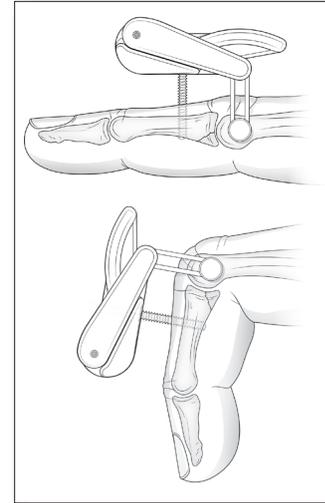


Agee PIP Fix[®]

For Dorsal Fracture Dislocations
of the PIP Joint



Surgeon's Manual

PIP Fix[®]

Item No. PFX-426

United States Patent 8,246,561

Surgeon's Manual, Part No. 342400A
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Illustrations by Tiffany Slaybaugh DaVanzo, MA, CMI

Hand Biomechanics Lab, Inc.
77 Scripps Drive, Ste. 104
Sacramento, CA 95825

www.handbiolab.com

800-522-5778 916-923-5073 916-920-2215 fax

How To Use This Manual

Cautions and Warnings

Errors

Although every attempt has been made to proofread this manual, typographical errors are possible. Please contact us at (800) 522-5778 if you find an error or have any questions about the **PIP Fix** and its application.

Organization

This surgeon's manual is organized into three main sections.

- Introduction
- Surgical Installation
- Post-Op Instructions

Please read the entire manual before using the **PIP Fix**.

Precautions

General device warnings and cautions appear within the Indications, Contraindications and Cautions of the introduction section. Task specific warnings and cautions are located within a box on the same page as the task.

Warnings and Cautions are meant to alert the surgeon to potential hazards associated with the use or misuse of the device. Note the difference in severity from the following definitions used in writing this manual.

WARNING: Possible injury, death or other serious adverse reactions could be associated with the use or misuse of the device.

CAUTION: Possible problem with the device associated with its use or misuse. Such problems include malfunctions, device failure, damage to the device or to other property.

These definitions come from the following U.S. Food and Drug Administration publication:

Backinger, C.L., Kingsley, P.A. Write it Right: Recommendations for Developing User Instruction Manuals for Medical Device Used in Home Health Care. HHS Publication FDA 93-4258 (August 1993) (64pp.).

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Introduction

An overview - by John Agee, MD

The **PIP Fix** is an external fixator designed to obtain and maintain concentric reduction of an unstable dorsal fracture dislocation of the PIP joint. Achieving an optimal result depends on the “geometry” of the bone and soft tissue injury that accompanies each of these difficult fractures. Please review the following principles carefully before deciding to use the **PIP Fix** on your patient’s unstable PIP fracture dislocation:

- **Achieve and maintain alignment of the injured PIP joint:**

For this device to obtain and maintain joint alignment, at least 50% of the dorsal base of the middle phalanx, from radial to ulnar sides, must be intact. AP, lateral and both oblique X-rays are necessary both preoperatively and during **PIP Fix** installation and adjustment, to confirm that at least 50% of the dorsal base of the middle phalanx is intact and can be concentrically realigned with the condyles of the head of the proximal phalanx.

- **Restore length:**

The dorsal fracture dislocation raises the extensor hood dorsally off the head of the proximal phalanx creating a space which fills with trauma fluids acutely. In some instances, the fluids and surrounding soft tissues stiffen. In these cases, fracture reduction may not be possible at the time of surgery. The device angle and tension adjustments should be positioned to provide an appropriate amount of length restoration force and joint ROM should be limited.

As the soft tissues undergo stress relaxation, the intact dorsal base should translate distally until length is restored, at which point dorsal to palmar translation should keep the fragment reduced. Frequent X-rays may be required to monitor progress followed by incremental adjustments as needed to alter the proportion of band tension in each direction relative to the plane of the hand.

- **Ensure that gliding motion exists during active and/or passive joint motion:**

Once the **PIP Fix** has reduced the joint, lateral X-rays should confirm that alignment of the dorsal base of the middle phalanx on the head of the proximal phalanx is maintained during active or passive joint motion. If, during active or passive motion, gliding motion arrests and the dorsal side of the joint “opens like a book”, the sharp palmar edge of the intact dorsal base will “dig into” and abrade the hyaline cartilage of the head of the proximal phalanx.

If this “rocking” motion persists, the potential for gliding motion is lost and such abnormal motion will evolve into traumatic arthritis. Once joint reduction is achieved, fluoroscopic evidence of “rocking” instead of gliding joint motion is evidence that joint reduction will not be maintained throughout the available range of PIP motion and that an alternative approach is needed for the patient’s injury.

Introduction

An overview - by John Agee, MD

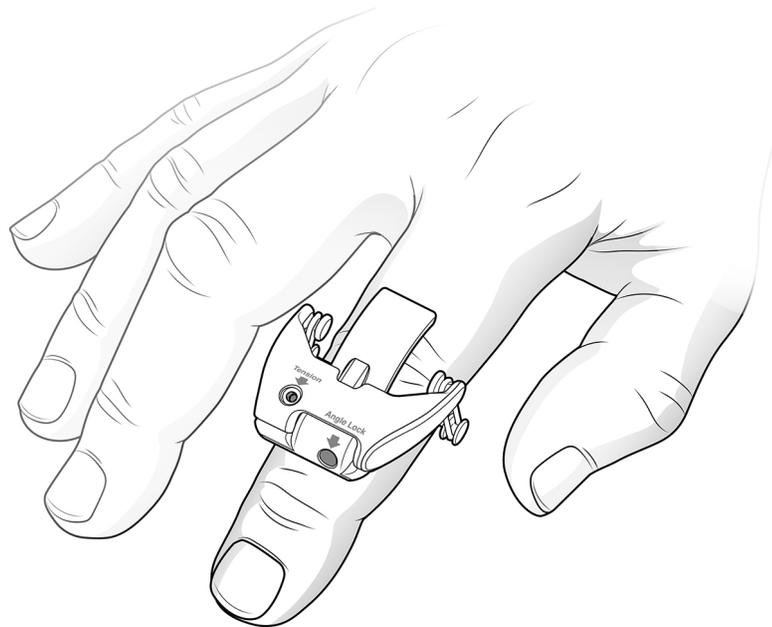
- ***Confirm that capsular ligaments are competent:***

The device's reduction force should create normal alignment of the intact dorsal base of the middle phalanx on the head of the proximal phalanx. However, maintenance of this alignment requires capsular ligaments that are competent to assure joint alignment and prevent palmar subluxation of the middle phalanx on the head of the proximal phalanx.

- ***Promote active joint motion during healing:***

The joint reduction potential of the **PIP Fix** is present throughout a complete range of PIP joint motion. Such motion, while less than normal secondary to fracture and soft tissue injury, will be adequate to facilitate an optimal result for a given injury only if concentric, gliding motion is maintained during healing. If the device can obtain and maintain concentric reduction of the dorsal base of the middle phalanx on the head of the proximal, the patient's own active hand use optimizes joint and tendon gliding during fracture and soft tissue healing.

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Implanted **PIP Fix**[®]

PIP Fix Description

Design

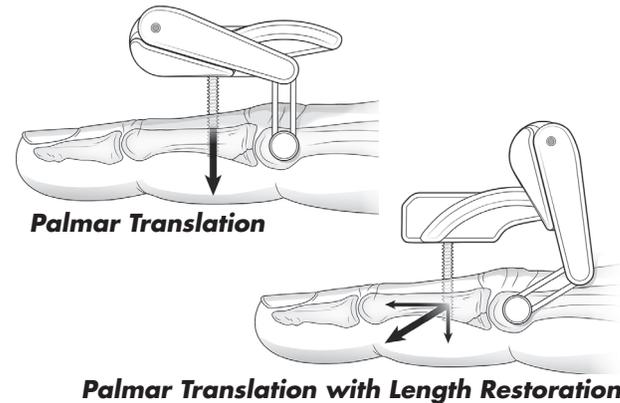
The **PIP Fix** is capable of exerting both palmar translating and length restoration forces to the middle phalanx while simultaneously exerting counter forces to the distal end of the proximal phalanx to restore joint alignment. With the dorsal dislocation of the middle phalanx reduced, the fractured fragments of the joint surface are “grossly” realigned. The effect of the **PIP Fix** is present throughout the complete range of finger motion facilitating active flexion and extension during healing of the bone and soft tissues.

Included with the **PIP Fix** is a custom Pin Placement Guide that facilitates accurate placement of a Transverse Bone Pin in the head of the proximal phalanx in a location that is optimal for both device function and for finger ROM. The Dorsal Bone Pin is inserted vertically into the middle phalanx. The **PIP Fix** is installed on the Dorsal Bone Pin and is linked to the Transverse Bone Pin with two Elastic Bands. These bands provide the translating force, and the option of a length restoration force, that obtains and maintains concentric joint reduction.

A Tension Adjust Screw on the **PIP Fix** provides a method for the surgeon to “fine tune” the amount of tension in the Elastic Bands so they exert the least amount of force necessary to maintain joint alignment.

The force acts in the direction of the Elastic Bands but may be resolved into two distinct forces relative to joint anatomy. The force angle can be adjusted by rotating the Elastic Band

Posts proximally. Adjusting this angle adjusts the relative proportion of total force allocated to palmar translation or length restoration. When in the distal position, the bands sit vertically over the Transverse Pin and provide only a palmar translation force. When rotated proximally, some of the palmar translation force converts into a length restoration force. Once the angle adjustment is optimized, the desired force is maintained using the Angle Lock Screw.



Materials

The **PIP Fix** is manufactured using metal and plastic.

The bone pins are fabricated from 316 L stainless steel.

Warning: **The Elastic Bands in this product contain natural rubber latex that may cause allergic reactions.** All components are designed for single use only.

Instrumentation and Sterilization

The **PIP Fix** is provided **STERILE** and for **SINGLE USE** only.

The kit includes pins and the following instrumentation necessary for application.

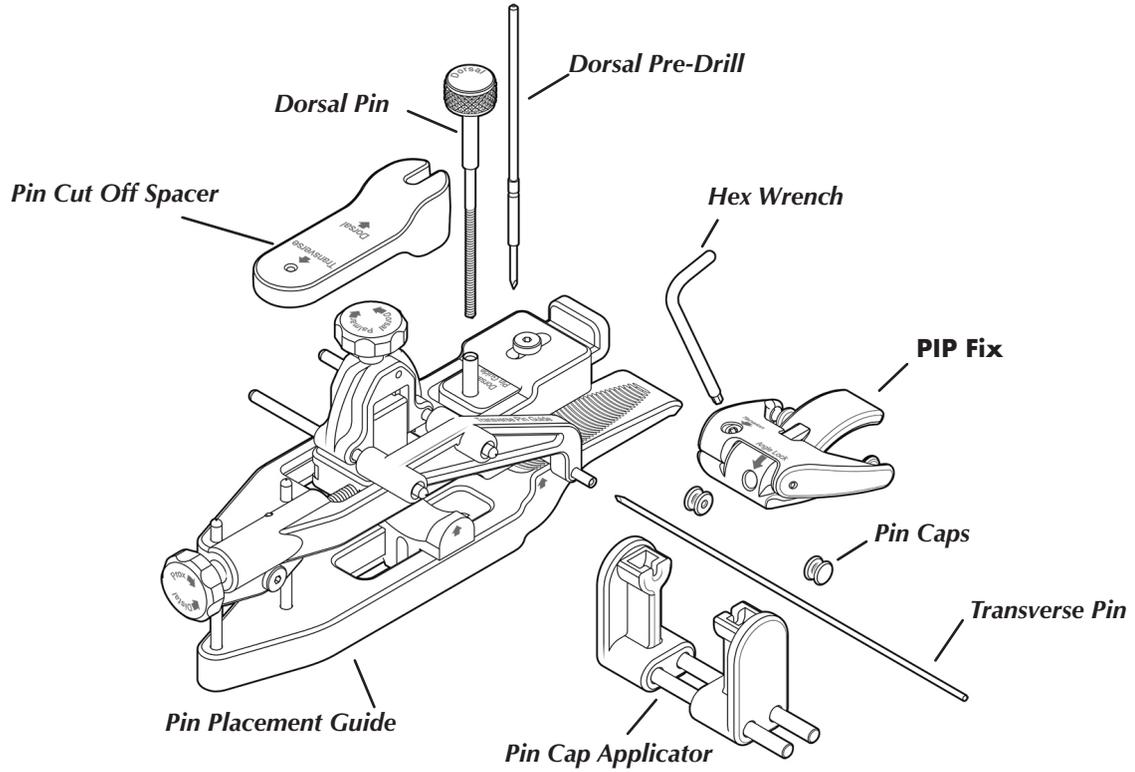
- Condensed Surgical Guide
- Pin Placement Guide
- Dorsal Pin and Pre-Drill
- Transverse Pin
- **PIP Fix**
- Pin Caps
- Pin Cap Applicator
- Pin Cut Off Spacer
- Hex Wrench
- Elastic Bands

In addition, the following non-sterile items are provided:

- Latex Elastic Bands (for post surgical patient use)
- Hex Wrench (for post surgical adjustments and device removal)
- Patient Information

CAUTION: The **PIP Fix** tray and contents are **STERILE** unless the expiration date has passed or packaging has been opened or damaged.

CAUTION: Do not reuse the **PIP Fix** Pre-Drill or Bone Pins. They are not designed to withstand multiple patient use.



Indications, Contraindications and Cautions

Indications and Contraindications

Indications for Use

The **PIP Fix** is indicated for the treatment of unstable dorsal fracture dislocations of the proximal interphalangeal (PIP) joint of the fingers in which external fixation as provided by the **PIP Fix** alone is sufficient to obtain and maintain concentric reduction of the fracture dislocation during bone and soft tissue healing.

Contraindications to use and/or continued use:

1. Patients in whom cooperation or mental competence is lacking thereby reducing patient compliance; or those with alcohol or substance abuse problems that may lead to poor patient compliance.
2. Where there is radiographic evidence of either pre-injury arthritis of the affected joint, injury to the bone of the head of the proximal phalanx, or depressed central articular fragments; all of which will prevent joint gliding of the middle phalanx on the condyles of the proximal phalanx.
3. Patients with inflammatory joint disorders such as rheumatoid arthritis, or with degenerative joint disease such as osteoarthritis.
4. If the surgeon determines, prior to installation or once the device is installed, that the force required to reduce the dorsal fracture dislocation results in a palmar subluxation of the middle phalanx on the head of the proximal phalanx.
5. In fracture dislocations of the PIP joint in which the middle phalanx is subluxed or dislocated on the head of the proximal phalanx in any other than a dorsal direction.
6. In patients young enough to have open growth plates in their fingers.

Specifics of Indications for Use:

1. The following fracture anatomy should be defined by pre-op AP, lateral and **both oblique X-rays** and, when appropriate, CAT scans:
 - a. Dorsal displacement of an intact dorsal base of the middle phalanx on the head of the proximal phalanx.
 - b. At least 50% of the dorsal base of the middle phalanx, from the radial to ulnar side of the joint, is intact. This requires both oblique X-rays to define a radial to ulnar “plate” of subchondral bone adequate to provide stable gliding motion of the intact dorsal base of the middle phalanx on the head of the proximal during tissue healing. With rare exceptions, normal alignment of a comminuted palmar base of the middle phalanx is not necessary for either joint stability or active range of motion exercises during fracture and soft tissue healing.
2. Gentle physical examination stresses applied to the radial and ulnar collateral ligaments confirm that adequate portions of these ligaments are present to maintain lateral joint stability during fracture and soft tissue healing. These intact portions of the collateral ligaments serve to prevent the **PIP Fix’s** translating forces from converting a dorsal dislocation to a palmar subluxation or dislocation of the middle phalanx on the head of the proximal phalanx.

Cautions (technique cautions noted with instructions)

1. Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
2. Patient cooperation and participation are important to effective **PIP Fix** use. Advise your patient to report adverse or unanticipated effects as soon as possible. Instruct the patient to keep extra Elastic Bands with him/her at all times. (See patient information sheet)
3. Skeletal pin 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.
4. The Elastic Bands should be installed from the device to the Pin Caps at all times. If they are removed, the device may separate from the Bone Pin. This could result in a loss of fracture reduction and/or a loss of the **PIP Fix** device itself.

Warnings (technique warnings noted with instructions)

1. Bone Pin placement requires accurate anatomic alignment to avoid damage to nerves, blood vessels and tendons.
2. Pre-drilling should be done using a low drill speed to minimize heat that can injure bone and soft tissue.
3. Use caution when handling the sharp tip of the Bone Pin and Pre-Drill. The pin ends should be held when clipped. Eye protection is recommended for all operating room personnel.
4. As with all percutaneous skeletal fixation, pin track care is important in reducing the incidence and

severity of pin track infections. The details of pin track care are the responsibility of the treating surgeon, his/her training and experience, and the orthopaedic literature they respect.

5. The Elastic Bands in this product contain natural rubber latex that may cause allergic reactions.
6. Fracture reduction may be compromised and/or the device and Bone Pins 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.

Potential Adverse Effects

1. Damage to tendons, nerves or vessels caused during insertion of the Bone Pins.
2. Superficial or deep pin track infection that may evolve into septic arthritis and/or osteomyelitis.
3. Edema about the pin track that may extend to involve the entire finger.
4. Persistent joint subluxation or dislocation with secondary loss of range of motion and traumatic arthritis.
5. Loosening or breakage of the device components.
6. Intractable pain.
7. Foreign body reaction to Bone Pins or other components.
8. Tissue necrosis from heat occurring during Bone Pin insertion.
9. Excessive operative bleeding.
10. The intrinsic risks associated with anesthesia.

Adjustment of the Elastic Band Tension

Guidelines and Precautions

The steps involved in the installation of the **PIP Fix** are depicted in the following section. These instructions and the Pin Placement Guide will assist you in placing the Bone Pins in the optimal location for both fracture reduction and range of motion during fracture healing.

Equally important to the health of the injured PIP joint is the application of the reduction force created by the Elastic Bands. Too little force and the dorsal dislocation will not be fully reduced. Too much force can damage the collateral ligaments and may result in a palmar subluxation or dislocation of the joint.

The **least amount of tension** should be applied to the bands to maintain fracture reduction. Increasing the tension in the Elastic Bands once the fracture is reduced is not necessary and can damage the joint.

Elastic Band tension and its effect on the joint should be evaluated intra-operatively using fluoroscopy and again within a week or less with the joint in both flexion and extension.

Keep the extra Hex Wrench included in the **PIP Fix** kit so that you can adjust the tension, if needed, in your office.

Fig. A1. The Elastic Band tension is translating the base of the middle phalanx in a palmar direction. Friction from the sharp edge of the fracture may dig into the cartilage of the proximal phalanx and prevent reduction. **Do not increase tension yet.**

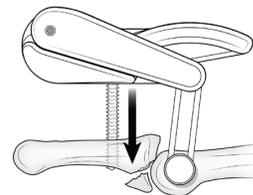


Fig. A1

Fig. A2. In fractures that cannot be manually reduced, application of the bands and adjustment of the force angle will provide a length restoration force to help move the joint into proper alignment. Follow up X-rays in 1-2 days are needed to confirm length restoration progression toward normal. Do not start active PIP motion until X-rays confirm concentric reduction of the joint.

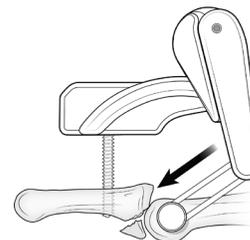


Fig. A2

Fig. B. In acute cases (a week or less post injury) application of the bands and gentle traction to the fingertip will typically result in joint reduction. If concentric reduction is maintained with passive and/or active motion, no additional tension or angle adjustment is needed. Follow up X-rays in a week or less are needed to confirm maintenance of reduction.

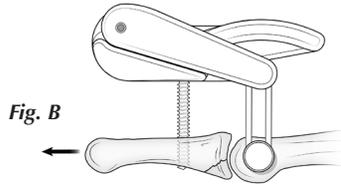


Fig. C. If the subchondral bone of the dorsal base of the middle phalanx is not concentrically aligned with the head of the proximal phalanx, hold the device to prevent rotation on the bone pin and add small increments of tension.

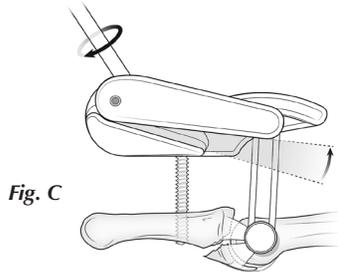


Fig. D. When concentric reduction has been confirmed under flouroscopy, no further tension is required. Follow up with X-rays in a week or less.

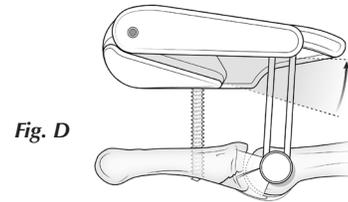


Fig. E. Additional force “stretches” the ligaments. The negative effects of excessive force may not be evident until several days later.

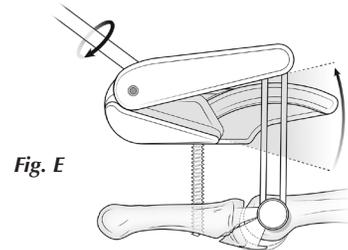


Fig. F. Maintenance of excessive translation force produces additional capsular elongation and may create a palmar dislocation of the joint.

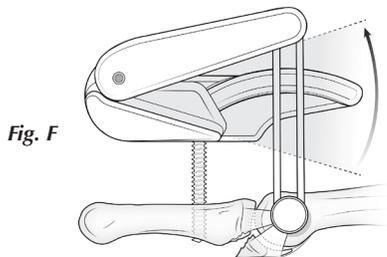
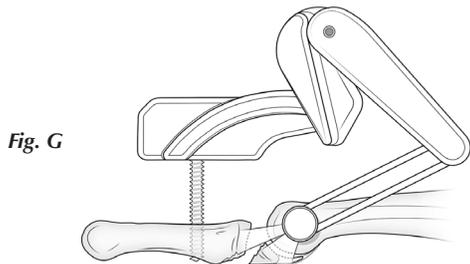


Fig. G. Maintenance of excessive length restoration force produces additional capsular elongation and may overdistract the joint or create a palmar dislocation of the joint.



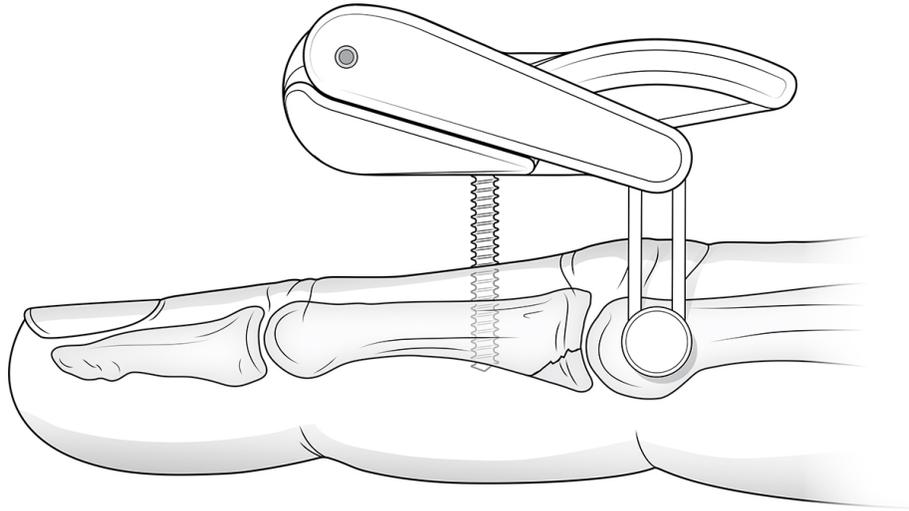
MRI Safety Information

The **PIP Fix** has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the **PIP Fix** in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Surgical Installation

Surgical Installation

Overview



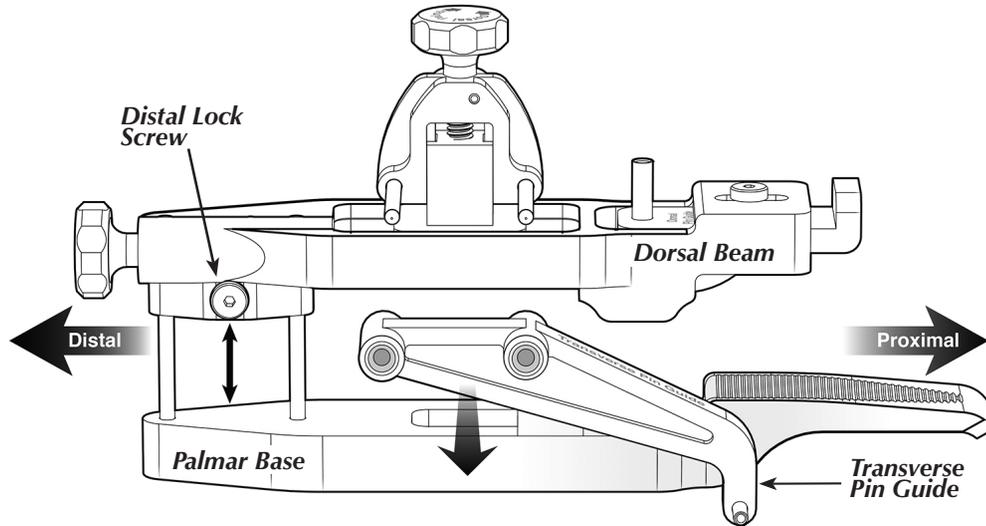
Lateral view depicting a typical sample installation of the PIP Fix.

- The smooth Transverse Pin is inserted through the distal end of the proximal phalanx.
- The threaded Dorsal Pin is inserted manually through a pre-drilled hole distal to the fracture. This pin extends through, but not beyond, the palmar cortex of the middle phalanx.
- The device Elastic Band Posts are directly dorsal to the transverse Pin Caps.
- There is sufficient tension in the Elastic Bands to reduce the joint and the fracture.

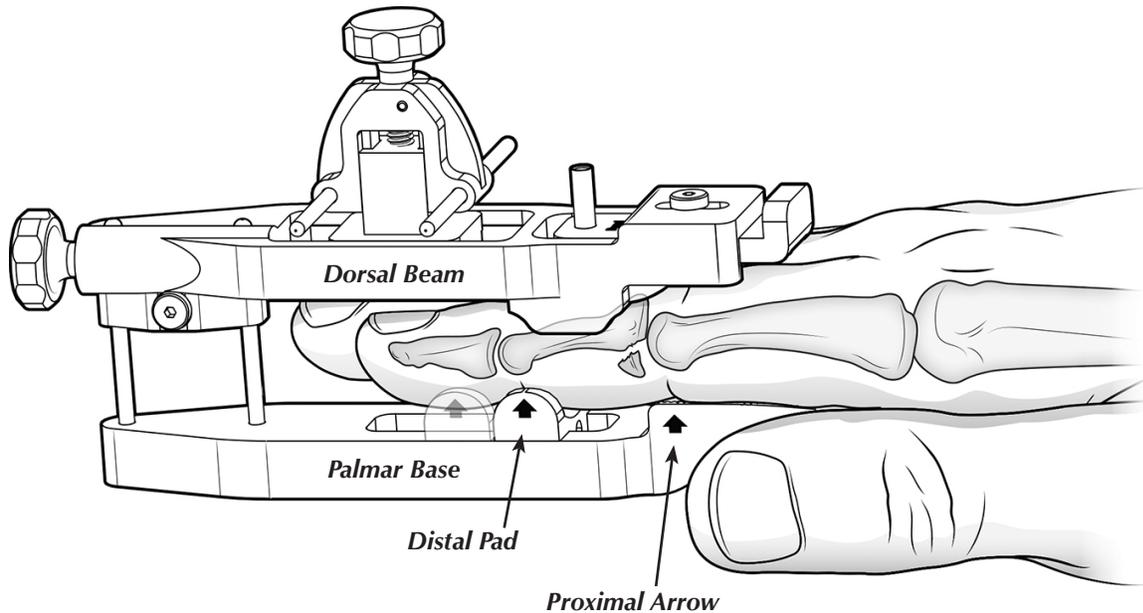
Surgical Installation

Positioning the Pin Placement Guide

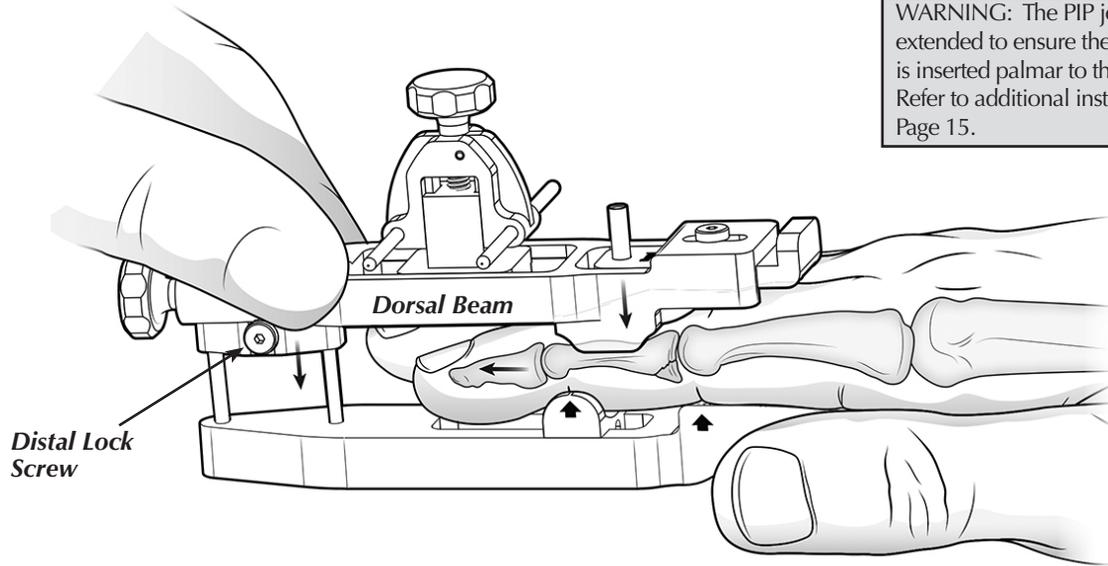
In fractures where some tissue healing has already occurred, manual reduction of the joint may not be possible. If this is the case, the PPG will be unable to reduce the joint prior to pin installation. In these situations, the surgeon must use his or her best judgement to determine the optimal Transverse Pin location based on the relevant alignment of the soft tissues with the skeletal bones. Use of the PPG to facilitate accurate installation of the skeletal pins will often still be advantageous in these cases.



- Remove the Transverse Pin Guide from its posts.
- Loosen the Distal Lock Screw with the Hex Wrench then slide the dorsal and palmar halves of the Pin Placement Guide apart to facilitate finger insertion.

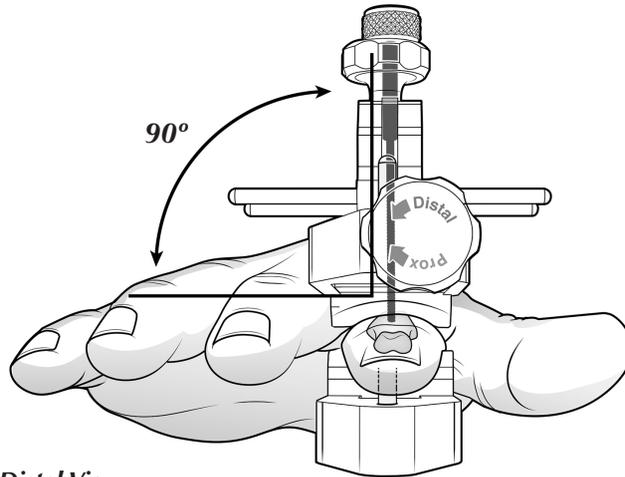


- Place finger onto the Palmar Base. The palm of the hand must be parallel with the Palmar Base. Do NOT try to align the fingernail with the Palmar Base by rotating the finger on the base.
- Position the finger with the PIP flexion crease aligned with the proximal arrow on the Palmar Base.
- Slide the Distal Pad until the distal arrow aligns with the DIP flexion crease.

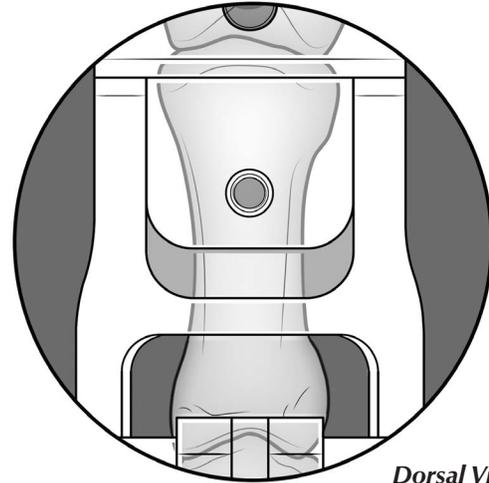


WARNING: The PIP joint must be extended to ensure the Transverse Pin is inserted palmar to the lateral bands. Refer to additional instructions on Page 15.

- Apply manual traction distal to the PIP joint as you gently clamp the finger into the Pin Placement Guide. (Surgeon's hand omitted for clarity.)
- Reduce the subluxed joint by lowering the Dorsal Beam onto the finger. In general, reduction of the dislocation results in reduction of the fracture. Three point fixation created by the two palmar pads and the dorsal pad maintains joint reduction during pin installation.
- Lock the Distal Lock Screw with the Hex Wrench to maintain joint reduction.
- Use fluoroscopy to confirm joint and fracture reduction.

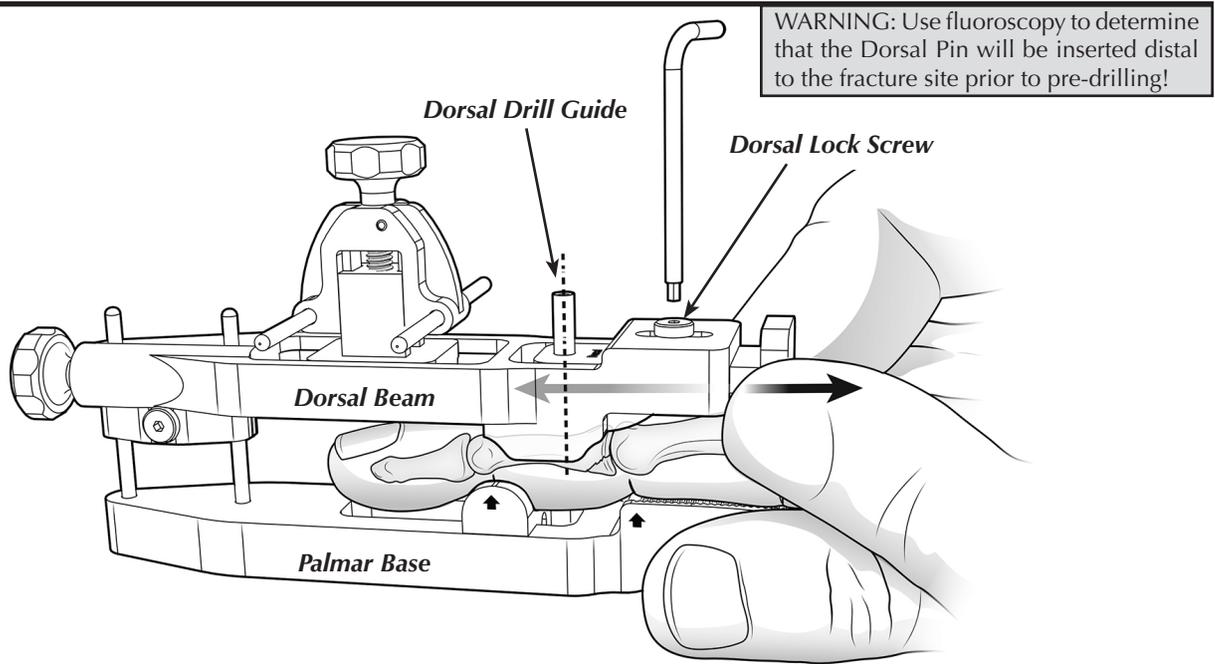


Distal View



Dorsal View

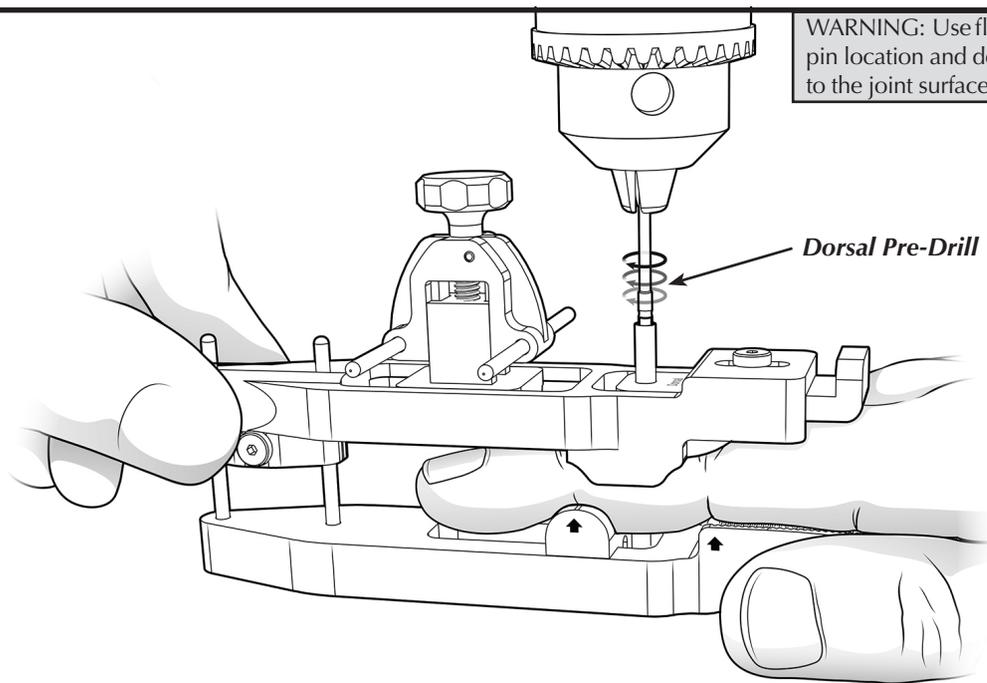
- Distal View - select the Dorsal Pin and place it into the Dorsal Drill Guide. Check the orientation of the Pin Placement Guide on the finger by looking at it from the distal end of the guide. The pin should appear perpendicular to the plane of the fingers as illustrated.
- Dorsal View - ensure the pin will be inserted in the “midline” of the middle phalanx by viewing the position of the Dorsal Drill Guide on the finger with no pin in the guide. The guide tube should be centered on the width of the middle phalanx.



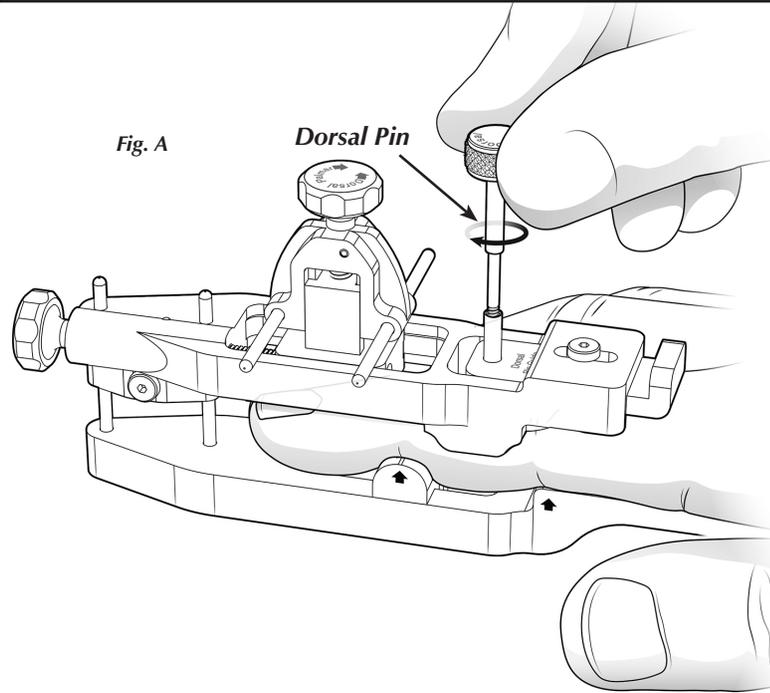
- Loosen the Dorsal Lock Screw with the Hex Wrench.
- Slide the Dorsal Drill Guide proximal or distal, as needed, to ensure the Dorsal Pin is placed slightly proximal to the mid shaft of the middle phalanx. Confirm using fluoroscopy that the Dorsal Pin will be installed distal to the fracture.
- Lock the Dorsal Drill Guide by tightening the Dorsal Lock Screw.

Surgical Installation

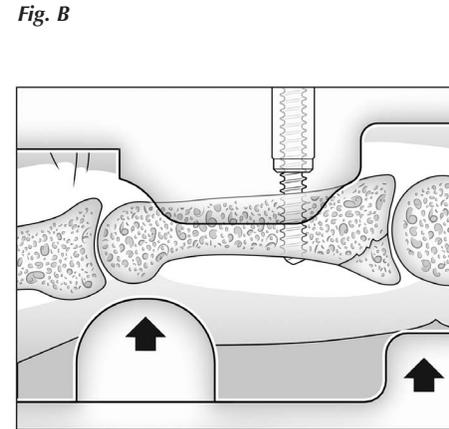
Placement of the Bone Pins



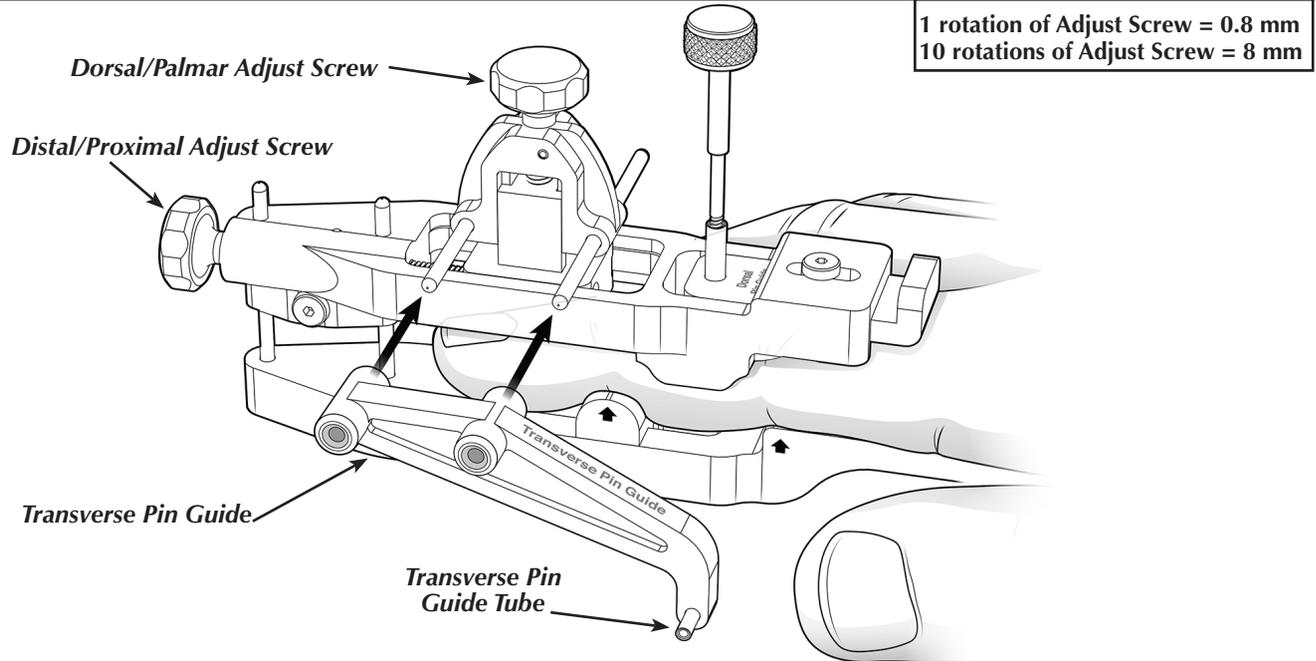
- Using a power drill, insert the Dorsal Pre-Drill through both cortices of the middle phalanx. The Pre-Drill should extend through, but not beyond, the palmar cortex.
- Keeping the Drill Guide aligned with the pre-drilled hole, remove the Dorsal Pre-Drill from the bone.
- Maintain Drill Guide alignment with the finger until completion of the next step.



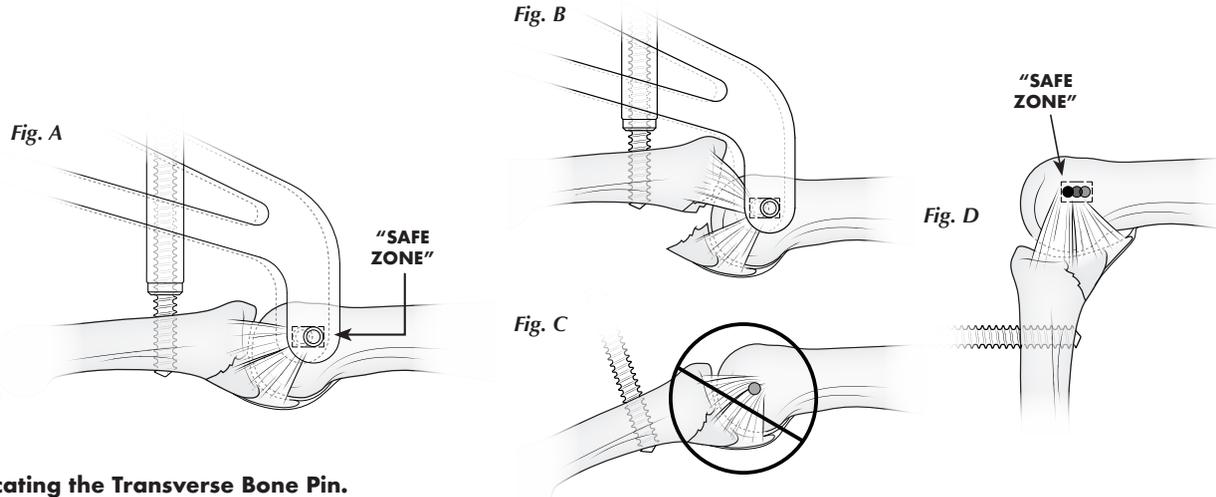
1.7 rotations of pin knob = 1 mm advancement
10 rotations of pin knob = 6 mm advancement



- Manually thread the Dorsal Pin into the middle phalanx by rotating it clockwise into the pre-drilled hole (Fig. A).
- The threads should extend through, but not beyond, the palmar cortex of the middle phalanx (Fig. B).
- The pin should stop short of the flexor tendons. Confirm pin depth using fluoroscopy.



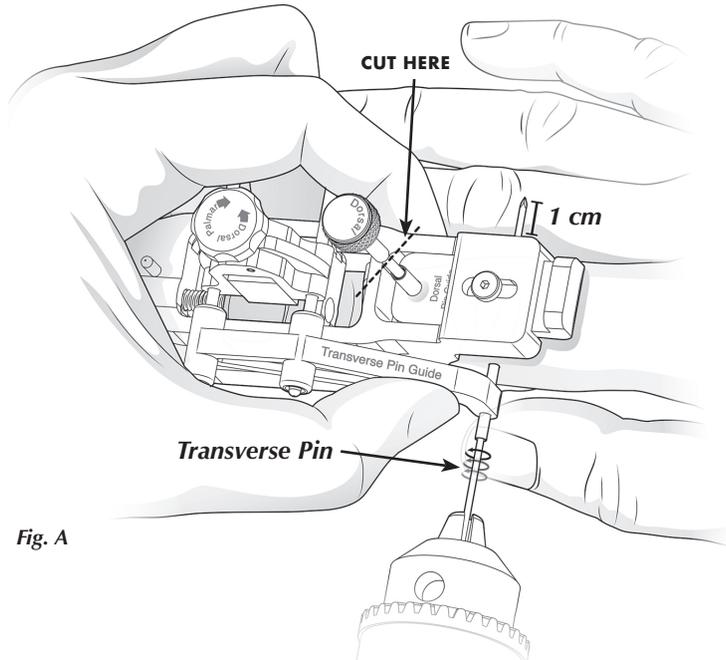
- Place the Transverse Pin Guide onto the Pin Placement Guide on the side (radial or ulnar) that is technically easiest for pin insertion.
- Use the Distal/Proximal and the Dorsal/Palmar Adjust Screws with fluoroscopic control to align the metal Transverse Pin Guide Tube at a point dorsal and proximal to the center of the head of the proximal phalanx (see facing page).
- Slide the pin guide tube snug against the skin before obtaining a final lateral fluoroscopic view centered on the tube axis to confirm the optimal position for the Transverse Pin.



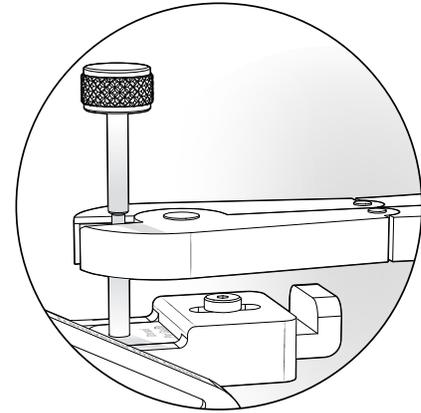
Locating the Transverse Bone Pin.

- The Transverse Pin Guide is properly aligned to ensure insertion of the Transverse Bone Pin dorsal and proximal to the axis of rotation (Fig. A). If the joint is unable to reduce prior to pin installation, the surgeon must use his or her best judgement to determine the optimal Transverse Pin location based on the relevant alignment of the soft tissues with the skeletal bones. Use of the PPG to facilitate accurate installation of the skeletal pins will often still be advantageous in these cases. (Fig. B).
- If the Transverse Bone Pin is inserted in the center of the head of the proximal phalanx, it may block the fibers of the collateral ligament and prevent the joint from flexing (Fig. C).
- With the Bone Pin installed dorsal and proximal to the axis of rotation, there is less impingement on the collateral ligaments, thereby facilitating active and passive finger flexion (Fig. D).
- Be aware that the bone surface at this location is not perpendicular to the pin axis. This can cause the pin to migrate dorsally during insertion. Holding the Transverse Pin Guide snugly against the skin when drilling will help obtain correct pin position.

Placement of the Bone Pins



CAUTION: Confirm correct Dorsal Pin depth using fluoroscopy prior to cutting off pin.



- Using a power drill, and while holding the Transverse Pin Guide snugly against the skin, insert the smooth Transverse Pin through the proximal phalanx until approximately 1 cm of the pin extends out of the skin on the far side (Fig. A).
- Cut the Dorsal Pin just below its shoulder to allow for Pin Placement Guide removal (Fig. B). The pin must be trimmed to final length after removal of the Pin Placement Guide.

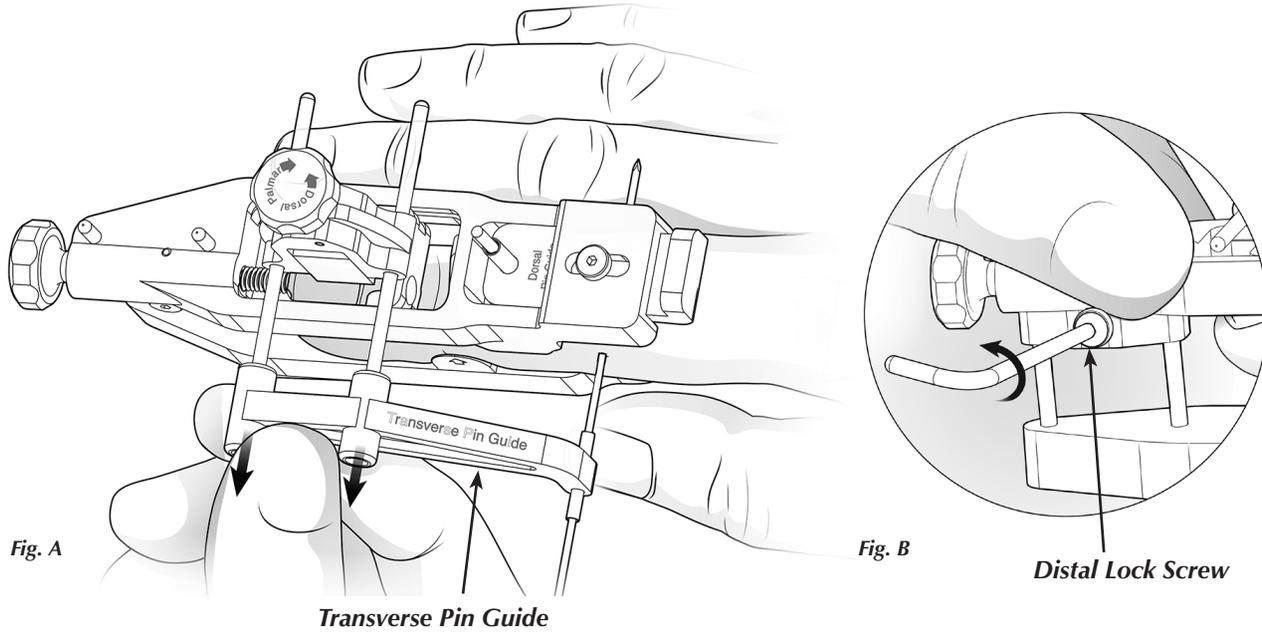


Fig. A

Fig. B

Transverse Pin Guide

Distal Lock Screw

- Remove the Transverse Pin Guide (Fig. A).
- Loosen the Distal Lock Screw (Fig. B) and remove the Pin Placement Guide from the finger.

Surgical Installation

Installation of the PIP Fix

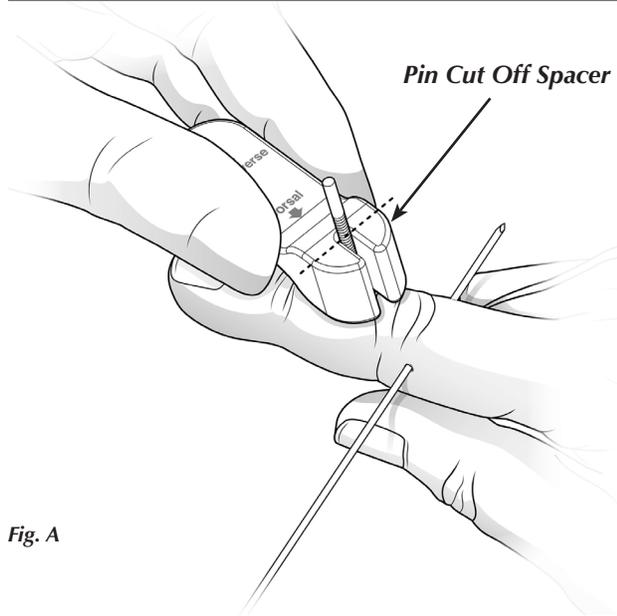


Fig. A

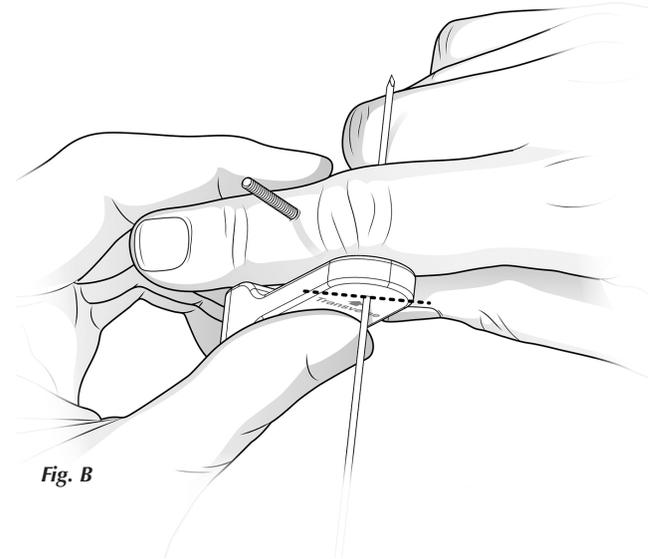


Fig. B

- Place the thick end of the Pin Cut Off Spacer marked “Dorsal” over the Dorsal Pin and against the dorsal skin of the patient’s finger. Cut the Dorsal Pin off flush with the Spacer (Fig. A). Note: The threads will continue beyond the length of the Pin Cut Off Spacer.
- Place the thin end of the Pin Cut Off Spacer marked “Transverse” over one end of the Transverse Pin and cut the pin off flush with the Spacer (Fig. B). Repeat on the opposite side of the finger.

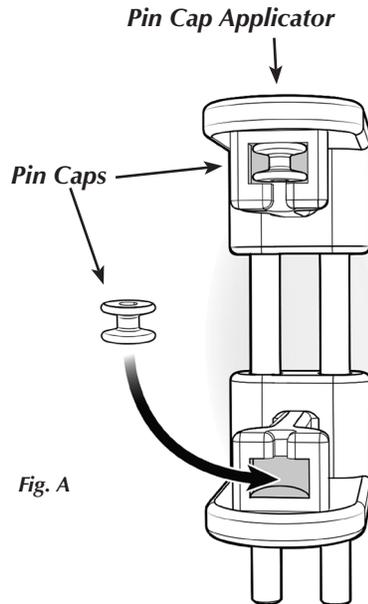


Fig. A

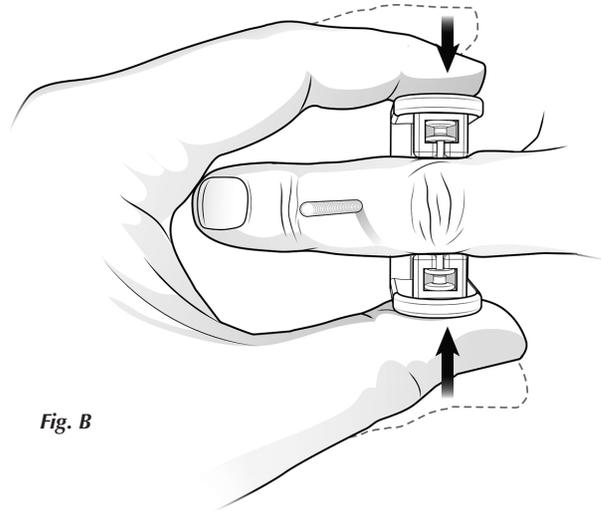
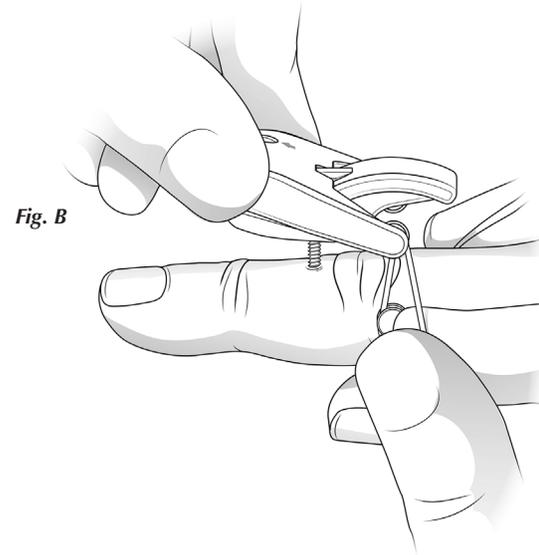
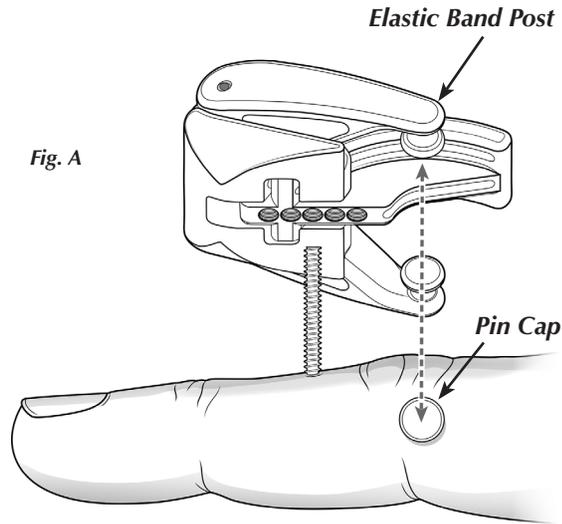


Fig. B



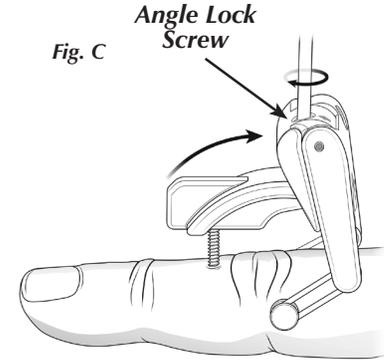
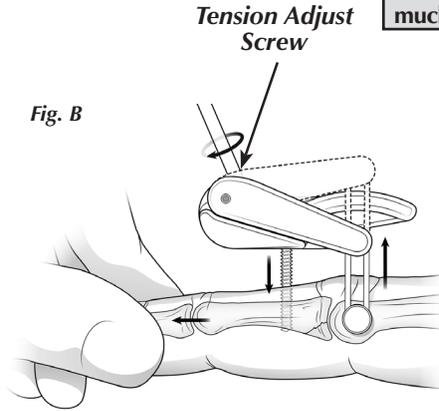
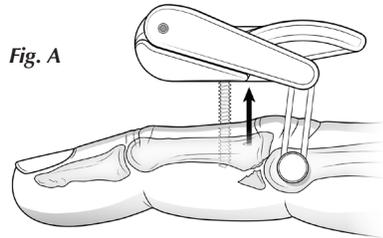
Fig. C

- Place the Pin Caps into the cavities of the Pin Cap Applicator (Fig. A). Ensure that the holes in the Pin Caps face each other.
- Align the slots in the Pin Cap Applicator with both ends of the Transverse Pin and squeeze the Pin Cap Applicator together, clamping the Transverse Pin between the Pin Caps (Fig. B). Continue to squeeze the applicator until both Pin Caps are firmly pressed onto the tips of the Transverse Pin. (Extra Pin Caps are supplied in the **PIP Fix** kit in case one is dropped.)
- The ends of the Transverse Pin must be completely inserted into the Pin Caps. Confirm pin depth with an AP fluoroscopic view (Fig. C).

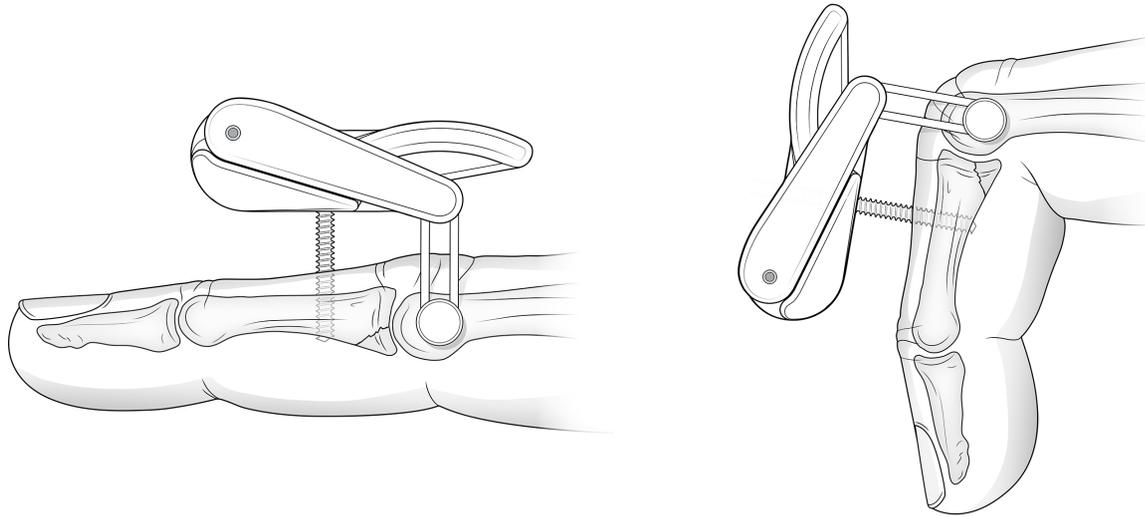


- Place the Dorsal Pin into one of the holes in the underside of the **PIP Fix** (Fig. A). The device slides over the threads; there is no need to rotate the device onto the pin.
- Choose a hole that positions the Elastic Band Posts directly dorsal to the Pin Caps.
- Note the device is locked in a position of pure translation during installation.
- Pre-stretch Elastic Bands prior to installation. Pre-stretching the bands minimizes fluctuations in force output during their initial application and immediately after band replacement. Install one Elastic Band between the Elastic Band Posts and Pin Caps on each side of the finger (Fig. B).

WARNING: Use the least amount of band tension necessary to reduce the dorsal dislocation. Too much tension can produce a palmar dislocation.



- Recurrent joint subluxation (or dislocation) may occur after the Pin Placement Guide is removed even with the Elastic Bands installed (Fig. A).
- Use longitudinal traction to the fingertip to help realign the joint. Evaluate if the initial Elastic Band tension is sufficient to maintain joint reduction. If not, reapply manual traction while increasing the Elastic Band tension by rotating the Tension Adjust Screw (Fig. B). Traction to the finger prevents the rough edges of the fractured bone from damaging the cartilage of the proximal phalanx.
- If a length restoration force is required, this can be achieved by moving the Elastic Band Posts proximally. Use the Hex Wrench to loosen the Angle Lock Screw. Manually slide the body of the device proximally along the arc to a point where the desired angle of the Elastic Bands is reached. Retighten the Angle Lock Screw to hold the device in this position (Fig. C).



- The optimal reduction force is evaluated with fluoroscopy including flexion and extension lateral views. Use the least force necessary to maintain joint reduction.
- Once the device has achieved concentric joint reduction, a reasonable arc of active and passive PIP joint motion should be possible.
- Lateral fluoroscopic views with the patient actively flexing and extending the finger are optimal in judging the ability of the device to maintain concentric joint reduction.

Post-Op Instructions & Device Removal

Post-Op Instructions

Care of the **PIP Fix**, Exercises and other Post-Op Issues

For the PIP Fix to maintain concentric joint reduction, Elastic Bands must remain installed. The patient must keep the Hex Wrench and extra Elastic Bands with them at all times.

To minimize risk of breakage, the Elastic Bands should be changed daily. The patient should have help when changing the bands. To minimize rotational torque on the joint during band changes, use the Hex Wrench to turn the Tension Adjust Screw counterclockwise reducing tension to a minimum. Pre-stretch new bands before application to minimize changes in tension during use. Place a new band onto the Pin Cap and the Elastic Band Post prior to removing the old one so reduction force is not lost during band change. Repeat band change on the opposite side. Reset tension to the appropriate level following band changes.

The **PIP Fix** is not damaged by water. The patient may wash their hand and shower.

Pin care is important in preventing pin track infections.

Instruct the patient according to your preferred method of pin site care. Petroleum based ointments will degrade the Elastic Bands if it comes in contact with them.

If an extensor lag at the DIP joint is noted following **PIP Fix** application, treatment for either an avulsion fracture or a torn extensor tendon at the DIP joint should be initiated.

Treating the DIP extensor lag will decrease the tendency of the PIP joint to hyperextend, improve final DIP extension and contribute to improved function of the finger.

Flexion and extension lateral X-rays should be taken at the first post-op visit and then intermittently to ensure that concentric joint reduction is maintained.

Active finger exercises are crucial to obtaining a good result. Review the exercises described in the Patient Care Card with your patient to determine if their particular circumstances require a more personalized exercise program.

The following ACTIVE exercises or their equivalent should be performed 4-6 times per day once concentric joint reduction has been achieved.

1. Stabilize the MCP joint of the involved finger in extension with the opposite hand and actively flex the DIP and PIP joints of the involved finger to the maximum range of motion. Hold for 5 seconds, then straighten and repeat ten times.
2. Hold the MCP joint of the involved finger in a flexed position and straighten the DIP and PIP joints of the involved finger to the maximum range of motion. Hold for 5 seconds, then relax and repeat ten times.
3. With all the fingers flexing together, *gently* make a fist to the maximum range of motion. Hold for 5 seconds, open the hand maximally, hold for 5 seconds. Alternate between the two positions ten times.
4. Keep the hand elevated to reduce swelling.
5. The hand may be used for light ADL.

If the active exercises cause excessive swelling and/or pain, flexion and extension lateral X-rays should be taken to ensure that concentric joint reduction is maintained.

PIP Fix Removal

Prior to **PIP Fix** removal, the surgeon may use flexion-extension lateral X-rays with the Elastic Bands removed to help determine if the fracture and soft tissues are adequately healed to maintain concentric joint reduction without the device on. This typically requires a minimum of 6 weeks, but ultimately depends on the rate of healing and the surgeon's assessment of the same.

1. If necessary, reduce tension to the lowest position by adjusting the Tension Adjust Screw.
2. Remove the Elastic Bands.
3. Remove the **PIP Fix** from the Dorsal Pin.
4. Cut a Pin Cap off the Transverse Pin on one side of the finger.
5. Using a large needle holder or similar tool, pull and rotate the Transverse Pin out of the finger.
6. Using the same tool from Step 5, unscrew the Dorsal Pin from the middle phalanx.
7. Place a small, non-restrictive dressing over the pin track holes.
8. Instruct the patient to continue with the active range of motion exercises.

