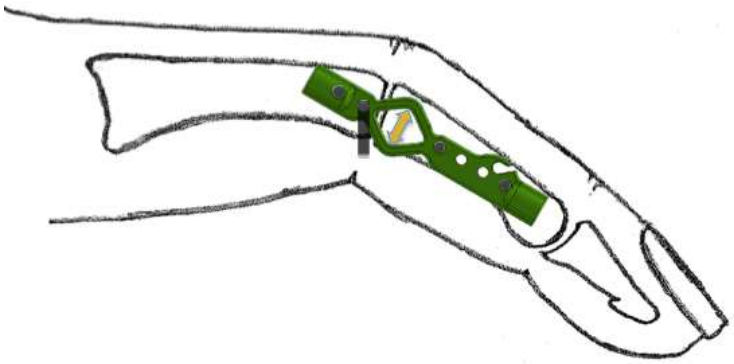


Figure: For static mode, an additional K-wire is placed through the *Proximal K-wire Hole* with the bone segments reduced in the desired position. The K-wire is cut flush with the Bracket and the *Proximal Set Screw* is tightened to lock the K-wire to the Bracket.

If compression is required, the *Diamond* is expanded (in the dorsal-volar plane) using the Compression Spreader instrument. Light gauze dressing is placed around the finger. The dressing may be removed in 3 – 5 days, and the hand washed with soap and water. If there is bleeding, daily light dressing changes are done until the bleeding ceases. Motion of the **adjacent joints** may be initiated and tailored to the particular needs of the patient and injury pattern.

Figure: Correct use of the Compression Spreader to open the *Diamond* in the dorsal-volar plane to provide compression. Do not compress beyond what is allowed by the instrument.



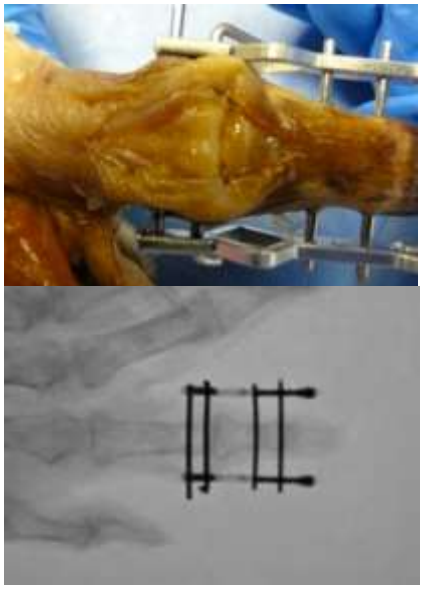


Figure: Example of a joint arthrodesis. After the DigiFix® is placed in the static mode, the *Diamond* is expanded to provide compression across the fusion site. Photograph and radiograph of PIP joint in compression.

OTHER CONSIDERATIONS

Depending on the actual fracture pattern or bone geometry and size, the DigiFix® Brackets may be reversed in the proximal-distal (*Hook* is proximal) and/or dorsal-volar (*Hook* is volar) directions. Because of the multiplanar (quadrilateral) fixation, **both Brackets must be pointing in the same direction.**

EXTERNAL FIXATOR REMOVAL

REQUIRED EQUIPMENT

- Hex driver (1.5mm)
- Needle holder (or similar tool)
- Wire cutter (if K-wires are bent)

The DigiFix® may be removed in the office setting by simply loosening the set screws and sliding the Brackets off the K-wires. The K-wires are removed in a routine fashion with a needle holder or similar tool. Non-restrictive dressing is placed over the K-wire holes in the skin, and the patient is instructed on therapy, as necessary.

ORDERING INFORMATION

IMPLANTS

Catalog #	Description	Minimum Suggested Qty	
1146-3000	DigiFix® Bracket	8	
1146-0006	K-wire 1.1mm (0.045”)	optional	
1146-0007	K-wire 1.4mm (0.054”)	12	
1146-0008	K-wire 1.6mm (0.062”)	optional	

INSTRUMENTS

Catalog #	Description	Tray Qty	
1146-0010	Hex driver 1.5mm	2	
1146-5000	Compression Spreader	1	
1146-5100	Pin guide	1	